

Flexsafe® 2D & 3D Pre-Designed Solutions for Storage and Shipping

Take Your Facility Into The Future

Simplifying Progress

SARTURIUS

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Flexsafe® 2D bags up to 50 L

Flexsafe $^{\circ}$  2D bags in shell 5 L, 10 L & 20 L

Flexsafe® 3D bags up to 500 L

Flexsafe® 3D bags up to 3,000 L

# Digital Selection Map Flexsafe® 2D

Please click on the box to select the right solution with the right connection for your process step

### Flexsafe® 2D bags:

20 mL, 50 mL, 150 mL, 250 mL, 500 mL, 1 L, 3 L, 5 L, 10 L, 20 L, 50 L

Media Preparation Sterile Weld to Biostat STR® and RM Single-use Bioreactors

Sterile Connection to other Single-use Bioreactors

Sterile Connection

Sterile Weld

Steaming Connection to Stainless Steel Bioreactors

Buffer Preparation Sterile Connection to Downstream Systems

Sanitary or Aseptic Connection to Downstream Systems

Sterile Connection

Sterile Weld

**Quick Coupler Connection** 

Tri-Clamp Connection



Cell Harvest & Downstream Intermediates Sterile Connection to Downstream Systems

Sterile Connection

Sterile Weld

Sanitary or Aseptic Connection Quick

Quick Coupler Connection

to Downstream Systems

Tri-Clamp Connection

Drug Substance Sterile Connection to Downstream Systems

Sterile Connection

Sterile Weld

to Downstream Sys

Quick Coupler Connection

Sanitary or Aseptic Connection to Downstream Systems

Tri-Clamp Connection

Drug Product

**Formulation** 

Purification

Sterile Connection to Downstream Systems

Sterile Connection

Sterile Weld

Flexsafe® 2D bags from 20 mL to 3 L

Flexsafe® 2D bags in shell 5 L, 10 L & 20 L

# Digital Selection Map Flexsafe® 3D

Please click on the box to select the right solution with the right connection for your process step

Flexsafe® 3D bags for Palletank®:

100 L, 200 L & 500 L

Flexsafe® 3D bags for drum:

50 L, 100 L, 200 L



Flexsafe® 3D up to 500 L

Media Preparation Sterile Weld to Biostat STR® and RM Single-use Bioreactors

Sterile Connection to other Single-use Bioreactors

Sterile Connection

Sterile Weld

Steaming Connection to Stainless Steel Bioreactors

Buffer Preparation Sterile Connection to Downstream Systems

Sanitary or Aseptic Connection to Downstream Systems

Sterile Connection

Sterile Weld

Quick Coupler Connection

Tri-Clamp Connection

Cell Harvest & Downstream Intermediates

Sterile Connection to Downstream Systems

Sanitary or Aseptic Connection to Downstream Systems

Sterile Connection

Sterile Weld

Quick Coupler Connection

Tri-Clamp Connection

Sterile Connection

Drug Substance Purification Sterile Connection to Downstream Systems

Sterile Weld

Sanitary or Aseptic Connection to Downstream Systems

Quick Coupler Connection

Tri-Clamp Connection

Drug Product Formulation

Sterile Connection to Final Filling

Sterile Connection

Sterile Weld

Aseptic Transfer to an Isolator

# Digital Selection Map Flexsafe® 3D

 $Please\ click\ on\ the\ box\ to\ select\ the\ right\ solution\ with\ the\ right\ connection\ for\ your\ process\ step$ 

#### Flexsafe® 3D bags for Palletank®:

1,000 L, 1,500 L, 2,000 L, 2,500 L & 3,000 L



Flexsafe® 3D up to 3,000 L

Media Preparation Sterile Weld to Biostat STR® Single-use Bioreactors

Sterile Connection to other Single-use Bioreactors

Sterile Connection

Sterile Weld

Steaming Connection to Stainless Steel Bioreactors

Buffer Preparation Sterile Connection to Downstream Systems

Sanitary or Aseptic Connection to Downstream Systems

Sterile Connection ½" ID

Sterile Weld ½" ID

Quick Coupler Connection ½" ID

Tri-Clamp Connection  $\frac{1}{2}$ " ID

Buffer Preparation Sterile Connection to Downstream Systems

Sanitary or Aseptic Connection to Downstream Systems

Sterile Connection 3/4" ID

Sterile Weld ¾" ID

Quick Coupler Connection 34" ID

Tri-Clamp Connection 3/4" ID

Cell Harvest & Downstream Intermediates Sterile Connection to Downstream Systems

Sanitary or Aseptic Connection to Downstream Systems

Sterile Connection ½" ID

Sterile Weld  $\frac{1}{2}$ " ID

Quick Coupler Connection  $\frac{1}{2}$ " ID

Tri-Clamp Connection ½" ID

Cell Harvest & Downstream Intermediates Sterile Connection to Downstream Systems

Sanitary or Aseptic Connection to Downstream Systems

Sterile Connection ¾" ID

Sterile Weld ¾" ID

Quick Coupler Connection ¾" ID

Tri-Clamp Connection ¾" ID

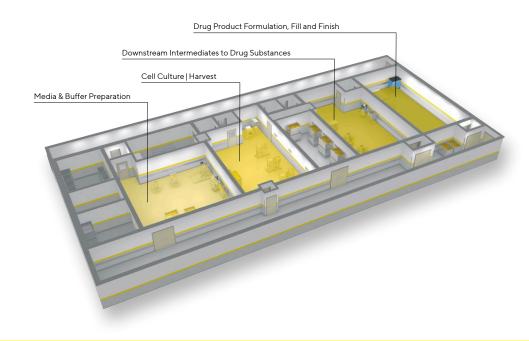
# Unprecedented Performance and Assurance of Quality Supply

Flexsafe® 2D & 3D Storage & Shipping Solutions for All Process Steps

Building on more than 20 years of experience in designing Single-use Fluid Management Solutions, we have established proven Pre Designed Solutions (PDS) for every media, buffer, harvest, downstream intermediates, drug substance and drug product process steps.

The performance and assurance of supply of Flexsafe® PDS are based on the complete control of our manufacturing process for the resins, the film, the bags, the filters and the assemblies. Other fluid-contact components are secured by strategic partnerships, long term contracts and quality agreements and are available off-the-shelf to provide best delivery reliability.

When you select a Flexsafe® PDS, you get the assurance of consistent quality and robust change control for every process steps of your bioproduction. Business continuity is guaranteed at any time with at least 24 months of change notification in case of a change.



#### Media



Pre-designed Solutions for media storage, shipping and feeding of bioreactors

#### Buffer



Pre-designed Solutions for storage and shipping of buffers used for purification or final formulation

# Cell Harvest & Downstream Intermediates



Pre-designed Solutions for harvesting cell cultures and for handling all the process intermediates before the last cross-flow step

## Drug Substance



Pre-designed Solutions for storage and shipping of drug substance post virus filtration after the last cross-flow step

### Sampling



Pre-designed Solutions for easy and safe sampling whatever the process step

### Drug Product



Pre-designed Solutions for sterile filtration, hold and transfer of drug products

## Material Science and Film Extrusion Expertise

The S80 PE film of Flexsafe® 2D & 3D bags is the result of combining material science and film extrusion expertise in collaboration with our resin suppliers and film partner. Such partnership ensure a full understanding of the resins formulation and the film manufaturing process.

Following the principles of Quality by Design (QbD), we have selected the raw materials and defined the thickness of each layer of the film to achieve excellent cell growth and superior robustness.

We have established the resin specification, extrusion design space and process controls that provide consistent quality and reproducible performance of the S80 film.

The extrusion process is optimized to avoid addition of antioxidants and process aids and to limit the generation of antioxidant breakdown products such as bis (2,4-di-tert-butylphenyl) phosphate (bDtBPP) during extrusion and gamma irradiation.

Welding and sealing parameters are optimized and are routinely controlled to ensure bag making process consistency.

#### Co-extruded PE | EVOH | PE Structure

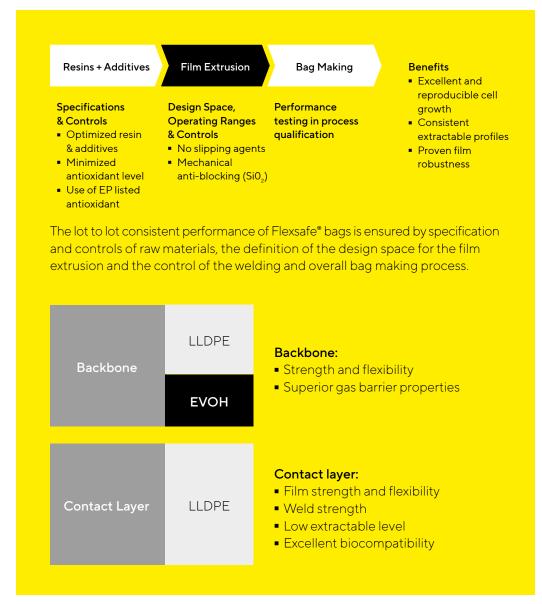
■ 400 µm thickness

Buffer

- Balance between strength, flexibility and gas barrier
- Large sealing window for bag robustness
- Best puncture resistance & elongation at break

#### S80 Film Features & Benefits

- Superior thickness and strength: Ideal for large scale storage bags and stirred bioreactors
- Excellent biocompatibility: Ideal for media storage and cell culture
- Superior flexibility: Ideal for shipping bags and rocking motion bioreactors
- Inert PE contact layer: Suitable for non buffered solutions
- High gas and water barrier properties: Suitable for long term storage of media, buffers and drug substances
- Low extractable profile: Ideal for drug substance and drug product process steps

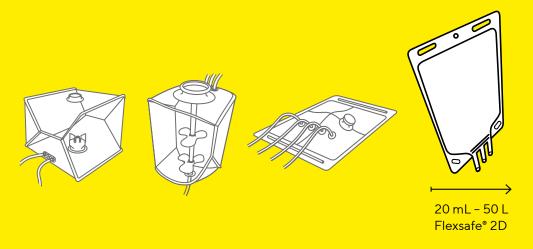


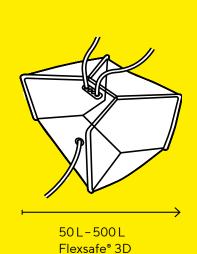
# Control of the Entire Manufacturing Process

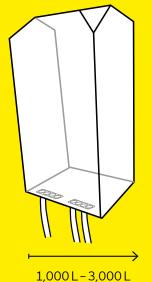
The complete control of the process and our quality management for critical fluid-contact components ensure reliable and consistent performance of our Flexsafe® PDS.

The establishment of long term supply contracts and quality agreements for the resins, the film and the fluid-contact components ensure unprecedented assurance of supply.

## One for All







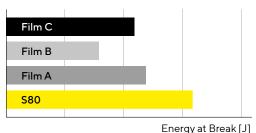
Flexsafe® 3D



#### Cell Growth

The resins and additives used for Flexsafe® bags are optimized to ensure excellent and reproducible growth. The control of our entire process guarantees consistent lot-to-lot cell growth after short and long term media storage.

## Reference: Borosilicate Glass **Cell Density** Flexsafe® Bags Standard Bags Time



Passed ASTM Shipping Test

#### Robustness & Ease of Use

The thickness, strength and flexibility of Flexsafe® bags make them suitable for all process steps and reduce the risk of damage due to inappropriate handling. Flexsafe® 3D bags in Palletank® are validated with the most stringent ASTM D4169 shipping test to offer safe transportation of critical drug substances.

The flexibility enables convenient installation and self-deployment of the bag in its container thus saving valuable operator time.

## Resins for S80 Film

## Resin specification & process control

- Resin & additives traceability
- Lot-to-lot raw material consistency

## Long term contract

- 2 year last time buy option
- 2 year stock of resin & film

## Film - S80

### Extrusion design space & control

- Consistent cell growth & robustness
- Lot-to-lot consistent extractable

### 10 year supply & quality contract

- 2 year last time buy option
- 2 year stock of resin & film

## Assurance of Quality Supply

Long-term supply contracts and quality agreements with suppliers and partners guarantee the traceability and control of the raw material and the film formulation. The control of the entire manufacturing process provides consistent quality, change control and business continuity.

## Components

### Long term supply contracts

2 year change notification

## **Quality Agreements**

- Bioburden, particle & endotoxin
- Extractable characterization

# 4 Year Guarantee of Unchanged Film

## **Business continuity plan**

Final PDS Assembly

Back up equipment & safety stocks

### Multiple manufacturing sites

- Worldwide cleanroom facilities
- Resin-to-bag process control

#### Consistent Extractable Profile

Specification and control of the resins and the film ensure well characterized and consistent extractables. Extractable data is readily available for risk assessment, thus saving end-users the time and money required for generating validation data. The validation studies and toxicological assessments remain valid and reproducible from lot-to-lot

# Assurance of Quality Supply for Fluid-Contact Components

## Component Quality, Change Control and **Business Continuity**

Media

All fluid-contact components of Flexsafe® PDS are secured by long term contracts and quality agreements and are available off-the-shelf to offer the best assurance of supply and the best delivery reliability.

Our supply contracts ensure at least a 2 year change notification thus providing robust change control and business continuity.

Components are selected to meet the most stringent quality requirements and all engagements with tubings are extensively qualified to ensure consistent robustness.

| Criteria for Component<br>Selection | Reference                               |
|-------------------------------------|---|
| Biological safety<br>(USP Class VI) | USP<87> & USP<88>                       |
| TSE-BSE questionnaire               | Compliance with EMA/410/01 and EP 5.2.8 |
| Endotoxin                           | USP<85> or EP 2.6.14                    |
| Bioburden                           | ISO 11737                               |
| Sub visible particles               | USP<788> or EP 2.9.19                   |
| Others                              | Bisphenol A free, REACH compliance      |

Our core expertise in plastics and polymers enables the selection of the cleanest and most inert materials to minimize chemical interactions with biopharmaceutical fluids, and leacheable substances and to provide consistent cell growth.

### **Design Qualification**

Component designs are selected to maximize tubing engagement tensile strength and tightness. All engagements with tubings are qualified for 3 year shelf life. Test samples are visually inspected for absence of defect and tested for leak, burst pressure, traction and compression.

Using a Flexsafe® Pre designed Solution in all your process steps provide you with best performance and assurance of quality supply.

## Material Qualification

Flexsafe® PDS components are evaluated for conformity against the EP and USP standards after reviewing technical documentation and certificates of quality available from our suppliers.

Additional internal qualification tests are performed to establish extractable profiles, post gamma sterilization shelf life and consistent functional properties.

### Flexsafe® PDS

| Components               | Biocompatibility USP<br><87> or USP<88> | Endotoxin<br>Sub visible particles bioburden | TSE-BSE EMA/410/01 & REACH | Notification period time |
|--------------------------|---|--|----------------------------|--------------------------|
|                          | Class VI                                |  |                            |                          |
| Flexsafe® bags           | Yes                                     | Yes  | Yes                        | 48 months                |
| Tuflux® tubes            | Yes                                     | Yes  | Yes                        | 24 months                |
| Opta® sterile connectors | Yes                                     | Yes  | Yes                        | 24 months                |
| Sartopore® filters       | Yes                                     | Yes  | Yes                        | 24 months                |
| Fittings                 | Yes                                     | Yes  | Yes                        | 24 months                |
| Connectors               | Yes                                     | Yes  | Yes                        | 24 months                |

# Validation and Quality Assurance

Flexsafe® PDS are qualified against extensive biological, chemical, physical, extractable and cell growth testing to provide reliable validation data applicable to a wide range of process conditions.

Sartorius Stedim Biotech Quality Systems for single-use products follow applicable ISO 9001 and FDA regulations. Because single-use systems replace traditional stainless steel equipment, suppliers own a more important part of the drug manufacturing process. Design, manufacture, quality control and sterilization of Flexsafe® PDS are conducted under conditions that mirror biopharmaceutical operations and meet cGMP like requirements to ensure they are supplied clean, pure, endotoxin free and sterile.

Flexsafe® 2D & 3D PDS are validated and routinely controlled to provide consistent performance for:

#### Robustness

- ASTM D4169 and D7386: Standard Practice for Performance Testing of Shipping Containers and Systems for Flexsafe® bag packaging
- ASTM D882/ISO 527-3 for tensile properties
- ASTM F392 for flex durability
- ASTM D3787 for puncture resistance For Flexsafe® 2D bags:
- 100% bag chamber leak test by pressure decay (ASTM F2095-07)
- 100 % finished product Helium integrity test for critical process steps or 2D and 3D bags up to 500 L

#### Gas transmission

- ASTM D3985 for oxygen transmission rate
- ISO 15106-3 for water vapor transmission rate

## Biocompatibility & chemical compatibility

- USP<87> and ISO 10993: Biological reactivity tests, in Vitro
- USP<88> and ISO 10993: Biological reactivity tests, in Vivo

- Internal standardized methods for cell growth compatibility evaluation
- USP<661> and EP 3.1.5: Containers, physico-chemical tests - Plastics
- ASTM D543-06: resistance of plastic to chemical reagents

#### Purity, extractable & leachable

- Extractable data based on knowledge and control of resins and film manufacturing process
- TSE/BSE: EP 5.2.8

#### Cleanliness, particles

- USP<788> and EP 2.9.19: Particulate Matter in Injections Endotoxin
- USP<85> and EP 2.6.14: Bacterial endotoxins Sterility
- ISO 11737 Sterilization of medical devices -Microbiological methods: Bioburden
- ISO 11137 Sterilization by irradiation of Medical Devices: Sterilization of Medical Devices

For the most critical drug product process step bioburden, sub-visible particulates and endotoxin testing is performed on representative finished products for every production batch.

- ISO 14644: Cleanroom environmental controls
- Gamma irradiation dose mapping

### Sterility

- ISO 11737 Sterilization of medical devices -Microbiological methods: Bioburden
- ISO 11137 Sterilization by irradiation of Medical Devices: Sterilization of Medical Devices
- ISO 14644: Cleanroom environmental controls
- Gamma irradiation dose mapping

Flexsafe® 2D & 3D PDS for media, buffer, harvest & downstream intermediates and drug substance process steps are released on the base of a weekly quality control for bioburden, sub-visible particulates and endotoxin performed on representative samples.

Continue >

# Validation and Quality Assurance

| Media, Buffer, Harvest & Downstream Intermediates                   | Drug Substance        | Drug Product   |
|---|-----------------------|--|
| Weekly testing of bioburden, particles and endotoxin on representat | ive finished products | Lot release testing of bioburden, particles and endotoxin on representative finished product |

## Certificate of Release

| Statement                             | Monitoring*              | 100% Batch testing             | Particle Prevention Program  |
|---------------------------------------|--------------------------|--------------------------------|------------------------------|
| USP Class VI                          | Bioburden                | Gamma irradiation              | Visible Particles Monitoring |
| USP<87> and ISO 10993:                | ISO 11737                | Dose mapping                   | ISO 16232                    |
| Biological reactivity tests, in Vitro |                          | ., -                           |                              |
| USP<88> and ISO 10993:                | Endotoxin:               | Visual inspection              |                              |
| Biological reactivity tests, in Vivo  | USP<85> and E.P. 2.6.14  | Film, bag, seal and packaging  |                              |
| Physico-chemical testing              | Sub-visible Particulates | Technical Drawing conformity   |                              |
| USP<661> and EP 3.1.5                 | USP<788> and EP 2.9.19   | Batch record review            |                              |
| TSE-BSE status                        |                          | 100% Leak Testing for 2D bags: |                              |
| EMA/410/01 and EP 5.2.8               |                          | Bag chamber and PE port        |                              |

<sup>\*</sup> performed weekly on representative finished products for buffer, media, harvest and drug substance process step and on each batch on representative finished product for drug product process step

# Assurance of Single-Use System Integrity

The assurance of container closure integrity of Flexsafe® 2D and 3D bags is proven along the entire product life cycle. Quality by design principles, process qualification, process control and quality control first ensure integrity of the film, the welds and the bag chamber.

A 100% bag chamber leak test is then performed in-process before line assembly for all Flexsafe® 2D bags. In addition, a Supplier Integrity Test (SIT) for the complete bag and line assemblies is available for 2D bags and for 3D bags up to 500 L, thus providing the best intergrity assurance of the industry, mainly for critical applications.

For those critical process steps, a 100% point-of-use leak test avoids the risk of losing high value product and enhances patient and operator safety by ensuring that no damage occurred during shipping, storage and handling of single-use single-use 2D and 3D bags at the user site.

#### Flexsafe® PDS Benefits

- Best assurance of supply thanks to full control of manufacturing processes
- Best assurance of integrity of high value drug substances and drug products according to ASTM F2095-07

## Sensitive Container Closure Integrity (CCI) for both process controls and at point of use

- Our BC-LT with detection limit of 20 90 µm for Flexsafe® 2D guaranties that no leaking bags are used to manufacture final products
- Our finished product SIT will guarantee that no defect > 2 µm occur in production of our 2D and 3D bags up to 500 L
- Our point-of-use integrity test PoU-IT with detection limit of 10 µm for Flexsafe® 2D allows end user to ensure safe use of the bags for critical process steps.

These tests in conjunction with the control of our process ensure the strongest level of Integrity and safety for patients and operators.

For scale up processes, our PoU-LT of Flexsafe® 3D bags allows gross leak detection (from 100 µm to 200 µm) after installation in the appropriate container at end user site.

## **Process qualification** at supplier

- Robustness validated in the extrusion design space
- Mechanical tests on film and weld
- Microbial immersion
- Packaging validation
- Shipping validation

## Process control & quality control at supplier

- Control of resin, extrusion and welding process parameters
- Seal quality tests
- Visual inspections
- Microbial immersion
- 100% bag chamber leak test for 2D bags
- Supplier integrity testing for 2D bags and 3D bags up to 500 L

## Process validation & process controls at end user

- Package integrity
- Visual inspection
- Media hold, media fill and stability test
- Microbial immersion test
- Operator training
- Point-of-use leak testing





# Safe & Reliable Handling & Shipping Solutions from 5 L to 500 L

The superior strength and flexibility of Flexsafe® bags make them safe for critical liquid shipping applications. The robustness of Flexsafe® bags is proven by applying extensive qualification regimes that combine the most stringent standard ASTM D4169 testing and real shipping conditions. Standard shipping test data can be leveraged by end-users to support their own qualification for liquid handling & shipping in single-use systems.

To learn more

## Flexsafe® 2D Bags in Shell for Liquid Handling & Shipping for 5 L, 10 L & 20 L

### **Complete Logistic Solution**

Robust and qualified solutions for liquid shipping qualified under the most stringent international norms ASTM D4169.

In addition, our experts have established a new protocol for qualifying handling steps, covering normal, worse case and accidental handling conditions based on a mix of ASTM, ISO and EN norms.

## Flexsafe® 3D for Shipping From 100 L to 500 L

#### Safe and Robust Solution

The Flexsafe® 3D bags in their shipping Palletank® offer the most robust solution for large volume liquid transportation. The solutions have been qualified under the most stringent international norms ASTM D4169 within a range of temperature of 4 °C to 40 °C.







# Safe, Self Deploying and Robust Solutions

## Flexsafe® 3D for Storage From 100 L to 3,000 L

### **Self Deploying Solution**

The high flexibility of Flexsafe® bags allows selfdeployment of the bags during filling thus providing ease of use, saving operator time and eliminating risky bag manipulations. Thanks to the self-deploying accessory\*, the Flexsafe® 3D bags from 100 L to 500 L can be filled without further handlig for Palletank® for Storage and In-Process fluid handling. The new lifting system system combined with a pre-deployed bag at the manufaturing step, allows self-delpoying and filling of Flexsafe® bags from 1,000 L to 3,000 L.

## Flexsafe® PDS Features & Benefits

- Full control of manufacturing processes ensure best quality and change control
- Long term contract and stocks of raw materials, films and components ensure best business continuity and delivery reliability
- Resin formulation optimized for consistent cell growth after short term and long term media storage
- Process controls provide well characterized and consistent extractable profile
- Ready to use extractable data save time and money by avoiding specific leachable studies for drug subtance
- Safe storage and shipping of high value drug substances and drug products validated according to ASTM D4169
- Best assurance of integrity of high value drug substances and drug products according to ASTM F2095
- Film flexibility and self-deploying ability whatever the bag size provide safety, ease of use and save operator time

To learn more

Self-deployment for Flexsafe® bags from 1,000 L to 3,000 L







Self-deployment for Flexsafe® bags from 100 L to 500 L



# Filtration & Storage for All Process Steps



The versatile range of Flexsafe® 2D PDS allows for sterile filtration, storage, shipping and transfer of all biopharmaceutical fluids in all process steps.

### Inlet Filters and Connectors

Flexsafe® 2D PDS are available with four sterilizing filtration options.

- Sartopore® 2 sterilizing-grade filter with 0.45 | 0.2 µm membranes optimized for buffer filtration
- Sartopore® 2 XLG sterilizing-grade filter with 0.8 | 0.2 µm membranes optimized for media filtration, cell harvest & downstream intermediates
- Sartopore® 2 XLM filter with advanced 0.2 | 0.1 µm pore size distribution and asymmetric prefilter membrane optimized for mycoplasma retention in media
- Sartopore® Platinum sterilizing-grade filter with 0.45 | 0.2 µm membranes optimized for drug substance and drug product filtration. The outstanding wetting properties reduce by ten times the flusing volumes required for integrity testing Silicone Tuflux® tube & C-Flex® enable filter sterile disconnection with Clipster® for post-use integrity testing and sterile seal of the bag Alternatively, PDS are available with a sterile connection to another filter line to provide more flexibility. The filter line is either connected with Opta® a" or welded with Biowelder® TC and subsequently disconnected for integrity using Biosealer®.

Another option is to perform an aseptic connection under Laminar Air Flow (LAF) using a CPC guick couplers.

### **Outlet Connectors**

- Opta® SFT Male enables sterile connections to other single-use systems
- STCII Steamthru<sup>™</sup> valve allows for steaming and sterile transfer to stainless steel systems
- CPC quick couplers are used for either sanitary connection or aseptic connection under ISO5 laminar air flow to single-use systems
- Tri-Clamp ¾" sanitary flange are used for either sanitary connection or aseptic connection under ISO5 laminar air flow to stainless steel systems
- Clave needleless sampling port enables for sterile sampling

### Tubes

- Tuflux® silicone or C-Flex tubing enable sterile disconnection with Clipster®
- Clear C-Flex® tubing allows for sterile weld connection with Biowelder® TC and sterile seal disconnection with Biosealer®

All fluid-contact components of Flexsafe® PDS are secured by supply contracts and quality agreements to provide:

- Best quality, change control and business continuity with at least 24 months change notification
- Best delivery reliability with available stocks
- Compliance to quality standards: USP<87> & USP<88>, TSE/BSE, REACH

# Filtration, Storage & Shipping in All Process Steps

Buffer



The versatile range of Flexsafe® PDS allows for sterile filtration, storage, shipping and transfer of all biopharmaceutical fluids in all process steps.

# Filtration, Storage & Shipping in All Process Steps

## Inlet Filters and Connectors

Media

Flexsafe® 3D PDS are available with four sterilizing filtration options.

- Sartopore® 2 sterilizing-grade filter with 0.45 | 0.2 µm membranes optimized for buffer filtration
- Sartopore® 2 XLG sterilizing-grade filter with 0.8 | 0.2 µm membranes optimized for media filtration, cell harvest & downstream intermediates
- Sartopore® 2 XLM filter with advanced 0.2 | 0.1 µm pore size distribution and asymmetric prefilter membrane optimized for mycoplasma retention in media
- Sartopore® Platinum sterilizing-grade filter with 0.45 | 0.2 µm membranes optimized for drug substance and drug product filtration. The outstanding wetting properties of the modified membrane reduce by ten times the flushing volumes required prior to integrity testing.
- Clear C-Flex® tubing enable filter disconnection with Biosealer® for post-use integrity testing and sterile seal of the bag.
- Alternatively, PDS are available with a sterile connection to another filter line to provide more flexibility. The filter line is either connected with Opta® 1/2" or welded with Biowelder® TC and subsequently disconnected for integrity using Biosealer®.
- Another option is to perform an aseptic connection under Laminar Air Flow (LAF) using a CPC quick couplers.

## **Outlet Connectors**

- Opta® SFT Male enables sterile connections to other single-use systems
- STCII Steamthru<sup>™</sup> valve allows for steaming and sterile transfer to stainless steel systems
- CPC quick couplers are used for either sanitary connection or aseptic connection under ISO5 laminar air flow to single-use systems
- Tri-Clamp 1½" sanitary flange are used for either sanitary connection or aseptic connection under ISO5 laminar air flow to stainless steel systems
- Clave needleless sampling port enables for sterile sampling

## Tubes

- Tuflux® silicone tubing enables long term pumping
- Clear C-Flex® tubing allows for sterile weld connection with Biowelder® TC and sterile seal disconnection with Biosealer®

All fluid-contact components of Flexsafe® PDS are secured by supply contracts and quality agreements to provide:

- Best quality, change control and business continuity with at least 24 months change notification
- Best delivery reliability with available stocks
- Compliance to quality standards: USP<87> & USP<88>, TSE/BSE, REACH

Buffer Flexsafe® 2D | Flexsafe® 3D | Flexsafe® 2D | Flexsafe® 3D | Flexsafe® 2D | Flexsafe® 3D | Flexsafe® 2D | Flexsafe® 3D | Flexs

Cell Harvest & DSP

Drug Substance Flexsafe® 2D | Flexsafe® 3D

Drug Product Flexsafe® 2D | Flexsafe® 3D Back to Table of Content

Flexsafe® 2D Pre-Designed Solutions for Media Preparation

Media **Preparation** 

Sterilizina Filtration

**Media Storage** 

Media Transfer

Sterile Weld to Biostat STR® and RM Single-use Bioreactors

Sterile Connection to other Single-use Bioreactors

**Steaming Connection to Stainless Steel Bioreactors**  Sterile Connection Sterile Weld

Flexsafe® 2D solutions for media are available with two Sartopore® filter options, Sartopore® 2 XLG for sterilizing filtration or Sartopore® 2 XLM for mycoplasma retention.

Flexsafe® 2D bags without filters are also available for:

- Sterile connection to alternative Sartopore® filter line using Opta® 3% or welding with Biowelder® TC
- Aseptic connection to alternative Sartopore® filter line with MPC quick coupler

Sartopore® filters can be disconnected for post-use integrity testing with sterile seal using Biosealer®.

Inlet and outlet lines are made of C-Flex® or Silicone Tuflux® tubing for welding, sealing and pumping.

Flexsafe® 2D bags allow for sterile media transfer to most common single-use and stainless steel bioreactors with a variety of sterile connections.

### **Outlet Line**

Sterile connection and transfer by pumping or gravity

- C-Flex® with CPC quick coupler and plua for sterile weld with Biowelder® TC to Biostat® RM and Biostat STR® bioreactors
- Opta® SFT male for sterile connection to other single-use bioreactors
- STCII Steamthru<sup>™</sup> valve for steaming connection to stainless steel bioreactors



#### Sampling

Clave needleless sampling port

#### Inlet Line

Sterilizing Filtration

- Sartopore® 2 XLG 0.8 | 0.2 µm
- Sartopore® 2 XLM 0.2 | 0.1 µm

Connections for Alternative Filter Line

- Opta® SFT female
- C-Flex® tube for sterile weld with Biowelder® TC
- MPC quick coupler female

Media **Preparation**  Sterile Weld to Biostat STR® and RM Single-use Bioreactors

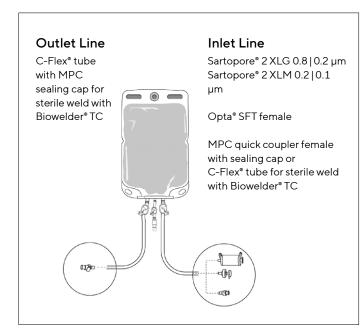
Sterile Connection to other Single-use Bioreactors

**Sterile Connection** Sterile Weld

Steaming Connection to **Stainless Steel Bioreactors** 

Sterile Weld to Biostat STR® and Biostat® RM Single-Use Bioreactors

|               |                |                  | Inlet <sup>1</sup>                         |                         | Outlet <sup>2</sup>               | Sampling   |
|---------------|----------------|------------------|--|-------------------------|-----------------------------------|--|
| Bag<br>volume | Part<br>number | Units<br>per box | Filter or distal connector on filling line | Filter type<br>and size | Distal connector on draining line | Sampling line  |
| 3 L           | FLS130131      | 16               | Sartopore® 2 XLG 0.8   0.2 μm              | Midicaps® size 4        |                                   |  |
|               | FLS130133      | 16               | Sartopore® 2 XLM 0.2   0.1 μm              | _                       |                                   |  |
|               | FLS130147      | 16               | %" Opta® SFT female                        | NA                      | _                                 |  |
|               | FLS130145      | 16               | %" MPC female + sealing cap                |                         |                                   |  |
| 5 L           | FLS130018      | 16               | Sartopore® 2 XLG 0.8   0.2 μm              | Midicaps® size 4        |                                   | %" ID Silicone Tuflux°<br>100 mm (4")<br>+ Luer Lock female<br>+ Clave connector |
|               | FLS130020      | 16               | Sartopore® 2 XLM 0.2   0.1 μm              |                         |                                   |  |
|               | FLS130042      | 16               | %" Opta® SFT female                        | NA                      |                                   |  |
|               | FLS130039      | 16               | %" MPC female + sealing cap                |                         |                                   |  |
| 10 L          | FLS130025      | 8                | Sartopore® 2 XLG 0.8   0.2 μm              | Midicaps® size 7        |                                   |  |
|               | FLS130029      | 8                | Sartopore® 2 XLM 0.2   0.1 μm              | _                       |                                   |  |
|               | FLS130043      | 8                | %" Opta® SFT female                        | NA                      | _                                 |  |
|               | FLS130040      | 8                | %" MPC female + sealing cap                | _                       |                                   |  |



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<sup>&</sup>lt;sup>1</sup> Inlet tubing line from end line to bag:  $\frac{3}{6}$ " ×  $\frac{5}{6}$ " Clear C-Flex $^{\circ}$  500 mm (20") + Clipster $^{\circ}$  in a separate pouch

<sup>&</sup>lt;sup>2</sup> Outlet tubing line from bag to end line: 3%" × 5%" Clear C-Flex® 500 mm (20")

Media **Preparation**  Sterile Weld to Biostat STR® and RM Single-use Bioreactors

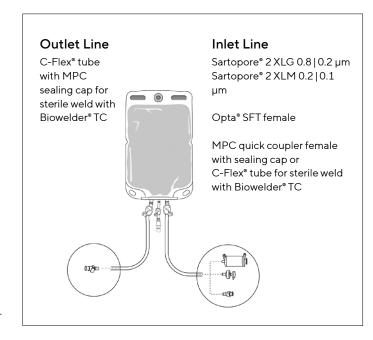
Sterile Connection to other Single-use Bioreactors

**Sterile Connection** Sterile Weld

Steaming Connection to **Stainless Steel Bioreactors** 

Sterile Weld to Biostat STR® and Biostat® RM Single-Use Bioreactors

|               |                |                  | Inlet¹                                     |                         | Outlet <sup>2</sup>                               | Sampling   |
|---------------|----------------|------------------|--|-------------------------|---|--|
| Bag<br>volume | Part<br>number | Units<br>per box | Filter or distal connector on filling line | Filter type<br>and size | Distal connector on draining line                 | Sampling line  |
| 20 L          | FLS130026      | 8                | Sartopore® 2 XLG 0.8   0.2 μm              | Midicaps® size 7        |   | 10 Silicone Tuflux° 100 mm (4") Luer Lock female Clave connector |
|               | FLS130030      | 8                | Sartopore® 2 XLM 0.2   0.1 μm              |                         |   |  |
|               | FLS130044      | 8                | %" Opta® SFT female                        | NA                      | _   |  |
|               | FLS130041      | 8                | %" MPC female + sealing cap                |                         | %"×%" C-Flex®<br>— + %" MPC male<br>+ sealing cap |  |
| 50 L          | FLS130138      | 8                | Sartopore® 2 XLG 0.8   0.2 μm              | Midicaps® size 7        |   |  |
|               | FLS130140      | 8                | Sartopore® 2 XLM 0.2   0.1 μm              |                         |   |  |
|               | FLS130148      | 8                | %" Opta® SFT female                        | NA                      | _   |  |
|               | FLS130146      | 8                | %" MPC female + sealing cap                | _                       |   |  |



<sup>&</sup>lt;sup>1</sup> Inlet tubing line from end line to bag:  $\frac{3}{6}$ " ×  $\frac{5}{6}$ " Clear C-Flex $^{\circ}$  500 mm (20") + Clipster $^{\circ}$  in a separate pouch

<sup>&</sup>lt;sup>2</sup> Outlet tubing line from bag to end line: 3%" × 5%" Clear C-Flex® 500 mm (20")

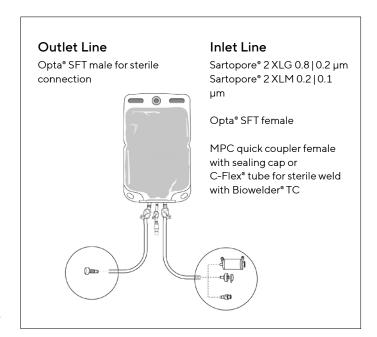
Media **Preparation**  Sterile Weld to Biostat STR® and RM Single-use Bioreactors

Sterile Connection to other Single-use Bioreactors

**Steaming Connection to Stainless Steel Bioreactors**  **Sterile Connection** Sterile Weld

Sterile Connection to Other Single-Use Bioreactors

|               |                |                  | Inlet¹                                     |                         | Outlet <sup>2</sup>               | Sampling   |
|---------------|----------------|------------------|--|-------------------------|-----------------------------------|--|
| Bag<br>volume | Part<br>number | Units<br>per box | Filter or distal connector on filling line | Filter type<br>and size | Distal connector on draining line | Sampling line  |
| 3 L           | FLS130136      | 16               | Sartopore® 2 XLG 0.8   0.2 μm              | Midicaps® size 4        |                                   |  |
|               | FLS130137      | 16               | Sartopore® 2 XLM 0.2   0.1 μm              |                         |                                   |  |
|               | FLS130155      | 16               | ¾" Opta® SFT female                        | NA                      | _                                 | ¼" ID Silicone Tuflux°<br>100 mm (4")<br>+ Luer Lock female<br>+ Clave connector |
|               | FLS130153      | 16               | 3/8" MPC female + sealing cap              |                         | —<br>— %" Opta® SFT male<br>—     |  |
| 5 L           | FLS130023      | 16               | Sartopore® 2 XLG 0.8   0.2 μm              | Midicaps® size 4        |                                   |  |
|               | FLS130024      | 16               | Sartopore® 2 XLM 0.2   0.1 μm              | <u> </u>                |                                   |  |
|               | FLS130054      | 16               | %" Opta® SFT female                        | NA                      |                                   |  |
|               | FLS130051      | 16               | 3/8" MPC female + sealing cap              | <u> </u>                |                                   |  |
| 10 L          | FLS130035      | 8                | Sartopore® 2 XLG 0.8   0.2 μm              | Midicaps® size 7        |                                   |  |
|               | FLS130037      | 8                | Sartopore® 2 XLM 0.2   0.1 μm              | _                       |                                   |  |
|               | FLS130055      | 8                | ¾" Opta® SFT female                        | NA                      | _                                 |  |
|               | FLS130052      | 8                | %" MPC female + sealing cap                |                         |                                   |  |



Media **Preparation**  Sterile Weld to Biostat STR® and RM Single-use Bioreactors

Sterile Connection to other Single-use Bioreactors

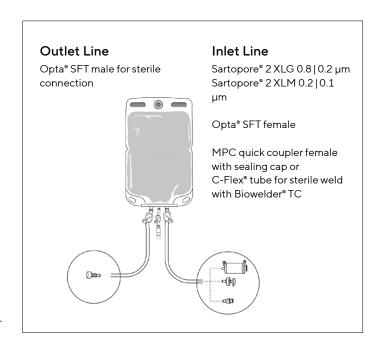
Sterile Weld

**Sterile Connection** 

Steaming Connection to **Stainless Steel Bioreactors** 

Sterile Connection to Other Single-Use Bioreactors

|               |                |                  | Inlet¹                                     |                         | Outlet <sup>2</sup>               | Sampling                                |
|---------------|----------------|------------------|--|-------------------------|-----------------------------------|---|
| Bag<br>volume | Part<br>number | Units<br>per box | Filter or distal connector on filling line | Filter type<br>and size | Distal connector on draining line | Sampling line                           |
| 20 L          | FLS130036      | 8                | Sartopore® 2 XLG 0.8   0.2 μm              | Midicaps® size 7        |                                   |   |
|               | FLS130038      | 8                | Sartopore® 2 XLM 0.2   0.1 μm              | _                       |                                   |   |
|               | FLS130056      | 8                | %" Opta® SFT female                        | NA                      | _                                 | 1/11 ID 0:11: T (1                      |
|               | FLS130053      | 8                | 3%" MPC female + sealing cap               |                         | 3/" O-4-9 CET                     | ¼" ID Silicone Tuflux® 100 mm (4")      |
| 50 L          | FLS130143      | 8                | Sartopore® 2 XLG 0.8   0.2 μm              | Midicaps® size 7        | — ¾" Opta® SFT male               | + Luer Lock female<br>+ Clave connector |
|               | FLS130144      | 8                | Sartopore® 2 XLM 0.2   0.1 μm              |                         |                                   | + Clave connector                       |
|               | FLS130156      | 8                | %" Opta® SFT female                        | NA                      | _                                 |   |
|               | FLS130154      | 8                | %" MPC female + sealing cap                | <del>_</del>            |                                   |   |



<sup>&</sup>lt;sup>1</sup> Inlet tubing line from end line to bag: 3/6" × 5/6" Clear C-Flex® 500 mm (20") + Clipster® in a separate pouch

<sup>&</sup>lt;sup>2</sup> Outlet tubing line from bag to end line: 3%" × 5%" Clear C-Flex® 500 mm (20")

Media **Preparation**  Sterile Weld to Biostat STR® and RM Single-use Bioreactors

Sterile Connection to other Single-use Bioreactors

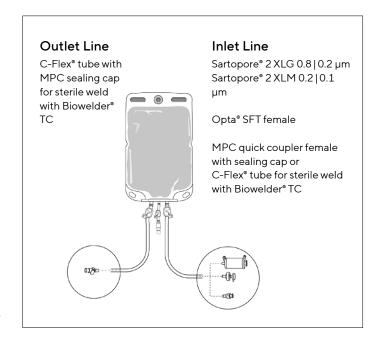
**Stainless Steel Bioreactors** 

Steaming Connection to

**Sterile Connection** Sterile Weld

Sterile Weld to Other Single-Use Bioreactors

|               |                |                  | Inlet¹                                     |                         | Outlet <sup>2</sup>               | Sampling                              |  |                                  |                    |
|---------------|----------------|------------------|--|-------------------------|-----------------------------------|---------------------------------------|--|----------------------------------|--------------------|
| Bag<br>volume | Part<br>number | Units<br>per box | Filter or distal connector on filling line | Filter type<br>and size | Distal connector on draining line | Sampling line                         |  |                                  |                    |
| 3 L           | FLS130131      | 16               | Sartopore® 2 XLG 0.8   0.2 μm              | Midicaps® size 4        |                                   |                                       |  |                                  |                    |
|               | FLS130133      | 16               | Sartopore® 2 XLM 0.2   0.1 μm              |                         | _                                 |                                       |  |                                  |                    |
|               | FLS130147      | 16               | %" Opta® SFT female                        | NA                      |                                   |                                       |  |                                  |                    |
|               | FLS130145      | 16               | 3/8" MPC female + sealing cap              |                         |                                   |                                       |  |                                  |                    |
| 5 L           | FLS130018      | 16               | Sartopore® 2 XLG 0.8   0.2 μm              | Midicaps® size 4        | %"×5%" C-Flex®                    | ¼" ID Silicone Tuflux°<br>100 mm (4") |  |                                  |                    |
|               | FLS130020      | 16               | Sartopore® 2 XLM 0.2   0.1 μm              | _                       |                                   |                                       |  |                                  |                    |
|               | FLS130042      | 16               | ¾" Opta® SFT female                        | NA                      | NA                                | NA                                    |  | — + ¾" MPC male<br>+ sealing cap | + Luer Lock female |
|               | FLS130039      | 16               | 3/8" MPC female + sealing cap              | _                       | - ,                               | + Clave connector                     |  |                                  |                    |
| 10 L          | FLS130025      | 8                | Sartopore® 2 XLG 0.8   0.2 μm              | Midicaps® size 7        | _                                 |                                       |  |                                  |                    |
|               | FLS130029      | 8                | Sartopore® 2 XLM 0.2   0.1 μm              | _                       |                                   |                                       |  |                                  |                    |
|               | FLS130043      | 8                | ¾" Opta® SFT female                        | NA                      | _                                 |                                       |  |                                  |                    |
|               | FLS130040      | 8                | 3/6" MPC female + sealing cap              | <del></del>             |                                   |                                       |  |                                  |                    |



<sup>&</sup>lt;sup>1</sup> Inlet tubing line from end line to bag:  $\frac{3}{6}$ " ×  $\frac{5}{6}$ " Clear C-Flex $^{\circ}$  500 mm (20") + Clipster $^{\circ}$  in a separate pouch

<sup>&</sup>lt;sup>2</sup> Outlet tubing line from bag to end line: 3%" × 5%" Clear C-Flex® 500 mm (20")

Buffer

Cell Harvest & DSP Flexsafe® 2D | Flexsafe® 3D | Flexsafe® 2D | Flexsafe® 3D | Flexsafe® 2D | Flexsafe® 3D | Flexs

Drug Substance Flexsafe® 2D | Flexsafe® 3D

Drug Product Flexsafe® 2D | Flexsafe® 3D Back to Table of Content

Flexsafe® 2D Pre-Designed Solutions for Media Preparation

Media **Preparation**  Sterile Weld to Biostat STR® and RM Single-use Bioreactors

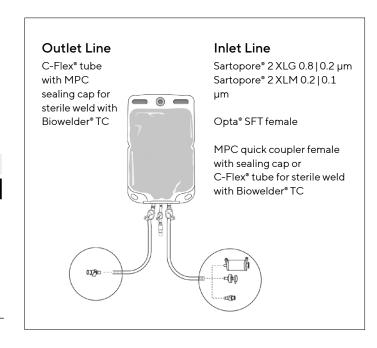
Sterile Connection to other Single-use Bioreactors

**Sterile Connection** Sterile Weld

Steaming Connection to **Stainless Steel Bioreactors** 

Sterile Weld to Other Single-Use Bioreactors

|               |                |                  | Inlet <sup>1</sup>                         |                         | Outlet <sup>2</sup>                                   | Sampling   |
|---------------|----------------|------------------|--|-------------------------|---|--|
| Bag<br>volume | Part<br>number | Units<br>per box | Filter or distal connector on filling line | Filter type<br>and size | Distal connector on draining line                     | Sampling line  |
| 20 L          | FLS130026      | 8                | Sartopore® 2 XLG 0.8   0.2 μm              | Midicaps® size 7        |   | ¼" ID Silicone Tuflux°<br>100 mm (4")<br>+ Luer Lock female<br>+ Clave connector |
|               | FLS130030      | 8                | Sartopore® 2 XLM 0.2   0.1 μm              |                         |   |  |
|               | FLS130044      | 8                | %" Opta® SFT female                        | NA                      | _   |  |
|               | FLS130041      | 8                | %" MPC female + sealing cap                | _                       | 3%" x 5%" C-Flex®                                     |  |
| 50 L          | FLS130138      | 8                | Sartopore® 2 XLG 0.8   0.2 μm              | Midicaps® size 7        | <ul><li>+ ¾" MPC male</li><li>+ sealing cap</li></ul> |  |
|               | FLS130140      | 8                | Sartopore® 2 XLM 0.2   0.1 μm              |                         |   |  |
|               | FLS130148      | 8                | %" Opta® SFT female                        | NA                      | _   |  |
|               | FLS130146      | 8                | %" MPC female + sealing cap                | _                       |   |  |



<sup>&</sup>lt;sup>1</sup> Inlet tubing line from end line to bag:  $\frac{3}{6}$ " ×  $\frac{5}{6}$ " Clear C-Flex $^{\circ}$  500 mm (20") + Clipster $^{\circ}$  in a separate pouch

<sup>&</sup>lt;sup>2</sup> Outlet tubing line from bag to end line: 3%" × 5%" Clear C-Flex® 500 mm (20")

Media **Preparation**  Sterile Weld to Biostat STR® and RM Single-use Bioreactors

Sterile Connection to other Single-use Bioreactors

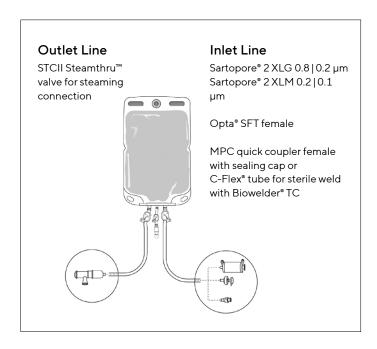
Sterile Weld

**Sterile Connection** 

**Steaming Connection to Stainless Steel Bioreactors** 

## Steaming Connection to Stainless Steel Bioreactors

|               |                |                  | Inlet¹                                     |                         | Outlet <sup>2</sup>               | Sampling  |
|---------------|----------------|------------------|--|-------------------------|-----------------------------------|---|
| Bag<br>volume | Part<br>number | Units<br>per box | Filter or distal connector on filling line | Filter type<br>and size | Distal connector on draining line | Sampling line   |
| 3 L           | FLS130134      | 16               | Sartopore® 2 XLG 0.8   0.2 μm              | Midicaps® size 4        | _                                 |   |
|               | FLS130135      | 16               | Sartopore® 2 XLM 0.2   0.1 μm              |                         |                                   |   |
|               | FLS130151      | 16               | ¾" Opta® SFT female                        | NA                      |                                   |   |
|               | FLS130149      | 16               | 3/8" MPC female + sealing cap              | _                       |                                   |   |
| 5 L           | FLS130021      | 16               | Sartopore® 2 XLG 0.8   0.2 μm              | Midicaps® size 4        | %" STCII %" sanitary flange       | 100 Silicone Tuflux* 100 mm (4") + Luer Lock female + Clave connector |
|               | FLS130022      | 16               | Sartopore® 2 XLM 0.2   0.1 μm              |                         |                                   |   |
|               | FLS130048      | 16               | %" Opta® SFT female                        | NA                      |                                   |   |
|               | FLS130045      | 16               | 3/8" MPC female + sealing cap              |                         |                                   |   |
| 10 L          | FLS130031      | 8                | Sartopore® 2 XLG 0.8   0.2 μm              | Midicaps® size 7        |                                   |   |
|               | FLS130033      | 8                | Sartopore® 2 XLM 0.2   0.1 μm              | _                       |                                   |   |
|               | FLS130049      | 8                | ¾" Opta® SFT female                        | NA                      | <del>_</del>                      |   |
|               | FLS130046      | 8                | ¾" MPC female + sealing cap                | <del></del>             |                                   |   |



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<sup>&</sup>lt;sup>1</sup> Inlet tubing line from end line to bag: 3/6" × 5/6" Clear C-Flex® 500 mm (20") + Clipster® in a separate pouch

<sup>&</sup>lt;sup>2</sup> Outlet tubing line from bag to end line: 3%" × 5%" Clear C-Flex® 500 mm (20")

Media **Preparation**  Sterile Weld to Biostat STR® and RM Single-use Bioreactors

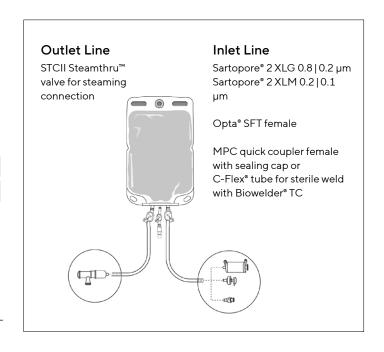
Sterile Connection to other Single-use Bioreactors

**Sterile Connection** Sterile Weld

**Steaming Connection to Stainless Steel Bioreactors** 

## Steaming Connection to Stainless Steel Bioreactors

|               |                |                  | Inlet <sup>1</sup>                         |                         | Outlet <sup>2</sup>               | Sampling   |
|---------------|----------------|------------------|--|-------------------------|-----------------------------------|--|
| Bag<br>volume | Part<br>number | Units<br>per box | Filter or distal connector on filling line | Filter type<br>and size | Distal connector on draining line | Sampling line  |
| 20 L          | FLS130032      | 8                | Sartopore® 2 XLG 0.8   0.2 μm              | Midicaps® size 7        |                                   |  |
|               | FLS130034      | 8                | Sartopore® 2 XLM 0.2   0.1 μm              |                         | <br>%" STCII                      | 1/4" ID Silicone Tuflux®<br>100 mm (4")<br>+ Luer Lock female<br>+ Clave connector |
|               | FLS130050      | 8                | %" Opta® SFT female                        | NA                      |                                   |  |
|               | FLS130047      | 8                | %" MPC female + sealing cap                |                         |                                   |  |
| 50 L          | FLS130141      | 8                | Sartopore® 2 XLG 0.8   0.2 μm              | Midicaps® size 7        | 3/4" sanitary flange              |  |
|               | FLS130142      | 8                | Sartopore® 2 XLM 0.2   0.1 μm              |                         |                                   |  |
|               | FLS130152      | 8                | %" Opta® SFT female                        | NA                      | _                                 |  |
|               | FLS130150      | 8                | %" MPC female + sealing cap                | _                       |                                   |  |



<sup>&</sup>lt;sup>1</sup> Inlet tubing line from end line to bag: 3/6" × 5/6" Clear C-Flex® 500 mm (20") + Clipster® in a separate pouch

<sup>&</sup>lt;sup>2</sup> Outlet tubing line from bag to end line: 3%" × 5%" Clear C-Flex® 500 mm (20")

Flexsafe® 3D Pre-Designed Solutions for Media Filtration, Storage and Shipping

Media **Preparation** 

Sterilizing Filtration from Mixer

**Media Storage** and Shipping

**Media Transfer** 

SUISCISAS

Sterile Weld to Biostat STR® Single-use Bioreactors

Sterile Connection to other Single-use Bioreactors

Steaming Connection to Stainless Steel Bioreactors Sterile Connection Sterile Weld

Flexsafe® 3D solutions for media are available with Sartopore® 2 XLG for sterilizing filtration or Sartopore® 2 XLM for mycoplasma retention

Flexsafe® 3D bags without filters are also available for:

- Sterile connection to alternative Sartopore® filter transfer set using Opta® 1/2" or welding with Biowelder® TC
- Aseptic connection to alternative Sartopore® filter transfer set with MPX quick coupler

Sartopore® filters can be disconnected for post-use integrity testing with sterile seal using Biosealer®.

Inlet and outlet lines are made of C-Flex® + Silicone Tuflux® tubings for welding, sealing and pumping.

Flexsafe® 3D bags allow for sterile media transfer to most common single-use and stainless steel bioreactors with a variety of sterile connections.

## Inlet Line Sterilizing Filtration ■ Sartopore® 2 XLG 0.8 | 0.2 µm ■ Sartopore® 2 XLM 0.2 | 0.1 µm Connections for Alternative Filter Line Opta® SFT female C-Flex® tube for sterile weld with Biowelder® TC MPC quick coupler female

### Sampling

Clave needleless sampling port

#### **Outlet Line**

Sterile connection and transfer by pumping or gravity

- C-Flex® with CPC quick coupler and plua for sterile weld with Biowelder® TC to Biostat® RM and Biostat STR® bioreactors
- Opta® SFT male for sterile connection to other single-use bioreactors
- STCII Steamthru<sup>™</sup> valve for steaming connection to stainless steel bioreactors

Flexsafe® 3D Pre-Designed Solutions for Media Filtration, Storage and Shipping in Palletank®

Media **Preparation**  Sterile Weld to Biostat STR® Single-use Bioreactors

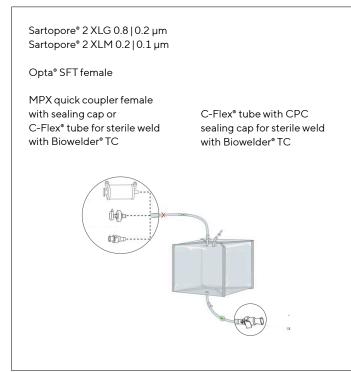
Sterile Connection to other Single-use Bioreactors

**Sterile Connection** Sterile Weld

Steaming Connection to **Stainless Steel Bioreactors** 

Sterile Weld to Biostat STR® and Biostat® RM Single-Use Bioreactors

|               |                |                  | Inlet <sup>1</sup>                         |                         | Outlet <sup>2</sup>               |
|---------------|----------------|------------------|--|-------------------------|-----------------------------------|
| Bag<br>Volume | Part<br>number | Units per<br>box | Filter or distal connector on filling line | Filter type<br>and size | Distal connector on draining line |
| 100 L         | FIS126678      | 2                | Sartopore® 2 XLG 0.8   0.2 µm              | Midicaps° size 9        |                                   |
|               | FIS126682      | 2                | Sartopore® 2 XLM 0.2   0.1 μm              |                         |                                   |
|               | FIS126706      | 3                | ½" Opta® SFT female                        | NA                      |                                   |
|               | FIS126243      | 3                | MPX female + sealing cap                   |                         | 3%"×5%" Clear C-Flex®             |
| 200 L         | FIS126679      | 2                | Sartopore® 2 XLG 0.8   0.2 µm              | Midicaps® size 0        |                                   |
|               | FIS126683      | 2                | Sartopore® 2 XLM 0.2   0.1 μm              |                         |                                   |
|               | FIS126707      | 3                | ½" Opta® SFT female                        | NA                      |                                   |
|               | FIS126244      | 3                | MPX female + sealing cap                   |                         |                                   |
| 500 L         | FIS126680      | 2                | Sartopore® 2 XLG 0.8   0.2 μm              | Maxicaps <sup>®</sup>   |                                   |
|               | FIS126684      | 2                | Sartopore® 2 XLM 0.2   0.1 μm              | size 1 T-style          | ½" ×¾" C-Flex®                    |
|               | FIS126708      | 3                | ½" Opta° SFT female                        | NA                      |                                   |
|               | FIS126245      | 3                | MPX female + sealing cap                   |                         | - ,                               |



- <sup>1</sup> Inlet tubing line from end line to bag: ½" × ¾" Clear C-Flex® 0.5 m (20") + ½" ID Silicone Tuflux® 1 m (40")
- <sup>2</sup> Outlet tubing line from bag to end line: For 100 L & 200 L: ½" ID Silicone Tuflux® 1 m (40") + 3%" × 5%" Clear C-Flex® 0.5 m (20") ½" ID Silicone Tuflux® 1 m (40") + ½" × ¾" Clear C-Flex® 0.5 m (20")

Flexsafe® 3D Pre-Designed Solutions for Media Filtration and Storage in Drum

Media **Preparation**  Sterile Weld to Biostat STR® Single-use Bioreactors

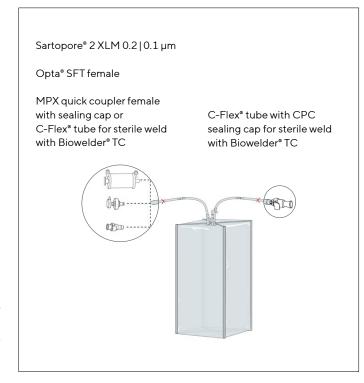
Sterile Connection to other Single-use Bioreactors

**Sterile Connection** Sterile Weld

Steaming Connection to **Stainless Steel Bioreactors** 

Sterile Weld to Biostat STR® and Biostat® RM Single-Use Bioreactors

|               |                |                  | Inlet¹   |                         | Outlet <sup>2</sup>                   |
|---------------|----------------|------------------|--|-------------------------|---------------------------------------|
| Bag<br>Volume | Part<br>number | Units per<br>box | Filter or distal connector on top filling line | Filter type<br>and size | Distal connector on top draining line |
| 50 L          | FIS127861      | 2                | Sartopore® 2 0.45   0.2 µm                     | Midicaps® size 8        |                                       |
|               | FIS127871      | 4                | ½" Opta® SFT female                            | NA                      |                                       |
|               | FIS127875      | 4                | MPX female + sealing cap                       |                         |                                       |
| 100 L         | FIS127862      | 2                | Sartopore® 2 0.45   0.2 μm                     | Midicaps® size 9        | <br>3%" × 5%" Clear C-Flex®           |
|               | FIS127872      | 4                | ½" Opta® SFT female                            | NA                      | + ¾" MPC male                         |
|               | FIS127876      | 4                | MPX female + sealing cap                       |                         | + sealing cap                         |
| 200 L         | FIS127863      | 2                | Sartopore® 2 0.45 0.2 µm                       | Midicaps® size 0        |                                       |
|               | FIS127873      | 4                | ½" Opta° SFT female                            | NA                      |                                       |
|               | FIS127877      | 4                | MPX female + sealing cap                       |                         |                                       |



<sup>&</sup>lt;sup>1</sup> Inlet tubing line from end line to bag:  $\frac{1}{2}$ " ×  $\frac{3}{4}$ " Clear C-Flex $^{\circ}$  0.5 m (20") +  $\frac{1}{2}$ " ID Silicone Tuflux $^{\circ}$  1 m (40")

<sup>&</sup>lt;sup>2</sup> Outlet tubing line from bag to end line: ½" ID Silicone Tuflux® 1 m (40") + 3/8" × 5/8" Clear C-Flex® 0.5 m (20")

Flexsafe® 3D Pre-Designed Solutions for Media Filtration, Storage and Shipping in Palletank®

Media **Preparation**  Sterile Weld to Biostat STR® Single-use Bioreactors

Sterile Connection to other Single-use Bioreactors

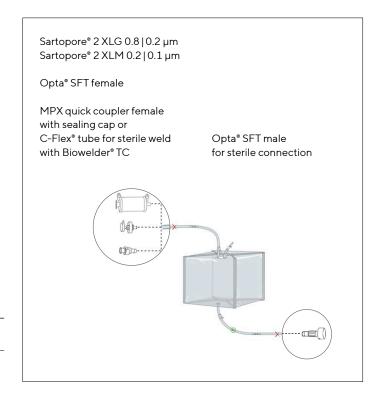
Sterile Weld

**Sterile Connection** 

Steaming Connection to **Stainless Steel Bioreactors** 

Sterile Connection to Other Single-Use Bioreactors

|               |                |                  | Inlet¹                                     |                          | Outlet <sup>2</sup>          |
|---------------|----------------|------------------|--|--------------------------|------------------------------|
| Bag<br>volume | Part<br>number | Units per<br>box | Filter or distal connector on filling line | Filter type<br>and size  | Distal connector             |
| 100 L         | FIS126698      | 2                | Sartopore® 2 XLG 0.8   0.2 μm              | Midicaps® size 9         |                              |
|               | FIS126702      | 2                | Sartopore® 2 XLM 0.2   0.1 μm              |                          |                              |
|               | FIS126718      | 3                | ½" Opta® SFT female                        | NA                       |                              |
|               | FIS126746      | 3                | MPX female + sealing cap                   |                          |                              |
| 200 L         | FIS126699      | 2                | Sartopore® 2 XLG 0.8   0.2 µm              | Midicaps® size 0         | _                            |
|               | FIS126703      | 2                | Sartopore® 2 XLM 0.2   0.1 μm              |                          | 1/" O = t = 0 C F T == = 1 = |
|               | FIS126719      | 3                | ½" Opta° SFT female                        | NA                       | — ½" Opta° SFT male          |
|               | FIS126747      | 3                | MPX female + sealing cap                   |                          |                              |
| 500 L         | FIS126700      | 2                | Sartopore® 2 XLG 0.8   0.2 μm              | Maxicaps® size 1 T-style | _                            |
|               | FIS126704      | 2                | Sartopore® 2 XLM 0.2   0.1 μm              |                          |                              |
|               | FIS126720      | 3                | ½" Opta° SFT female                        | NA                       | _                            |
|               | FIS126748      | 3                | MPX female + sealing cap                   |                          |                              |



<sup>&</sup>lt;sup>1</sup> Inlet tubing line from end line to bag:  $\frac{1}{2}$ " ×  $\frac{3}{4}$ " Clear C-Flex $^{\circ}$  0.5 m (20") +  $\frac{1}{2}$ " ID Silicone Tuflux $^{\circ}$  1 m (40")

<sup>&</sup>lt;sup>2</sup> Outlet tubing line from bag to end line: ½" ID Silicone Tuflux® 1 m (40") + ½" × ¾" Clear C-Flex® 0.5 m (20")

Flexsafe® 3D Pre-Designed Solutions for Media Filtration, Storage and Shipping in Palletank®

Media **Preparation**  Sterile Weld to Biostat STR® Single-use Bioreactors

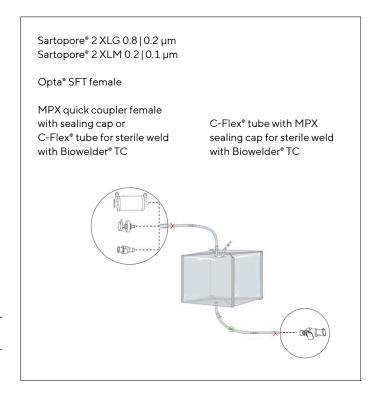
Sterile Connection to other Single-use Bioreactors

**Sterile Connection** Sterile Weld

Steaming Connection to **Stainless Steel Bioreactors** 

Sterile Weld to Other Single-Use Bioreactors

|               |                |                  | Inlet <sup>1</sup>                         |                          | Outlet <sup>2</sup>               |
|---------------|----------------|------------------|--|--------------------------|-----------------------------------|
| Bag<br>volume | Part<br>number | Units per<br>box | Filter or distal connector on filling line | Filter type<br>and size  | Distal connector on draining line |
| 100 L         | FIS127159      | 2                | Sartopore® 2 XLG 0.8   0.2 μm              | Midicaps® size 9         |                                   |
|               | FIS127161      | 2                | Sartopore® 2 XLM 0.2   0.1 µm              |                          |                                   |
|               | FIS126722      | 3                | ½" Opta° SFT female                        | NA                       | _                                 |
|               | FIS126247      | 3                | MPX female + sealing cap                   |                          |                                   |
| 200 L         | FIS127160      | 2                | Sartopore® 2 XLG 0.8   0.2 µm              | Midicaps® size 0         | _                                 |
|               | FIS127162      | 2                | Sartopore® 2 XLM 0.2   0.1 µm              |                          | ½"×¾" C-Flex®<br>— +½" MPX male   |
|               | FIS126723      | 3                | ½" Opta° SFT female                        | NA                       | + sealing cap                     |
|               | FIS126248      | 3                | MPX female + sealing cap                   |                          |                                   |
| 500 L         | FIS126680      | 2                | Sartopore® 2 XLG 0.8   0.2 μm              | Maxicaps® size 1 T-style |                                   |
|               | FIS126684      | 2                | Sartopore® 2 XLM 0.2   0.1 μm              |                          |                                   |
|               | FIS126708      | 3                | ½" Opta® SFT female                        | NA                       | _                                 |
|               | FIS126245      | 3                | MPX female + sealing cap                   |                          |                                   |



<sup>&</sup>lt;sup>1</sup> Inlet tubing line from end line to bag:  $\frac{1}{2}$ " ×  $\frac{3}{4}$ " Clear C-Flex $^{\circ}$  0.5 m (20") +  $\frac{1}{2}$ " ID Silicone Tuflux $^{\circ}$  1 m (40")

<sup>&</sup>lt;sup>2</sup> Outlet tubing line from bag to end line: ½" ID Silicone Tuflux® 1 m (40") + ½" × ¾" Clear C-Flex® 0.5 m (20")

Flexsafe® 3D Pre-Designed Solutions for Media Filtration and Storage in Drum

Media **Preparation**  Sterile Weld to Biostat STR® Single-use Bioreactors

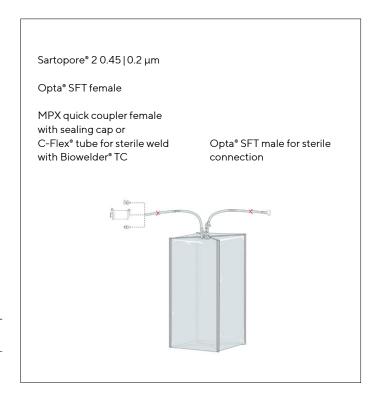
Sterile Connection to other Single-use Bioreactors

**Sterile Connection** Sterile Weld

Steaming Connection to **Stainless Steel Bioreactors** 

Sterile Connection to Other Single-Use Bioreactors

|               |                |                  | Inlet¹   |                         | Outlet <sup>2</sup>                   |
|---------------|----------------|------------------|--|-------------------------|---------------------------------------|
| Bag<br>Volume | Part<br>number | Units per<br>box | Filter or distal connector on top filling line | Filter type<br>and size | Distal connector on top draining line |
| 50 L          | FIS127868      | 2                | Sartopore® 2 0.45   0.2 µm                     | Midicaps® size 8        |                                       |
|               | FIS127906      | 4                | ½" Opta® SFT female                            | NA                      |                                       |
|               | FIS127909      | 4                | MPX female + sealing cap                       |                         |                                       |
| 100 L         | FIS127869      | 2                | Sartopore® 2 0.45   0.2 μm                     | Midicaps® size 9        |                                       |
|               | FIS127907      | 4                | ½" Opta° SFT female                            | NA                      | <br>½" Opta° SFT male                 |
|               | FIS127910      | 4                | MPX female + sealing cap                       |                         |                                       |
| 200 L         | FIS127870      | 2                | Sartopore® 2 0.45   0.2 μm                     | Midicaps® size 0        |                                       |
|               | FIS127908      | 4                | ½" Opta® SFT female                            | NA                      |                                       |
|               | FIS127911      | 4                | MPX female + sealing cap                       |                         |                                       |



<sup>&</sup>lt;sup>1</sup> Inlet tubing line from end line to bag:  $\frac{1}{2}$ " ×  $\frac{3}{4}$ " Clear C-Flex $^{\circ}$  0.5 m (20") +  $\frac{1}{2}$ " ID Silicone Tuflux $^{\circ}$  1 m (40")

<sup>&</sup>lt;sup>2</sup> Outlet tubing line from bag to end line: ½" ID Silicone Tuflux® 1 m (40") + ½" × ¾" Clear C-Flex® 0.5 m (20")

Flexsafe® 3D Pre-Designed Solutions for Media Filtration and Storage in Drum

Media **Preparation**  Sterile Weld to Biostat STR® Single-use Bioreactors

Sterile Connection to other Single-use Bioreactors

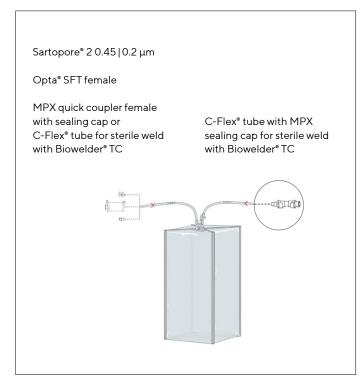
Sterile Weld

**Sterile Connection** 

Steaming Connection to **Stainless Steel Bioreactors** 

Sterile Weld to Other Single-Use Bioreactors

|               |                |                  | Inlet <sup>1</sup>                             |                         | Outlet <sup>2</sup>                   |
|---------------|----------------|------------------|--|-------------------------|---------------------------------------|
| Bag<br>volume | Part<br>number | Units per<br>box | Filter or distal connector on top filling line | Filter type<br>and size | Distal connector on top draining line |
| 50 L          | FIS127888      | 2                | Sartopore® 2 0.45   0.2 μm                     | Midicaps° size 7        |                                       |
|               | FIS127900      | 4                | ½" Opta° SFT female                            | NA                      |                                       |
|               | FIS127903      | 4                | MPX female + sealing cap                       |                         |                                       |
| 100 L         | FIS127889      | 2                | Sartopore® 2 0.45   0.2 μm                     | Midicaps® size 8        | <br>½" × ¾" Clear C-Flex®             |
|               | FIS127901      | 4                | ½" Opta° SFT female                            | NA                      | + MPX male<br>+ MPX double female     |
|               | FIS127904      | 4                | MPX female + sealing cap                       |                         | + sealing cap                         |
| 200 L         | FIS127890      | 2                | Sartopore® 2 0.45   0.2 μm                     | Midicaps® size 9        |                                       |
|               | FIS127902      | 4                | ½" Opta° SFT female                            | NA                      |                                       |
|               | FIS127905      | 4                | MPX female + sealing cap                       |                         |                                       |



<sup>&</sup>lt;sup>1</sup> Inlet tubing line from end line to bag:  $\frac{1}{2}$ " ×  $\frac{3}{4}$ " Clear C-Flex $^{\circ}$  0.5 m (20") +  $\frac{1}{2}$ " ID Silicone Tuflux $^{\circ}$  1 m (40")

<sup>&</sup>lt;sup>2</sup> Outlet tubing line from bag to end line: ½" ID Silicone Tuflux® 1 m (40") + ½" × ¾" Clear C-Flex® 0.5 m (20")

Flexsafe® 3D Pre-Designed Solutions for Media Filtration, Storage and Shipping in Palletank®

Media **Preparation**  Sterile Weld to Biostat STR® Single-use Bioreactors

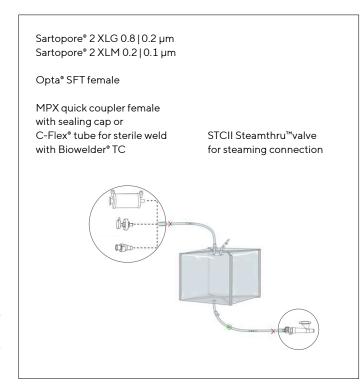
Sterile Connection to other Single-use Bioreactors

**Sterile Connection** Sterile Weld

**Steaming Connection to Stainless Steel Bioreactors** 

Steaming Connection to Stainless Steel Bioreactors

|               |                |                  | Inlet <sup>1</sup>                         |                          | Outlet <sup>2</sup>   |
|---------------|----------------|------------------|--|--------------------------|-----------------------|
| Bag<br>Volume | Part<br>number | Units per<br>box | Filter or distal connector on filling line | Filter type<br>and size  | Distal connector      |
| 100 L         | FIS126686      | 2                | Sartopore® 2 XLG 0.8   0.2 μm              | Midicaps® size 9         |                       |
|               | FIS126690      | 2                | Sartopore® 2 XLM 0.2   0.1 μm              |                          |                       |
|               | FIS126710      | 3                | ½" Opta® SFT female                        | NA                       | _                     |
|               | FIS126714      | 3                | MPX female + sealing cap                   |                          |                       |
| 200 L         | FIS126687      | 2                | Sartopore® 2 XLG 0.8   0.2 µm              | Midicaps® size 0         |                       |
|               | FIS126691      | 2                | Sartopore® 2 XLM 0.2   0.1 μm              |                          | ½" STCII 1½" sanitary |
|               | FIS126711      | 3                | ½" Opta® SFT female                        | NA                       | flange                |
|               | FIS126715      | 3                | MPX female + sealing cap                   |                          |                       |
| 500 L         | FIS126688      | 2                | Sartopore® 2 XLG 0.8   0.2 µm              | Maxicaps® size 1 T-style |                       |
|               | FIS126692      | 2                | Sartopore® 2 XLM 0.2   0.1 μm              |                          |                       |
|               | FIS126712      | 3                | ½" Opta® SFT female                        | NA                       | _                     |
|               | FIS126716      | 3                | MPX female + sealing cap                   |                          |                       |



<sup>&</sup>lt;sup>1</sup> Inlet tubing line from end line to bag:  $\frac{1}{2}$ " ×  $\frac{3}{4}$ " Clear C-Flex $^{\circ}$  0.5 m (20") +  $\frac{1}{2}$ " ID Silicone Tuflux $^{\circ}$  1 m (40")

<sup>&</sup>lt;sup>2</sup> Outlet tubing line from bag to end line: ½" ID Silicone Tuflux® 1 m (40") + ½" × ¾" Clear C-Flex® 0.5 m (20")

Flexsafe® 3D Pre-Designed Solutions for Media Filtration and Storage in Drum

Media **Preparation**  Sterile Weld to Biostat STR® Single-use Bioreactors

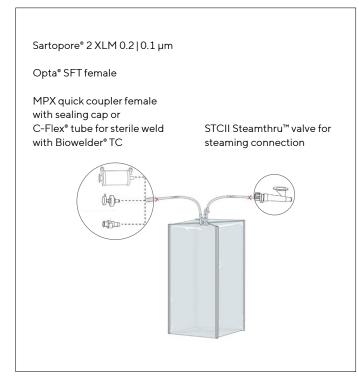
Sterile Connection to other Single-use Bioreactors

**Sterile Connection** Sterile Weld

**Steaming Connection to Stainless Steel Bioreactors** 

Steaming Connection to Stainless Steel Bioreactors

|               |                |                  | Inlet <sup>1</sup>                             |                         | Outlet <sup>2</sup>                   |
|---------------|----------------|------------------|--|-------------------------|---------------------------------------|
| Bag<br>Volume | Part<br>number | Units per<br>box | Filter or distal connector on top filling line | Filter type<br>and size | Distal connector on top draining line |
| 50 L          | FIS127864      | 2                | Sartopore® 2 0.45   0.2 μm                     | Midicaps° size 8        |                                       |
|               | FIS127878      | 4                | ½" Opta® SFT female                            | NA                      |                                       |
|               | FIS127881      | 4                | MPX female + sealing cap                       |                         |                                       |
| 100 L         | FIS127865      | 2                | Sartopore® 2 0.45   0.2 µm                     | Midicaps® size 9        |                                       |
|               | FIS127879      | 4                | ½" Opta® SFT female                            | NA                      | ½" STCII 1½" sanitary<br>flange       |
|               | FIS127882      | 4                | MPX female + sealing cap                       |                         | nango                                 |
| 200 L         | FIS127866      | 2                | Sartopore® 2 0.45   0.2 µm                     | Midicaps® size 0        |                                       |
|               | FIS127880      | 4                | ½" Opta° SFT female                            | NA                      |                                       |
|               | FIS127883      | 4                | MPX female + sealing cap                       |                         |                                       |



<sup>&</sup>lt;sup>1</sup> Inlet tubing line from end line to bag:  $\frac{1}{2}$ " ×  $\frac{3}{4}$ " Clear C-Flex $^{\circ}$  0.5 m (20") +  $\frac{1}{2}$ " ID Silicone Tuflux $^{\circ}$  1 m (40")

<sup>&</sup>lt;sup>2</sup> Outlet tubing line from bag to end line: ½" ID Silicone Tuflux® 1 m (40") + ½" × ¾" Clear C-Flex® 0.5 m (20")

Media **Preparation**  Sterile Weld to Biostat STR® Single-use Bioreactors

Sterile Connection to other Single-use Bioreactors

Steaming Connection to **Stainless Steel Bioreactors**  Sterile Connection Sterile Weld

Sterile Weld to Biostat STR® Single-Use Bioreactors

|               |                |                  | Inlet <sup>1</sup>                         |                         | Outlet <sup>2</sup>               |
|---------------|----------------|------------------|--|-------------------------|-----------------------------------|
| Bag<br>Volume | Part<br>number | Units per<br>box | Filter or distal connector on filling line | Filter type<br>and size | Distal connector on draining line |
| 1,000 L       | FIS500360      | 2                | Sartopore® 2 XLG                           | Maxicaps® Size 2        |                                   |
|               | FIS500274      | 2                | Sartopore® 2 XLM                           | Maxicaps® Size 2        |                                   |
|               | FIS500330      | 2                | ½" Opta® SFT female                        | NA                      |                                   |
|               | FIS302338      | 2                | MPX female + sealing cap                   |                         |                                   |
| 1,500 L       | FIS500361      | 2                | Sartopore® 2 XLG                           | Maxicaps® Size 2        |                                   |
|               | FIS500277      | 2                | Sartopore® 2 XLM                           | Maxicaps® Size 2        | ─── ½"×¾" C-Flex®<br>+ MPX male   |
|               | FIS500334      | 2                | ½" Opta® SFT female                        |                         | + MPX double female               |
|               | FIS302339      | 2                | MPX female + sealing cap                   |                         | + sealing cap                     |
| 2,000 L       | FIS500362      | 1                | Sartopore® 2 XLG                           | Maxicaps® Size 3        |                                   |
|               | FIS500278      | 1                | Sartopore® 2 XLM                           | Maxicaps® Size 3        |                                   |
|               | FIS500331      | 2                | ½" Opta° SFT female                        | NA                      |                                   |
|               | FIS302340      | 2                | MPX female + sealing cap                   |                         |                                   |

Sartopore® 2 XLG 0.8 | 0.2 µm Sartopore® 2 XLM 0.2 | 0.1 µm Opta® SFT female C-Flex® tube with CPC sealing cap for sterile weld MPX quick coupler female with Biowelder® TC and MPX with sealing cap or quick coupler male &female C-Flex® tube for sterile weld with cap for sanitary or with Biowelder® TC aseptic connection

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<sup>&</sup>lt;sup>1</sup> Inlet tubing line from end line to bag: 1/2" × 3/4" Clear C-Flex® 1.5 m (60")

<sup>&</sup>lt;sup>2</sup> Outlet tubing line from bag to end line: ½" ID Silicone Tuflux® 2,5 m (98") + ½" × ¾" Clear C-Flex® 0.5 m (20")

Media **Preparation**  Sterile Weld to Biostat STR® Single-use Bioreactors

Sterile Connection to other Single-use Bioreactors

**Sterile Connection** Sterile Weld

Steaming Connection to **Stainless Steel Bioreactors** 

Sterile Weld to Biostat STR® Single-Use Bioreactors

|               |                |                  | Inlet <sup>1</sup>                         |                         | Outlet <sup>2</sup>               |
|---------------|----------------|------------------|--|-------------------------|-----------------------------------|
| Bag<br>Volume | Part<br>number | Units per<br>box | Filter or distal connector on filling line | Filter type<br>and size | Distal connector on draining line |
| 2,500 L       | FIS500363      | 1                | Sartopore® 2 XLG                           | Maxicaps® Size 3        |                                   |
|               | FIS500279      | 1                | Sartopore® 2 XLM                           | Maxicaps® Size 3        |                                   |
|               | FIS500332      | 1                | ½" Opta® SFT female                        | NA                      |                                   |
|               | FIS302341      | 1                | MPX female + sealing cap                   |                         |                                   |
| 3,000 L       | FIS500364      | 1                | Sartopore® 2 XLG                           | Maxicaps® Size 3        |                                   |
|               | FIS500280      | 1                | Sartopore® 2 XLM                           | Maxicaps® Size 3        |                                   |
|               | FIS500333      | 1                | ½" Opta® SFT female                        | NA                      |                                   |
|               | FIS302342      | 1                | MPX female + sealing cap                   |                         |                                   |

Sartopore® 2 XLG 0.8 | 0.2 µm Sartopore® 2 XLM 0.2 | 0.1 µm Opta® SFT female C-Flex® tube with CPC sealing cap for sterile weld MPX quick coupler female with Biowelder® TC and MPX with sealing cap or quick coupler male &female C-Flex® tube for sterile weld with cap for sanitary or with Biowelder® TC aseptic connection

<sup>&</sup>lt;sup>1</sup> Inlet tubing line from end line to bag: ½" × ¾" Clear C-Flex® 1.5 m (60")

<sup>&</sup>lt;sup>2</sup> Outlet tubing line from bag to end line: ½" ID Silicone Tuflux® 2,5 m (98") + ½" × ¾" Clear C-Flex® 0.5 m (20")

Media **Preparation**  Sterile Weld to Biostat STR® Single-use Bioreactors

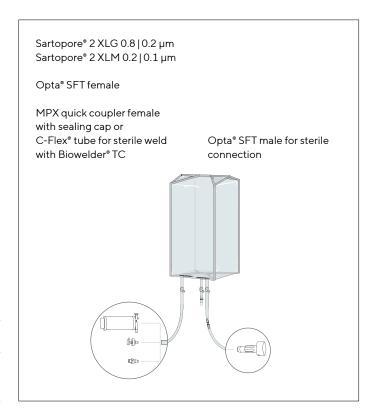
Sterile Connection to other Single-use Bioreactors

**Sterile Connection** Sterile Weld

Steaming Connection to **Stainless Steel Bioreactors** 

Sterile Connection to Other Single-Use Bioreactors

|               |                |                  | Inlet <sup>1</sup>                         |                         | Outlet <sup>2</sup>               |
|---------------|----------------|------------------|--|-------------------------|-----------------------------------|
| Bag<br>Volume | Part<br>number | Units per<br>box | Filter or distal connector on filling line | Filter type<br>and size | Distal connector on draining line |
| 1,000 L       | FIS500273      | 2                | Sartopore® 2 XLG                           | Maxicaps® Size 2        |                                   |
|               | FIS500258      | 2                | Sartopore® XLM                             | Maxicaps® Size 2        |                                   |
|               | FIS500290      | 2                | ½" Opta® SFT female                        | NA                      |                                   |
|               | FIS500300      | 2                | MPX female + sealing cap                   |                         |                                   |
| 1,500 L       | FIS500281      | 2                | Sartopore® 2 XLG                           | Maxicaps® Size 2        |                                   |
|               | FIS500259      | 2                | Sartopore® XLM                             | Maxicaps® Size 2        | 1/# Onto @ CET mode               |
|               | FIS500291      | 2                | ½" Opta® SFT female                        |                         | —— ½" Opta® SFT male              |
|               | FIS500301      | 2                | MPX female + sealing cap                   |                         |                                   |
| 2,000 L       | FIS500282      | 1                | Sartopore® 2 XLG                           | Maxicaps® Size 3        |                                   |
|               | FIS500262      | 1                | Sartopore® XLM                             | Maxicaps® Size 3        |                                   |
|               | FIS500292      | 2                | ½" Opta® SFT female                        | NA                      |                                   |
|               | FIS500302      | 2                | MPX female + sealing cap                   |                         |                                   |



<sup>&</sup>lt;sup>1</sup> Inlet tubing line from end line to bag: ½" × ¾" Clear C-Flex® 1.5 m (60")

<sup>&</sup>lt;sup>2</sup> Outlet tubing line from bag to end line: ½" ID Silicone Tuflux® 2,5 m (98") + ½" × ¾" Clear C-Flex® 0.5 m (20")

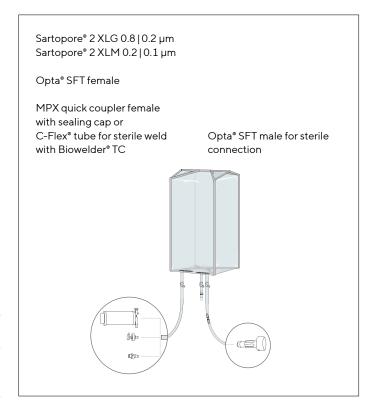
Media **Preparation**  Sterile Weld to Biostat STR® Single-use Bioreactors

Sterile Connection to other Single-use Bioreactors

Steaming Connection to **Stainless Steel Bioreactors**  **Sterile Connection** Sterile Weld

Sterile Connection to Other Single-Use Bioreactors

|               |                |                  | Inlet <sup>1</sup>                         |                         | Outlet <sup>2</sup>               |
|---------------|----------------|------------------|--|-------------------------|-----------------------------------|
| Bag<br>Volume | Part<br>number | Units per<br>box | Filter or distal connector on filling line | Filter type<br>and size | Distal connector on draining line |
| 2,500 L       | FIS500283      | 1                | Sartopore® 2 XLG                           | Maxicaps® Size 3        |                                   |
|               | FIS500263      | 1                | Sartopore® XLM                             | Maxicaps® Size 3        |                                   |
|               | FIS500293      | 1                | ½" Opta° SFT female                        | NA                      |                                   |
|               | FIS500303      | 1                | MPX female + sealing cap                   |                         |                                   |
| 3,000 L       | FIS500284      | 1                | Sartopore® 2 XLG                           | Maxicaps® Size 3        |                                   |
|               | FIS500265      | 1                | Sartopore® XLM                             | Maxicaps® Size 3        |                                   |
|               | FIS500294      | 1                | ½" Opta® SFT female                        | NA                      |                                   |
|               | FIS500304      | 1                | MPX female + sealing cap                   |                         |                                   |



<sup>&</sup>lt;sup>1</sup> Inlet tubing line from end line to bag: ½" × ¾" Clear C-Flex® 1.5 m (60")

<sup>&</sup>lt;sup>2</sup> Outlet tubing line from bag to end line: ½" ID Silicone Tuflux® 2,5 m (98") + ½" × ¾" Clear C-Flex® 0.5 m (20")

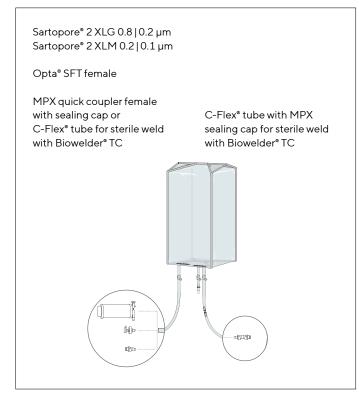
Media **Preparation**  Sterile Weld to Biostat STR® Single-use Bioreactors

Sterile Connection to other Single-use Bioreactors

Steaming Connection to **Stainless Steel Bioreactors**  **Sterile Connection** Sterile Weld

Sterile Weld to Other Single-Use Bioreactors

|               |                |                  | Inlet¹                                     |                         | Outlet <sup>2</sup>               |
|---------------|----------------|------------------|--|-------------------------|-----------------------------------|
| Bag<br>Volume | Part<br>number | Units per<br>box | Filter or distal connector on filling line | Filter type<br>and size | Distal connector on draining line |
| 1,000 L       | FIS500360      | 2                | Sartopore® 2 XLG                           | Maxicaps® Size 2        |                                   |
|               | FIS500274      | 2                | Sartopore® XLM                             | Maxicaps® Size 2        |                                   |
|               | FIS500330      | 2                | ½" Opta® SFT female                        | NA                      |                                   |
|               | FIS302338      | 2                | MPX female + sealing cap                   |                         |                                   |
| 1,500 L       | FIS500361      | 2                | Sartopore® 2 XLG                           | Maxicaps® Size 2        | 1/1 3/1 0 51 8                    |
|               | FIS500277      | 2                | Sartopore® XLM                             | Maxicaps® Size 2        | ── ½"×¾" C-Flex°<br>+ MPX male    |
|               | FIS500334      | 2                | ½" Opta® SFT female                        |                         | + MPX double female               |
|               | FIS302339      | 2                | MPX female + sealing cap                   |                         | + sealing cap                     |
| 2,000 L       | FIS500362      | 1                | Sartopore® 2 XLG                           | Maxicaps® Size 3        |                                   |
|               | FIS500278      | 1                | Sartopore® XLM                             | Maxicaps® Size 3        |                                   |
|               | FIS500331      | 2                | ½" Opta° SFT female                        | NA                      |                                   |
|               | FIS302340      | 2                | MPX female + sealing cap                   | <del></del>             |                                   |



<sup>&</sup>lt;sup>1</sup> Inlet tubing line from end line to bag: ½" × ¾" Clear C-Flex® 1.5 m (60")

<sup>&</sup>lt;sup>2</sup> Outlet tubing line from bag to end line: ½" ID Silicone Tuflux® 2,5 m (98") + ½" × ¾" Clear C-Flex® 0.5 m (20")

Media **Preparation**  Sterile Weld to Biostat STR® Single-use Bioreactors

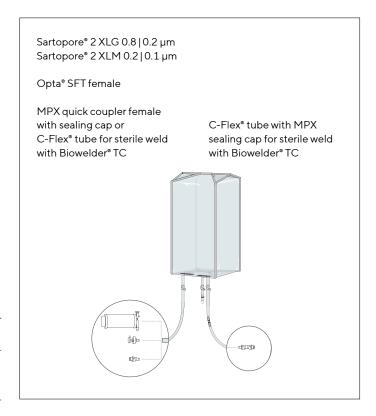
Sterile Connection to other Single-use Bioreactors

**Sterile Connection** Sterile Weld

Steaming Connection to **Stainless Steel Bioreactors** 

Sterile Weld to Other Single-Use Bioreactors

|               |                |                  | Inlet <sup>1</sup>                         |                         | Outlet <sup>2</sup>               |  |
|---------------|----------------|------------------|--|-------------------------|-----------------------------------|--|
| Bag<br>Volume | Part<br>number | Units per<br>box | Filter or distal connector on filling line | Filter type<br>and size | Distal connector on draining line |  |
| 2,500 L       | FIS500363      | 1                | Sartopore® 2 XLG                           | Maxicaps® Size 3        |                                   |  |
|               | FIS500279      | 1                | Sartopore® XLM                             | Maxicaps® Size 3        | _                                 |  |
|               | FIS500332      | 1                | ½" Opta° SFT female                        | NA                      |                                   |  |
|               | FIS302341      | 1                | MPX female + sealing cap                   |                         | ½"×¾" C-Flex°<br>+ MPX male       |  |
| 3,000 L       | FIS500364      | 1                | Sartopore® 2 XLG                           | Maxicaps® Size 3        | + MPX double female               |  |
|               | FIS500280      | 1                | Sartopore® XLM                             | Maxicaps® Size 3        | —— + sealing cap                  |  |
|               | FIS500333      | 1                | ½" Opta° SFT female                        | NA                      |                                   |  |
|               | FIS302342      | 1                | MPX female + sealing cap                   |                         |                                   |  |



<sup>&</sup>lt;sup>1</sup> Inlet tubing line from end line to bag: ½" × ¾" Clear C-Flex® 1.5 m (60")

<sup>&</sup>lt;sup>2</sup> Outlet tubing line from bag to end line: ½" ID Silicone Tuflux® 2,5 m (98") + ½" × ¾" Clear C-Flex® 0.5 m (20")

Media **Preparation**  Sterile Weld to Biostat STR® Single-use Bioreactors

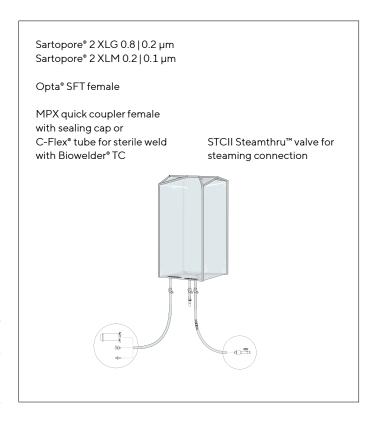
Sterile Connection to other Single-use Bioreactors

**Sterile Connection** Sterile Weld

**Steaming Connection to Stainless Steel Bioreactors** 

Steaming Connection to Stainless Steel Bioreactors

|               |                |                  | Inlet <sup>1</sup>                         |                         | Outlet <sup>2</sup>               |
|---------------|----------------|------------------|--|-------------------------|-----------------------------------|
| Bag<br>Volume | Part<br>number | Units per<br>box | Filter or distal connector on filling line | Filter type<br>and size | Distal connector on draining line |
| 1,000 L       | FIS500266      | 2                | Sartopore® 2 XLG                           | Maxicaps® Size 2        |                                   |
|               | FIS500285      | 2                | Sartopore® XLM                             | Maxicaps® Size 2        |                                   |
|               | FIS500295      | 2                | ½" Opta® SFT female                        | NA                      |                                   |
|               | FIS500305      | 2                | MPX female + sealing cap                   |                         |                                   |
| 1,500 L       | FIS500267      | 2                | Sartopore® 2 XLG                           | Maxicaps® Size 2        |                                   |
|               | FIS500286      | 2                | Sartopore® XLM                             | Maxicaps® Size 2        | <br>½" STCII 1½" sanitary         |
|               | FIS500296      | 2                | ½" Opta® SFT female                        |                         | flange                            |
|               | FIS500306      | 2                | MPX female + sealing cap                   |                         |                                   |
| 2,000 L       | FIS500268      | 1                | Sartopore® 2 XLG                           | Maxicaps® Size 3        |                                   |
|               | FIS500287      | 1                | Sartopore® XLM                             | Maxicaps® Size 3        |                                   |
|               | FIS500297      | 2                | ½" Opta° SFT female                        | NA                      |                                   |
|               | FIS500307      | 2                | MPX female + sealing cap                   |                         |                                   |



<sup>&</sup>lt;sup>1</sup> Inlet tubing line from end line to bag:  $\frac{1}{2}$ " ×  $\frac{3}{4}$ " Clear C-Flex $^{\circ}$  1.5 m (60")

<sup>&</sup>lt;sup>2</sup> Outlet tubing line from bag to end line: ½" ID Silicone Tuflux® 2,5 m (98") + ½" × ¾" Clear C-Flex® 0.5 m (20")

Media **Preparation**  Sterile Weld to Biostat STR® Single-use Bioreactors

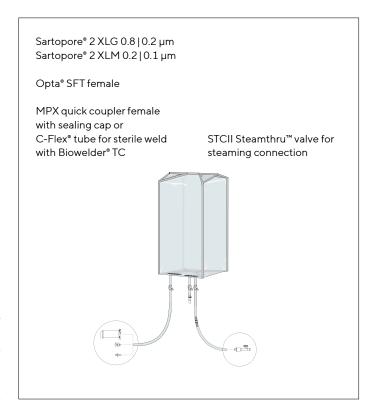
Sterile Connection to other Single-use Bioreactors

**Sterile Connection** Sterile Weld

**Steaming Connection to Stainless Steel Bioreactors** 

Steaming Connection to Stainless Steel Bioreactors

|               |                |                  | Inlet¹                                     |                         | Outlet <sup>2</sup>               |
|---------------|----------------|------------------|--|-------------------------|-----------------------------------|
| Bag<br>Volume | Part<br>number | Units per<br>box | Filter or distal connector on filling line | Filter type<br>and size | Distal connector on draining line |
| 2,500 L       | FIS500270      | 1                | Sartopore® 2 XLG                           | Maxicaps® Size 3        |                                   |
|               | FIS500288      | 1                | Sartopore® XLM                             | Maxicaps® Size 3        |                                   |
|               | FIS500298      | 1                | ½" Opta° SFT female                        | NA                      |                                   |
|               | FIS500308      | 1                | MPX female + sealing cap                   |                         | ½" STCII 1½" sanitary             |
| 3,000 L       | FIS500272      | 1                | Sartopore® 2 XLG                           | Maxicaps® Size 3        | flange                            |
|               | FIS500289      | 1                | Sartopore® XLM                             | Maxicaps® Size 3        |                                   |
|               | FIS500299      | 1                | ½" Opta® SFT female                        | NA                      |                                   |
|               | FIS500309      | 1                | MPX female + sealing cap                   |                         |                                   |



<sup>&</sup>lt;sup>1</sup> Inlet tubing line from end line to bag: ½" × ¾" Clear C-Flex® 1.5 m (60")

<sup>&</sup>lt;sup>2</sup> Outlet tubing line from bag to end line:  $\frac{1}{2}$ " ID Silicone Tuflux° 2,5 m (98") +  $\frac{1}{2}$ " ×  $\frac{3}{4}$ " Clear C-Flex° 0.5 m (20")

Buffer **Preparation** 

Sterilizing Filtration from Mixer

**Buffer Storage** and Shipping

Buffer Transfer

Sterile Connection to Downstream Systems

Sanitary or Aseptic Connection to Downstream Systems

Sterile Connection Sterile Weld

**Quick Coupler Connection** 

**Tri-Clamp Connection** 

Flexsafe® 2D solutions for buffer are available with Sartopore® 2 0.45 | 0.2 µm filter for high flow rate sterilizing filtration after mixing step.

Flexsafe® 2D bags without filters are also available for:

- Sterile connection to alternative Sartopore® filter line using Opta® 3/8" or welding with Biowelder® TC
- Aseptic connection to alternative Sartopore® filter line with MPC quick coupler

Sartopore® filters can be disconnected for post-use integrity testing with sterile seal using Biosealer®

Inlet and outlet lines are made of clear C-Flex® tubing for welding and sealing or with Silicone Tuflux® for the Tri-Clamp connection.

Flexsafe® 2D bags allow for sterile buffer transfer to most common single-use and stainless steel downstream purification and formulation systems with a variety of sterile and aseptic connections.



Buffer **Preparation**  **Sterile Connection** to Downstream Systems Sterile Connection

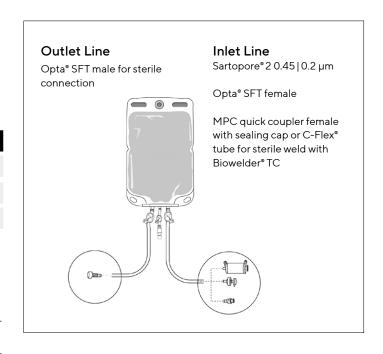
Sterile Weld

Sanitary or Aseptic Connection to Downstream Systems

**Quick Coupler Connection Tri-Clamp Connection** 

### Sterile Connection to Downstream Systems

|               |                |                  | Inlet¹                                     |                         | Outlet <sup>2</sup>               | Sampling                          |
|---------------|----------------|------------------|--|-------------------------|-----------------------------------|-----------------------------------|
| Bag<br>volume | Part<br>number | Units<br>per box | Filter or distal connector on filling line | Filter type<br>and size | Distal connector on draining line | Sampling line                     |
| 3 L           | FLS130159      | 16               | Sartopore® 2 0.45   0.2 μm                 | Midicaps® size 4        |                                   |                                   |
|               | FLS130155      | 16               | ¾" Opta® SFT female                        | NA                      | _                                 |                                   |
|               | FLS130153      | 16               | 3/8" MPC female + sealing cap              |                         |                                   |                                   |
| 5 L           | FLS130059      | 16               | Sartopore® 2 0.45   0.2 μm                 | Midicaps® size 4        | _                                 | 1/4" ID Silicone Tuflux®          |
|               | FLS130054      | 16               | ¾" Opta® SFT female                        | NA                      | -<br>%" Opta® SFT male            | 100 mm (4")<br>+ Luer Lock female |
|               | FLS130051      | 16               | 3/8" MPC female + sealing cap              |                         |                                   | + Clave connector                 |
| 10 L          | FLS130064      | 8                | Sartopore® 2 0.45   0.2 μm                 | Midicaps® size 7        | _                                 |                                   |
|               | FLS130055      | 8                | ¾" Opta® SFT female                        | NA                      | _                                 |                                   |
|               | FLS130052      | 8                | %" MPC female + sealing cap                |                         |                                   |                                   |



<sup>&</sup>lt;sup>1</sup> Inlet tubing line from end line to bag: 3/8" × 5/8" Clear C-Flex® 500 mm (20") + Clipster® in a separate pouch

<sup>&</sup>lt;sup>2</sup> Outlet tubing line from bag to end line: 3%" × 5%" Clear C-Flex® 500 mm (20")

Buffer **Preparation**  **Sterile Connection** to Downstream Systems Sterile Connection

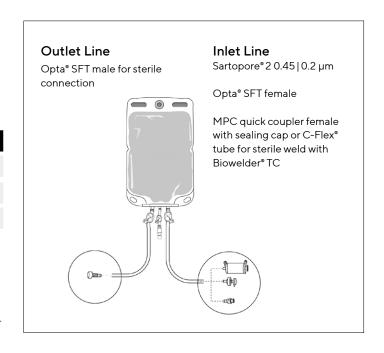
Sterile Weld

Sanitary or Aseptic Connection to Downstream Systems

**Quick Coupler Connection Tri-Clamp Connection** 

# Sterile Connection to Downstream Systems

|               |                |                  | Inlet¹                                     |                         | Outlet <sup>2</sup>               | Sampling  |
|---------------|----------------|------------------|--|-------------------------|-----------------------------------|---|
| Bag<br>volume | Part<br>number | Units<br>per box | Filter or distal connector on filling line | Filter type<br>and size | Distal connector on draining line | Sampling line   |
| 20 L          | FLS130065      | 8                | Sartopore® 2 0.45   0.2 μm                 | Midicaps® size 7        |                                   | ¼" ID Silicone Tuflux°<br>100 mm (4")<br>+ Luer Lock female |
|               | FLS130056      | 8                | ¾" Opta® SFT female                        | NA                      | _                                 |   |
|               | FLS130053      | 8                | 3/8" MPC female + sealing cap              |                         |                                   |   |
| 50 L          | FLS130162      | 8                | Sartopore® 2 0.45   0.2 μm                 | Midicaps® size 7        | – ¾" Opta® SFT male               |   |
|               | FLS130156      | 8                | ¾" Opta® SFT female                        | NA                      | _                                 | + Clave connector   |
|               | FLS130154      | 8                | 3%" MPC female + sealing cap               | <del></del>             |                                   |   |



<sup>&</sup>lt;sup>1</sup> Inlet tubing line from end line to bag: 3/8" × 5/8" Clear C-Flex® 500 mm (20") + Clipster® in a separate pouch

<sup>&</sup>lt;sup>2</sup> Outlet tubing line from bag to end line: 3%" × 5%" Clear C-Flex® 500 mm (20")

Buffer **Preparation**  **Sterile Connection** to Downstream Systems Sterile Connection

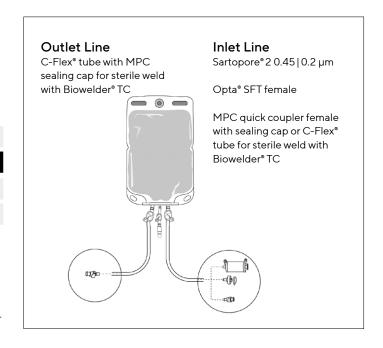
Sterile Weld

Sanitary or Aseptic Connection to Downstream Systems

**Quick Coupler Connection Tri-Clamp Connection** 

### Sterile Weld to Downstream Systems

|               |                |                  | Inlet¹                                     |                         | Outlet <sup>2</sup>                 | Sampling  |
|---------------|----------------|------------------|--|-------------------------|-------------------------------------|---|
| Bag<br>volume | Part<br>number | Units<br>per box | Filter or distal connector on filling line | Filter type<br>and size | Distal connector on draining line   | Sampling line   |
| 3 L           | FLS130157      | 16               | Sartopore® 2 0.45   0.2 μm                 | Midicaps® size 4        |                                     |   |
|               | FLS130147      | 16               | %" Opta® SFT female                        | NA                      | _                                   |   |
|               | FLS130145      | 16               | %" MPC female + sealing cap                |                         | —<br>%"×%" C-Flex*<br>+ %" MPC male | %" ID Silicone Tuflux° 100 mm (4") + Luer Lock female |
| 5 L           | FLS130057      | 16               | Sartopore® 2 0.45   0.2 μm                 | Midicaps® size 4        |                                     |   |
|               | FLS130042      | 16               | %" Opta® SFT female                        | NA                      |                                     |   |
|               | FLS130039      | 16               | %" MPC female + sealing cap                |                         | + sealing cap                       | + Clave connector                                     |
| 10 L          | FLS130060      | 8                | Sartopore® 2 0.45   0.2 μm                 | Midicaps® size 7        | _                                   |   |
|               | FLS130043      | 8                | %" Opta® SFT female                        | NA                      | _                                   |   |
|               | FLS130040      | 8                | %" MPC female + sealing cap                |                         |                                     |   |



<sup>&</sup>lt;sup>1</sup> Inlet tubing line from end line to bag: 3/8" × 5/8" Clear C-Flex® 500 mm (20") + Clipster® in a separate pouch

<sup>&</sup>lt;sup>2</sup> Outlet tubing line from bag to end line: 3%" × 5%" Clear C-Flex® 500 mm (20")

Buffer **Preparation**  **Sterile Connection** to Downstream Systems Sterile Connection

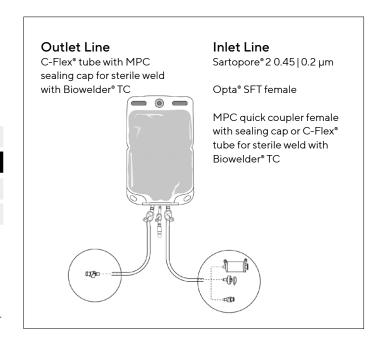
Sterile Weld

Sanitary or Aseptic Connection to Downstream Systems

**Quick Coupler Connection Tri-Clamp Connection** 

### Sterile Weld to Downstream Systems

|               |                |                  | Inlet <sup>1</sup>                         |                         | Outlet <sup>2</sup>               | Sampling                           |
|---------------|----------------|------------------|--|-------------------------|-----------------------------------|------------------------------------|
| Bag<br>volume | Part<br>number | Units<br>per box | Filter or distal connector on filling line | Filter type<br>and size | Distal connector on draining line | Sampling line                      |
| 20 L          | FLS130061      | 8                | Sartopore® 2 0.45   0.2 µm                 | Midicaps® size 7        |                                   |                                    |
|               | FLS130044      | 8                | %" Opta® SFT female                        | NA                      | _                                 |                                    |
|               | FLS130041      | 8                | 3%" MPC female + sealing cap               | <del></del>             | 3%"×5%" C-Flex®                   | ¼" ID Silicone Tuflux® 100 mm (4") |
| 50 L          | FLS130160      | 8                | Sartopore® 2 0.45   0.2 μm                 | Midicaps® size 7        | - + ¾" MPC male<br>+ sealing cap  | + Luer Lock female                 |
|               | FLS130148      | 8                | %" Opta® SFT female                        | NA                      | _                                 | + Clave connector                  |
|               | FLS130146      | 8                | ¾" MPC female + sealing cap                |                         |                                   |                                    |



<sup>&</sup>lt;sup>1</sup> Inlet tubing line from end line to bag: 3/8" × 5/8" Clear C-Flex® 500 mm (20") + Clipster® in a separate pouch

<sup>&</sup>lt;sup>2</sup> Outlet tubing line from bag to end line: 3%" × 5%" Clear C-Flex® 500 mm (20")

**Buffer** 

Cell Harvest & DSP Flexsafe® 2D | Flexsafe® 3D | Flexsafe® 2D | Flexs

Drug Substance Flexsafe® 2D | Flexsafe® 3D

Drug Product Flexsafe® 2D | Flexsafe® 3D Back to Table of Content

Flexsafe® 2D Pre-Designed Solutions for **Buffer Preparation** 

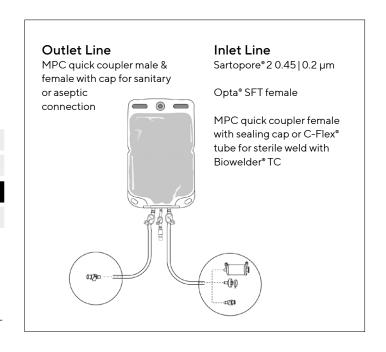
Buffer **Preparation**  Sterile Connection to Downstream Systems Sterile Connection Sterile Weld

Sanitary or Aseptic Connection to Downstream Systems

Quick Coupler Connection **Tri-Clamp Connection** 

# Quick Coupler Connection to Downstream Systems

|               |                |                  | Inlet <sup>1</sup>                         |                         | Outlet <sup>2</sup>               | Sampling  |
|---------------|----------------|------------------|--|-------------------------|-----------------------------------|---|
| Bag<br>volume | Part<br>number | Units<br>per box | Filter or distal connector on filling line | Filter type<br>and size | Distal connector on draining line | Sampling line   |
| 3 L           | FLS130157      | 16               | Sartopore® 2 0.45   0.2 μm                 | Midicaps® size 4        |                                   |   |
|               | FLS130147      | 16               | %" Opta® SFT female                        | NA                      | _                                 |   |
|               | FLS130145      | 16               | 3/8" MPC female + sealing cap              |                         |                                   |   |
| 5 L           | FLS130057      | 16               | Sartopore® 2 0.45   0.2 μm                 | Midicaps® size 4        | <br>%"×%" C-Flex®                 | ¼" ID Silicone Tuflux°<br>100 mm (4")<br>+ Luer Lock female |
|               | FLS130042      | 16               | ¾" Opta® SFT female                        | NA                      | + a" MPC male                     |   |
|               | FLS130039      | 16               | 3/8" MPC female + sealing cap              |                         | + sealing cap                     | + Clave connector   |
| 10 L          | FLS130060      | 8                | Sartopore® 2 0.45   0.2 μm                 | Midicaps® size 7        | _                                 |   |
|               | FLS130043      | 8                | ¾" Opta® SFT female                        | NA                      | _                                 |   |
|               | FLS130040      | 8                | %" MPC female + sealing cap                |                         |                                   |   |



<sup>&</sup>lt;sup>1</sup> Inlet tubing line from end line to bag: % "  $\times$  % " Clear C-Flex  $^{\circ}$  500 mm (20") + Clipster  $^{\circ}$  in a separate pouch

<sup>&</sup>lt;sup>2</sup> Outlet tubing line from bag to end line: 3%" × 5%" Clear C-Flex® 500 mm (20")

Buffer **Preparation** 

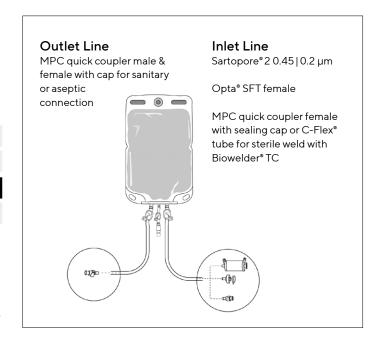
Sterile Connection to Downstream Systems Sterile Connection Sterile Weld

Sanitary or Aseptic Connection to Downstream Systems

Quick Coupler Connection **Tri-Clamp Connection** 

# Quick Coupler Connection to Downstream Systems

|               |                |                  | Inlet¹                                     |                         | Outlet <sup>2</sup>               | Sampling                           |
|---------------|----------------|------------------|--|-------------------------|-----------------------------------|------------------------------------|
| Bag<br>volume | Part<br>number | Units<br>per box | Filter or distal connector on filling line | Filter type<br>and size | Distal connector on draining line | Sampling line                      |
| 20 L          | FLS130061      | 8                | Sartopore® 2 0.45   0.2 μm                 | Midicaps® size 7        |                                   |                                    |
|               | FLS130044      | 8                | %" Opta® SFT female                        | NA                      | _                                 |                                    |
|               | FLS130041      | 8                | 3%" MPC female + sealing cap               | <del></del>             | 3/8" × 5/8" C-Flex®               | ¼" ID Silicone Tuflux® 100 mm (4") |
| 50 L          | FLS130160      | 8                | Sartopore® 2 0.45   0.2 μm                 | Midicaps® size 7        | – + a" MPC male<br>+ sealing cap  | + Luer Lock female                 |
|               | FLS130148      | 8                | %" Opta® SFT female                        | NA                      | = ' '                             | + Clave connector                  |
|               | FLS130146      | 8                | 3/4" MPC female + sealing cap              |                         |                                   |                                    |



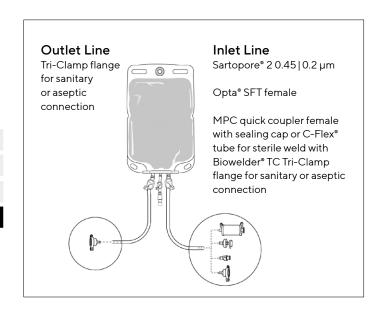
<sup>&</sup>lt;sup>1</sup> Inlet tubing line from end line to bag: % "  $\times$  % " Clear C-Flex  $^{\circ}$  500 mm (20") + Clipster  $^{\circ}$  in a separate pouch

<sup>&</sup>lt;sup>2</sup> Outlet tubing line from bag to end line: 3%" × 5%" Clear C-Flex® 500 mm (20")

Buffer **Preparation**  Sterile Connection to Downstream Systems Sterile Connection Sterile Weld

Sanitary or Aseptic Connection to Downstream Systems

**Quick Coupler Connection** Tri-Clamp Connection



# Tri-Clamp Connection to Downstream Systems

|               |                |                  | Inlet¹  |                         | Outlet <sup>2</sup>                      | Sampling                                |
|---------------|----------------|------------------|---|-------------------------|--|---|
| Bag<br>volume | Part<br>number | Units<br>per box | Filter or distal connector on filling line                | Filter type<br>and size | Distal connector on draining line        | Sampling line                           |
| 3 L           | FLS130158      | 16               | Sartopore° 2 0.45   0.2 μm                                | Midicaps® size 4        |  |   |
|               | FLS130165      | 16               | %" Opta® SFT female                                       | NA                      | _  |   |
|               | FLS130163      | 16               | %" MPC female + sealing cap                               | _                       |  |   |
|               | FLS130191      | 16               | ⅓" Tri-Clamp ¾" sanitary flange with gasket, cap & union³ | _                       |  |   |
| 5 L           | FLS130058      | 16               | Sartopore® 2 0.45   0.2 μm                                | Midicaps® size 4        | _  | 1/# ID C::: T.:(I®                      |
|               | FLS130069      | 16               | %" Opta® SFT female                                       | NA                      | %" Tri-Clamp ¾"                          | ¼" ID Silicone Tuflux®<br>100 mm (4")   |
|               | FLS130066      | 16               | %" MPC female + sealing cap                               | _                       | sanitary flange with gasket, cap & union | + Luer Lock female<br>+ Clave connector |
|               | FLS130108      | 16               | ¾" Tri-Clamp ¾" sanitary flange with gasket, cap & union³ | _                       |  | + Clave connector                       |
| 10 L          | FLS130062      | 8                | Sartopore® 2 0.45   0.2 μm                                | Midicaps® size 7        | _  |   |
|               | FLS130070      | 8                | %" Opta® SFT female                                       | NA                      | _  |   |
|               | FLS130067      | 8                | %" MPC female + sealing cap                               | _                       |  |   |
|               | FLS130109      | 8                | %" Tri-Clamp ¾" sanitary flange with gasket, cap & union³ | _                       |  |   |

<sup>&</sup>lt;sup>1</sup> Inlet tubing line from end line to bag: 3%" × 5%" Clear C-Flex 500 mm (20") + Clipster® in a separate pouch

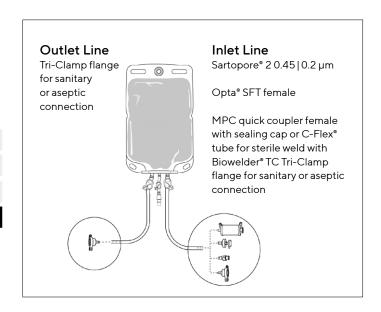
<sup>&</sup>lt;sup>2</sup> Outlet tubing line from bag to end line: 3%" x 5%" Clear C-Flex® 500 mm (20")

<sup>&</sup>lt;sup>3</sup> %" TuFlux® SIL 300 mm (12") for design with two Tri-Clamps

Buffer **Preparation**  Sterile Connection to Downstream Systems Sterile Connection Sterile Weld

Sanitary or Aseptic Connection to Downstream Systems

**Quick Coupler Connection** Tri-Clamp Connection



# Tri-Clamp Connection to Downstream Systems

|               |                |                  | Inlet <sup>1</sup>  |                         | Outlet <sup>2</sup>  | Sampling                                |
|---------------|----------------|------------------|---|-------------------------|--|---|
| Bag<br>volume | Part<br>number | Units<br>per box | Filter or distal connector on filling line                | Filter type<br>and size | Distal connector on draining line                                    | Sampling line                           |
| 20 L          | FLS130063      | 8                | Sartopore° 2 0.45   0.2 μm                                | Midicaps® size 7        |  |   |
|               | FLS130071      | 8                | %" Opta° SFT female                                       | NA                      | _  |   |
|               | FLS130068      | 8                | %" MPC female + sealing cap                               |                         |  | 1/IIID 0:11: T (I                       |
|               | FLS130110      | 8                | ¾" Tri-Clamp ¾" sanitary flange with gasket, cap & union³ |                         | %" Tri-Clamp %"  | 100 mm (4")                             |
| 50 L          | FLS130161      | 8                | Sartopore® 2 0.45   0.2 μm                                | Midicaps® size 7        | <ul> <li>sanitary flange with<br/>gasket, cap &amp; union</li> </ul> | + Luer Lock female<br>+ Clave connector |
|               | FLS130166      | 8                | %" Opta® SFT female                                       | NA                      | _  | + Clave connector                       |
|               | FLS130164      | 8                | %" MPC female + sealing cap                               |                         |  |   |
|               | FLS130192      | 8                | %" Tri-Clamp ¾" sanitary flange with gasket, cap & union³ |                         |  |   |

<sup>&</sup>lt;sup>1</sup> Inlet tubing line from end line to bag: 3%" × 5%" Clear C-Flex 500 mm (20") + Clipster® in a separate pouch

<sup>&</sup>lt;sup>2</sup> Outlet tubing line from bag to end line: 3%" x 5%" Clear C-Flex® 500 mm (20")

<sup>&</sup>lt;sup>3</sup> %" TuFlux® SIL 300 mm (12") for design with two Tri-Clamps

Buffer **Preparation** 

Sterilizing Filtration from Mixer

**Buffer Storage** and Shipping

Buffer Transfer

Sterile Connection to Downstream Systems

Sanitary or Aseptic Connection to Downstream Systems

Sterile Connection Sterile Weld

**Quick Coupler Connection** 

**Tri-Clamp Connection** 

Flexsafe® 3D solutions for buffer are available with Sartopore® 2 0.45 | 0.2 µm filter for high flowrate sterilizing filtration after mixing step.

Flexsafe® 3D bags without filters are also available for:

- Sterile connection to alternative Sartopore® filter transfer set using Opta® 1/2" or welding with Biowelder® TC
- Aseptic connection to alternative Sartopore® filter transfer set with MPX quick coupler

Sartopore® filters can be disconnected for post-use integrity testing with sterile seal using Biosealer®.

Inlet and outlet lines are made of C-Flex® + Silicone Tuflux® tubings for welding, sealing and pumping.

Flexsafe® 3D Bags allow for sterile buffer transfer to most common single-use and stainless steel downstream purification and formulation systems with a variety of sterile and aseptic connections



#### Sampling

Needleless sampling port

#### **Outlet Line**

Connection and transfer by pumping or gravity

- Opta® SFT male for sterile connection
- C-Flex® tube for sterile weld with Biowelder® TC
- MPX quick coupler male & female for sanitary or aseptic connection to single-use systems
- Tri-Clamp flange for sanitary or aseptic connection to stainless steel systems

Buffer **Preparation**  **Sterile Connection** to Downstream Systems Sterile Connection

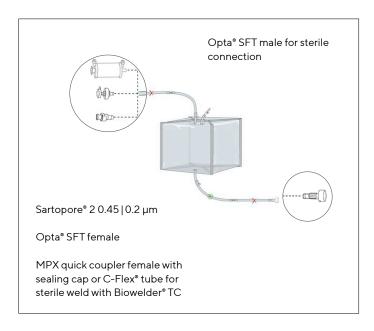
Sterile Weld

Sanitary or Aseptic Connection to Downstream Systems

**Quick Coupler Connection Tri-Clamp Connection** 

Sterile Connection to Downstream Systems

|               |                |                  | Inlet <sup>1</sup>                         |                         | Outlet <sup>2</sup>               |
|---------------|----------------|------------------|--|-------------------------|-----------------------------------|
| Bag<br>volume | Part<br>number | Units per<br>box | Filter or distal connector on filling line | Filter type<br>and size | Distal connector on draining line |
| 100 L         | FIS126734      | 2                | Sartopore® 2 0.45   0.2 µm                 | Midicaps® size 8        |                                   |
|               | FIS126718      | 3                | ½" Opta® SFT female                        | NA                      |                                   |
|               | FIS126746      | 3                | MPX female + sealing cap                   |                         |                                   |
| 200 L         | FIS126735      | 2                | Sartopore® 2 0.45   0.2 µm                 | Midicaps® size 9        |                                   |
|               | FIS126719      | 3                | ½" Opta® SFT female                        | NA                      | ½" Opta® SFT male                 |
|               | FIS126747      | 3                | MPX female + sealing cap                   |                         |                                   |
| 500 L         | FIS126736      | 2                | Sartopore® 2 0.45   0.2 μm                 | Maxicaps® size 0        |                                   |
|               | FIS126720      | 3                | ½" Opta® SFT female                        | NA                      |                                   |
|               | FIS126748      | 3                | MPX female + sealing cap                   |                         |                                   |



<sup>&</sup>lt;sup>1</sup> Inlet tubing line from end line to bag:  $\frac{1}{2}$ " ×  $\frac{3}{4}$ " Clear C-Flex $^{\circ}$  0.5 m (20") +  $\frac{1}{2}$ " ID Silicone Tuflux $^{\circ}$  1 m (40")

<sup>&</sup>lt;sup>2</sup> Outlet tubing line from bag to end line: ½" ID Silicone Tuflux® 1 m (40") + ½" × ¾" Clear C-Flex® 0.5 m (20")

Buffer **Preparation**  **Sterile Connection** to Downstream Systems Sterile Connection

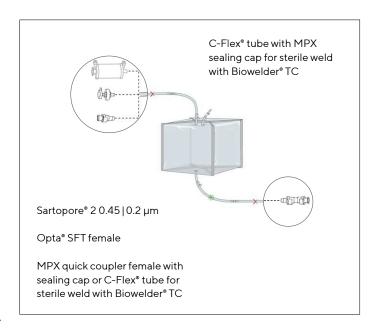
Sterile Weld

Sanitary or Aseptic Connection to Downstream Systems

**Quick Coupler Connection Tri-Clamp Connection** 

# Sterile Weld to Downstream Systems

|               |                |                  | Inlet¹                                     |                         | Outlet <sup>2</sup>               |
|---------------|----------------|------------------|--|-------------------------|-----------------------------------|
| Bag<br>volume | Part<br>number | Units per<br>box | Filter or distal connector on filling line | Filter type<br>and size | Distal connector on draining line |
| 100 L         | FIS126730      | 2                | Sartopore® 2 0.45   0.2 µm                 | Midicaps® size 8        |                                   |
|               | FIS126742      | 3                | ½" Opta® SFT female                        | NA                      |                                   |
|               | FIS126489      | 3                | MPX female + sealing cap                   |                         |                                   |
| 200 L         | FIS126731      | 2                | Sartopore® 2 0.45   0.2 µm                 | Midicaps® size 9        | <br>½"×¾" C-Flex®                 |
|               | FIS126743      | 3                | ½" Opta® SFT female                        | NA                      | + MPX male<br>+ MPX double female |
|               | FIS126490      | 3                | MPX female + sealing cap                   |                         | + sealing cap                     |
| 500 L         | FIS126732      | 2                | Sartopore® 2 0.45   0.2 µm                 | Maxicaps® size 0        |                                   |
|               | FIS126744      | 3                | ½" Opta® SFT female                        | NA                      |                                   |
|               | FIS126491      | 3                | MPX female + sealing cap                   |                         |                                   |



<sup>&</sup>lt;sup>1</sup> Inlet tubing line from end line to bag:  $\frac{1}{2}$ " ×  $\frac{3}{4}$ " Clear C-Flex $^{\circ}$  0.5 m (20") +  $\frac{1}{2}$ " ID Silicone Tuflux $^{\circ}$  1 m (40")

<sup>&</sup>lt;sup>2</sup> Outlet tubing line from bag to end line: ½" ID Silicone Tuflux® 1 m (40") + ½" × ¾" Clear C-Flex® 0.5 m (20")

Flexsafe® 3D Pre-Designed Solutions for Buffer Filtration and Storage in Drum

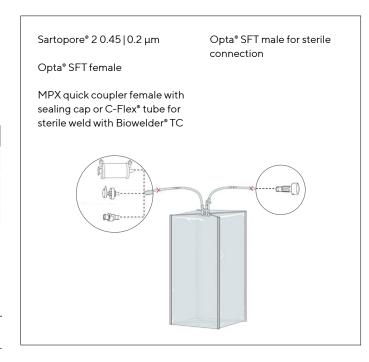
Buffer **Preparation**  **Sterile Connection** to Downstream Systems Sterile Connection Sterile Weld

Sanitary or Aseptic Connection to Downstream Systems

**Quick Coupler Connection Tri-Clamp Connection** 

Sterile Connection to Downstream Systems

|               |                |                  | Inlet¹   |                         | Outlet <sup>2</sup>                   |
|---------------|----------------|------------------|--|-------------------------|---------------------------------------|
| Bag<br>volume | Part<br>number | Units per<br>box | Filter or distal connector on top filling line | Filter type<br>and size | Distal connector on top draining line |
| 50 L          | FIS127891      | 2                | Sartopore® 2 0.45   0.2 μm                     | Midicaps® size 7        |                                       |
|               | FIS127906      | 4                | ½" Opta° SFT female                            | NA                      |                                       |
|               | FIS127909      | 4                | MPX female + sealing cap                       |                         |                                       |
| 100 L         | FIS127892      | 2                | Sartopore® 2 0.45   0.2 μm                     | Midicaps® size 8        |                                       |
|               | FIS127907      | 4                | ½" Opta° SFT female                            | NA                      | <br>½" Opta° SFT male                 |
|               | FIS127910      | 4                | MPX female + sealing cap                       |                         |                                       |
| 200 L         | FIS127893      | 2                | Sartopore® 2 0.45   0.2 μm                     | Midicaps® size 9        |                                       |
|               | FIS127908      | 4                | ½" Opta° SFT female                            | NA                      |                                       |
|               | FIS127911      | 4                | MPX female + sealing cap                       |                         |                                       |



<sup>&</sup>lt;sup>1</sup> Inlet tubing line from end line to bag:  $\frac{1}{2}$ " ×  $\frac{3}{4}$ " Clear C-Flex  $^{\circ}$  0.5 m (20") +  $\frac{1}{2}$ " ID Silicone Tuflux  $^{\circ}$  1 m (40")

<sup>&</sup>lt;sup>2</sup> Outlet tubing line from bag to end line:  $\frac{1}{2}$ " ID Silicone Tuflux° 1 m (40") +  $\frac{1}{2}$ " ×  $\frac{3}{4}$ " Clear C-Flex° 0.5 m (20")

Flexsafe® 3D Pre-Designed Solutions for Buffer Filtration and Storage in Drum

Buffer **Preparation**  **Sterile Connection** to Downstream Systems Sterile Connection

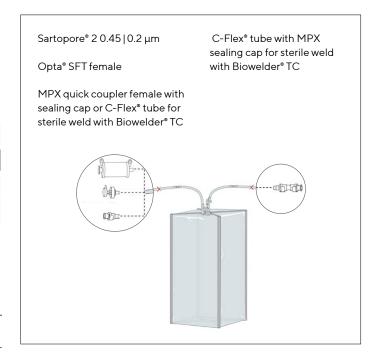
Sterile Weld

Sanitary or Aseptic Connection to Downstream Systems

**Quick Coupler Connection Tri-Clamp Connection** 

# Sterile Weld to Downstream Systems

|               |                |                  | Inlet <sup>1</sup>                             |                         | Outlet <sup>2</sup>                   |
|---------------|----------------|------------------|--|-------------------------|---------------------------------------|
| Bag<br>volume | Part<br>number | Units per<br>box | Filter or distal connector on top filling line | Filter type<br>and size | Distal connector on top draining line |
| 50 L          | FIS127888      | 2                | Sartopore® 2 0.45   0.2 µm                     | Midicaps® size 7        |                                       |
|               | FIS127900      | 4                | ½" Opta® SFT female                            | NA                      |                                       |
|               | FIS127903      | 4                | MPX female + sealing cap                       |                         |                                       |
| 100 L         | FIS127889      | 2                | Sartopore® 2 0.45   0.2 μm                     | Midicaps® size 8        | <br>½"×¾" C-Flex®                     |
|               | FIS127901      | 4                | ½" Opta° SFT female                            | NA                      | + MPX male<br>+ MPX double female     |
|               | FIS127904      | 4                | MPX female + sealing cap                       |                         | + sealing cap                         |
| 200 L         | FIS127890      | 2                | Sartopore® 2 0.45   0.2 μm                     | Midicaps® size 9        |                                       |
|               | FIS127902      | 4                | ½" Opta° SFT female                            | NA                      |                                       |
|               | FIS127905      | 4                | MPX female + sealing cap                       |                         |                                       |



<sup>&</sup>lt;sup>1</sup> Inlet tubing line from end line to bag:  $\frac{1}{2}$ " ×  $\frac{3}{4}$ " Clear C-Flex  $^{\circ}$  0.5 m (20") +  $\frac{1}{2}$ " ID Silicone Tuflux  $^{\circ}$  1 m (40")

<sup>&</sup>lt;sup>2</sup> Outlet tubing line from bag to end line: ½" ID Silicone Tuflux® 1 m (40") + ½" × ¾" Clear C-Flex® 0.5 m (20")

Buffer **Preparation**  Sterile Connection to Downstream Systems Sterile Connection

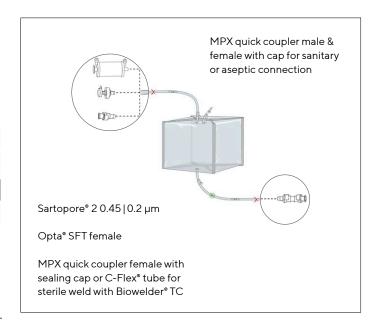
Sterile Weld

Sanitary or Aseptic Connection to Downstream Systems

Quick Coupler Connection **Tri-Clamp Connection** 

Quick Coupler Connection to Downstream Systems

|               |                |                  | Inlet <sup>1</sup>                         |                      | Outlet <sup>2</sup>               |
|---------------|----------------|------------------|--|----------------------|-----------------------------------|
| Bag<br>volume | Part<br>number | Units per<br>box | Filter or distal connector on filling line | Filter type and size | Distal connector on draining line |
| 100 L         | FIS126730      | 2                | Sartopore® 2 0.45   0.2 µm                 | Midicaps® size 8     |                                   |
|               | FIS126742      | 3                | ½" Opta® SFT female                        | NA                   | _                                 |
|               | FIS126489      | 3                | MPX female + sealing cap                   |                      |                                   |
| 200 L         | FIS126731      | 2                | Sartopore® 2 0.45   0.2 µm                 | Midicaps® size 9     | –<br>⅓" MPX male                  |
|               | FIS126743      | 3                | ½" Opta® SFT female                        | NA                   | + MPX double female               |
|               | FIS126490      | 3                | MPX female + sealing cap                   |                      | + sealing cap                     |
| 500 L         | FIS126732      | 2                | Sartopore® 2 0.45   0.2 µm                 | Maxicaps® size 0     | _                                 |
|               | FIS126744      | 3                | ½" Opta° SFT female                        | NA                   | _                                 |
|               | FIS126491      | 3                | MPX female + sealing cap                   |                      |                                   |



<sup>&</sup>lt;sup>1</sup> Inlet tubing line from end line to bag:  $\frac{1}{2}$ " ×  $\frac{3}{4}$ " Clear C-Flex $^{\circ}$  0.5 m (20") +  $\frac{1}{2}$ " ID Silicone Tuflux $^{\circ}$  1 m (40")

<sup>&</sup>lt;sup>2</sup> Outlet tubing line from bag to end line: ½" ID Silicone Tuflux® 1 m (40") + ½" × ¾" Clear C-Flex® 0.5 m (20")

Buffer **Preparation**  Sterile Connection to Downstream Systems Sterile Connection

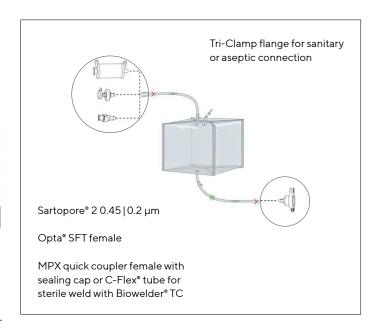
Sterile Weld

Sanitary or Aseptic Connection to Downstream Systems

**Quick Coupler Connection** Tri-Clamp Connection

### Tri-Clamp Connection to Downstream Systems

|               |                |                  | Inlet¹                                     |                      | Outlet <sup>2</sup>               |
|---------------|----------------|------------------|--|----------------------|-----------------------------------|
| Bag<br>volume | Part<br>number | Units per<br>box | Filter or distal connector on filling line | Filter type and size | Distal connector on draining line |
| 100 L         | FIS126251      | 2                | Sartopore® 2 0.45   0.2 µm                 | Midicaps® size 8     |                                   |
|               | FIS126738      | 3                | ½" Opta° SFT female                        | NA                   | _                                 |
|               | FIS126255      | 3                | MPX female + sealing cap                   |                      |                                   |
| 200 L         | FIS126252      | 2                | Sartopore® 2 0.45   0.2 µm                 | Midicaps® size 9     | —<br>_ ½" Tri-Clamp 1½" sanitary  |
|               | FIS126739      | 3                | ½" Opta® SFT female                        | NA                   | flange with gasket,               |
|               | FIS126256      | 3                | MPX female + sealing cap                   |                      | cap & union                       |
| 500 L         | FIS126253      | 2                | Sartopore® 2 0.45   0.2 µm                 | Maxicaps® size 0     | _                                 |
|               | FIS126740      | 3                | ½" Opta° SFT female                        | NA                   | _                                 |
|               | FIS126257      | 3                | MPX female + sealing cap                   |                      |                                   |



<sup>&</sup>lt;sup>1</sup> Inlet tubing line from end line to bag:  $\frac{1}{2}$ " ×  $\frac{3}{4}$ " Clear C-Flex $^{\circ}$  0.5 m (20") +  $\frac{1}{2}$ " ID Silicone Tuflux $^{\circ}$  1 m (40")

<sup>&</sup>lt;sup>2</sup> Outlet tubing line from bag to end line: ½" ID Silicone Tuflux® 1,5 m (60")

Flexsafe® 3D Pre-Designed Solutions for Buffer Filtration and Storage in Drum

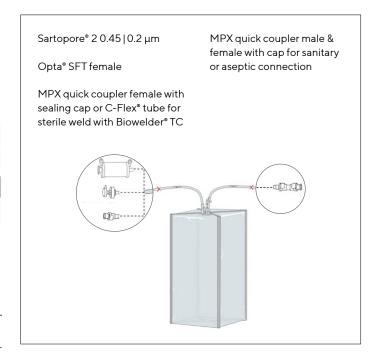
Buffer **Preparation**  Sterile Connection to Downstream Systems Sterile Connection Sterile Weld

Sanitary or Aseptic Connection to Downstream Systems

Quick Coupler Connection **Tri-Clamp Connection** 

Quick Coupler Connection to Downstream Systems

|               |                |                  | Inlet <sup>1</sup>                             |                         | Outlet <sup>2</sup>                   |
|---------------|----------------|------------------|--|-------------------------|---------------------------------------|
| Bag<br>volume | Part<br>number | Units per<br>box | Filter or distal connector on top filling line | Filter type<br>and size | Distal connector on top draining line |
| 50 L          | FIS127888      | 2                | Sartopore® 2 0.45   0.2 μm                     | Midicaps® size 7        |                                       |
|               | FIS127900      | 4                | ½" Opta® SFT female                            | NA                      |                                       |
|               | FIS127903      | 4                | MPX female + sealing cap                       |                         |                                       |
| 100 L         | FIS127889      | 2                | Sartopore® 2 0.45   0.2 μm                     | Midicaps® size 8        | <br>½" MPX male                       |
|               | FIS127901      | 4                | ½" Opta° SFT female                            | NA                      | + MPX double female                   |
|               | FIS127904      | 4                | MPX female + sealing cap                       |                         | + sealing cap                         |
| 200 L         | FIS127890      | 2                | Sartopore® 2 0.45   0.2 μm                     | Midicaps® size 9        |                                       |
|               | FIS127902      | 4                | ½" Opta° SFT female                            | NA                      |                                       |
|               | FIS127905      | 4                | MPX female + sealing cap                       |                         |                                       |



<sup>&</sup>lt;sup>1</sup> Inlet tubing line from end line to bag: 

<sup>&</sup>lt;sup>2</sup> Outlet tubing line from bag to end line: ½" ID Silicone Tuflux® 1 m (40") + ½" × ¾" Clear C-Flex® 0.5 m (20")

Flexsafe® 3D Pre-Designed Solutions for Buffer Filtration and Storage in Drum

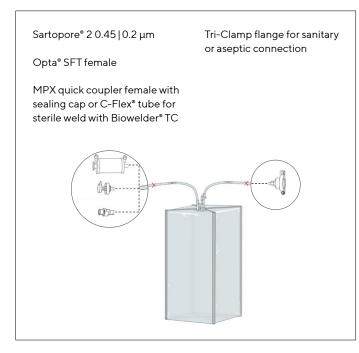
Buffer **Preparation**  Sterile Connection to Downstream Systems Sterile Connection Sterile Weld

Sanitary or Aseptic Connection to Downstream Systems

**Quick Coupler Connection** Tri-Clamp Connection

Tri-Clamp Connection to Downstream Systems

|               |                |                  | Inlet <sup>1</sup>                             |                         | Outlet <sup>2</sup>                                       |
|---------------|----------------|------------------|--|-------------------------|---|
| Bag<br>volume | Part<br>number | Units per<br>box | Filter or distal connector on top filling line | Filter type<br>and size | Distal connector on top draining line                     |
| 50 L          | FIS127885      | 2                | Sartopore® 2 0.45   0.2 µm                     | Midicaps° size 7        |   |
|               | FIS127894      | 4                | ½" Opta® SFT female                            | NA                      |   |
|               | FIS127897      | 4                | MPX female + sealing cap                       |                         |   |
|               | FIS127912      | 4                | ½" Tri-Clamp 1½" flange3                       |                         |   |
| 100 L         | FIS127886      | 2                | Sartopore® 2 0.45   0.2 µm                     | Midicaps® size 8        |   |
|               | FIS127895      | 4                | ½" Opta® SFT female                            | NA                      | ½" Tri-Clamp  |
|               | FIS127898      | 4                | MPX female + sealing cap                       |                         | $1\frac{1}{2}$ " sanitary flange with gasket, cap & union |
|               | FIS127913      | 4                | ½" Tri-Clamp 1½" flange3                       |                         |   |
| 200 L         | FIS127887      | 2                | Sartopore® 2 0.45   0.2 µm                     | Midicaps® size 9        |   |
|               | FIS127896      | 4                | ½" Opta® SFT female                            | NA                      |   |
|               | FIS127899      | 4                | MPX female + sealing cap                       |                         |   |
|               | FIS127914      | 4                | ½" Tri-Clamp 1½" flange3                       |                         |   |



<sup>&</sup>lt;sup>1</sup> Inlet tubing line from end line to bag:  $\frac{1}{2}$ " ×  $\frac{3}{4}$ " Clear C-Flex  $^{\circ}$  0.5 m (20") +  $\frac{1}{2}$ " ID Silicone Tuflux  $^{\circ}$  1 m (40")

<sup>&</sup>lt;sup>2</sup> Tubing line from bag to end line: ½" ID Silicone Tuflux® 1,5 m (60")

Buffer **Preparation**  **Sterile Connection** to Downstream Systems Sterile Connection

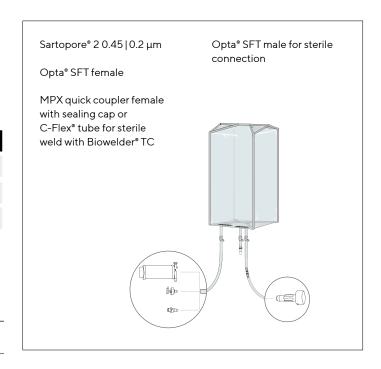
Sterile Weld

Sanitary or Aseptic Connection to Downstream Systems

**Quick Coupler Connection Tri-Clamp Connection** 

### Sterile Connection to Downstream Systems

|               |                |                  | Inlet¹                                     |                         | Outlet <sup>2</sup>               |
|---------------|----------------|------------------|--|-------------------------|-----------------------------------|
| Bag<br>Volume | Part<br>number | Units per<br>box | Filter or distal connector on filling line | Filter type<br>and size | Distal connector on draining line |
| 1,000 L       | FIS500325      | 2                | Sartopore® 2                               | Maxicaps® Size 1        |                                   |
|               | FIS500290      | 2                | ½" Opta® SFT female                        | NA                      |                                   |
|               | FIS500300      | 2                | MPX female + sealing cap                   |                         |                                   |
| 1,500 L       | FIS500326      | 2                | Sartopore® 2                               | Maxicaps® Size 1        |                                   |
|               | FIS500291      | 2                | ½" Opta® SFT female                        |                         | ½" Opta® SFT male                 |
|               | FIS500301      | 2                | MPX female + sealing cap                   |                         |                                   |
| 2,000 L       | FIS500327      | 1                | Sartopore® 2                               | Maxicaps® Size 2        |                                   |
|               | FIS500292      | 2                | ½" Opta° SFT female                        | NA                      |                                   |
|               | FIS500302      | 2                | MPX female + sealing cap                   |                         |                                   |



<sup>&</sup>lt;sup>1</sup> Inlet tubing line from end line to bag: ½" × ¾" Clear C-Flex® 1.5 m (60")

<sup>&</sup>lt;sup>2</sup> Outlet tubing line from bag to end line:  $\frac{1}{2}$ " ID Silicone Tuflux° 2,5 m (98") +  $\frac{1}{2}$ " ×  $\frac{3}{4}$ " Clear C-Flex° 0.5 m (20")

Buffer **Preparation**  **Sterile Connection** to Downstream Systems Sterile Connection

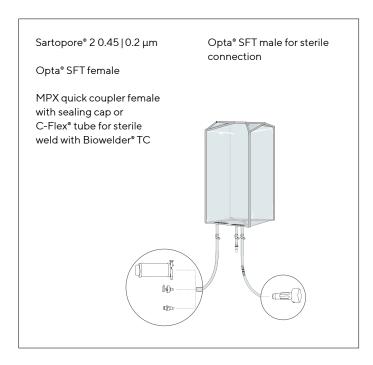
Sterile Weld

Sanitary or Aseptic Connection to Downstream Systems

**Quick Coupler Connection Tri-Clamp Connection** 

Sterile Connection to Downstream Systems

|               |                |                  | Inlet¹                                     |                         | Outlet <sup>2</sup>               |
|---------------|----------------|------------------|--|-------------------------|-----------------------------------|
| Bag<br>Volume | Part<br>number | Units per<br>box | Filter or distal connector on filling line | Filter type<br>and size | Distal connector on draining line |
| 2,500 L       | FIS500328      | 1                | Sartopore® 2                               | Maxicaps® Size 2        |                                   |
|               | FIS500293      | 1                | ½" Opta° SFT female                        | NA                      |                                   |
|               | FIS500303      | 1                | MPX female + sealing cap                   |                         | 1/II O + @ CET - I                |
| 3,000 L       | FIS500329      | 1                | Sartopore® 2                               | Maxicaps® Size 2        | ½" Opta® SFT male                 |
|               | FIS500294      | 1                | ½" Opta° SFT female                        | NA                      |                                   |
|               | FIS500304      | 1                | MPX female + sealing cap                   |                         |                                   |



<sup>&</sup>lt;sup>1</sup> Inlet tubing line from end line to bag: ½" × ¾" Clear C-Flex® 1.5 m (60")

<sup>&</sup>lt;sup>2</sup> Outlet tubing line from bag to end line:  $\frac{1}{2}$ " ID Silicone Tuflux° 2,5 m (98") +  $\frac{1}{2}$ " ×  $\frac{3}{4}$ " Clear C-Flex° 0.5 m (20")

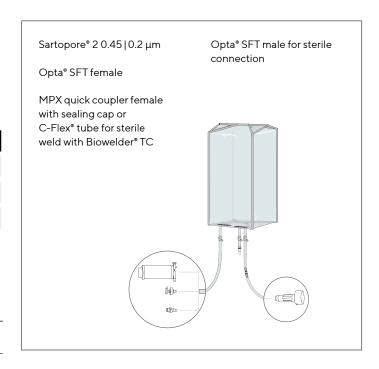
Buffer **Preparation**  **Sterile Connection** to Downstream Systems Sterile Connection Sterile Weld

Sanitary or Aseptic Connection to Downstream Systems

**Quick Coupler Connection Tri-Clamp Connection** 

Sterile Connection to Downstream Systems - High Flow Rate

|               |                |                  | Inlet¹                                     |                         | Outlet <sup>2</sup>               |
|---------------|----------------|------------------|--|-------------------------|-----------------------------------|
| Bag<br>Volume | Part<br>number | Units per<br>box | Filter or distal connector on filling line | Filter type<br>and size | Distal connector on draining line |
| 1,000 L       | FIS500335      | 2                | Sartopore® 2                               | Maxicaps® Size 1        |                                   |
|               | FIS302278      | 2                | ¾" Opta° SFT female                        | NA                      |                                   |
| 1,500 L       | FIS500336      | 2                | Sartopore® 2                               | Maxicaps® Size 1        |                                   |
|               | FIS302279      | 2                | ¾" Opta® SFT female                        | NA                      |                                   |
| 2,000 L       | FIS500337      | 1                | Sartopore® 2                               | Maxicaps® Size 2        | 3/!! Out a 8 CFT and la           |
|               | FIS500275      | 2                | ¾" Opta® SFT female                        | NA                      | —— ¾" Opta® SFT male              |
| 2,500 L       | FIS500338      | 1                | Sartopore® 2                               | Maxicaps® Size 2        |                                   |
|               | FIS500276      | 1                | ¾" Opta® SFT female                        | NA                      |                                   |
| 3,000 L       | FIS500339      | 1                | Sartopore® 2                               | Maxicaps® Size 2        |                                   |
|               | FIS302282      | 1                | ¾" Opta® SFT female                        | NA                      |                                   |



<sup>&</sup>lt;sup>1</sup> Inlet tubing line from end line to bag: ½" × ¾" Clear C-Flex® 1.5 m (60")

<sup>&</sup>lt;sup>2</sup> Outlet tubing line from bag to end line:  $\frac{1}{2}$ " ID Silicone Tuflux° 2,5 m (98") +  $\frac{1}{2}$ " ×  $\frac{3}{4}$ " Clear C-Flex° 0.5 m (20")

Buffer **Preparation**  **Sterile Connection** to Downstream Systems Sterile Connection

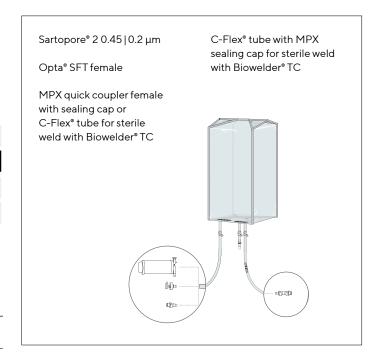
Sterile Weld

Sanitary or Aseptic Connection to Downstream Systems

**Quick Coupler Connection Tri-Clamp Connection** 

### Sterile Weld to Downstream Systems

|               |                |                  | Inlet <sup>1</sup>                         |                         | Outlet <sup>2</sup>               |
|---------------|----------------|------------------|--|-------------------------|-----------------------------------|
| Bag<br>Volume | Part<br>number | Units per<br>box | Filter or distal connector on filling line | Filter type<br>and size | Distal connector on draining line |
| 1,000 L       | FIS500310      | 2                | Sartopore® 2                               | Maxicaps® Size 1        |                                   |
|               | FIS500330      | 2                | ½" Opta® SFT female                        | NA                      |                                   |
|               | FIS302338      | 2                | MPX female + sealing cap                   |                         |                                   |
| 1,500 L       | FIS500311      | 2                | Sartopore® 2                               | Maxicaps® Size 1        | <br>½" × ¾" C-Flex®               |
|               | FIS500334      | 2                | ½" Opta® SFT female                        |                         | + MPX male<br>+ MPX double female |
|               | FIS302339      | 2                | MPX female + sealing cap                   |                         | + sealing cap                     |
| 2,000 L       | FIS500312      | 1                | Sartopore® 2                               | Maxicaps® Size 2        |                                   |
|               | FIS500331      | 2                | ½" Opta° SFT female                        | NA                      |                                   |
|               | FIS302340      | 2                | MPX female + sealing cap                   |                         |                                   |



<sup>&</sup>lt;sup>1</sup> Inlet tubing line from end line to bag: ½" × ¾" Clear C-Flex® 1.5 m (60")

<sup>&</sup>lt;sup>2</sup> Outlet tubing line from bag to end line:  $\frac{1}{2}$ " ID Silicone Tuflux° 2,5 m (98") +  $\frac{1}{2}$ " ×  $\frac{3}{4}$ " Clear C-Flex° 0.5 m (20")

Buffer **Preparation**  **Sterile Connection** to Downstream Systems Sterile Connection

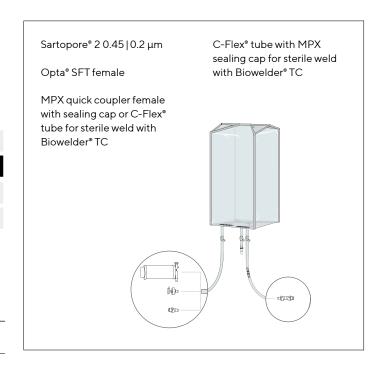
Sterile Weld

Sanitary or Aseptic Connection to Downstream Systems

**Quick Coupler Connection Tri-Clamp Connection** 

Sterile Weld to Downstream Systems

|               |                |                  | Inlet¹                                     |                         | Outlet <sup>2</sup>               |
|---------------|----------------|------------------|--|-------------------------|-----------------------------------|
| Bag<br>Volume | Part<br>number | Units per<br>box | Filter or distal connector on filling line | Filter type<br>and size | Distal connector on draining line |
| 2,500 L       | FIS500313      | 1                | Sartopore® 2                               | Maxicaps® Size 2        |                                   |
|               | FIS500332      | 1                | ½" Opta® SFT female                        | NA                      |                                   |
|               | FIS302341      | 1                | MPX female + sealing cap                   |                         | ½" × ¾" C-Flex°<br>+ MPX male     |
| 3,000 L       | FIS500314      | 1                | Sartopore® 2                               | Maxicaps® Size 2        | + MPX double female               |
|               | FIS500333      | 1                | ½" Opta® SFT female                        | NA                      | + sealing cap                     |
|               | FIS302342      | 1                | MPX female + sealing cap                   |                         |                                   |



<sup>&</sup>lt;sup>1</sup> Inlet tubing line from end line to bag: ½" × ¾" Clear C-Flex® 1.5 m (60")

<sup>&</sup>lt;sup>2</sup> Outlet tubing line from bag to end line:  $\frac{1}{2}$ " ID Silicone Tuflux° 2,5 m (98") +  $\frac{1}{2}$ " ×  $\frac{3}{4}$ " Clear C-Flex° 0.5 m (20")

Buffer **Preparation**  **Sterile Connection** to Downstream Systems Sterile Connection

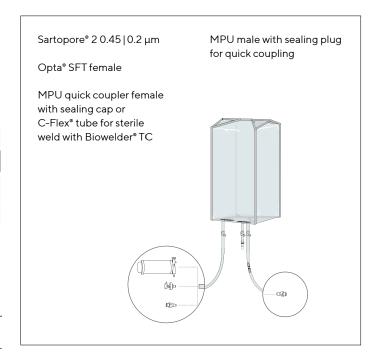
Sterile Weld

Sanitary or Aseptic Connection to Downstream Systems

**Quick Coupler Connection Tri-Clamp Connection** 

Sterile Weld to Downstream Systems - High Flow Rate

|               |                |                  | Inlet¹                                     |                         | Outlet <sup>2</sup>                        |
|---------------|----------------|------------------|--|-------------------------|--|
| Bag<br>Volume | Part<br>number | Units per<br>box | Filter or distal connector on filling line | Filter type<br>and size | Distal connector on draining line          |
| 1,000 L       | FIS500370      | 2                | Sartopore® 2                               | Maxicaps® Size 1        |  |
|               | FIS500375      | 2                | ¾" Opta® SFT female                        | NA                      |  |
|               | FIS500365      | 2                | MPX female + sealing cap                   |                         |  |
| 1,500 L       | FIS500371      | 2                | Sartopore® 2                               | Maxicaps® Size 1        | 3/4" × 1" C-Flex° + MPU male + sealing cap |
|               | FIS500376      | 2                | ¾" Opta® SFT female                        |                         |  |
|               | FIS500366      | 2                | MPX female + sealing cap                   |                         |  |
| 2,000 L       | FIS500372      | 1                | Sartopore® 2                               | Maxicaps® Size 2        |  |
|               | FIS500377      | 2                | ¾" Opta® SFT female                        | NA                      |  |
|               | FIS500367      | 2                | MPX female + sealing cap                   |                         |  |



<sup>&</sup>lt;sup>1</sup> Inlet tubing line from end line to bag with filter: ½" × ¾" Clear C-Flex® 1.5 m (60")

<sup>&</sup>lt;sup>1</sup> Inlet tubing line from connector to bag: 3/4" × 1" Clear C-Flex® 1.5 m (60")

<sup>&</sup>lt;sup>2</sup> Outlet tubing line from bag to end line:  $\frac{3}{4}$ " ID Silicone Tuflux° 2.5 m (98") +  $\frac{3}{4}$ " × 1" Clear C-Flex° 0.5 m (20")

Buffer **Preparation**  **Sterile Connection** to Downstream Systems Sterile Connection

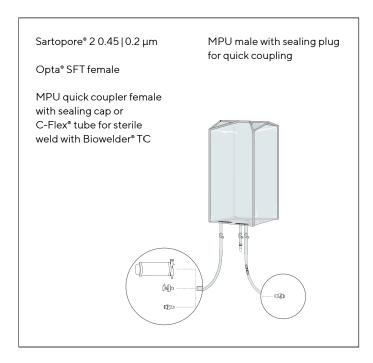
Sterile Weld

Sanitary or Aseptic Connection to Downstream Systems

**Quick Coupler Connection Tri-Clamp Connection** 

Sterile Weld to Downstream Systems - High Flow Rate

|               |                |                  | Inlet <sup>1</sup>                         |                         | Outlet <sup>2</sup>               |
|---------------|----------------|------------------|--|-------------------------|-----------------------------------|
| Bag<br>Volume | Part<br>number | Units per<br>box | Filter or distal connector on filling line | Filter type<br>and size | Distal connector on draining line |
| 2,500 L       | FIS500373      | 1                | Sartopore® 2                               | Maxicaps® Size 2        |                                   |
|               | FIS500378      | 1                | ¾" Opta® SFT female                        | NA                      |                                   |
|               | FIS500368      | 1                | MPX female + sealing cap                   |                         | 3/4" × 1" C-Flex®                 |
| 3,000 L       | FIS500374      | 1                | Sartopore® 2                               | Maxicaps® Size 2        |                                   |
|               | FIS500379      | 1                | ¾" Opta® SFT female                        | NA                      |                                   |
|               | FIS500369      | 1                | MPX female + sealing cap                   |                         |                                   |



<sup>&</sup>lt;sup>1</sup> Inlet tubing line from end line to bag with filter: ½" × ¾" Clear C-Flex® 1.5 m (60")

<sup>&</sup>lt;sup>1</sup> Inlet tubing line from connector to bag: 3/4" × 1" Clear C-Flex® 1.5 m (60")

<sup>&</sup>lt;sup>2</sup> Outlet tubing line from bag to end line:  $\frac{3}{4}$ " ID Silicone Tuflux° 2.5 m (98") +  $\frac{3}{4}$ " × 1" Clear C-Flex° 0.5 m (20")

Buffer **Preparation**  Sterile Connection to Downstream Systems Sterile Connection

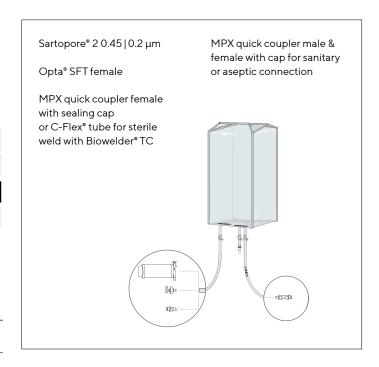
Sterile Weld

Sanitary or Aseptic Connection to Downstream Systems

Quick Coupler Connection **Tri-Clamp Connection** 

Quick Coupler Connection to Downstream Systems

|               |                |                  | Inlet¹                                     |                         | Outlet <sup>2</sup>                                |
|---------------|----------------|------------------|--|-------------------------|--|
| Bag<br>Volume | Part<br>number | Units per<br>box | Filter or distal connector on filling line | Filter type<br>and size | Distal connector on draining line                  |
| 1,000 L       | FIS500310      | 2                | Sartopore® 2                               | Maxicaps® Size 1        |  |
|               | FIS500330      | 2                | ½" Opta® SFT female                        | NA                      |  |
|               | FIS302338      | 2                | MPX female + sealing cap                   |                         |  |
| 1,500 L       | FIS500311      | 2                | Sartopore® 2                               | Maxicaps® Size 1        | <br>½"×¾" C-Flex®                                  |
|               | FIS500334      | 2                | ½" Opta° SFT female                        |                         | + MPX male<br>+ MPX double female<br>+ sealing cap |
|               | FIS302339      | 2                | MPX female + sealing cap                   |                         |  |
| 2,000 L       | FIS500312      | 1                | Sartopore® 2                               | Maxicaps® Size 2        |  |
|               | FIS500331      | 2                | ½" Opta° SFT female                        | NA                      |  |
|               | FIS302340      | 2                | MPX female + sealing cap                   |                         |  |



<sup>&</sup>lt;sup>1</sup> Inlet tubing line from end line to bag: ½" × ¾" Clear C-Flex® 1.5 m (60")

<sup>&</sup>lt;sup>2</sup> Outlet tubing line from bag to end line:  $\frac{1}{2}$ " ID Silicone Tuflux° 2,5 m (98") +  $\frac{1}{2}$ " ×  $\frac{3}{4}$ " Clear C-Flex° 0.5 m (20")

Buffer **Preparation**  Sterile Connection to Downstream Systems Sterile Connection

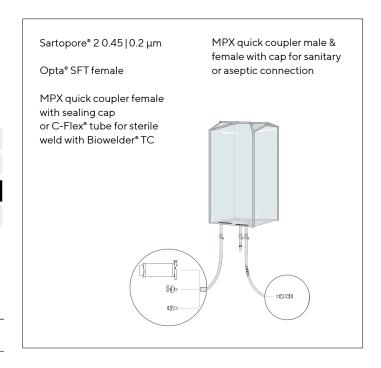
Sterile Weld

Sanitary or Aseptic Connection to Downstream Systems

Quick Coupler Connection **Tri-Clamp Connection** 

Quick Coupler Connection to Downstream Systems

|               |                |                  | Inlet¹                                     |                         | Outlet <sup>2</sup>               |
|---------------|----------------|------------------|--|-------------------------|-----------------------------------|
| Bag<br>Volume | Part<br>number | Units per<br>box | Filter or distal connector on filling line | Filter type<br>and size | Distal connector on draining line |
| 2,500 L       | FIS500313      | 1                | Sartopore® 2                               | Maxicaps® Size 2        |                                   |
|               | FIS500332      | 1                | ½" Opta® SFT female                        | NA                      |                                   |
|               | FIS302341      | 1                | MPX female + sealing cap                   |                         | ½"×¾" C-Flex°<br>+ MPX male       |
| 3,000 L       | FIS500314      | 1                | Sartopore® 2                               | Maxicaps® Size 2        | + MPX double female               |
|               | FIS500333      | 1                | ½" Opta° SFT female                        | NA                      | —— + sealing cap                  |
|               | FIS302342      | 1                | MPX female + sealing cap                   |                         |                                   |



<sup>&</sup>lt;sup>1</sup> Inlet tubing line from end line to bag: ½" × ¾" Clear C-Flex® 1.5 m (60")

<sup>&</sup>lt;sup>2</sup> Outlet tubing line from bag to end line:  $\frac{1}{2}$ " ID Silicone Tuflux° 2,5 m (98") +  $\frac{1}{2}$ " ×  $\frac{3}{4}$ " Clear C-Flex° 0.5 m (20")

Buffer **Preparation**  Sterile Connection to Downstream Systems Sterile Connection

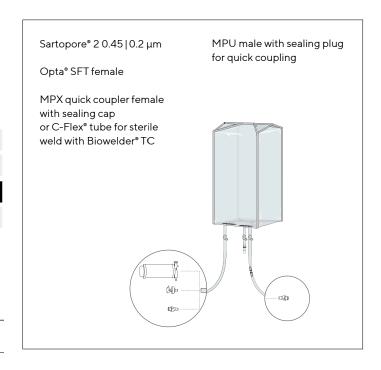
Sterile Weld

Sanitary or Aseptic Connection to Downstream Systems

Quick Coupler Connection **Tri-Clamp Connection** 

Quick Coupler Connection to Downstream Systems - High Flow Rate

|               |                |                  | Inlet <sup>1</sup>                         |                         | Outlet <sup>2</sup>               |
|---------------|----------------|------------------|--|-------------------------|-----------------------------------|
| Bag<br>Volume | Part<br>number | Units per<br>box | Filter or distal connector on filling line | Filter type<br>and size | Distal connector on draining line |
| 1,000 L       | FIS500370      | 2                | Sartopore® 2                               | Maxicaps® Size 1        |                                   |
|               | FIS500375      | 2                | ¾" Opta® SFT female                        | NA                      |                                   |
|               | FIS500365      | 2                | MPX female + sealing cap                   |                         |                                   |
| 1,500 L       | FIS500371      | 2                | Sartopore® 2                               | Maxicaps® Size 1        | <br>3⁄4"×1" C-Flex®               |
|               | FIS500376      | 2                | ¾" Opta® SFT female                        |                         | + MPU male                        |
|               | FIS500366      | 2                | MPX female + sealing cap                   |                         | + sealing cap                     |
| 2,000 L       | FIS500372      | 1                | Sartopore® 2                               | Maxicaps® Size 2        |                                   |
|               | FIS500377      | 2                | ¾" Opta° SFT female                        | NA                      |                                   |
|               | FIS500367      | 2                | MPX female + sealing cap                   |                         |                                   |



<sup>&</sup>lt;sup>1</sup> Inlet tubing line from end line to bag with filter: ½" × ¾" Clear C-Flex® 1.5 m (60")

<sup>&</sup>lt;sup>1</sup> Inlet tubing line from connector to bag: 3/4" × 1" Clear C-Flex® 1.5 m (60")

<sup>&</sup>lt;sup>2</sup> Outlet tubing line from bag to end line: 3/4" ID Silicone Tuflux® 2.5 m (98") + 3/4" × 1" Clear C-Flex® 0.5 m (20")

Buffer **Preparation**  Sterile Connection to Downstream Systems Sterile Connection

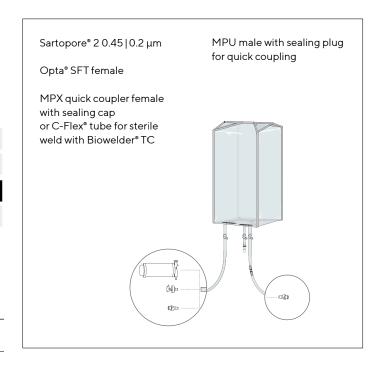
Sterile Weld

Sanitary or Aseptic Connection to Downstream Systems

Quick Coupler Connection **Tri-Clamp Connection** 

Quick Coupler Connection to Downstream Systems - High Flow Rate

|               |                |                  | Inlet¹                                     |                         | Outlet <sup>2</sup>               |
|---------------|----------------|------------------|--|-------------------------|-----------------------------------|
| Bag<br>Volume | Part<br>number | Units per<br>box | Filter or distal connector on filling line | Filter type<br>and size | Distal connector on draining line |
| 2,500 L       | FIS500373      | 1                | Sartopore® 2                               | Maxicaps® Size 2        |                                   |
|               | FIS500378      | 1                | ¾" Opta® SFT female                        | NA                      |                                   |
|               | FIS500368      | 1                | MPX female + sealing cap                   |                         | ³⁄4" × 1" C-Flex®                 |
| 3,000 L       | FIS500374      | 1                | Sartopore® 2                               | Maxicaps® Size 2        | + MPU male<br>+ sealing cap       |
|               | FIS500379      | 1                | ¾" Opta® SFT female                        | NA                      |                                   |
|               | FIS500369      | 1                | MPX female + sealing cap                   |                         |                                   |



<sup>&</sup>lt;sup>1</sup> Inlet tubing line from end line to bag with filter: ½" × ¾" Clear C-Flex® 1.5 m (60")

<sup>&</sup>lt;sup>2</sup> Inlet tubing line from connector to bag: 3/4" × 1" Clear C-Flex® 1.5 m (60")

<sup>&</sup>lt;sup>2</sup> Outlet tubing line from bag to end line:  $\frac{3}{4}$ " ID Silicone Tuflux° 2.5 m (98") +  $\frac{3}{4}$ " × 1" Clear C-Flex° 0.5 m (20")

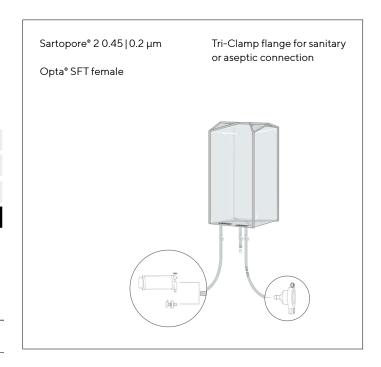
Buffer **Preparation**  Sterile Connection to Downstream Systems Sterile Connection Sterile Weld

Sanitary or Aseptic Connection to Downstream Systems

**Quick Coupler Connection** Tri-Clamp Connection

## Tri-Clamp Connection to Downstream Systems

|               |                |                  | Inlet¹                                     |                         | Outlet <sup>2</sup>                             |
|---------------|----------------|------------------|--|-------------------------|---|
| Bag<br>Volume | Part<br>number | Units per<br>box | Filter or distal connector on filling line | Filter type<br>and size | Distal connector on draining line               |
| 1,000 L       | FIS500315      | 2                | Sartopore® 2                               | Maxicaps® Size 1        |   |
|               | FIS500350      | 2                | ½" Opta® SFT female                        | NA                      |   |
| 1,500 L       | FIS500316      | 2                | Sartopore® 2                               | Maxicaps® Size 1        |   |
|               | FIS500351      | 2                | ½" Opta® SFT female                        | NA                      |   |
| 2,000 L       | FIS500317      | 1                | Sartopore® 2                               | Maxicaps® Size 2        | ½" Tri-Clamp                                    |
|               | FIS500352      | 2                | ½" Opta® SFT female                        | NA                      | —— 1½" sanitary flange with gasket, cap & union |
| 2,500 L       | FIS500318      | 1                | Sartopore® 2                               | Maxicaps® Size 2        | <u> </u>  |
|               | FIS500353      | 1                | ½" Opta® SFT female                        | NA                      |   |
| 3,000 L       | FIS500319      | 1                | Sartopore® 2                               | Maxicaps® Size 2        |   |
|               | FIS500354      | 1                | ½" Opta® SFT female                        | NA                      |   |



<sup>&</sup>lt;sup>1</sup> Inlet tubing line from end line to bag: ½" × ¾" Clear C-Flex® 1.5 m (60")

<sup>&</sup>lt;sup>2</sup> Outlet tubing line from bag to end line: ½" ID Silicone Tuflux® 3 m (118")

Buffer **Preparation**  Sterile Connection to Downstream Systems Sterile Connection

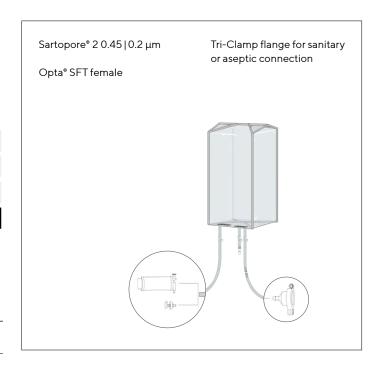
Sterile Weld

Sanitary or Aseptic Connection to Downstream Systems

**Quick Coupler Connection** Tri-Clamp Connection

Tri-Clamp Connection to Downstream Systems - High Flow Rate

|               |                |                  | Inlet <sup>1</sup>                         |                         | Outlet <sup>2</sup>                            |
|---------------|----------------|------------------|--|-------------------------|--|
| Bag<br>Volume | Part<br>number | Units per<br>box | Filter or distal connector on filling line | Filter type<br>and size | Distal connector on draining line              |
| 1,000 L       | FIS500320      | 2                | Sartopore® 2                               | Maxicaps® Size 1        |  |
|               | FIS500355      | 2                | ¾" Opta® SFT female                        | NA                      |  |
| 1,500 L       | FIS500321      | 2                | Sartopore® 2                               | Maxicaps® Size 1        |  |
|               | FIS500356      | 2                | ¾" Opta® SFT female                        | NA                      |  |
| 2,000 L       | FIS500322      | 1                | Sartopore® 2                               | Maxicaps® Size 2        | 3/4" Tri-Clamp                                 |
|               | FIS500357      | 2                | ¾" Opta® SFT female                        | NA                      | 1½" sanitary flange with gasket, cap $&$ union |
| 2,500 L       | FIS500323      | 1                | Sartopore® 2                               | Maxicaps® Size 2        |  |
|               | FIS500358      | 1                | ¾" Opta® SFT female                        | NA                      |  |
| 3,000 L       | FIS500324      | 1                | Sartopore® 2                               | Maxicaps® Size 2        |  |
|               | FIS500359      | 1                | ¾" Opta® SFT female                        | NA                      |  |



<sup>&</sup>lt;sup>1</sup> Inlet tubing line from end line to bag with filter: ½" × ¾" Clear C-Flex® 1.5 m (60")

<sup>&</sup>lt;sup>1</sup> Inlet tubing line from connector to bag: 3/4" × 1" Clear C-Flex® 1.5 m (60")

<sup>&</sup>lt;sup>2</sup> Outlet tubing line from bag to end line: 34" ID Silicone Tuflux® 3 m (118")

## Cell Harvest & Downstream Intermediates

# **Cell Harvest** & Downstream **Intermediates**

Clarification and Sterilizing Filtration from Bioreactor

**Cell Harvest** or Downstream Intermediates Storage and Shipping

Harvest or Downstream Intermediates Transfer

Sterile Connection to Downstream Systems

Sanitary or Aseptic Connection to Downstream Systems

Sterile Connection Sterile Weld

**Quick Coupler Connection Tri-Clamp Connection** 

Flexsafe® 2D solutions for cell harvest & downstream intermediates are available with Sartopore® 2 XLG 0.8 | 0.2 µm for high throughput sterilizing filtration after cell culture clarification step and for the handling of all process intermediates before the final UFDF step.

Flexsafe® 2D bags without filters are also available for:

- Sterile connection to alternative Sartopore® filter line using Opta® or welding with Biowelder® TC
- Aseptic connection to alternative Sartopore® filter line with MPC quick coupler

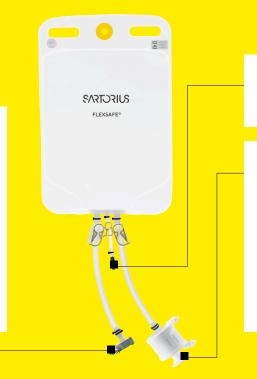
Sartopore® filters can be disconnected for post-use integrity testing with sterile seal using Biosealer®. Inlet and outlet lines are made of Clear C-Flex® tubings for welding and sealing.

Flexsafe® 2D bags allow for cell harvest transfer to most common single-use and stainless steel downstream purification systems with a variety of sterile and aseptic connections

### **Outlet Line**

Connection and transfer by pumping or gravity

- Opta® SFT male for sterile connection
- C-Flex® tube for sterile weld with Biowelder® TC
- MPC quick coupler male & cap for sanitary or aseptic connection to single-use systems
- Tri-Clamp flange for sanitary or aseptic connection to stainless steel systems



### Sampling

• Clave needleless sampling port

### Inlet Line

Sterilizing Filtration

■ Sartopore® 2 XLG 0.8 | 0.2 µm

Connections for Alternative Filter Line

- Opta® SFT female C-Flex® tube for sterile weld with Biowelder® TC
- MPC quick coupler female

**Cell Harvest & Downstream Intermediates** 

**Sterile Connection** to Downstream Systems Sterile Connection

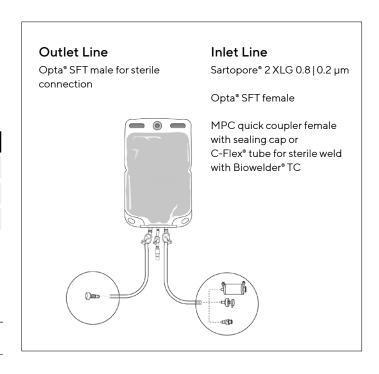
Sterile Weld

Sanitary or Aseptic Connection to Downstream Systems

**Quick Coupler Connection Tri-Clamp Connection** 

Sterile Connection to Downstream Systems

|               |                |                  | Inlet¹                                     |                         | Outlet <sup>2</sup>               | Sampling                          |
|---------------|----------------|------------------|--|-------------------------|-----------------------------------|-----------------------------------|
| Bag<br>volume | Part<br>number | Units<br>per box | Filter or distal connector on filling line | Filter type<br>and size | Distal connector on draining line | Sampling line                     |
| 3 L           | FLS130136      | 16               | Sartopore® 2 XLG 0.8   0.2 μm              | Midicaps® size 4        |                                   |                                   |
|               | FLS130155      | 16               | ¾" Opta® SFT female                        | NA                      | _                                 |                                   |
|               | FLS130153      | 16               | %" MPC female + sealing cap                |                         |                                   |                                   |
| 5 L           | FLS130023      | 16               | Sartopore® 2 XLG 0.8   0.2 μm              | Midicaps® size 4        | _                                 | ⅓" ID Silicone Tuflux®            |
|               | FLS130054      | 16               | %" Opta® SFT female                        | NA                      | -<br>¾" Opta° SFT male            | 100 mm (4")<br>+ Luer Lock female |
|               | FLS130051      | 16               | %" MPC female + sealing cap                |                         |                                   | + Clave connector                 |
| 10 L          | FLS130035      | 8                | Sartopore® 2 XLG 0.8   0.2 μm              | Midicaps® size 7        | _                                 |                                   |
|               | FLS130055      | 8                | %" Opta® SFT female                        | NA                      | _                                 |                                   |
|               | FLS130052      | 8                | ¾" MPC female + sealing cap                |                         |                                   |                                   |



<sup>&</sup>lt;sup>1</sup> Inlet tubing line from end line to bag: 3/8" × 5/8" Clear C-Flex® 500 mm (20") + Clipster® in a separate pouch

<sup>&</sup>lt;sup>2</sup> Outlet tubing line from bag to end line: 3%" × 5%" Clear C-Flex® 500 mm (20")

**Cell Harvest & Downstream Intermediates** 

**Sterile Connection** to Downstream Systems Sterile Connection

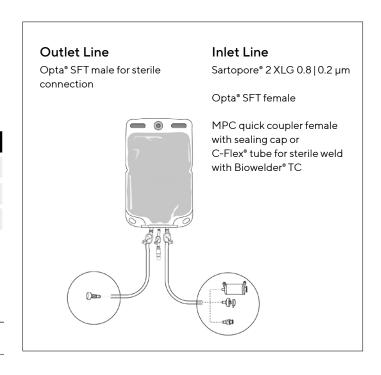
Sterile Weld

Sanitary or Aseptic Connection to Downstream Systems

**Quick Coupler Connection Tri-Clamp Connection** 

Sterile Connection to Downstream Systems

|               |                |                  | Inlet¹                                     |                         | Outlet <sup>2</sup>               | Sampling                              |
|---------------|----------------|------------------|--|-------------------------|-----------------------------------|---------------------------------------|
| Bag<br>volume | Part<br>number | Units<br>per box | Filter or distal connector on filling line | Filter type<br>and size | Distal connector on draining line | Sampling line                         |
| 20 L          | FLS130036      | 8                | Sartopore® 2 XLG 0.8   0.2 μm              | Midicaps® size 7        |                                   |                                       |
|               | FLS130056      | 8                | %" Opta® SFT female                        | NA                      | _                                 |                                       |
|               | FLS130053      | 8                | %" MPC female + sealing cap                |                         | 3/II.O. + 8.0FT - 1               | ¼" ID Silicone Tuflux°<br>100 mm (4") |
| 50 L          | FLS130143      | 8                | Sartopore® 2 XLG 0.8   0.2 μm              | Midicaps® size 7        | – ¾" Opta° SFT male               | + Luer Lock female                    |
|               | FLS130156      | 8                | ¾" Opta® SFT female                        | NA                      | _                                 | + Clave connector                     |
|               | FLS130154      | 8                | a" MPC female + sealing cap                |                         |                                   |                                       |



<sup>&</sup>lt;sup>1</sup> Inlet tubing line from end line to bag: 3/8" × 5/8" Clear C-Flex® 500 mm (20") + Clipster® in a separate pouch

<sup>&</sup>lt;sup>2</sup> Outlet tubing line from bag to end line: 3%" × 5%" Clear C-Flex® 500 mm (20")

**Cell Harvest & Downstream Intermediates** 

Sterile Connection to Downstream Systems Sterile Connection

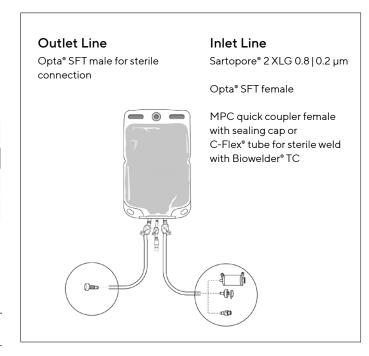
Sterile Weld

Sanitary or Aseptic Connection to Downstream Systems

**Quick Coupler Connection Tri-Clamp Connection** 

### Sterile Weld to Downstream Systems

|               |                |                  | Inlet¹                                     |                         | Outlet <sup>2</sup>                   | Sampling  |
|---------------|----------------|------------------|--|-------------------------|---------------------------------------|---|
| Bag<br>volume | Part<br>number | Units<br>per box | Filter or distal connector on filling line | Filter type<br>and size | Distal connector on draining line     | Sampling line   |
| 3 L           | FLS130131      | 16               | Sartopore® 2 XLG 0.8   0.2 μm              | Midicaps® size 4        |                                       |   |
|               | FLS130147      | 16               | %" Opta® SFT female                        |                         | _                                     |   |
|               | FLS130145      | 16               | %" MPC female + sealing cap                |                         |                                       |   |
| 5 L           | FLS130018      | 16               | Sartopore® 2 XLG 0.8   0.2 μm              | Midicaps® size 4        | _<br>_ ¾"×¾" C-Flex°<br>+ a" MPC male | 1/4" ID Silicone Tuflux®<br>100 mm (4")<br>+ Luer Lock female |
|               | FLS130042      | 16               | %" Opta® SFT female                        | NA                      |                                       |   |
|               | FLS130039      | 16               | 3%" MPC female + sealing cap               | <u> </u>                | + sealing cap                         | + Clave connector   |
| 10 L          | FLS130025      | 8                | Sartopore® 2 XLG 0.8   0.2 μm              | Midicaps® size 7        | _                                     |   |
|               | FLS130043      | 8                | %" Opta® SFT female                        | NA                      | _                                     |   |
|               | FLS130040      | 8                | %" MPC female + sealing cap                |                         |                                       |   |



<sup>&</sup>lt;sup>1</sup> Inlet tubing line from end line to bag: 3/8" × 5/8" Clear C-Flex® 500 mm (20") + Clipster® in a separate pouch

<sup>&</sup>lt;sup>2</sup> Outlet tubing line from bag to end line: 3%" × 5%" Clear C-Flex® 500 mm (20")

**Cell Harvest & Downstream Intermediates** 

Sterile Connection to Downstream Systems Sterile Connection

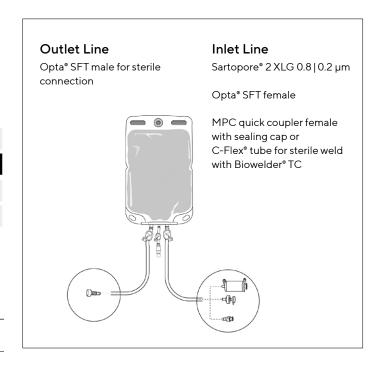
Sterile Weld

Sanitary or Aseptic Connection to Downstream Systems

**Quick Coupler Connection Tri-Clamp Connection** 

### Sterile Weld to Downstream Systems

|               |                |                  | Inlet <sup>1</sup>                         |                         | Outlet <sup>2</sup>               | Sampling   |
|---------------|----------------|------------------|--|-------------------------|-----------------------------------|--|
| Bag<br>volume | Part<br>number | Units<br>per box | Filter or distal connector on filling line | Filter type<br>and size | Distal connector on draining line | Sampling line  |
| 20 L          | FLS130026      | 8                | Sartopore® 2 XLG 0.8   0.2 μm              | Midicaps® size 7        |                                   | ¼" ID Silicone Tuflux°<br>100 mm (4")<br>+ Luer Lock female<br>+ Clave connector |
|               | FLS130044      | 8                | %" Opta° SFT female                        | NA                      |                                   |  |
|               | FLS130041      | 8                | 3%" MPC female + sealing cap               | <del></del>             |                                   |  |
| 50 L          | FLS130138      | 8                | Sartopore® 2 XLG 0.8   0.2 μm              | Midicaps® size 7        | – + a" MPC male<br>+ sealing cap  |  |
|               | FLS130148      | 8                | ¾" Opta® SFT female                        | NA                      | _                                 |  |
|               | FLS130146      | 8                | %" MPC female + sealing cap                |                         |                                   |  |



<sup>&</sup>lt;sup>1</sup> Inlet tubing line from end line to bag: 3/8" × 5/8" Clear C-Flex® 500 mm (20") + Clipster® in a separate pouch

<sup>&</sup>lt;sup>2</sup> Outlet tubing line from bag to end line: 3%" × 5%" Clear C-Flex® 500 mm (20")

**Cell Harvest & Downstream Intermediates** 

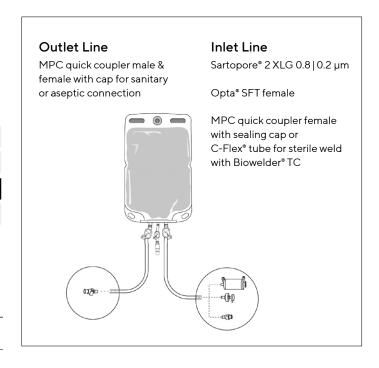
Sterile Connection to Downstream Systems Sterile Connection Sterile Weld

Sanitary or Aseptic Connection to Downstream Systems

Quick Coupler Connection **Tri-Clamp Connection** 

### Quick Coupler Connection to Downstream Systems

|               |                |                  | Inlet <sup>1</sup>                         |                         | Outlet <sup>2</sup>                             | Sampling   |
|---------------|----------------|------------------|--|-------------------------|---|--|
| Bag<br>volume | Part<br>number | Units<br>per box | Filter or distal connector on filling line | Filter type<br>and size | Distal connector on draining line               | Sampling line                                      |
| 3 L           | FLS130131      | 16               | Sartopore® 2 XLG 0.8   0.2 μm              | Midicaps® size 4        |   |  |
|               | FLS130147      | 16               | %" Opta® SFT female                        | NA                      | _   |  |
|               | FLS130145      | 16               | 3/8" MPC female + sealing cap              |                         |   |  |
| 5 L           | FLS130018      | 16               | Sartopore® 2 XLG 0.8   0.2 μm              | Midicaps® size 4        | %"×%" C-Flex*<br>+ %" MPC male<br>+ sealing cap | 100 mm (4")  + Luer Lock female  + Clave connector |
|               | FLS130042      | 16               | ¾" Opta® SFT female                        | NA                      |   |  |
|               | FLS130039      | 16               | 3/8" MPC female + sealing cap              |                         |   |  |
| 10 L          | FLS130025      | 8                | Sartopore® 2 XLG 0.8   0.2 μm              | Midicaps® size 7        | _   |  |
|               | FLS130043      | 8                | %" Opta® SFT female                        | NA                      | _   |  |
|               | FLS130040      | 8                | ¾" MPC female + sealing cap                |                         |   |  |



<sup>&</sup>lt;sup>1</sup> Inlet tubing line from end line to bag: % "  $\times$  % " Clear C-Flex  $^{\circ}$  500 mm (20") + Clipster  $^{\circ}$  in a separate pouch

<sup>&</sup>lt;sup>2</sup> Outlet tubing line from bag to end line: 3%" × 5%" Clear C-Flex® 500 mm (20")

**Cell Harvest & Downstream Intermediates** 

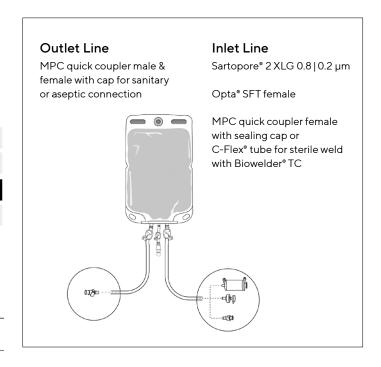
Sterile Connection to Downstream Systems Sterile Connection Sterile Weld

Sanitary or Aseptic Connection to Downstream Systems

Quick Coupler Connection **Tri-Clamp Connection** 

### Quick Coupler Connection to Downstream Systems

|               |                |                  | Inlet <sup>1</sup>                         |                         | Outlet <sup>2</sup>                                      | Sampling   |
|---------------|----------------|------------------|--|-------------------------|--|--|
| Bag<br>volume | Part<br>number | Units<br>per box | Filter or distal connector on filling line | Filter type<br>and size | Distal connector on draining line                        | Sampling line  |
| 20 L          | FLS130026      | 8                | Sartopore® 2 XLG 0.8   0.2 μm              | Midicaps® size 7        |  | 10 Silicone Tuflux° 100 mm (4") + Luer Lock female + Clave connector |
|               | FLS130044      | 8                | ¾" Opta® SFT female                        | NA                      |  |  |
|               | FLS130041      | 8                | 3/8" MPC female + sealing cap              |                         |  |  |
| 50 L          | FLS130138      | 8                | Sartopore® 2 XLG 0.8   0.2 μm              | Midicaps® size 7        | <ul> <li>+ ¾" MPC male</li> <li>+ sealing cap</li> </ul> |  |
|               | FLS130148      | 8                | ¾" Opta® SFT female                        | NA                      | _  |  |
|               | FLS130146      | 8                | 3/4" MPC female + sealing cap              |                         |  |  |



<sup>&</sup>lt;sup>1</sup> Inlet tubing line from end line to bag: % "  $\times$  % " Clear C-Flex  $^{\circ}$  500 mm (20") + Clipster  $^{\circ}$  in a separate pouch

<sup>&</sup>lt;sup>2</sup> Outlet tubing line from bag to end line: 3%" × 5%" Clear C-Flex® 500 mm (20")

**Cell Harvest** & Downstream **Intermediates** 

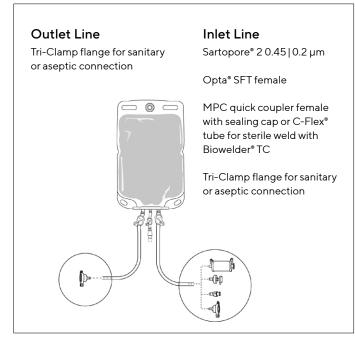
Sterile Connection to Downstream Systems Sterile Connection Sterile Weld

Sanitary or Aseptic Connection to Downstream Systems

**Quick Coupler Connection** Tri-Clamp Connection

## Tri-Clamp Connection to Downstream Systems

|               |                |                  | Inlet <sup>1</sup>  |                         | Outlet <sup>2</sup>               | Sampling                          |
|---------------|----------------|------------------|---|-------------------------|-----------------------------------|-----------------------------------|
| Bag<br>volume | Part<br>number | Units<br>per box | Filter or distal connector on filling line                | Filter type<br>and size | Distal connector on draining line | Sampling line                     |
| 3 L           | FLS130132      | 16               | Sartopore® 2 XLG 0.8   0.2 μm                             | Midicaps® size 4        |                                   |                                   |
|               | FLS130165      | 16               | %" Opta® SFT female                                       | NA                      | _                                 |                                   |
|               | FLS130163      | 16               | %" MPC female + sealing cap                               |                         |                                   |                                   |
|               | FLS130191      | 16               | %" Tri-Clamp %" sanitary flange with gasket, cap & union3 |                         |                                   |                                   |
| 5 L           | FLS130019      | 16               | Sartopore® 2 XLG 0.8   0.2 μm                             | Midicaps® size 4        | _                                 |                                   |
|               | FLS130069      | 16               | %" Opta® SFT female                                       | NA                      | -<br>%" Tri-Clamp                 | 1/4" ID Silicone Tuflux®          |
|               | FLS130066      | 16               | %" MPC female + sealing cap                               |                         | 34" sanitary flange with          | 100 mm (4")<br>+ Luer Lock female |
|               | FLS130108      | 16               | %" Tri-Clamp %" sanitary flange with gasket, cap & union3 | <u> </u>                | gasket, cap & union               | + Clave connector                 |
| 10 L          | FLS130027      | 8                | Sartopore® 2 XLG 0.8   0.2 μm                             | Midicaps® size 7        | _                                 |                                   |
|               | FLS130070      | 8                | %" Opta® SFT female                                       | NA                      | _                                 |                                   |
|               | FLS130067      | 8                | %" MPC female + sealing cap                               |                         |                                   |                                   |
|               | FLS130109      | 8                | %" Tri-Clamp %" sanitary flange with gasket, cap & union3 |                         |                                   |                                   |



<sup>&</sup>lt;sup>1</sup> Inlet tubing line from end line to bag: 3/8" × 5/8" Clear C-Flex® 500 mm (20") + Clipster® in a separate pouch

<sup>&</sup>lt;sup>2</sup> Outlet tubing line from bag to end line: %" Tuflux® SIL 300 mm (12")

<sup>&</sup>lt;sup>3</sup> %" Tuflux<sup>®</sup> SIL 300 mm (12") for design with two Tri-Clamps

**Cell Harvest** & Downstream **Intermediates** 

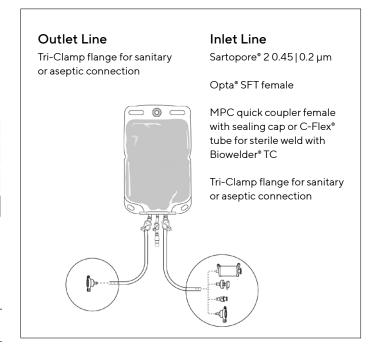
Sterile Connection to Downstream Systems Sterile Connection Sterile Weld

Sanitary or Aseptic Connection to Downstream Systems

**Quick Coupler Connection** Tri-Clamp Connection

Tri-Clamp Connection to Downstream Systems

|               |                |                  | Inlet <sup>1</sup>  |                         | Outlet <sup>2</sup>   | Sampling                           |
|---------------|----------------|------------------|---|-------------------------|---|------------------------------------|
| Bag<br>volume | Part<br>number | Units<br>per box | Filter or distal connector on filling line                | Filter type<br>and size | Distal connector on draining line   | Sampling line                      |
| 20 L          | FLS130028      | 8                | Sartopore® 2 XLG 0.8   0.2 μm                             | Midicaps® size 7        |   |                                    |
|               | FLS130071      | 8                | %" Opta® SFT female                                       | NA                      | _   |                                    |
|               | FLS130068      | 8                | %" MPC female + sealing cap                               |                         |   |                                    |
|               | FLS130110      | 8                | %" Tri-Clamp %" sanitary flange with gasket, cap & union3 |                         | 3/8" Tri-Clamp  | ½" ID Silicone Tuflux° 100 mm (4") |
| 50 L          | FLS130139      | 8                | Sartopore® 2 XLG 0.8   0.2 μm                             | Midicaps® size 7        | <ul> <li>- ¾" sanitary flange with<br/>gasket, cap &amp; union</li> </ul> | + Luer Lock female                 |
|               | FLS130166      | 8                | ¾" Opta® SFT female                                       | NA                      | _   | + Clave connector                  |
|               | FLS130164      | 8                | 3%" MPC female + sealing cap                              | <u>—</u>                |   |                                    |
|               | FLS130192      | 8                | %" Tri-Clamp ¾" sanitary flange with gasket, cap & union3 |                         |   |                                    |



<sup>&</sup>lt;sup>1</sup> Inlet tubing line from end line to bag: 3/8" × 5/8" Clear C-Flex® 500 mm (20") + Clipster® in a separate pouch

<sup>&</sup>lt;sup>2</sup> Outlet tubing line from bag to end line: %" Tuflux® SIL 300 mm (12")

<sup>&</sup>lt;sup>3</sup> %" Tuflux<sup>®</sup> SIL 300 mm (12") for design with two Tri-Clamps

## Cell Harvest & Downstream Intermediates Filtration, Storage and Shipping

# **Cell Harvest** & Downstream **Intermediates**

Clarification and Sterilizing Filtration from Bioreactor

**Cell Harvest** or Downstream Intermediates Storage and Shipping

Harvest or Downstream Intermediates Transfer

Sterile Connection to Downstream Systems

Sanitary or Aseptic Connection to Downstream Systems

Sterile Connection Sterile Weld

**Quick Coupler Connection Tri-Clamp Connection** 

Flexsafe® 3D solutions for cell harvest & downstream intermediates are available with Sartopore® 2 XLG 0.8 | 0.2 µm for high throughput sterilizing filtration after cell culture clarification step and for the handling of all process intermediates before the cross-flow step.

Flexsafe® 3D bags without filters are also available for:

- Sterile connection to alternative Sartopore® filter transfer set using Opta® ½" or welding with Biowelder® TC
- Aseptic connection to alternative Sartopore® filter transfer set with MPX quick coupler

Sartopore® filters can be disconnected for post-use integrity testing with sterile seal using Biosealer®. Inlet and outlet lines are made of C-Flex® + Silicone Tuflux® tubings for welding, sealing and pumping

Flexsafe® 3D bags allow for cell harvest transfer to most common single-use and stainless steel downstream purification systems with a variety of sterile and aseptic connections



Cell Harvest & Downstream Intermediates Filtration, Storage and Shipping in Palletank®

**Cell Harvest** & Downstream **Intermediates** 

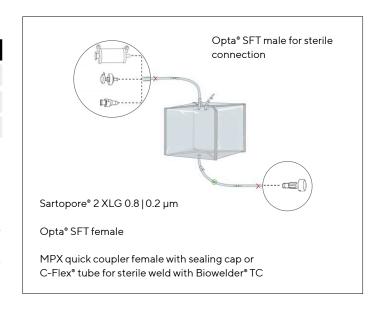
Sterile Connection to Downstream Systems Sterile Connection Sterile Weld

Sanitary or Aseptic Connection to Downstream Systems

**Quick Coupler Connection Tri-Clamp Connection** 

Sterile Connection to Downstream Systems

|               |                |                  | Inlet¹                                     |                         | Outlet <sup>2</sup>             |
|---------------|----------------|------------------|--|-------------------------|---------------------------------|
| Bag<br>volume | Part<br>number | Units per<br>box | Filter or distal connector on filling line | Filter type<br>and size | Distal connector on outlet line |
| 100 L         | FIS126698      | 2                | Sartopore® 2 XLG<br>0.8 0.2 µm             | Midicaps® size 9        |                                 |
|               | FIS126718      | 3                | ½" Opta® SFT female                        | NA                      |                                 |
|               | FIS126746      | 3                | MPX female + sealing cap                   |                         |                                 |
| 200 L         | FIS126699      | 2                | Sartopore® 2 XLG<br>0.8   0.2 µm           | Midicaps® size 0        | _                               |
|               | FIS126719      | 3                | ½" Opta® SFT female                        | NA                      | <sup>—</sup> ½" Opta® SFT male  |
|               | FIS126747      | 3                | MPX female + sealing cap                   |                         |                                 |
| 500 L         | FIS126700      | 2                | Sartopore® 2 XLG<br>0.8 0.2 µm             | Maxicaps® size 1T-style | _                               |
|               | FIS126720      | 3                | ½" Opta® SFT female                        | NA                      | _                               |
|               | FIS126748      | 3                | MPX female + sealing cap                   |                         |                                 |



<sup>&</sup>lt;sup>1</sup> Inlet tubing line from end line to bag: ½" × ¾" C-Flex® 0.5 m (20") + ½" ID Silicone Tuflux® 1 m (40")

<sup>&</sup>lt;sup>2</sup> Outlet tubing line from bag to end line: ½" ID Silicone Tuflux® 1 m (40") + ½" × ¾" Clear C-Flex® 0.5 m (20")

Cell Harvest & Downstream Intermediates Filtration, Storage and Shipping in Palletank®

**Cell Harvest** & Downstream **Intermediates** 

Sterile Connection to Downstream Systems Sterile Connection

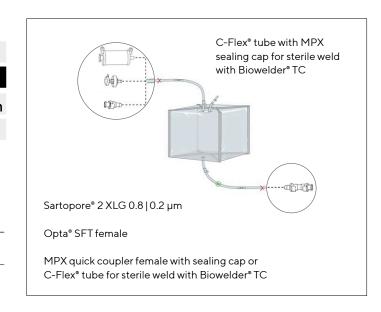
Sterile Weld

Sanitary or Aseptic Connection to Downstream Systems

**Quick Coupler Connection Tri-Clamp Connection** 

Sterile Weld to Downstream Systems

|               |                |                  | Inlet¹                                     |                         | Outlet <sup>2</sup>                     |
|---------------|----------------|------------------|--|-------------------------|---|
| Bag<br>volume | Part<br>number | Units per<br>box | Filter or distal connector on filling line | Filter type<br>and size | Distal connector on outlet line         |
| 100 L         | FIS126767      | 2                | Sartopore® XLG<br>0.8 0.2 µm               | Midicaps° size 9        |   |
|               | FIS126742      | 3                | ½" Opta® SFT female                        | NA                      |   |
|               | FIS126489      | 3                | MPX female + sealing cap                   |                         |   |
| 200 L         | FIS126768      | 2                | Sartopore® XLG<br>0.8   0.2 µm             | Midicaps® size 0        | <br>½" × ¾" Clear C-Flex°<br>+ MPX male |
|               | FIS126743      | 3                | ½" Opta° SFT female                        | NA                      | + MPX double female                     |
|               | FIS126490      | 3                | MPX female + sealing cap                   |                         | + sealing cap<br>—                      |
| 500 L         | FIS126769      | 2                | Sartopore® XLG<br>0.8 0.2 µm               | Maxicaps® size 1T-style |   |
|               | FIS126744      | 3                | ½" Opta° SFT female                        | NA                      | _                                       |
|               | FIS126491      | 3                | MPX female + sealing cap                   |                         |   |



<sup>&</sup>lt;sup>1</sup> Inlet tubing line from end line to bag:  $\frac{1}{2}$ " ×  $\frac{3}{4}$ " Clear C-Flex $^{\circ}$  0.5 m (20") +  $\frac{1}{2}$ " ID Silicone Tuflux $^{\circ}$  1 m (40")

<sup>&</sup>lt;sup>2</sup> Outlet tubing line from bag to end line: ½" ID Silicone Tuflux® 1 m (40") + ½" × ¾" Clear C-Flex® 0.5 m (20")

Cell Harvest & Downstream Intermediates Filtration, Storage and Shipping in Palletank®

**Cell Harvest** & Downstream **Intermediates** 

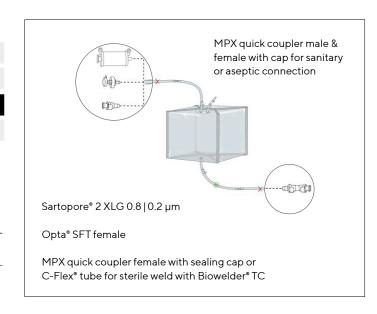
Sterile Connection to Downstream Systems Sterile Connection Sterile Weld

Sanitary or Aseptic Connection to Downstream Systems

Quick Coupler Connection **Tri-Clamp Connection** 

Quick Coupler Connection to Downstream Systems

|               |                |                  | Inlet¹                                     |                              | Outlet <sup>2</sup>   |
|---------------|----------------|------------------|--|------------------------------|---|
| Bag<br>volume | Part<br>number | Units per<br>box | Filter or distal connector on filling line | Filter type<br>and size      | Distal connector on draining line                           |
| 100 L         | FIS126767      | 2                | Sartopore® 2 XLG<br>0.8 0.2 µm             | Midicaps <sup>®</sup> size 9 |   |
|               | FIS126742      | 3                | ½" Opta° SFT female                        | NA                           | _   |
|               | FIS126489      | 3                | MPX female + sealing cap                   |                              |   |
| 200 L         | FIS126768      | 2                | Sartopore® 2 XLG<br>0.8   0.2 µm           | Midicaps® size 0             | −<br>½" MPX male  |
|               | FIS126743      | 3                | ½" Opta° SFT female                        | NA                           | <ul><li>+ MPX double female</li><li>+ sealing cap</li></ul> |
|               | FIS126490      | 3                | MPX female + sealing cap                   |                              | + sealing cap   |
| 500 L         | FIS126769      | 2                | Sartopore® 2 XLG<br>0.8   0.2 µm           | Maxicaps® size 1T-style      | _   |
|               | FIS126744      | 3                | ½" Opta° SFT female                        | NA                           | _   |
|               | FIS126491      | 3                | MPX female + sealing cap                   |                              |   |



<sup>&</sup>lt;sup>1</sup> Inlet tubing line from end line to bag: ½" × ¾" C-Flex® 0.5 m (20") + ½" ID Silicone Tuflux® 1 m (40")

<sup>&</sup>lt;sup>2</sup> Outlet tubing line from bag to end line: ½" ID Silicone Tuflux® 1 m (40") + ½" × ¾" Clear C-Flex® 0.5 m (20")

Cell Harvest & Downstream Intermediates Filtration, Storage and Shipping in Palletank®

**Cell Harvest** & Downstream **Intermediates** 

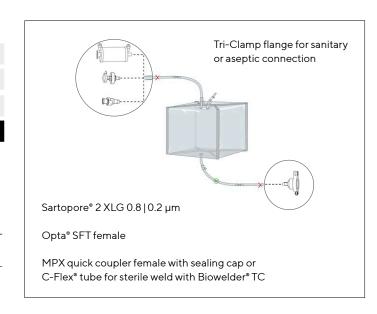
Sterile Connection to Downstream Systems Sterile Connection Sterile Weld

Sanitary or Aseptic Connection to Downstream Systems

**Quick Coupler Connection Tri-Clamp Connection** 

Tri-Clamp Connection to Downstream Systems

|               |                |                  | Inlet¹  |                              | Outlet <sup>2</sup>                     |
|---------------|----------------|------------------|---|------------------------------|---|
| Bag<br>volume | Part<br>number | Units per<br>box | Filter or distal<br>connector on filling line | Filter type<br>and size      | Distal connector on draining line       |
| 100 L         | FIS126759      | 2                | Sartopore® XLG<br>0.8 0.2 µm                  | Midicaps <sup>®</sup> size 9 |   |
|               | FIS126738      | 3                | ½" Opta° SFT female                           | NA                           |   |
|               | FIS126255      | 3                | MPX female + sealing cap                      |                              |   |
| 200 L         | FIS126760      | 2                | Sartopore® XLG<br>0.8 0.2 µm                  | Midicaps® size 0             | _<br>½" Tri-Clamp 1½"                   |
|               | FIS126739      | 3                | ½" Opta° SFT female                           | NA                           | anitary flange with gasket, cap & union |
|               | FIS126256      | 3                | MPX female + sealing cap                      |                              | gasket, cap & dilloit                   |
| 500 L         | FIS126761      | 2                | Sartopore® XLG<br>0.8   0.2 µm                | Maxicaps® size 1T-style      | _                                       |
|               | FIS126740      | 3                | ½" Opta° SFT female                           | NA                           | _                                       |
|               | FIS126257      | 3                | MPX female + sealing cap                      |                              |   |



<sup>&</sup>lt;sup>1</sup> Inlet tubing line from end line to bag: ½" ×¾" Clear C-Flex® 0.5 m (20") + ½" ID Silicone Tuflux® 1 m (40")

<sup>&</sup>lt;sup>2</sup> Outlet tubing line from bag to end line: 1/2" ID Silicone Tuflux® 1,5 m (60") +

Cell Harvest & Downstream Intermediates Filtration, Storage and Shipping in Palletank®

**Cell Harvest** & Downstream **Intermediates** 

Sterile Connection to Downstream Systems Sterile Connection

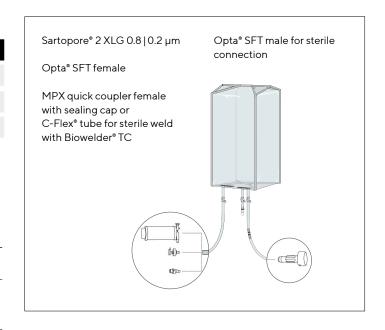
Sterile Weld

Sanitary or Aseptic Connection to Downstream Systems

**Quick Coupler Connection Tri-Clamp Connection** 

Sterile Connection to Downstream Systems

|               |                |                  | Inlet¹                                     |                         | Outlet <sup>2</sup>               |
|---------------|----------------|------------------|--|-------------------------|-----------------------------------|
| Bag<br>Volume | Part<br>number | Units per<br>box | Filter or distal connector on filling line | Filter type<br>and size | Distal connector on draining line |
| 1,000 L       | FIS500273      | 2                | Sartopore® 2 XLG                           | Maxicaps® Size 2        |                                   |
|               | FIS500290      | 2                | ½" Opta® SFT female                        | NA                      |                                   |
|               | FIS500300      | 2                | MPX female + sealing cap                   |                         |                                   |
| 1,500 L       | FIS500281      | 2                | Sartopore® 2 XLG                           | Maxicaps® Size 2        |                                   |
|               | FIS500291      | 2                | ½" Opta° SFT female                        |                         | ½" Opta® SFT male                 |
|               | FIS500301      | 2                | MPX female + sealing cap                   |                         |                                   |
| 2,000 L       | FIS500282      | 1                | Sartopore® 2 XLG                           | Maxicaps® Size 3        |                                   |
|               | FIS500292      | 2                | ½" Opta® SFT female                        | NA                      |                                   |
|               | FIS500302      | 2                | MPX female + sealing cap                   |                         |                                   |



<sup>&</sup>lt;sup>1</sup> Inlet tubing line from end line to bag: ½" × ¾" Clear C-Flex® 1.5 m (60") +

<sup>&</sup>lt;sup>2</sup> Outlet tubing line from bag to end line: ½" ID Silicone Tuflux® 1 m (98") + ½" × ¾" Clear C-Flex® 0.5 m (20")

Cell Harvest & Downstream Intermediates Filtration, Storage and Shipping in Palletank®

**Cell Harvest & Downstream Intermediates** 

Sterile Connection to Downstream Systems Sterile Connection

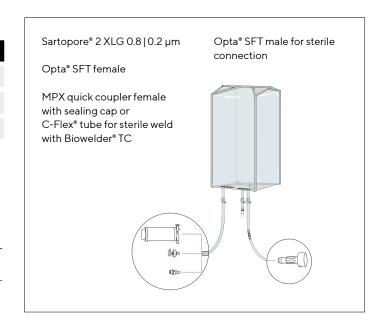
Sterile Weld

Sanitary or Aseptic Connection to Downstream Systems

**Quick Coupler Connection Tri-Clamp Connection** 

## Sterile Connection to Downstream Systems

|               |                |                  | Inlet¹                                     |                         | Outlet <sup>2</sup>               |
|---------------|----------------|------------------|--|-------------------------|-----------------------------------|
| Bag<br>Volume | Part<br>number | Units per<br>box | Filter or distal connector on filling line | Filter type<br>and size | Distal connector on draining line |
| 2,500 L       | FIS500283      | 1                | Sartopore® 2 XLG                           | Maxicaps® Size 3        |                                   |
|               | FIS500293      | 1                | ½" Opta® SFT female                        | NA                      |                                   |
|               | FIS500303      | 1                | MPX female + sealing cap                   |                         | 1/11 O OFT                        |
| 3,000 L       | FIS500284      | 1                | Sartopore® 2 XLG                           | Maxicaps® Size 3        | ½" Opta® SFT male                 |
|               | FIS500294      | 1                | ½" Opta® SFT female                        | NA                      |                                   |
|               | FIS500304      | 1                | MPX female + sealing cap                   |                         |                                   |



<sup>&</sup>lt;sup>1</sup> Inlet tubing line from end line to bag:  $\frac{1}{2}$ " ×  $\frac{3}{4}$ " Clear C-Flex $^{\circ}$  1.5 m (60")

<sup>&</sup>lt;sup>2</sup> Outlet tubing line from bag to end line: ½" ID Silicone Tuflux® 1 m (98") + ½" × ¾" Clear C-Flex® 0.5 m (20")

Cell Harvest & Downstream Intermediates Filtration, Storage and Shipping in Palletank®

**Cell Harvest** & Downstream **Intermediates** 

**Sterile Connection** to Downstream Systems Sterile Connection

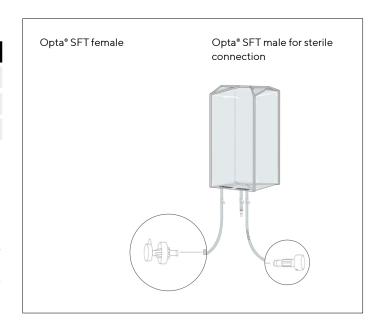
Sterile Weld

Sanitary or Aseptic Connection to Downstream Systems

**Quick Coupler Connection Tri-Clamp Connection** 

Sterile Connection to Downstream Systems - High Flow Rate

|               |                |                  | Inlet¹                                     |                         | Outlet <sup>2</sup>               |
|---------------|----------------|------------------|--|-------------------------|-----------------------------------|
| Bag<br>Volume | Part<br>number | Units per<br>box | Filter or distal connector on filling line | Filter type<br>and size | Distal connector on draining line |
| 1,000 L       | FIS302278      | 2                | ¾" Opta® SFT female                        | NA                      |                                   |
| 1,500 L       | FIS302279      | 2                | ¾" Opta® SFT female                        | NA                      |                                   |
| 2,000 L       | FIS500275      | 2                | ¾" Opta° SFT female                        | NA                      | 34" Opta® SFT male                |
| 2,500 L       | FIS500276      | 1                | ¾" Opta® SFT female                        | NA                      |                                   |
| 3,000 L       | FIS302282      | 1                | ¾" Opta® SFT female                        | NA                      |                                   |



<sup>&</sup>lt;sup>1</sup> Inlet tubing line from connector Opta® to bag: 3/4" × 1" Clear C-Flex® 1.5 m (60")

<sup>&</sup>lt;sup>2</sup> Outlet tubing line from bag to end line:  $\frac{3}{4}$ " ID Silicone Tuflux $^{\circ}$  2.5 m (98") +  $\frac{3}{4}$ " × 1" Clear C-Flex $^{\circ}$  0.5 m (20")

# Cell Harvest & Downstream Intermediates Filtration, Storage and Shipping in Palletank®

**Cell Harvest** & Downstream Intermediates

Sterile Connection to Downstream Systems Sterile Connection

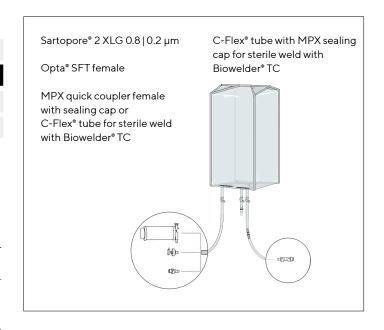
Sterile Weld

Sanitary or Aseptic Connection to Downstream Systems

**Quick Coupler Connection Tri-Clamp Connection** 

### Sterile Weld to Downstream Systems

|               |                |                  | Inlet¹                                     |                         | Outlet <sup>2</sup>               |
|---------------|----------------|------------------|--|-------------------------|-----------------------------------|
| Bag<br>Volume | Part<br>number | Units per<br>box | Filter or distal connector on filling line | Filter type<br>and size | Distal connector on draining line |
| 1,000 L       | FIS500360      | 2                | Sartopore® 2 XLG                           | Maxicaps® Size 2        |                                   |
|               | FIS500330      | 2                | ½" Opta® SFT female                        | NA                      |                                   |
|               | FIS302338      | 2                | MPX female + sealing cap                   |                         |                                   |
| 1,500 L       | FIS500361      | 2                | Sartopore® 2 XLG                           | Maxicaps® Size 2        | 1½"×¾" C-Flex®                    |
|               | FIS500334      | 2                | ½" Opta® SFT female                        |                         | + MPX male<br>+ MPX double female |
|               | FIS302339      | 2                | MPX female + sealing cap                   |                         | + sealing cap                     |
| 2,000 L       | FIS500362      | 1                | Sartopore® 2 XLG                           | Maxicaps® Size 3        |                                   |
|               | FIS500331      | 2                | ½" Opta® SFT female                        | NA                      |                                   |
|               | FIS302340      | 2                | MPX female + sealing cap                   |                         |                                   |



<sup>&</sup>lt;sup>1</sup> Inlet tubing line from end line to bag:  $\frac{1}{2}$ " ×  $\frac{3}{4}$ " Clear C-Flex $^{\circ}$  1.5 m (60")

<sup>&</sup>lt;sup>2</sup> Outlet tubing line from bag to end line: ½" ID Silicone Tuflux® 2,5 m (98") + ½" × ¾" Clear C-Flex® 0.5 m (20")

Cell Harvest & Downstream Intermediates Filtration, Storage and Shipping in Palletank®

**Cell Harvest & Downstream Intermediates** 

Sterile Connection to Downstream Systems Sterile Connection

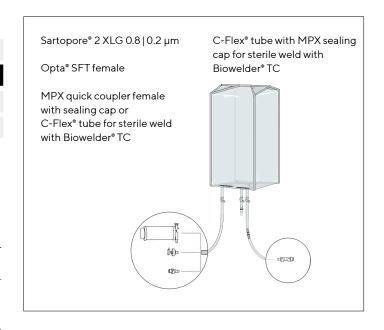
Sterile Weld

Sanitary or Aseptic Connection to Downstream Systems

**Quick Coupler Connection Tri-Clamp Connection** 

### Sterile Weld to Downstream Systems

|               |                |                  | Inlet¹                                     |                         | Outlet <sup>2</sup>                  |
|---------------|----------------|------------------|--|-------------------------|--------------------------------------|
| Bag<br>Volume | Part<br>number | Units per<br>box | Filter or distal connector on filling line | Filter type<br>and size | Distal connector on<br>draining line |
| 2,500 L       | FIS500363      | 1                | Sartopore® 2 XLG                           | Maxicaps® Size 3        |                                      |
|               | FIS500332      | 1                | ½" Opta® SFT female                        | NA                      |                                      |
|               | FIS302341      | 1                | MPX female + sealing cap                   |                         | ½"×¾" C-Flex°<br>+ MPX male          |
| 3,000 L       | FIS500364      | 1                | Sartopore® 2 XLG                           | Maxicaps® Size 3        | + MPX double female<br>              |
|               | FIS500333      | 1                | ½" Opta® SFT female                        | NA                      |                                      |
|               | FIS302342      | 1                | MPX female + sealing cap                   |                         |                                      |



<sup>&</sup>lt;sup>1</sup> Inlet tubing line from end line to bag: ½" × ¾" Clear C-Flex® 1.5 m (60")

<sup>&</sup>lt;sup>2</sup> Outlet tubing line from bag to end line: ½" ID Silicone Tuflux® 2,5 m (98") + ½" × ¾" Clear C-Flex® 0.5 m (20")

Cell Harvest & Downstream Intermediates Filtration, Storage and Shipping in Palletank®

**Cell Harvest & Downstream Intermediates** 

Sterile Connection to Downstream Systems Sterile Connection

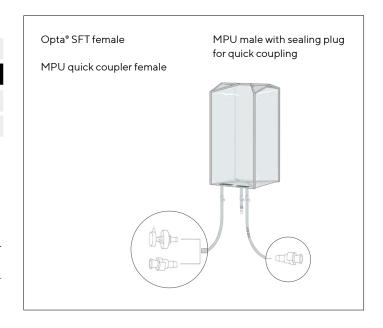
Sterile Weld

Sanitary or Aseptic Connection to Downstream Systems

**Quick Coupler Connection Tri-Clamp Connection** 

Sterile Weld to Downstream Systems - High Flow Rate

|               |                |                  | Inlet¹                                     |                         | Outlet <sup>2</sup>               |
|---------------|----------------|------------------|--|-------------------------|-----------------------------------|
| Bag<br>Volume | Part<br>number | Units per<br>box | Filter or distal connector on filling line | Filter type<br>and size | Distal connector on draining line |
| 1,000 L       | FIS500375      | 2                | ¾" Opta® SFT female                        | NA                      |                                   |
|               | FIS500365      | 2                | MPU female + sealing cap                   |                         |                                   |
| 1,500 L       | FIS500376      | 2                | ¾" Opta® SFT female                        | NA                      |                                   |
|               | FIS500366      | 2                | MPU female + sealing cap                   |                         |                                   |
| 2,000 L       | FIS500377      | 2                | ¾" Opta® SFT female                        | NA                      | 3/4" × 1" C-Flex®                 |
|               | FIS500367      | 2                | MPU female + sealing cap                   |                         |                                   |
| 2,500 L       | FIS500378      | 1                | ¾" Opta® SFT female                        | NA                      |                                   |
|               | FIS500368      | 1                | MPU female + sealing cap                   |                         |                                   |
| 3,000 L       | FIS500379      | 1                | ¾" Opta® SFT female                        | NA                      |                                   |
|               | FIS500369      | 1                | MPU female + sealing cap                   |                         | <del></del>                       |



<sup>&</sup>lt;sup>1</sup> Inlet tubing line from connector Opta® to bag: 3/4" × 1" Clear C-Flex® 1.5 m (60")

<sup>&</sup>lt;sup>2</sup> Outlet tubing line from bag to end line: 3/4" ID Silicone Tuflux® 2.5 m (98") + 3/4" × 1" Clear C-Flex® 0.5 m (20")

# Cell Harvest & Downstream Intermediates Filtration, Storage and Shipping in Palletank®

**Cell Harvest** & Downstream **Intermediates** 

Sterile Connection to Downstream Systems Sterile Connection

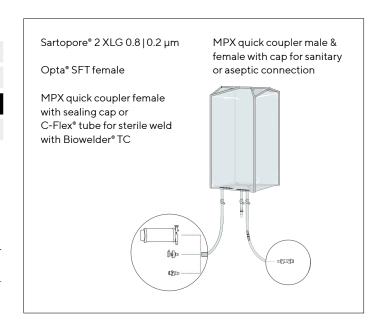
Sterile Weld

Sanitary or Aseptic Connection to Downstream Systems

Quick Coupler Connection **Tri-Clamp Connection** 

### Quick Coupler Connection to Downstream Systems

|               |                |                  | Inlet¹                                     |                         | Outlet <sup>2</sup>               |
|---------------|----------------|------------------|--|-------------------------|-----------------------------------|
| Bag<br>Volume | Part<br>number | Units per<br>box | Filter or distal connector on filling line | Filter type<br>and size | Distal connector on draining line |
| 1,000 L       | FIS500360      | 2                | Sartopore® 2 XLG                           | Maxicaps® Size 2        |                                   |
|               | FIS500330      | 2                | ½" Opta® SFT female                        | NA                      |                                   |
|               | FIS302338      | 2                | MPX female + sealing cap                   |                         |                                   |
| 1,500 L       | FIS500361      | 2                | Sartopore® 2 XLG                           | Maxicaps® Size 2        | ½"×¾" C-Flex®                     |
|               | FIS500334      | 2                | ½" Opta® SFT female                        |                         | + MPX male<br>+ MPX double female |
|               | FIS302339      | 2                | MPX female + sealing cap                   |                         | + sealing cap                     |
| 2,000 L       | FIS500362      | 1                | Sartopore® 2 XLG                           | Maxicaps® Size 3        |                                   |
|               | FIS500362      | 2                | ½" Opta® SFT female                        | NA                      |                                   |
|               | FIS302340      | 2                | MPX female + sealing cap                   |                         |                                   |



<sup>&</sup>lt;sup>1</sup> Inlet tubing line from end line to bag: ½" × ¾" Clear C-Flex® 1.5 m (60")

<sup>&</sup>lt;sup>2</sup> Outlet tubing line from bag to end line: ½" ID Silicone Tuflux® 2,5 m (98") + ½" × ¾" Clear C-Flex® 0.5 m (20")

# Cell Harvest & Downstream Intermediates Filtration, Storage and Shipping in Palletank®

**Cell Harvest** & Downstream **Intermediates** 

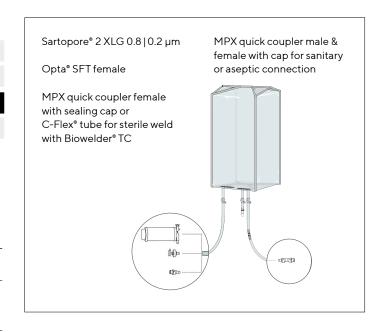
Sterile Connection to Downstream Systems Sterile Connection Sterile Weld

Sanitary or Aseptic Connection to Downstream Systems

Quick Coupler Connection **Tri-Clamp Connection** 

Quick Coupler Connection to Downstream Systems

|               |                |                  | Inlet¹                                     |                         | Outlet <sup>2</sup>               |
|---------------|----------------|------------------|--|-------------------------|-----------------------------------|
| Bag<br>Volume | Part<br>number | Units per<br>box | Filter or distal connector on filling line | Filter type<br>and size | Distal connector on draining line |
| 2,500 L       | FIS500363      | 1                | Sartopore® 2 XLG                           | Maxicaps® Size 3        |                                   |
|               | FIS500332      | 1                | ½" Opta° SFT female                        | NA                      |                                   |
|               | FIS302341      | 1                | MPX female + sealing cap                   |                         | ½"×¾" C-Flex°<br>+ MPX male       |
| 3,000 L       | FIS500364      | 1                | Sartopore® 2 XLG                           | Maxicaps® Size 3        | + MPX double female               |
|               | FIS500333      | 1                | ½" Opta° SFT female                        | NA                      | + sealing cap                     |
|               | FIS302342      | 1                | MPX female + sealing cap                   |                         |                                   |



<sup>&</sup>lt;sup>1</sup> Inlet tubing line from end line to bag: ½" × ¾" Clear C-Flex® 1.5 m (60")

<sup>&</sup>lt;sup>2</sup> Outlet tubing line from bag to end line: ½" ID Silicone Tuflux® 2,5 m (98") + ½" × ¾" Clear C-Flex® 0.5 m (20")

# Cell Harvest & Downstream Intermediates Filtration, Storage and Shipping in Palletank®

**Cell Harvest** & Downstream **Intermediates** 

Sterile Connection to Downstream Systems Sterile Connection

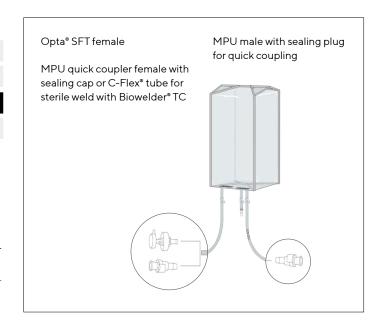
Sterile Weld

Sanitary or Aseptic Connection to Downstream Systems

Quick Coupler Connection **Tri-Clamp Connection** 

Quick Coupler Connection to Downstream Systems - High Flow Rate

|               |                |                  | Inlet¹                                     |                         | Outlet <sup>2</sup>               |
|---------------|----------------|------------------|--|-------------------------|-----------------------------------|
| Bag<br>Volume | Part<br>number | Units per<br>box | Filter or distal connector on filling line | Filter type<br>and size | Distal connector on draining line |
| 1,000 L       | FIS500375      | 2                | ¾" Opta® SFT female                        | NA                      |                                   |
|               | FIS500365      | 2                | MPU female + sealing cap                   |                         |                                   |
| 1,500 L       | FIS500376      | 2                | ¾" Opta® SFT female                        | NA                      |                                   |
|               | FIS500366      | 2                | MPU female + sealing cap                   |                         |                                   |
| 2,000 L       | FIS500377      | 2                | ¾" Opta® SFT female                        | NA                      | 3/4" × 1" C-Flex®                 |
|               | FIS500367      | 2                | MPU female + sealing cap                   |                         |                                   |
| 2,500 L       | FIS500378      | 1                | ¾" Opta® SFT female                        | NA                      |                                   |
|               | FIS500368      | 1                | MPU female + sealing cap                   |                         |                                   |
| 3,000 L       | FIS500379      | 1                | ¾" Opta® SFT female                        | NA                      | <del></del>                       |
|               | FIS500369      | 1                | MPU female + sealing cap                   |                         | <del></del>                       |



<sup>&</sup>lt;sup>1</sup> Inlet tubing line from connector Opta® to bag: 3/4" × 1" Clear C-Flex® 1.5 m (60")

<sup>&</sup>lt;sup>2</sup> Outlet tubing line from bag to end line: 3/4" ID Silicone Tuflux® 2.5 m (98") + 3/4" × 1" Clear C-Flex® 0.5 m (20")

Cell Harvest & Downstream Intermediates Filtration, Storage and Shipping in Palletank®

**Cell Harvest** & Downstream **Intermediates** 

Sterile Connection to Downstream Systems Sterile Connection

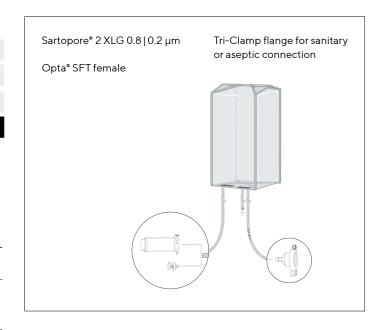
Sterile Weld

Sanitary or Aseptic Connection to Downstream Systems

**Quick Coupler Connection** Tri-Clamp Connection

## Tri-Clamp Connection to Downstream Systems

|               |                |                  | Inlet¹                                     |                         | Outlet <sup>2</sup>                             |
|---------------|----------------|------------------|--|-------------------------|---|
| Bag<br>Volume | Part<br>number | Units per<br>box | Filter or distal connector on filling line | Filter type<br>and size | Distal connector on draining line               |
| 1,000 L       | FIS500340      | 2                | Sartopore® 2 XLG                           | Maxicaps® Size 2        |   |
|               | FIS500350      | 2                | ½" Opta® SFT female                        | NA                      |   |
| 1,500 L       | FIS500341      | 2                | Sartopore® 2 XLG                           | Maxicaps® Size 2        |   |
|               | FIS500351      | 2                | ½" Opta® SFT female                        | NA                      |   |
| 2,000 L       | FIS500342      | 1                | Sartopore® 2 XLG                           | Maxicaps® Size 3        | ½" ID tubing, Tri-Clamp                         |
|               | FIS500352      | 2                | ½" Opta® SFT female                        | NA                      | —— 1½" sanitary flange with gasket, cap & union |
| 2,500 L       | FIS500343      | 1                | Sartopore® 2 XLG                           | Maxicaps® Size 3        |   |
|               | FIS500353      | 1                | ½" Opta® SFT female                        | NA                      |   |
| 3,000 L       | FIS500344      | 1                | Sartopore® 2 XLG                           | Maxicaps® Size 3        |   |
|               | FIS500354      | 1                | ½" Opta® SFT female                        | NA                      | <del></del>                                     |



<sup>&</sup>lt;sup>1</sup> Inlet tubing line from connector Opta® to bag: 3/4" × 1" Clear C-Flex® 1.5 m (60")

<sup>&</sup>lt;sup>2</sup> Outlet tubing line from bag to end line: 3/4" ID Silicone Tuflux® 2.5 m (98") + 3/4" × 3/4" Clear C-Flex® 0.5 m (20")

## Cell Harvest & Downstream Intermediates Filtration, Storage and Shipping in Palletank®

**Cell Harvest** & Downstream **Intermediates** 

Sterile Connection to Downstream Systems Sterile Connection

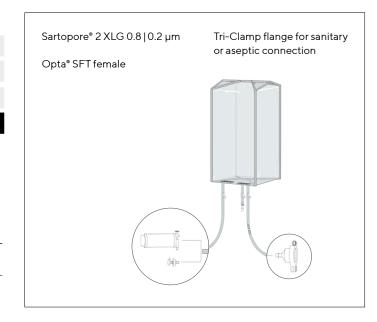
Sterile Weld

Sanitary or Aseptic Connection to Downstream Systems

**Quick Coupler Connection** Tri-Clamp Connection

Tri-Clamp Connection to Downstream Systems - High Flow Rate

|               |                |                  | Inlet¹                                     |                         | Outlet <sup>2</sup>                             |
|---------------|----------------|------------------|--|-------------------------|---|
| Bag<br>Volume | Part<br>number | Units per<br>box | Filter or distal connector on filling line | Filter type<br>and size | Distal connector on draining line               |
| 1,000 L       | FIS500345      | 2                | Sartopore® 2 XLG                           | Maxicaps® Size 2        |   |
|               | FIS500355      | 2                | ¾" Opta® SFT female                        | NA                      |   |
| 1,500 L       | FIS500346      | 2                | Sartopore® 2 XLG                           | Maxicaps® Size 2        |   |
|               | FIS500356      | 2                | ¾" Opta® SFT female                        | NA                      |   |
| 2,000 L       | FIS500347      | 1                | Sartopore® 2 XLG                           | Maxicaps® Size 3        | 3/4" ID tubing, Tri-Clamp                       |
|               | FIS500357      | 2                | ¾" Opta® SFT female                        | NA                      | —— 1½" sanitary flange with gasket, cap & union |
| 2,500 L       | FIS500348      | 1                | Sartopore® 2 XLG                           | Maxicaps® Size 3        |   |
|               | FIS500358      | 1                | ¾" Opta® SFT female                        | NA                      |   |
| 3,000 L       | FIS500349      | 1                | Sartopore® 2 XLG                           | Maxicaps® Size 3        |   |
|               | FIS500359      | 1                | ¾" Opta® SFT female                        | NA                      |   |



<sup>&</sup>lt;sup>1</sup> Inlet tubing line from end line to bag with filter: ½" × ¾" Clear C-Flex® 1.5 m (60")

<sup>&</sup>lt;sup>1</sup> Inlet tubing line from connector to bag: 3/4" × 1" Clear C-Flex® 1.5 m (60")

<sup>&</sup>lt;sup>2</sup> Outlet tubing line from bag to end line: 3/4" ID Silicone Tuflux® 3 m (118")

# Drug **Substance Purification**

Sterilizing Filtration between **Purification Steps** 

**Drug Substance** Storage and Shipping

Drug Substance Transfer

Sterile Connection to Downstream Systems

Sanitary or Aseptic Connection to Downstream Systems

SARTURIUS

FLEXSAFE®

Sterile Connection

Sterile Weld

**Quick Coupler Connection** 

**Tri-Clamp Connection** 

Flexsafe® 2D solutions for durg substances purification are available with Sartopore® Platinum 0.45 | 0.2 µm. The outstanding wetting properties of the modified membrane reduce by ten times the flushing volumes and facilitate pre-use filter integrity testing

Flexsafe® 2D bags without filters are also available for:

- Sterile connection to alternative Sartopore® filter line using Opta® or welding with Biowelder® TC
- Aseptic connection to alternative Sartopore® filter line with MPC quick coupler

Test line with Midisart® BV 0.2 µm filteris installed on the inlet line to allowsterile point of use leak testing using the Flexact® BT

Sartopore® filters can be disconnected for post-use integrity testing with sterile seal using Biosealer®. Inlet and outlet lines are made of Clear C-Flex® tubings for welding and sealing.

Flexsafe® 2D bags allow for cell harvest transfer to most common single-use and stainless steel downstream purification systems with a variety of sterile and aseptic connections.

### Sampling

Clave needleless sampling port

### Outlet Line

Connection and transfer by pumping or gravity

- Opta® SFT male for sterile connection
- C-Flex® tube for sterile weld with Biowelder® TC
- MPC quick coupler male & cap for sanitary or aseptic connection to single-use systems
- Tri-Clamp flange for sanitary or aseptic connection to stainless steel systems

### Test Line for Flexact® BT

- Test line with Midisart® BV 0.2 µm filter and 1/4" Tri-Clamp for point of use leak test with Flexact® BT
- C-Flex® tube for sterile weld with Biowelder® TC

### Inlet Line

Sterilizing Filtration

 Sartopore® Platinum 0.45 | 0.2 µm

Connections for Alternative Filter Line

- Opta® SFT female C-Flex® tube for sterile weld with Biowelder® TC
- MPC quick coupler female

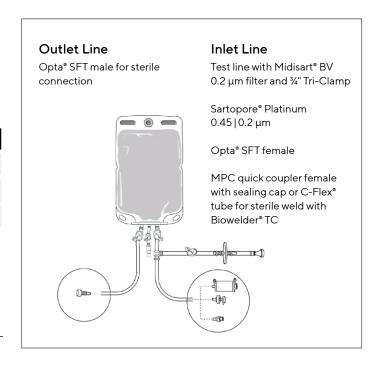
Drug **Substance Purification**  **Sterile Connection** to Downstream Systems Sterile Connection Sterile Weld

Sanitary or Aseptic Connection to Downstream Systems

**Quick Coupler Connection Tri-Clamp Connection** 

## Sterile Connection to Downstream Systems

|               |                |                  | Inlet <sup>1</sup>                         |                         | Outlet <sup>2</sup>               | Sampling                          |
|---------------|----------------|------------------|--|-------------------------|-----------------------------------|-----------------------------------|
| Bag<br>volume | Part<br>number | Units<br>per box | Filter or distal connector on filling line | Filter type<br>and size | Distal connector on draining line | Sampling line                     |
| 3 L           | FLS130169      | 16               | Sartopore® Platinum 0.45   0.2 μm          | Midicaps® size 4        |                                   |                                   |
|               | FLS130183      | 16               | %" Opta® SFT female                        | NA                      | _                                 |                                   |
|               | FLS130181      | 16               | %" MPC female + sealing cap                | <u> </u>                |                                   |                                   |
| 5 L           | FLS130074      | 16               | Sartopore® Platinum 0.45   0.2 μm          | Midicaps® size 4        | _                                 | ½" ID Silicone Tuflux®            |
|               | FLS130096      | 16               | %" Opta® SFT female                        | NA                      | <br>¾" Opta® SFT male             | 100 mm (4")<br>+ Luer Lock female |
|               | FLS130093      | 16               | %" MPC female + sealing cap                | <u> </u>                |                                   | + Clave connector                 |
| 10 L          | FLS130079      | 8                | Sartopore® Platinum 0.45   0.2 μm          | Midicaps® size 7        | _                                 |                                   |
|               | FLS130097      | 8                | %" Opta® SFT female                        | NA                      | _                                 |                                   |
|               | FLS130094      | 8                | %" MPC female + sealing cap                | <del>_</del>            |                                   |                                   |



#### **Leak Test Line**

- 1/4" × 3/8" Clear C-Flex® 300 mm (12")
- + Midisart® BV 0.2 µm
- + 1/4" ID Silicone Tuflux® 100 mm (4")
- + ¾" Tri-Clamp with gasket, cap & union

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<sup>&</sup>lt;sup>1</sup> Inlet tubing line from end line to bag:  $\%" \times \%"$  Clear C-Flex $^{\circ}$  500 mm (20") + Clipster $^{\circ}$  in a separate pouch

<sup>&</sup>lt;sup>2</sup> Outlet tubing line from bag to end line: 3%" × 5%" Clear C-Flex® 500 mm (20")

Drug **Substance Purification**  **Sterile Connection** to Downstream Systems Sterile Connection

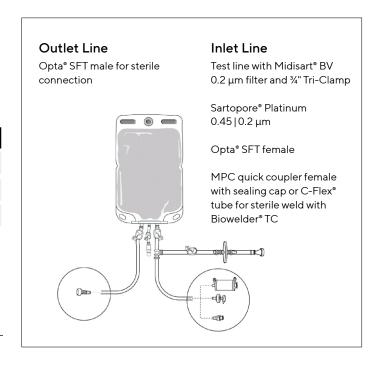
Sterile Weld

Sanitary or Aseptic Connection to Downstream Systems

**Quick Coupler Connection Tri-Clamp Connection** 

## Sterile Connection to Downstream Systems

|               |                |                  | Inlet¹                                     |                         | Outlet <sup>2</sup>               | Sampling                              |
|---------------|----------------|------------------|--|-------------------------|-----------------------------------|---------------------------------------|
| Bag<br>volume | Part<br>number | Units<br>per box | Filter or distal connector on filling line | Filter type<br>and size | Distal connector on draining line | Sampling line                         |
| 20 L          | FLS130080      | 8                | Sartopore® Platinum 0.45   0.2 μm          | Midicaps® size 7        |                                   |                                       |
|               | FLS130098      | 8                | %" Opta® SFT female                        | NA                      | _                                 |                                       |
|               | FLS130095      | 8                | 3/4" MPC female + sealing cap              | <del></del>             |                                   | ¼" ID Silicone Tuflux°<br>100 mm (4") |
| 50 L          | FLS130172      | 8                | Sartopore® Platinum 0.45   0.2 μm          | Midicaps° size 7        | – ¾" Opta® SFT male               | + Luer Lock female                    |
|               | FLS130184      | 8                | %" Opta® SFT female                        | NA                      | =                                 | + Clave connector                     |
|               | FLS130182      | 8                | %" MPC female + sealing cap                | <del></del>             |                                   |                                       |



### **Leak Test Line**

- ¼"×¾" Clear C-Flex® 300 mm (12")
- + Midisart® BV 0.2 µm
- + 1/4" ID Silicone Tuflux® 100 mm (4")
- + 3/4" Tri-Clamp with gasket, cap & union

<sup>&</sup>lt;sup>1</sup> Inlet tubing line from end line to bag:  $\%" \times \%"$  Clear C-Flex $^{\circ}$  500 mm (20") + Clipster $^{\circ}$  in a separate pouch

<sup>&</sup>lt;sup>2</sup> Outlet tubing line from bag to end line: 3%" × 5%" Clear C-Flex® 500 mm (20")

Drug **Substance Purification**  **Sterile Connection** to Downstream Systems Sterile Connection

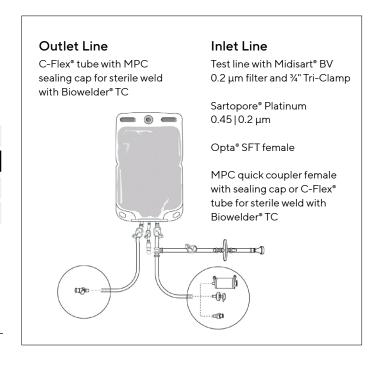
Sterile Weld

Sanitary or Aseptic Connection to Downstream Systems

**Quick Coupler Connection Tri-Clamp Connection** 

## Sterile Weld to Downstream Systems

|               |                |                  | Inlet <sup>1</sup>                         |                         | Outlet <sup>2</sup>                                    | Sampling   |
|---------------|----------------|------------------|--|-------------------------|--|--|
| Bag<br>volume | Part<br>number | Units<br>per box | Filter or distal connector on filling line | Filter type<br>and size | Distal connector on draining line                      | Sampling line  |
| 3 L           | FLS130167      | 16               | Sartopore® Platinum 0.45   0.2 μm          | Midicaps® size 4        |  |  |
|               | FLS130179      | 16               | %" Opta® SFT female                        | NA                      | _  |  |
|               | FLS130177      | 16               | %" MPC female + sealing cap                | <u> </u>                | —<br>¾" × ½" C-Flex°<br>+ ¾" MPC male<br>+ sealing cap | 1/4" ID Silicone Tuflux°<br>100 mm (4")<br>+ Luer Lock female<br>+ Clave connector |
| 5 L           | FLS130072      | 16               | Sartopore® Platinum 0.45   0.2 μm          | Midicaps® size 4        |  |  |
|               | FLS130090      | 16               | %" Opta® SFT female                        | NA                      |  |  |
|               | FLS130087      | 16               | %" MPC female + sealing cap                | <u> </u>                |  |  |
| 10 L          | FLS130075      | 8                | Sartopore® Platinum 0.45   0.2 μm          | Midicaps® size 7        | _  |  |
|               | FLS130091      | 8                | %" Opta® SFT female                        | NA                      | _  |  |
|               | FLS130088      | 8                | 3/8" MPC female + sealing cap              | <del>_</del>            |  |  |



### **Leak Test Line**

- 1/4" × 3/4" Clear C-Flex® 300 mm (12")
- + Midisart® BV 0.2 µm
- + 1/4" ID Silicone Tuflux® 100 mm (4")
- + ¾" Tri-Clamp with gasket, cap & union

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<sup>&</sup>lt;sup>1</sup> Inlet tubing line from end line to bag:  $\%" \times \%"$  Clear C-Flex $^{\circ}$  500 mm (20") + Clipster $^{\circ}$  in a separate pouch

<sup>&</sup>lt;sup>2</sup> Outlet tubing line from bag to end line: 3%" × 5%" Clear C-Flex® 500 mm (20")

Drug **Substance Purification**  **Sterile Connection** to Downstream Systems Sterile Connection

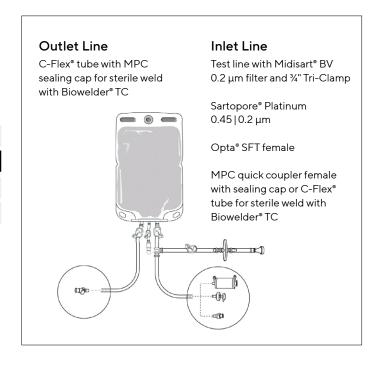
Sterile Weld

Sanitary or Aseptic Connection to Downstream Systems

**Quick Coupler Connection Tri-Clamp Connection** 

### Sterile Weld to Downstream Systems

|               |                |                  | Inlet¹                                     |                         |                                   | Outlet <sup>2</sup>                   |
|---------------|----------------|------------------|--|-------------------------|-----------------------------------|---------------------------------------|
| Bag<br>volume | Part<br>number | Units<br>per box | Filter or distal connector on filling line | Filter type<br>and size | Distal connector on draining line | Sampling line                         |
| 20 L          | FLS130076      | 8                | Sartopore® Platinum 0.45   0.2 μm          | Midicaps® size 7        |                                   |                                       |
|               | FLS130092      | 8                | %" Opta® SFT female                        | NA                      | 3%"×5%" C-Flex®                   | ¼" ID Silicone Tuflux°<br>100 mm (4") |
|               | FLS130089      | 8                | %" MPC female + sealing cap                | <del>_</del>            |                                   |                                       |
| 50 L          | FLS130170      | 8                | Sartopore® Platinum 0.45   0.2 μm          | Midicaps® size 7        | —+ ¾" MPC male<br>+ sealing cap   | + Luer Lock female                    |
|               | FLS130180      | 8                | %" Opta® SFT female                        | NA                      |                                   | + Clave connector                     |
|               | FLS130178      | 8                | 3%" MPC female + sealing cap               | <del></del>             |                                   |                                       |



### **Leak Test Line**

- ¼"×¾" Clear C-Flex® 300 mm (12")
- + Midisart® BV 0.2 µm
- + 1/4" ID Silicone Tuflux® 100 mm (4")
- + 3/4" Tri-Clamp with gasket, cap & union

<sup>&</sup>lt;sup>1</sup> Inlet tubing line from end line to bag:  $\%" \times \%"$  Clear C-Flex $^{\circ}$  500 mm (20") + Clipster $^{\circ}$  in a separate pouch

<sup>&</sup>lt;sup>2</sup> Outlet tubing line from bag to end line: 3%" × 5%" Clear C-Flex® 500 mm (20")

Buffer

Cell Harvest & DSP Flexsafe® 2D | Flexsafe® 3D | Flexsafe® 2D | Flexsafe® 3D | Flexsafe® 2D | Flexsafe® 3D | Flexs

**Drug Substance** Flexsafe® 2D | Flexsafe® 3D

Drug Product Flexsafe® 2D | Flexsafe® 3D Back to Table of Content

Flexsafe® 2D Pre-Designed Solutions for Drug Substances

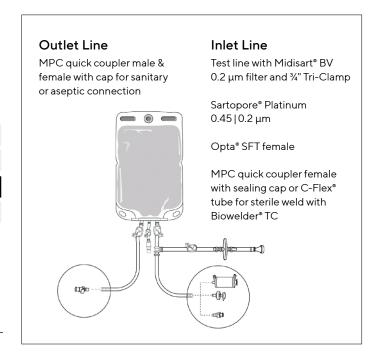
Drug **Substance Purification**  Sterile Connection to Downstream Systems Sterile Connection Sterile Weld

Sanitary or Aseptic Connection to Downstream Systems

Quick Coupler Connection **Tri-Clamp Connection** 

## Quick Coupler Connection to Downstream Systems

|               |                |                  | Inlet <sup>1</sup>                         |                         | Outlet <sup>2</sup>                                   | Sampling  |
|---------------|----------------|------------------|--|-------------------------|---|---|
| Bag<br>volume | Part<br>number | Units<br>per box | Filter or distal connector on filling line | Filter type<br>and size | Distal connector on draining line                     | Sampling line                                     |
| 3 L           | FLS130167      | 16               | Sartopore® Platinum 0.45   0.2 μm          | Midicaps® size 4        |   |   |
|               | FLS130179      | 16               | ¾" Opta® SFT female                        | NA                      | <br>¾" × ½" C-Flex*<br>+ ¾" MPC male<br>+ sealing cap |   |
|               | FLS130177      | 16               | 3/8" MPC female + sealing cap              | <del></del>             |   |   |
| 5 L           | FLS130072      | 16               | Sartopore® Platinum 0.45   0.2 μm          | Midicaps® size 4        |   | 100 mm (4")  + Luer Lock female + Clave connector |
|               | FLS130090      | 16               | ¾" Opta® SFT female                        | NA                      |   |   |
|               | FLS130087      | 16               | 3/8" MPC female + sealing cap              | <del></del>             |   |   |
| 10 L          | FLS130075      | 8                | Sartopore® Platinum 0.45   0.2 μm          | Midicaps® size 7        | =   |   |
|               | FLS130091      | 8                | ¾" Opta® SFT female                        | NA                      | =   |   |
|               | FLS130088      | 8                | 3/6" MPC female + sealing cap              |                         |   |   |



#### **Leak Test Line**

- 1/4" × 3/4" Clear C-Flex® 300 mm (12")
- + Midisart® BV 0.2 µm
- + 1/4" ID Silicone Tuflux® 100 mm (4")
- + ¾" Tri-Clamp with gasket, cap & union

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<sup>&</sup>lt;sup>1</sup> Inlet tubing line from end line to bag:  $\%" \times \%"$  Clear C-Flex $^{\circ}$  500 mm (20") + Clipster $^{\circ}$  in a separate pouch

<sup>&</sup>lt;sup>2</sup> Outlet tubing line from bag to end line: 3%" × 5%" Clear C-Flex® 500 mm (20")

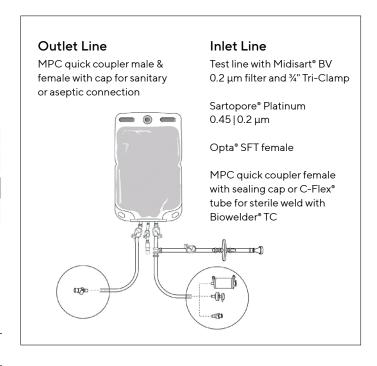
Drug **Substance Purification**  Sterile Connection to Downstream Systems Sterile Connection Sterile Weld

Sanitary or Aseptic Connection to Downstream Systems

Quick Coupler Connection **Tri-Clamp Connection** 

### Quick Coupler Connection to Downstream Systems

|               |                |                  | Inlet <sup>1</sup>                         |                         | Outlet <sup>2</sup>               | Sampling  |
|---------------|----------------|------------------|--|-------------------------|-----------------------------------|---|
| Bag<br>volume | Part<br>number | Units<br>per box | Filter or distal connector on filling line | Filter type<br>and size | Distal connector on draining line | Sampling line   |
| 20 L          | FLS130076      | 8                | Sartopore® Platinum 0.45   0.2 μm          | Midicaps® size 7        | %"×5%" C-Flex®                    | ¼" ID Silicone Tuflux°<br>100 mm (4")<br>+ Luer Lock female |
|               | FLS130092      | 8                | %" Opta® SFT female                        | NA                      |                                   |   |
|               | FLS130089      | 8                | 3%" MPC female + sealing cap               | <del></del>             |                                   |   |
| 50 L          | FLS130170      | 8                | Sartopore® Platinum 0.45   0.2 μm          | Midicaps° size 7        | — + ¾" MPC male<br>+ sealing cap  |   |
|               | FLS130180      | 8                | %" Opta® SFT female                        | NA                      | _ · ·                             | + Clave connector   |
|               | FLS130178      | 8                | 3/8" MPC female + sealing cap              | <del></del>             |                                   |   |



### **Leak Test Line**

- 1/4" × 3/8" Clear C-Flex® 300 mm (12")
- + Midisart® BV 0.2 µm
- + 1/4" ID Silicone Tuflux® 100 mm (4")
- + 3/4" Tri-Clamp with gasket, cap & union

<sup>&</sup>lt;sup>1</sup> Inlet tubing line from end line to bag:  $\%" \times \%"$  Clear C-Flex $^{\circ}$  500 mm (20") + Clipster $^{\circ}$  in a separate pouch

<sup>&</sup>lt;sup>2</sup> Outlet tubing line from bag to end line: 3%" × 5%" Clear C-Flex® 500 mm (20")

Flexsafe® 2D Pre-Designed Solutions for Drug Substances

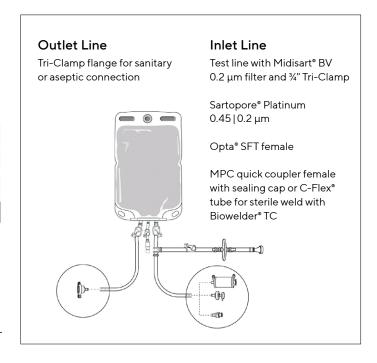
Drug **Substance Purification**  Sterile Connection to Downstream Systems Sterile Connection Sterile Weld

Sanitary or Aseptic Connection to Downstream Systems

**Quick Coupler Connection** Tri-Clamp Connection

### Tri-Clamp Connection to Downstream Systems

|               |                |                  | Inlet <sup>1</sup>                         |                         | Outlet <sup>2</sup>                  | Sampling  |
|---------------|----------------|------------------|--|-------------------------|--------------------------------------|---|
| Bag<br>volume | Part<br>number | Units<br>per box | Filter or distal connector on filling line | Filter type<br>and size | Distal connector on draining line    | Sampling line   |
| 3 L           | FLS130168      | 16               | Sartopore® Platinum 0.45   0.2 μm          | Midicaps® size 4        |                                      |   |
|               | FLS130175      | 16               | ¾" Opta® SFT female                        | NA                      | _                                    |   |
|               | FLS130173      | 16               | 3/8" MPC female + sealing cap              | <del>_</del>            |                                      |   |
| 5 L           | FLS130073      | 16               | Sartopore® Platinum 0.45   0.2 μm          | Midicaps° size 4        | —<br>¾" Tri-Clamp                    | 1/4" ID Silicone Tuflux®<br>100 mm (4")<br>+ Luer Lock female |
|               | FLS130084      | 16               | ¾" Opta® SFT female                        | NA                      | — ¾" sanitary flange<br>with gasket, |   |
|               | FLS130081      | 16               | 3/8" MPC female + sealing cap              | <del></del>             | cap & union                          | + Clave connector   |
| 10 L          | FLS130077      | 8                | Sartopore® Platinum 0.45   0.2 μm          | Midicaps° size 7        | _                                    |   |
|               | FLS130085      | 8                | %" Opta® SFT female                        | NA                      | _                                    |   |
|               | FLS130082      | 8                | 3/6" MPC female + sealing cap              |                         |                                      |   |



#### **Leak Test Line**

- ¼"×¾" Clear C-Flex® 300 mm (12")
- + Midisart® BV 0.2 µm
- + 1/4" ID Silicone Tuflux® 100 mm (4")
- + ¾" Tri-Clamp with gasket, cap & union

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<sup>&</sup>lt;sup>1</sup> Inlet tubing line from end line to bag: % "  $\times$  % " Clear C-Flex  $^{\circ}$  500 mm (20") + Clipster  $^{\circ}$  in a separate pouch

<sup>&</sup>lt;sup>2</sup> Outlet tubing line from bag to end line: 3/8" × 5/8" Tuflux® SIL 300 mm (12")

Flexsafe® 2D Pre-Designed Solutions for Drug Substances

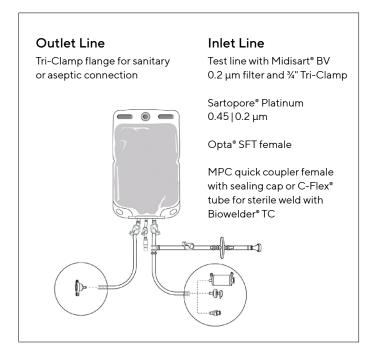
Drug **Substance Purification**  Sterile Connection to Downstream Systems Sterile Connection Sterile Weld

Sanitary or Aseptic Connection to Downstream Systems

**Quick Coupler Connection** Tri-Clamp Connection

# Tri-Clamp Connection to Downstream Systems

|               |                |                  | Inlet <sup>1</sup>                         |                         | Outlet <sup>2</sup>                | Sampling   |  |
|---------------|----------------|------------------|--|-------------------------|------------------------------------|--|--|
| Bag<br>volume | Part<br>number | Units<br>per box | Filter or distal connector on filling line | Filter type<br>and size | Distal connector on draining line  | Sampling line                                      |  |
| 20 L          | FLS130078      | 8                | Sartopore® Platinum 0.45   0.2 μm          | Midicaps® size 7        |                                    |  |  |
|               | FLS130086      | 8                | ¾" Opta® SFT female                        | NA                      | _                                  | 100 mm (4")  + Luer Lock female  + Clave connector |  |
|               | FLS130083      | 8                | 3/8" MPC female + sealing cap              | <del>_</del>            | %" Tri-Clamp<br>%" sanitary flange |  |  |
| 50 L          | FLS130171      | 8                | Sartopore® Platinum 0.45   0.2 μm          | Midicaps® size 7        | with gasket,                       |  |  |
|               | FLS130176      | 8                | ¾" Opta® SFT female                        | NA                      | — cap & union                      |  |  |
|               | FLS130174      | 8                | %" MPC female + sealing cap                | <del>_</del>            |                                    |  |  |



#### **Leak Test Line**

■ ¼"×¾" Clear C-Flex® 300 mm (12") + Midisart® BV 0.2 µm + 1/4" ID Silicone Tuflux® 100 mm (4") + 3/4" Tri-Clamp with gasket, cap & union

<sup>&</sup>lt;sup>1</sup> Inlet tubing line from end line to bag: % "  $\times$  % " Clear C-Flex  $^{\circ}$  500 mm (20") + Clipster  $^{\circ}$  in a separate pouch

<sup>&</sup>lt;sup>2</sup> Outlet tubing line from bag to end line: 3/8" × 5/8" Tuflux® SIL 300 mm (12")

# Drug Substance Filtration, Storage and Shipping

# Drug **Substance Purification**

Sterilizing **Filtration** between Purification Steps

Drug Substance Storage and Shipping

Drug Substance Transfer

Sterile Connection to Downstream Systems

Sanitary or Aseptic Connection to Downstream Systems

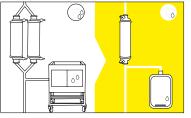
Sterile Connection

Sterile Weld

**Quick Coupler Connection** 

**Tri-Clamp Connection** 

Sartopore® Platinum reduce by ten times the wetting volumes for integrity testing



2×20" Filters |

1×20" Sartopore® Platinum | 1×200 L Flushing Tank 1×20 L Flushing Bag

Flexsafe® PDS for drug substance feature the Sartopore® Platinum 0.45 | 0.2 µm with exceptional throughput, flowrate and wetting performances for a cheaper and faster filtration process. The outstanding wetting properties of the modified membrane reduce by ten times the flushing volumes required prior to integrity testing and eliminate retesting due to insufficient wetting.

Flexsafe® 3D bags without filters are also available for sterile connection to alternative Sartopore® filter transfer set using Opta® ½" or welding with Biowelder® TC. Sartopore® filters can be disconnected for post-use integrity testing with sterile seal using Biosealer®.

Inlet and outlet lines are made of C-Flex® + Silicone Tuflux® for welding, sealing and pumping.

Flexsafe® 3D Bags allow for sterile drug substance transfer to most common single-use and stainless steel downstream purification systems after the cross-flow step with a variety of sterile connections.

#### Inlet Line

Sterilizing-grade filtration between purification steps

Sartopore® Platinum 0.45 | 0.2 µm for efficient wetting and integrity testing

Connection for alternative filter transfer set

- Opta® SFT female
- C-Flex® tube for sterile weld with Biowelder® TC
- MPX quick coupler female



#### Test line for Point of use leak test

- C-Flex® for sterile weld with Biowelder® TC
- Sartopore® Air Filter size 7 keeps the sterility of the 3D bag during testing and filling

#### **Outlet Line**

Connection and transfer by pumping or gravity

- Opta® SFT male for sterile connection
- C-Flex® with MPX plug for sterile weld to single-use system
- MPX Quick couplers for sanitary or aseptic connection to singleuse system
- Tri-Clamp flange for sanitary or aseptic connection to stainless steel system

Drug Substance Filtration, Storage and Shipping in Palletank®

Drug Substance **Purification**  Sterile Connection to Downstream Systems Sterile Connection Sterile Weld

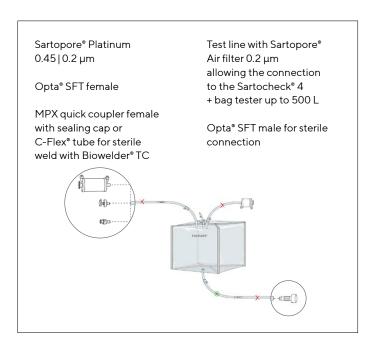
Sanitary or Aseptic Connection to Downstream Systems

**Quick Coupler Connection Tri-Clamp Connection** 

# Sterile Connection to Downstream Systems

|               |                |                  | Inlet¹  |                         | Outlet <sup>2</sup>               |
|---------------|----------------|------------------|---|-------------------------|-----------------------------------|
| Bag<br>volume | Part<br>number | Units per<br>box | Filter or distal<br>connector on filling line | Filter type<br>and size | Distal connector on draining line |
| 100 L         | FIS126792      | 2                | Sartopore® Platinum 0.45   0.2 µm             | Midicaps® size 7        |                                   |
|               | FIS301530      | 3                | ½" Opta® SFT female                           | NA                      |                                   |
|               | FIS301531      | 3                | MPX female + sealing cap                      |                         |                                   |
| 200 L         | FIS126793      | 2                | Sartopore® Platinum 0.45   0.2 µm             | Midicaps® size 8        |                                   |
|               | FIS301535      | 3                | ½" Opta® SFT female                           | NA                      | ½" Opta® SFT male                 |
|               | FIS301536      | 3                | MPX female + sealing cap                      | <del></del>             |                                   |
| 500 L         | FIS126794      | 2                | Sartopore® Platinum 0.45   0.2 μm             | Midicaps® size 9        |                                   |
|               | FIS301542      | 3                | ½" Opta® SFT female                           | NA                      |                                   |
|               | FIS301543      | 3                | MPX female + sealing cap                      |                         |                                   |

<sup>1</sup> Inlet tubing line from end line to bag: ½"×¾" Clear C-Flex® 0.5 m (20") + ½" ID Silicone Tuflux® 1 m (40")



#### **Leak Test Line**

■ ½"×¾" Clear C-Flex® 1,500 mm (59") + Sartopore® Air filter 0.2 µm size 7 (Inlet 1½" tri-clamp) up to 500 L



<sup>&</sup>lt;sup>2</sup> Outlet tubing line from bag to end line: ½" ID Silicone Tuflux® 1 m (40") + ½" × ¾" Clear C-Flex® 0.5 m (20")

Drug Substance Filtration, Storage and Shipping in Palletank®

Drug **Substance Purification**  **Sterile Connection** to Downstream Systems Sterile Connection

Sterile Weld

Sanitary or Aseptic Connection to Downstream Systems

**Quick Coupler Connection Tri-Clamp Connection** 

# Sartopore® Platinum Test line with Sartopore® 0.45 | 0.2 µm Air filter 0.2 μm allowing the connection Opta® SFT female to the Sartocheck® 4 + bag tester up to 500 L MPX quick coupler female with sealing cap or C-Flex® tube with MPX C-Flex® tube for sterile sealing cap for sterile weld weld with Biowelder® TC

#### Sterile Weld to Downstream Systems

|               |                |                  | Inlet¹  |                         | Outlet <sup>2</sup>               |
|---------------|----------------|------------------|---|-------------------------|-----------------------------------|
| Bag<br>volume | Part<br>number | Units per<br>box | Filter or distal<br>connector on filling line | Filter type<br>and size | Distal connector on draining line |
| 100 L         | FIS126788      | 2                | Sartopore® Platinum 0.45   0.2 µm             | Midicaps® size 7        |                                   |
|               | FIS301532      | 3                | ½" Opta® SFT female                           | NA                      |                                   |
|               | FIS300131      | 3                | MPX female + sealing cap                      |                         |                                   |
| 200 L         | FIS126789      | 2                | Sartopore® Platinum 0.45   0.2 µm             | Midicaps® size 8        | ½"×¾" C-Flex®                     |
|               | FIS301537      | 3                | ½" Opta® SFT female                           | NA                      | + MPX male<br>+ MPX double female |
|               | FIS300132      | 3                | MPX female + sealing cap                      |                         | + sealing cap                     |
| 500 L         | FIS126790      | 2                | Sartopore® Platinum 0.45   0.2 µm             | Midicaps® size 9        |                                   |
|               | FIS301544      | 3                | ½" Opta® SFT female                           | NA                      |                                   |
|               | FIS300133      | 3                | MPX female + sealing cap                      |                         |                                   |

<sup>1</sup> Inlet tubing line from end line to bag: ½"×¾" Clear C-Flex® 0.5 m (20") + ½" ID Silicone Tuflux® 1 m (40")



<sup>&</sup>lt;sup>2</sup> Outlet tubing line from bag to end line: ½" ID Silicone Tuflux® 1 m (40") + ½" × ¾" Clear C-Flex® 0.5 m (20")

Drug Substance Filtration, Storage and Shipping in Palletank®

Drug **Substance Purification**  Sterile Connection to Downstream Systems Sterile Connection Sterile Weld

Sanitary or Aseptic Connection to Downstream Systems

Quick Coupler Connection **Tri-Clamp Connection** 

#### Sartopore® Platinum Test line with Sartopore® 0.45 | 0.2 µm Air filter 0.2 μm allowing the connection Opta® SFT female to the Sartocheck® 4 + bag tester up to 500 L MPX quick coupler female with sealing cap or MPX quick coupler male & C-Flex® tube for sterile female with cap for sanitary weld with Biowelder® TC or aseptic connection

# Quick Coupler Connection to Downstream Systems

|                |   | Inlet¹   |  | Outlet <sup>2</sup>  |
|----------------|---|--|--|--|
| Part<br>number | Units per<br>box  | Filter or distal<br>connector on filling line  | Filter type<br>and size  | Distal connector on draining line  |
| FIS126788      | 2   | Sartopore® Platinum 0.45   0.2 µm  | Midicaps® size 7   |  |
| FIS301532      | 3   | ½" Opta® SFT female  | NA   |  |
| FIS300131      | 3   | MPX female + sealing cap   |  |  |
| FIS126789      | 2   | Sartopore® Platinum 0.45   0.2 µm  | Midicaps® size 8   | ½"×¾" C-Flex®  |
| FIS301537      | 3   | ½" Opta® SFT female  | NA   | + MPX male<br>+ MPX double female  |
| FIS300132      | 3   | MPX female + sealing cap   |  | + sealing cap  |
| FIS126790      | 2   | Sartopore° Platinum 0.45   0.2 µm  | Midicaps® size 9   |  |
| FIS301544      | 3   | ½" Opta® SFT female  | NA   |  |
| FIS300133      | 3   | MPX female + sealing cap   |  |  |
|                | FIS126788 FIS301532 FIS300131 FIS126789 FIS300132 FIS126790 FIS301544 | number         box           FIS126788         2           FIS301532         3           FIS300131         3           FIS126789         2           FIS301537         3           FIS300132         3           FIS126790         2           FIS301544         3 | Part number         Units per box         Filter or distal connector on filling line           FIS126788         2         Sartopore® Platinum 0.45   0.2 μm           FIS301532         3         ½" Opta® SFT female           FIS300131         3         MPX female + sealing cap           FIS126789         2         Sartopore® Platinum 0.45   0.2 μm           FIS301537         3         ½" Opta® SFT female           FIS300132         3         MPX female + sealing cap           FIS126790         2         Sartopore® Platinum 0.45   0.2 μm           FIS301544         3         ½" Opta® SFT female | Part numberUnits per boxFilter or distal connector on filling lineFilter type and sizeFIS1267882Sartopore® Platinum 0.45   0.2 μmMidicaps® size 7FIS3015323½" Opta® SFT femaleNAFIS3001313MPX female + sealing capFIS1267892Sartopore® Platinum 0.45   0.2 μmMidicaps® size 8FIS3015373½" Opta® SFT femaleNAFIS3001323MPX female + sealing capFIS1267902Sartopore® Platinum 0.45   0.2 μmMidicaps® size 9FIS3015443½" Opta® SFT femaleNA |

<sup>1</sup> Inlet tubing line from end line to bag: ½"×¾" Clear C-Flex® 0.5 m (20") + ½" ID Silicone Tuflux® 1 m (40")



<sup>&</sup>lt;sup>2</sup> Outlet tubing line from bag to end line: ½" ID Silicone Tuflux® 1 m (40") + ½" × ¾" Clear C-Flex® 0.5 m (20")

Drug Substance Filtration, Storage and Shipping in Palletank®

Drug **Substance Purification**  Sterile Connection to Downstream Systems Sterile Connection Sterile Weld

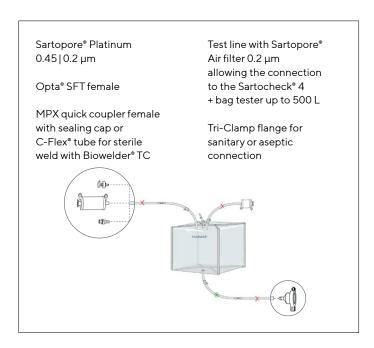
Sanitary or Aseptic Connection to Downstream Systems

**Quick Coupler Connection** Tri-Clamp Connection

# Tri-Clamp Connection to Downstream Systems

|               |                |                  | Inlet¹  |                         | Outlet <sup>2</sup>               |
|---------------|----------------|------------------|---|-------------------------|-----------------------------------|
| Bag<br>volume | Part<br>number | Units per<br>box | Filter or distal<br>connector on filling line | Filter type<br>and size | Distal connector on draining line |
| 100 L         | FIS126780      | 2                | Sartopore® Platinum 0.45   0.2 μm             | Midicaps® size 7        |                                   |
|               | FIS301533      | 3                | ½" Opta® SFT female                           | NA                      |                                   |
|               | FIS301534      | 3                | MPX female + sealing cap                      |                         |                                   |
| 200 L         | FIS126781      | 2                | Sartopore® Platinum 0.45   0.2 μm             | Midicaps® size 8        | ½" Tri-Clamp 1½"                  |
|               | FIS301538      | 3                | ½" Opta® SFT female                           | NA                      | sanitary flange with              |
|               | FIS301539      | 3                | MPX female + sealing cap                      |                         | gasket, cap & union               |
| 500 L         | FIS126782      | 2                | Sartopore® Platinum 0.45   0.2 µm             | Midicaps® size 9        |                                   |
|               | FIS301545      | 3                | ½" Opta® SFT female                           | NA                      |                                   |
|               | FIS301546      | 3                | MPX female + sealing cap                      | <del></del>             |                                   |

<sup>1</sup> Inlet tubing line from end line to bag: ½"×¾" Clear C-Flex® 0.5 m (20") + ½" ID Silicone Tuflux® 1 m (40")





<sup>&</sup>lt;sup>2</sup> Outlet tubing line from bag to end line: ½" ID Silicone Tuflux® 1,5 m (60")

Flexsafe® 2D Pre-Designed Solutions for Drug Product Formulation

# **Drug Product Formulation**

Sterilizing **Filtration** 

Drug **Product** Storage

Drug **Product** Transfer

Sterile Connection to Final Filling

SARTURIUS

FLEXSAFE®

Sterile Connection Sterile Weld

Flexsafe® 2D advanced solutions for drug product feature the Sartopore® Platinum 0.45 | 0.2 µm. The outstanding wetting properties of the modified membrane reduce by ten times the flushing volumes and facilitate pre-use filter integrity testing.

Flexsafe® 2D bags without filters are also available for sterile connection to alternative Sartopore® filter line using Opta® or welding with Biowelder® TC.

Sartopore® filters can be disconnected for post-use integrity testing using Biosealer®.

Inlet and outlet lines are made of Silicone Tuflux® or C-Flex® tubings for welding and sealing.

Test line with Midisart® BV 0.2 µm filter is installed on the inlet line to allow sterile point of use leak testing using the Flexact® BT

Flexsafe® 2D bags allow for sterile drug product transfer to most common singleuse and stainless steel final filling systems.

Opta® SFT allows for sterile connection to our Biosafe® Raft products for liquid transfer to the final filling area.

#### Sampling

Clave needleless sampling port

#### Outlet Line

Connection and transfer by pumping or gravity

- Opta® SFT male for sterile connection
- C-Flex® tube for sterile weld with Biowelder® TC
- MPC quick coupler male & cap for sanitary or aseptic connection to single-use systems
- Tri-Clamp flange for sanitary or aseptic connection to stainless steel systems

#### Test Line for Flexact® BT

- Test line with Midisart® BV 0.2 µm filter and 1/4" Tri-Clamp for point of use leak test with Flexact® BT
- C-Flex® tube for sterile weld with Biowelder® TC

#### Inlet Line

Sterilizing Filtration

 Sartopore® Platinum 0.45 | 0.2 µm

Connections for Alternative Filter Line

- Opta® SFT female C-Flex® tube for sterile weld with Biowelder® TC
- MPC quick coupler female

Flexsafe® 2D Pre-Designed Solutions for Drug Substances

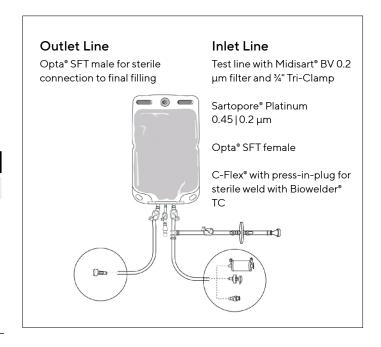
**Drug Product Formulation** 

**Sterile Connection** to Final Filling

Sterile Connection Sterile Weld

Sterile Connection to Final Formulation & Filling

|               |                |                  | Inlet¹                                     |                         | Outlet <sup>2</sup>               | Sampling           |
|---------------|----------------|------------------|--|-------------------------|-----------------------------------|--------------------|
| Bag<br>volume | Part<br>number | Units<br>per box | Filter or distal connector on filling line | Filter type<br>and size | Distal connector on draining line | Sampling line      |
| 3 L           | FLS130185      | 16               | Sartopore® Platinum 0.45   0.2 μm          | Midicaps® size 4        |                                   |                    |
|               | FLS130187      | 16               | ¾" Opta® SFT female                        | NA                      | _                                 |                    |
| 5 L           | FLS130099      | 16               | Sartopore® Platinum 0.45   0.2 μm          | Midicaps® size 4        | _                                 |                    |
|               | FLS130102      | 16               | ¾" Opta® SFT female                        | NA                      | _                                 | 1/IIID 6:11: T. (I |
| 10 L          | FLS130100      | 8                | Sartopore® Platinum 0.45   0.2 μm          | Midicaps® size 7        |                                   | 100 mm (4")        |
|               | FLS130103      | 8                | ¾" Opta® SFT female                        | NA                      | — ¾" Opta® SFT male               | + Luer Lock female |
| 20 L          | FLS130101      | 8                | Sartopore® Platinum 0.45   0.2 μm          | Midicaps® size 7        | _                                 | + Clave connector  |
|               | FLS130104      | 8                | ¾" Opta® SFT female                        | NA                      | _                                 |                    |
| 50 L          | FLS130186      | 8                | Sartopore® Platinum 0.45   0.2 μm          | Midicaps® size 7        | _                                 |                    |
|               | FLS130188      | 8                | %" Opta® SFT female                        | NA                      | _                                 |                    |



#### **Leak Test Line**

- ¼"×¾" Clear C-Flex® 300 mm (12")
- + Midisart® BV 0.2 µm
- + 1/4" ID Silicone Tuflux® 100 mm (4")
- + 3/4" Tri-Clamp with gasket, cap & union

<sup>&</sup>lt;sup>1</sup> Inlet tubing line from end line to bag: 3%"×5%" Clear C-Flex® 500 mm (20") + Clipster® in a separate pouch

<sup>&</sup>lt;sup>2</sup> Outlet tubing line from bag to end line: 3%" × 5%" Clear C-Flex® 500 mm (20")

Flexsafe® 2D Pre-Designed Solutions for Drug Substances

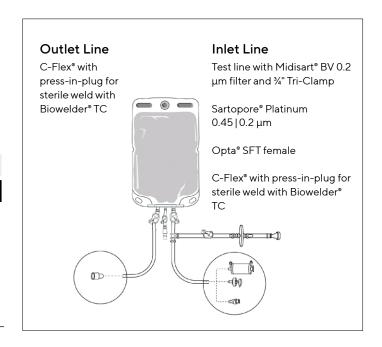
**Drug Product Formulation** 

**Sterile Connection** to Final Filling

Sterile Connection Sterile Weld

#### Sterile Weld to Final Formulation & Filling

|               |                |                  | Inlet¹                           | Outlet <sup>2</sup>                 | Sampling                      |
|---------------|----------------|------------------|----------------------------------|-------------------------------------|-------------------------------|
| Bag<br>volume | Part<br>number | Units<br>per box | Distal connector on filling line | Distal connector on draining line   | Sampling line                 |
| 3 L           | FLS130189      | 16               | %" ID C-Flex® + %" press-in-plug |                                     |                               |
| 5 L           | FLS130105      | 16               | %" ID C-Flex® + %" press-in-plug |                                     | 1/4" ID Silicone Tuflux® 100  |
| 10 L          | FLS130106      | 8                | %" ID C-Flex® + %" press-in-plug | %" ID C-Flex°<br>+ %" press-in-plug | mm (4")<br>+ Luer Lock female |
| 20 L          | FLS130107      | 8                | %" ID C-Flex® + %" press-in-plug | · /* press in plug                  | + Clave connector             |
| 50 L          | FLS130190      | 8                | %" ID C-Flex® + %" press-in-plug |                                     |                               |



#### **Leak Test Line**

- 1/4" × 3/8" Clear C-Flex® 300 mm (12")
- + Midisart® BV 0.2 µm
- + 1/4" ID Silicone Tuflux® 100 mm (4")
- + 3/4" Tri-Clamp with gasket, cap & union

<sup>&</sup>lt;sup>1</sup> Inlet tubing line from end line to bag: % "  $\times$  % " Clear C-Flex  $^{\circ}$  500 mm (20") + Clipster  $^{\circ}$  in a separate pouch

<sup>&</sup>lt;sup>2</sup> Outlet tubing line from bag to end line: 3%" × 5%" Clear C-Flex® 500 mm (20")

Flexsafe® 2D | Flexsafe® 3D

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# Flexsafe® 3D Pre-Designed Solutions for

# Drug Product Filtration, Storage and Filling

# **Drug Product Formulation**

Sterilizing **Filtration** 

Drug **Product** Storage

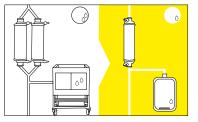
Drug **Product** Transfer

Sterile Connection to Final Filling

Sterile Connection Sterile Weld

**Aseptic Transfer** to an Isolator

Sartopore® Platinum reduce by ten times the wetting volumes for integrity testing



2×20" Filters |

1×20" Sartopore® Platinum | 1×200 L Flushing Tank 1×20 L Flushing Bag

Flexsafe® 3D advanced solutions for drug product feature the Sartopore® Platinum 0.45 | 0.2 µm. The outstanding wetting properties of the modified membrane reduce by ten times the flushing volumes and facilitate pre-use filter integrity testing.

Flexsafe® 3D bags without filters are also available for sterile connection to alternative Sartopore® filter transfer set using Opta® 1/2" or welding with Biowelder® TC. Sartopore® filters can be disconnected for post-use integrity testing using Biosealer®.

Inlet and outlet lines are made of C-Flex® + Silicone Tuflux® for welding, sealing and pumping.

Flexsafe® 3D Bags allow for sterile drug product transfer to most common single-use and stainless steel final filling systems.

Opta® SFT allows for sterile connection to our Biosafe® Raft products for liquid transfer to the final filling area

#### Inlet Line

Sterilizing-grade filtration from formulation mixer

■ Sartopore® Platinum 0.45 | 0.2 µm for efficient wetting and integrity testing

Connection for alternative filter transfer set

- Opta® SFT female
- C-Flex® tube for sterile weld with Biowelder® TC

Every production batch of Flexsafe® 3D Bags for drug product are tested for bioburden, particles and endotoxins.

# Sampling Needleless sampling port

#### Test line for Point of use leak test

- C-Flex® for sterile weld with Biowelder® TC
- Sartopore® Air Filter size 7 keeps the sterility of the 3D bag during testing and filling

#### **Outlet Line**

Connection and transfer by pumping

- Opta® SFT male for sterile connection
- C-Flex® with quick coupler and plug for sterile welding to single-use system

Flexsafe® 3D Pre-Designed Solutions for Drug Product Filtration and Storage in Palletank®

**Drug Product Formulation** 

Sterile Connection to Final Filling

**Sterile Connection** Sterile Weld **Aseptic Transfer** to an Isolator

#### Sterile Connection to Final Filling

|               |                |                  | Inlet <sup>1</sup>                            |                         | Outlet <sup>2</sup>             |
|---------------|----------------|------------------|---|-------------------------|---------------------------------|
| Bag<br>volume | Part<br>number | Units per<br>box | Filter or distal<br>connector on filling line | Filter type<br>and size | Distal connector on outlet line |
| 100 L         | FIS127157      | 2                | Sartopore® Platinum 0.45   0.2 µm             | Midicaps® size 7        |                                 |
|               | FIS126819      | 3                | ½" Opta® SFT female                           | NA                      |                                 |
|               | FIS126821      | 3                | Press in plug                                 |                         | 1/11 0 1 9 0 5 5 7 1            |
| 200 L         | FIS127158      | 2                | Sartopore° Platinum 0.45   0.2 µm             | Midicaps® size 8        | —— ½" Opta® SFT male            |
|               | FIS301540      | 3                | ½" Opta® SFT female                           | NA                      |                                 |
|               | FIS126822      | 3                | Press in plug                                 |                         |                                 |

Sartopore® Platinum Test line with Sartopore® 0.45 | 0.2 µm Air filter 0.2 μm allowing the connection to Opta® SFT female the Sartocheck® 4+ bag tester C-Flex® with press-in-plug Opta® SFT male for sterile for sterile weld with connection to final filling Biowelder® TC



¹ Inlet tubing line from end line to bag: ½" x ¾" Clear C-Flex® 0.5 m (20") + ½" ID Silicone Tuflux® 1 m (40")

<sup>&</sup>lt;sup>2</sup> Outlet tubing line from bag to end line: ½" ID Silicone Tuflux® 1 m (40") + ½" × ¾" Clear C-Flex® 0.5 m (20")

Flexsafe® 3D Pre-Designed Solutions for Drug Product Filtration and Storage in Palletank®

**Drug Product Formulation** 

Sterile Connection to Final Filling

Sterile Connection Sterile Weld

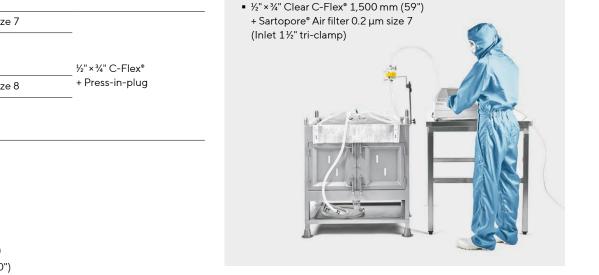
**Aseptic Transfer** to an Isolator

#### Sterile Weld to Final Filling

|               |                |                  | Inlet <sup>1</sup>                         |                         | Outlet <sup>2</sup>             |
|---------------|----------------|------------------|--|-------------------------|---------------------------------|
| Bag<br>volume | Part<br>number | Units per<br>box | Filter or distal connector on filling line | Filter type<br>and size | Distal connector on outlet line |
| 100 L         | FIS126879      | 2                | Sartopore® Platinum 0.45   0.2 µm          | Midicaps® size 7        |                                 |
|               | FIS126823      | 3                | ½" Opta® SFT female                        | NA                      |                                 |
|               | FIS126825      | 3                | Press in plug                              |                         | ½" ×¾" C-Flex®                  |
| 200 L         | FIS126880      | 2                | Sartopore® Platinum 0.45   0.2 µm          | Midicaps® size 8        | + Press-in-plug                 |
|               | FIS126824      | 3                | ½" Opta® SFT female                        | NA                      |                                 |
|               | FIS126826      | 3                | Press in plug                              |                         |                                 |

Sartopore® Platinum Test line with Sartopore® 0.45 | 0.2 µm Air filter 0.2 μm allowing the connection to Opta® SFT female the Sartocheck® 4+ bag tester C-Flex® with press-in-plug C-Flex® with press-in-plug for sterile weld with for sterile weld with Biowelder® TC Biowelder® TC

¹ Inlet tubing line from end line to bag: ½" x ¾" Clear C-Flex® 0.5 m (20") + ½" ID Silicone Tuflux® 1 m (40") <sup>2</sup> Outlet tubing line from bag to end line: ½" ID Silicone Tuflux® 1 m (40") + ½" × ¾" Clear C-Flex® 0.5 m (20")



Leak Test Line

Flexsafe® 3D Pre-Designed Solutions for Drug Product Filtration and Storage in Palletank®

**Drug Product Formulation** 

Sterile Connection to Final Filling

Sterile Connection Sterile Weld **Aseptic Transfer** to an Isolator

Sterile Connection to an Isolator for Final Filling

|               |                |                  | Inlet¹                                     |                         | Outlet <sup>2</sup>                 |
|---------------|----------------|------------------|--|-------------------------|-------------------------------------|
| Bag<br>volume | Part<br>number | Units per<br>box | Filter or distal connector on filling line | Filter type<br>and size | Distal connector on outlet line     |
| 100 L         | FIS126817      | 2                | Sartopore® Platinum 0.45   0.2 µm          | Midicaps® size 7        |                                     |
|               | FIS126827      | 3                | ½" Opta® SFT female                        | NA                      |                                     |
|               | FIS126829      | 3                | Press in plug                              |                         | %" GammaSart®                       |
| 200 L         | FIS126818      | 2                | Sartopore° Platinum 0.45   0.2 µm          | Midicaps® size 8        | —— for aseptic transfer in isolator |
|               | FIS126828      | 3                | ½" Opta® SFT female                        | NA                      |                                     |
|               | FIS301541      | 3                | Press in plug                              |                         |                                     |

Sartopore® Platinum Test line with Sartopore® 0.45 | 0.2 µm Air filter 0.2 μm allowing the connection to Opta® SFT female the Sartocheck® 4+ bag tester C-Flex® with press-in-plug GammaSart® sterile for sterile weld with connection for aseptic Biowelder® TC transfer to an isolator



¹ Inlet tubing line from end line to bag: ½" x ¾" Clear C-Flex® 0.5 m (20") + ½" ID Silicone Tuflux® 1 m (40")

<sup>&</sup>lt;sup>2</sup> Outlet tubing line from bag to end line: ¾" ID Clear C-Flex® 0.5 m (20") + ½" ×¾" Silicone Tuflux® 2 m (80")

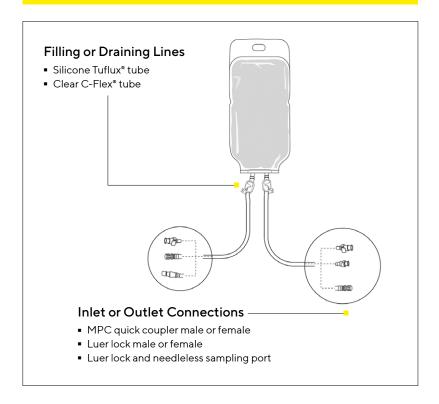
# Sampling in Flexsafe® 2D Bags

Media

|            |             |               | Inlet <sup>1</sup>               | Outlet <sup>1</sup>                |
|------------|-------------|---------------|----------------------------------|------------------------------------|
| Bag Volume | Part Number | Units per box | Distal Connector on Filling Line | Distal Connector on Draining Line  |
| <br>20 mL  | FLS130111   | 20            |                                  |                                    |
| 50 mL      | FLS130112   | 20            | _                                |                                    |
| 150 mL     | FLS130000   | 20            | _                                |                                    |
| 250 mL     | FLS130001   | 20            | <br>¼" MPC male + sealing cap    | 1/4" MPC male + sealing cap        |
| 500 mL     | FLS130002   | 20            | _                                |                                    |
| 1,000 mL²  | FLS130123   | 20            | _                                |                                    |
| 3,000 mL²  | FLS130124   | 16            | _                                |                                    |
| 20 mL      | FLS130113   | 20            |                                  |                                    |
| 50 mL      | FLS130114   | 20            |                                  |                                    |
| 150 mL     | FLS130003   | 20            | <u> </u>                         |                                    |
| 250 mL     | FLS130004   | 20            |                                  | 1/4" MPC male + sealing cap        |
| 500 mL     | FLS130005   | 20            | <u> </u>                         |                                    |
| 1,000 mL²  | FLS130125   | 20            | <del></del>                      |                                    |
| 3,000 mL²  | FLS130126   | 16            | <del></del>                      |                                    |
| 20 mL      | FLS130115   | 20            |                                  |                                    |
| 50 mL      | FLS130116   | 20            | <del></del>                      |                                    |
| 150 mL     | FLS130006   | 20            |                                  | Luer Lock female + Clave connecto  |
| 250 mL     | FLS130007   | 20            | <u> </u>                         |                                    |
| 500 mL     | FLS130008   | 20            | <del>_</del>                     |                                    |
| 20 mL      | FLS130117   | 20            |                                  |                                    |
| 50 mL      | FLS130118   | 20            | <del></del>                      |                                    |
| 150 mL     | FLS130009   | 20            | <br>Luer Lock female + cap       | Luer Lock female + Clave connector |
| 250 mL     | FLS130010   | 20            |                                  |                                    |
| <br>500 mL | FLS130011   | 20            |                                  |                                    |

Flexsafe® 2D pre-designed solutions for sampling are designed to easily take samples across all your process steps.

Flexsafe® 2D pre-designed solutions allow for sanitary sampling through usual connectors or aseptic sampling when the connection is performed under laminar air flow conditions.



- <sup>1</sup> Inlet and outlet tubing: ¼" × ¾" Silicone 150 mm (6")
- $^{2}$  Third line with Silicone tubing and needleless Clave connecteur for 1 L and 3 L bags

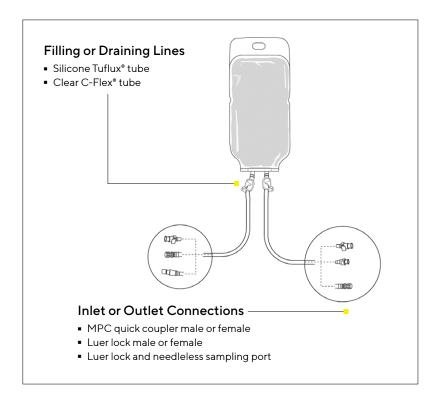
# Sampling in Flexsafe® 2D Bags

|            |             |               | Inlet¹                           | Outlet <sup>1</sup>               |
|------------|-------------|---------------|----------------------------------|-----------------------------------|
| Bag Volume | Part Number | Units per box | Distal Connector on Filling Line | Distal Connector on Draining Line |
| <br>20 mL  | FLS130119   | 20            |                                  |                                   |
| 50 mL      | FLS130120   | 20            |                                  |                                   |
| 150 mL     | FLS130012   | 20            | <del></del>                      |                                   |
| 250 mL     | FLS130013   | 20            | Luer Lock female + cap           | Luer Lock male + cap              |
| 500 mL     | FLS130014   | 20            |                                  |                                   |
| 1,000 mL²  | FLS130127   | 20            | _                                |                                   |
| 3,000 mL²  | FLS130128   | 16            | <u> </u>                         |                                   |

<sup>&</sup>lt;sup>1</sup> Inlet and outlet tubing: ¼" × ¾" Silicone 150 mm (6")

|                       |             |               | Inlet²                           | Outlet <sup>2</sup>               |
|-----------------------|-------------|---------------|----------------------------------|-----------------------------------|
| Bag Volume            | Part Number | Units per box | Distal Connector on Filling Line | Distal Connector on Draining Line |
| 20 mL                 | FLS130121   | 10            |                                  |                                   |
| 50 mL                 | FLS130122   | 10            |                                  |                                   |
| 150 mL                | FLS130015   | 10            |                                  |                                   |
| 250 mL                | FLS130016   | 10            |                                  | 1/4" MPC male + sealing cap       |
| 500 mL                | FLS130017   | 10            |                                  |                                   |
| 1,000 mL <sup>3</sup> | FLS130129   | 10            | <del>_</del>                     |                                   |
| 3,000 mL <sup>3</sup> | FLS130130   | 16            | <del></del>                      |                                   |
|                       |             |               |                                  |                                   |

<sup>&</sup>lt;sup>2</sup> Inlet and outlet tubing: ½" × ½" Clear C-Flex® 500 mm (20")



<sup>&</sup>lt;sup>2</sup> Third line with Silicone tubing and needleless Clave connecteur for 1L and 3L bags

<sup>&</sup>lt;sup>3</sup> Third line with Silicone tubing and needleless Clave connecteur for 1L and 3L bags

# Flexsafe® 2D Bags in Shell for Robust Liquid Handling and Shipping

The Outstanding Strength & Flexibility of Flexsafe® Bags Provide Safe & Reliable Liquid Handling & Shipping

#### Filling Site: Flexsafe® Shipping System

5 L, 10 L & 20 L













|            |             |               |                                      | Inlet <sup>1</sup>               | Outlet  |
|------------|-------------|---------------|--------------------------------------|----------------------------------|---|
| Bag Volume | Part Number | Units per box | Description                          | Distal Connector on Filling Line | Distal Connector on Draining Line             |
| <br>5 L    | FLS303106   | 2             | Flexsafe® 5 L (Shell, MPC, TC)       |                                  | Tri-clamp ¾" flange with gasket, union & cap² |
| 10 L       | FLS303108   | 2             | Flexsafe® 10 L (Shell, MPC, LT MPC)³ |                                  | 36" MPC male + sealing cap1                   |
| 10 L       | FLS303107   | 1             | Flexsafe® 10 L (Shell, MPC, TC)      | <br>3%" MPC female +             | Tri-clamp ¾" flange with gasket, union & cap² |
| 10 L       | FLS303109   | 1             | Flexsafe® 10 L (Shell, MPC, LT MPC)³ | sealing cap                      | %" MPC male + sealing cap <sup>1</sup>        |
| 20 L       | FLS303814   | 1             | Flexsafe® 20 L (Shell, MPC, TC)      |                                  | Tri-clamp ¾" flange with gasket, union & cap² |
| 20 L       | FLS303815   | 1             | Flexsafe® 20 L (Shell, MPC, LT MPC)³ |                                  | %" MPC male + sealing cap <sup>1</sup>        |

<sup>&</sup>lt;sup>1</sup> Inlet & outlet tubing: %" Clear C-Flex® 500 mm (20"). Third line with Silicon tubing & needleless clave connector. | 2 Outlet tubing: %" Silicone TuFlux® 500 mm (20")

³ Leak Test Line: ¼" × ¾" Clear C-Flex° 300 mm (12") + Midisart° BV 0.2 µm + ¼" ID Silicone TuFlux° 100 mm (4") + ¾" Tri-Clamp with gasket, cap & union

# Flexsafe® 2D Bags in Shell for Robust Liquid Handling and Shipping

# Shippers & Standalone Shells

|      | Part Number | Units per box                                | Description   |  |
|------|-------------|--|---|--|
| 5 L  | FLA302721   | 10 units shippers<br>20 units PE overpouches | Standard Shipper for 5 L shell with double PE overpouches per shipper   |  |
| 10 L | FLA300318   | 10 units shippers<br>20 units PE overpouches | Standard Shipper for 10 L shell with double PE overpouches per shipper  |  |
| 5 L  | FLA302701   | 5 top + 5 bottom                             | Standard Shell 5 L 2D bag handling                                      |  |
| 10 L | FLA300213   | 5 top + 5 bottom                             | Standard Shell 10 L 2D bag handling                                     |  |
| 20 L | FLA302723   | 7 units shippers<br>15 units overpouches     | Standard Shipper for 20 L shell with double PE overpounches per shipper |  |
| 20 L | FLA302706   | 5 top + 5 bottom                             | Standard Shell 20 L 2D bag handling                                     |  |





# Point-of-Use Integrity Test for Flexsafe® 2D Bags

Current regulatory standards and associated guidelines have been moving quickly in the past few years and continue to evolve towards increased patient safety. The most recent up-date of the GMP Annex 1: Manufacture of sterile products issued in draft in 2020 provides "general guidance that should be used for the manufacture of all sterile products using the principles of Quality Risk Management (QRM), to ensure that microbial, particulate and pyrogen contamination is prevented in the final product." The risk of holes or leakages induced by implementation of single-use systems in bioprocessing has to be addressed into the process risk analysis as part of the contamination control strategy (CCS) and has to be mitigated by appropriate controls and | or validation steps. Point-of-Use Integrity test is the post installation test providing assurance of bag integrity right before filling.

#### Safe

- The precision of Sartocheck 4 + bag tester allows adequate integrity testing just before filling the 2D or 3D bags
- The test is performed through a sterilizing vent filter (Midisart® BV or Sartopore® Air) to maintain the bag sterility therefore ensuring patient safety.

#### Reliable

- For the Flexsafe® 2D bags, the restraining plates reduce heat transfers, maintain a small inflation volume and allow a high test pressure for a sensitivity of 30 µm
- For Flexsafe® 3D bags, the test performed in the Palletank® provides a sensitivity of 100 to 200 µm.
- The porous spacers between plates avoid any potential masking effect
- The leak detection is validated thanks to validation study done with extensive tests, a differentiation of defective bags based on with 6 sigma confidence interval (see graph on the right)

#### Fast & Easy to Use

- The well-known ASTM F2095-07 standard pressure decay leak test at point of use and the well-established Sartocheck® technology make it easy to implement - The restraining plates allow a small inflation volume thus reduce the total test time to less than 10 minutes
- The 3D bags are tested in their container, avoiding any further handling before filling
- The MultiUnit tester option increases test productivity by testing two 2D bags simultaneously and allows filter integrity testing

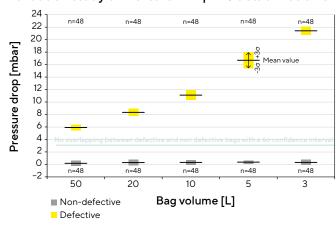
#### Easy to Validate

- A robust validation of the test parameters and specifications makes the validation approach at user site easy
- A strong on-site IQ, OQ, PQ, SOP development and operator training ease the validation documentation process at user site





#### Validation study of Flexsafe® 2D | 240 s stabilization time | 180 s test time



# Point-of-Use Leak Test for Flexsafe® 3D Bags

With the evolution of current regulations, bioprocessing bags which are part of the drug manufactruing process are under increased regulatory scrutiny. To avoid contamination risks and to mitigate commercial loss, bioprocessing bags have to be safe and leak proof. This is why the risk of holes or leakages induced by implementation of single-use systems in bioprocessing has to be addressed into the process risk analysis as part of the contamination control strategy (CCS) and has to be mitigated by appropriate controls and | or validation steps. Point-of-Use Integrity test is the post installation test providing assurance of bag integrity right before filling.

#### Safe

- The precision of Sartocheck 4 + bag tester allows adequate integrity testing just before filling the 3D bags
- The test is performed through a sterilizing vent filter (Sartopore® Air) to maintain the bag sterility therefore ensuring patient safety

#### Reliable

- For Flexsafe® 3D bags, the test performed in the Palletank® provides a leak test sensitivity of 100 to 200 µm.
- The porous spacers between plates avoid any potential masking effect
- The leak detection is validated through extensive tests with a differentiation of defective bags based on with 6 sigma confidence interval.

#### Fast & Easy to Use

- The well-known ASTM F2095-07 standard pressure decay leak test at point of use and the well-established Sartocheck® technology make it easy to implement
- The Sartocheck® Fast Filling Kit allows to save up to 15 minutes of test for 3D bags
- The MultiUnit tester option increases test productivity by testing two 2D bags simultaneously and allows filter integrity testing

#### Easy to Validate

- A robust validation of the test parameters and specifications makes the validation approach at user site easy
- A strong on-site IQ, OQ, PQ, SOP development and operator training ease the validation documentation process at user site

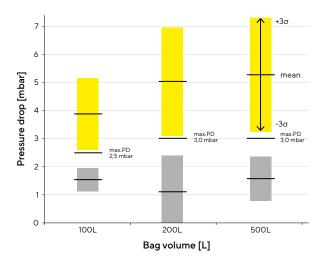
#### **Bag Tester Fleeces**

| Part Number  | Description  Bag tester fleece for Palletank* 200L ( 3 pcs) |  |
|--------------|---|--|
| DZ200L-PTSIT |   |  |
| DZ500L-PTSIT | Bag tester fleece for Palletank® 500L (3 pcs)               |  |

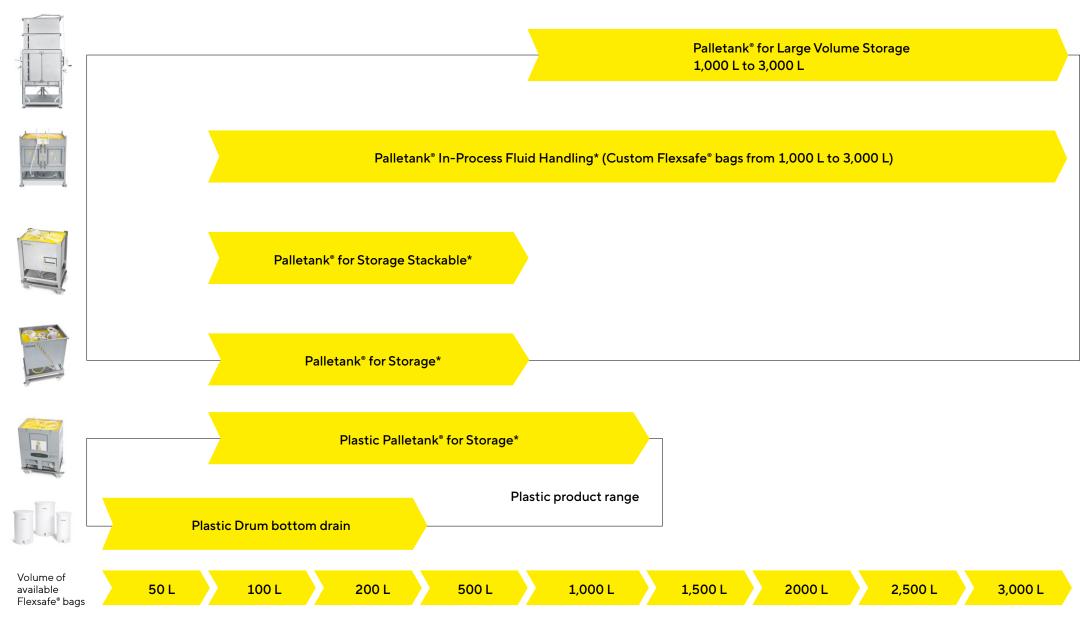
#### Filter Holder

| Part Number | Description                        |
|-------------|------------------------------------|
| FXC301477   | Filter Holder for Palletank® 75 mm |

#### Validation study of Flexsafe® 3D



# Palletank® for Storage



# Palletank® for Storage | In Process Fluid Handling Small Volume

Palletank® for storage are stainless steel containers designed for the safe and robust storage of biopharmaceutical fluids such as high value drug substances contained in Flexsafe® 3D Bags. They are available in volumes of 50 L, 200 L and 500 L. The Flexsafe® 3D Bags are manufactured according to a qualified design that precisely fits the Palletank®.

Palletank® for in-process fluid handling are specifically developed for users who wish to leave the containers in close proximity to process equipment. They are available in 200 L and 500 L for use with Flexsafe® 3D bags. The double hinged front doors allow bag replacement, installation and manipulation whilst Palletank® are stacked up in the process area thus enabling continuous processing without movement of the containers. As a result, a forklift is not routinely required in the manufacturing area.

#### Features & Benefits

Media

#### Qualified System:

• perfect fit and protection of the Flexsafe® 3D Bag in its Palletank®

#### Stackable Version:

space saving containment system

#### Easy access

• through double hinged front doors with safety latches

#### Easy operation

• due to continuous processing without movement of the containers

#### Optimal bag unfolding

• without operator manipulation with the selfdeploying accessory



Palletank® for Storage



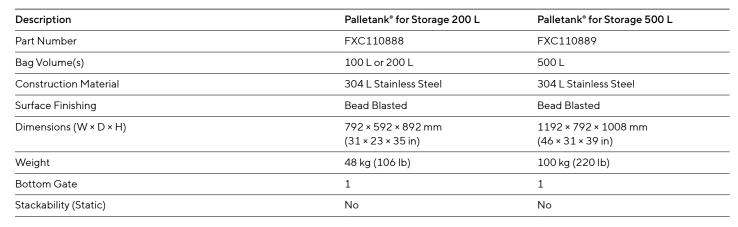
Palletank® for Storage Stackable



Palletank® In-Process Fluid Handling

# Technical Specifications

| Description                          | Palletank® for Storage Stackable 50 L   | Palletank® for Storage Stackable 200 L  | Palletank® for Storage Stackable 500 L    |
|--------------------------------------|---|---|---|
| Part Number                          | FXC113946                               | FXC110733                               | FXC110734                                 |
| Bag Volume(s)                        | 50 L                                    | 100 L or 200 L                          | 500 L                                     |
| Construction Material                | 304 L Stainless Steel                   | 304 L Stainless Steel                   | 304 L Stainless Steel                     |
| Surface Finishing                    | Bead Blasted                            | Bead Blasted                            | Bead Blasted                              |
| Dimensions (W $\times$ D $\times$ H) | 490 × 490 × 750 mm<br>(19 × 19 × 30 in) | 792 × 592 × 929 mm<br>(31 × 23 × 37 in) | 1192 × 792 × 1045 mm<br>(47 × 31 × 41 in) |
| Weight                               | 25 kg (55 lb)                           | 70 kg (154 lb)                          | 110 kg (242 lb)                           |
| Bottom Gate                          | 1                                       | 1                                       | 1   |
| Stackability (Static)                | 3 high                                  | 3 high                                  | 2 high                                    |



| Description            | Dolly for Palletank® for<br>Storage and Shipping 200 L | Dolly for Palletank® for<br>Storage and Shipping 500 L |
|------------------------|--|--|
| Part Number            | FXS102254  | FXS102256  |
| Construction Material  | 304 L and polyamide (wheels)                           | 304 L and polyamide (wheels)                           |
| Surface Finishing      | Glass Bead Blasted                                     | Glass Bead Blasted                                     |
| Dimensions (W × D × H) | 815 × 615 × 188 mm                                     | 1215 × 815 × 161 mm                                    |
|                        | $(32.1 \times 24.2 \times 6.4 \text{ in})$             | $(47.8 \times 32.1 \times 6.4 \text{ in})$             |
| Weight (approx.)       | 10 kg (22 lb)  | 18 kg (39.7 lb)  |







# Technical Specifications

| Description                          | Palletank® for In-Process Fluid Handling 200 L | Palletank® for In-Process Fluid Handling 500 L | Palletank® for In-Process Fluid Handling 1,000 L |
|--------------------------------------|--|--|--|
| Part Number                          | FXC106230                                      | FXC106235                                      | FXC106223  |
| Bag Volume(s)                        | 100 L or 200 L                                 | 500 L  | 1,000 L  |
| Construction Material                | 304 L Stainless Steel                          | 304 L Stainless Steel                          | 304 L Stainless Steel                            |
| Surface Finishing                    | Glass Bead Blasted                             | Glass Bead Blasted                             | Glass Bead Blasted                               |
| Dimensions (W $\times$ D $\times$ H) | 860 × 660 × 929 mm<br>(33.9 × 26 × 36.6 in)    | 1260 × 860 × 989 mm<br>(49.6 × 33.9 × 38.9 in) | 1259 × 1059 × 1443 mm<br>(49.6 × 41.7 × 56.8 in) |
| Weight                               | 73 kg (161 lb)                                 | 94 kg (207 lb)                                 | 145 kg (320 lb)                                  |
| Bottom Gate                          | 1  | 1  | 2  |
| Stackability                         | 3 high   | 3 high   | 2 high   |

| Description                          | Dolly for Palletank® IPFH 200 L | Dolly for Palletank® IPFH 500 L | Dolly for Palletank® IPFH 1,000 L |
|--------------------------------------|---------------------------------|---------------------------------|-----------------------------------|
| Part Number                          | FXS102255                       | FXS102257                       | FXS102259                         |
| Construction Material                | 304 L and polyamide (wheels)    | 304 L and polyamide (wheels)    | 304 L and polyamide (wheels)      |
| Surface Finishing                    | Glass Bead Blasted              | Glass Bead Blasted              | Glass Bead Blasted                |
| Dimensions (W $\times$ D $\times$ H) | 807 × 607 × 255 mm              | 1207 × 807 × 258 mm             | 1205 × 1005 × 258 mm              |
|                                      | (31.8 × 23.9 × 10 in)           | (47.5 × 31.8 × 10.2 in)         | (47.4 × 39.6 × 10.2 in)           |
| Weight (approx.)                     | 10 kg (22 lb)                   | 20 kg (44 lb)                   | 22 kg (48.5 lb)                   |
|                                      |                                 |                                 |                                   |



| Description            | Palletank® for In-Process Fluid Handling 1,500   | L Palletank® for In-Process Fluid Handling 2,000 L | Palletank® for In-Process Fluid Handling 2,500 L | Palletank® for In-Process Fluid Handling 3,000 L  |
|------------------------|--|--|--|---|
| Part Number            | FXC109797  | FXC109798  | FXC109799  | FXC109764   |
| Bag Volume(s)          | 1,500 L  | 2,000 L  | 2,500 L  | 3,000 L   |
| Construction Material  | 304 L Stainless Steel                            | 304 L Stainless Steel                              | 304 L Stainless Steel                            | 304 L Stainless Steel                             |
| Surface Finishing      | Glass Bead Blasted                               | Glass Bead Blasted                                 | Glass Bead Blasted                               | Glass Bead Blasted                                |
| Dimensions (W × D × H) | 1323 × 1210 × 2099 mm<br>(52.1 × 47.6 × 82.6 in) | 1323 × 1210 × 2599 mm<br>(52.1 × 47.6 × 102.3 in)  | 1323 × 1210 × 3099 mm<br>(52.1 × 47.6 × 122 in)  | 1323 × 1210 × 3599 mm<br>(52.1 × 47.6 × 141.7 in) |
| Weight                 | 326 kg (719 lb)                                  | 386 kg (851 lb)                                    | 447 kg (986 lb)                                  | 507 kg (1118 lb)                                  |
| Bottom Gate            | 3  | 3  | 3  | 3   |
| Stackability           | 0  | 0  | 0  | 0   |

# Plastic Palletank® for Storage of Sterile Buffer or Media

Buffer

Plastic Palletank® for Storage in 200 L and 500 L represents a cost-effective containment solution for the storage and processing of biopharmaceutical fluids such as sterile media, buffers contained in Flexsafe® 3D Bags. Their flat, smooth surfaces and rounded corners facilitate cleaning and sanitization for clean room operations. The Plastic Palletank® for storage are foldable for minimal storage space when empty. They are also stackable for optimal floor space utilization when filled with biopharmaceutical solutions.

#### Features & Benefits

PP and ABS containers: Low cost and robust storage solution Stackable when full and collapsible when empty: Minimize storage volume Smooth scratch-resistant plastic surface: Clean room compatible Optimal bag unfolding without operator manipulation with the self-deploying accessory

# Technical Specifications

| Description                     | Plastic Palletank® for Storage 200 L  | Plastic Palletank® for Storage 500 L    | Plastic Palletank® for Storage 1,000 L   |
|---------------------------------|---------------------------------------|---|--|
| Part Number                     | FXC116215                             | FXC116220                               | FXC116217                                |
| Bag Volume(s)                   | 100 L or 200 L                        | 500 L                                   | 1,000 L                                  |
| Main Construction Material      | PP                                    | HDPE/ABS                                | PP                                       |
| Dimensions (W × D × H) Unfolded | 805 × 607 × 969 mm (32 × 24 × 38 in.) | 1215 × 805 × 1086 mm (48 × 31 × 43 in.) | 1200 × 1000 × 1245 mm (47 × 39 × 49 in.) |
| Folded                          | 805 × 607 × 510 mm (32 × 24 × 20 in.) | 1215 × 805 × 572 mm (48 × 31 × 22 in.)  | 1200 × 1000 × 451 mm (48 × 31 × 18 in.)  |
| Bottom Gate                     | 1                                     | 1                                       | 2  |
| Filled Static Stackability      | 2                                     | 2                                       | 2  |



| Description            | Plastic Palletank® Dolly 200 L          | Plastic Palletank® Dolly 500 L           | Plastic Palletank® Dolly 1,000 L          |
|------------------------|---|--|---|
| Part Number            | FXA116630                               | FXA116631                                | FXA116632                                 |
| Construction Material  | 304 L and polyamide (wheels)            | 304 L and polyamide (wheels)             | 304 L and polyamide (wheels)              |
| Surface Finishing      | Glass Bead Blasted                      | Glass Bead Blasted                       | Glass Bead Blasted                        |
| Dimensions (W × D × H) | 807 × 607 × 214 mm<br>(32 × 24 × 8 in.) | 1207 × 807 × 214 mm<br>(47 × 32 × 8 in.) | 1210 × 1010 × 227 mm<br>(48 × 40 × 9 in.) |
| Weight (approx.)       | 10 kg (22 lb)                           | 20 kg (44 lb)                            | 35 kg (77 lb)                             |

# Palletank® for Large Volume Storage

Large volume storage are designed with ergonomic features and design to limit operator manipulations and overall simplify operations. This results in increased process safety by minimizing risks for product, operator and process. True ease of use also leads to fast set up, filling and draining for maximized process efficiency.

#### Features & Benefits

#### Easy

Large doors at ergonomic height for easy bag installation and front access to lines

#### Fast

Set-up is done in less than 2 minutes. The pre-deployed bags avoids further bag handling during filling. The high flow pre-designed solutions speed-up filling and draining operations.

#### Safe operations

No operator manipulation, the bag self-fills and self-drains. The sloped bottom increase fluid recovery.

# **Tubing and filters holders**





# Palletank® for Large Volume Storage

# Palletank® for Large Volume Storage

| Description                     | Palletank® Storage 1,000 L         | Palletank® Storage 1,500 L         | Palletank® Storage 2,000 L         |
|---------------------------------|------------------------------------|------------------------------------|------------------------------------|
| Bag Volume                      | 1,000L                             | 1,500L                             | 2,000L                             |
| Construction Material           | 304 L Stainless Steel              | 304 L Stainless Steel              | 304 L Stainless Steel              |
| Surface Finishing               | Bead Blasted, pickled & passivated | Bead Blasted, pickled & passivated | Bead Blasted, pickled & passivated |
| External Dimensions (W × D × H) |                                    |                                    |                                    |
| w  ergonomic module             | 1245+1045+2001 mm (49+41+78 in)    | 1245+1045+2501 mm (49+41+98 in)    | 1245×1045×3001 mm (49×41×118 in)   |
| w o ergonomic module            | 1245+1045+1690 mm (49+41+66 in)    | 1245+1045+2191 mm (49+41+86 in)    | 1245×1045×2691 mm (49×41×106 in)   |
| Built on wheels                 | 1245+1045+1790 mm (49+41+70 in)    | N A                                | N A                                |
| Bottom gate   Sliding gate      | 2                                  | 2                                  | 2                                  |
| Stackability                    | No                                 | No                                 | No                                 |

| Description                     | Palletank® Storage 2,500 L         | Palletank® Storage 3,000 L         |
|---------------------------------|------------------------------------|------------------------------------|
| Bag Volume                      | 2,500L                             | 3,000L                             |
| Construction Material           | 304 L Stainless Steel              | 304 L Stainless Steel              |
| Surface Finishing               | Bead Blasted, pickled & passivated | Bead Blasted, pickled & passivated |
| External Dimensions (W × D × H) |                                    |                                    |
| w  ergonomic module             | 1245×1045×3501 mm (49×41×138 in)   | 1245×1045×4001 mm (49×41×157 in)   |
| w o ergonomic module            | 1245×1045×3191 mm (45×49×125 in)   | 1245×1045×3691 mm (49×41×145 in)   |
| Built on wheels                 | N A                                | N A                                |
| Bottom gate   Sliding gate      | 2                                  | 2                                  |
| Stackability                    | No                                 | No                                 |

# Palletank® for Large Volume Storage

| Description                             | Palletank® Storage 1,000 L | Palletank® Storage 1,500 L | Palletank® Storage 2,000 L | Palletank® Storage 2,500 L | Palletank® Storage 3,000 L |
|---|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|
| w  ergonomic module                     | FXC302072                  | FXC302073                  | FXC302074                  | FXC302075                  | FXC302076                  |
| w  ergonomic module<br>and w  weighing  | FXC304053                  | FXC304054                  | FXC304055                  | FXC304056                  | FXC304057                  |
| w o ergonomic module                    | FXC304027                  | FXC301928                  | FXC301929                  | FXC302070                  | FXC302071                  |
| w o ergonomic module<br>and w  weighing | FXC304028                  | FXC304029                  | FXC304050                  | FXC304051                  | FXC304052                  |
| Built on wheels                         | FXC302077                  | N A                        | N A                        | N A                        | N A                        |
| Built on wheels and w  weighing         | FXC301927                  | N A                        | N A                        | N A                        | N A                        |



Palletank® Storage 1,000 L - 3,000 L at ergonomic height



Palletank® Storage 1,000 L - 3,000 L at low height



Palletank® Storage 1,000 L Built-on wheels

Media

# Palletank® Large Volume for Storage Accessories

| Part Number | Description                      |
|-------------|----------------------------------|
| FXC301562   | STD tubing holder single %"      |
| FXC301563   | STD tubing holder twin %"        |
| FXC301564   | STD tubing holder triple %"      |
| FXC301565   | STD tubing holder quattro %"     |
| FXC301566   | STD tubing holder single ¾"      |
| FXC301567   | STD tubing holder twin ¾"        |
| FXC301568   | STD tubing holder triple ¾"      |
| FXC301569   | STD tubing holder quattro ¾"     |
| FXC301570   | STD tubing holder single 1"      |
| FXC301571   | STD tubing holder twin 1"        |
| FXC301572   | STD tubing holder triple 1"      |
| FXC301573   | STD tubing holder quattro 1"     |
| FXC301574   | STD tubing holder single 1-1/6"  |
| FXC301575   | STD tubing holder twin 1-1/6"    |
| FXC301576   | STD tubing holder triple 1-1/8"  |
| FXC301577   | STD tubing holder quattro 1-1/6" |
| FXC301578   | STD tubing holder single 1-1/4"  |
| FXC301579   | STD tubing holder twin 1-1/6"    |
| FXC301580   | STD tubing holder triple 1-1/8"  |
| FXC301586   | STD tubing holder quattro 1-1/4" |
|             |                                  |

| Part Number | Description                |
|-------------|----------------------------|
| FXC301582   | Filter Holder Short 55 mm  |
| FXC301583   | Filter Holder Long 55 mm   |
| FXC301584   | Filter Holder Short 75 mm  |
| FXC301585   | Filter Holder Long 75 mm   |
| FXC301586   | Filter Holder Short 100 mm |
| FXC301587   | Filter Holder Long 100 mm  |
| FXA304201   | FT Holder Short H 55 mm    |
| FXA304200   | FT Holder Short H 75 mm    |
| FXA304202   | FT Holder Short H 100 mm   |







# Standard Drum for Storage and Processing

The plastic drum containers offer a cost-effective containment solution for the storage and processing of media and buffer in Flexsafe® 3D Bags for drum. Their flat, smooth surfaces facilitate cleaning and sanitization for clean room operations. They are available with volumes of 50 L, 100 L and 200 L to fit with Flexsafe® 3D Bags for drum of the same volumes.

The drums are available with a lid and a bottom gate for use with Flexsafe® 3D Bag for drum fitted or not with a bottom drain line.

The drum and filled Flexsafe® 3D Bags can be moved safely with a stainless steel dolly available in two sizes 50 L | 100 L and 200 L.

#### Drum

| Description                | STD Drum          |                     |                    |
|----------------------------|-------------------|---------------------|--------------------|
|                            | 50 L              | 100 L               | 200 L              |
| Part Number                | FBC125627         | FBC125628           | FBC125629          |
| Construction Material      | HDPE              |                     |                    |
| nternal Diameter (Approx.) | 346 mm (13.6 in)  | 467 mm (18.4 in)    | 559 mm (22 in)     |
| nternal Height (Approx.)   | 702 mm (27.6 in)  | 759 mm (29.8 in)    | 918 (36.6 in)      |
| Weight                     | 4.3 kg (9.46 lb.) | 6.25 kg (13.75 lb.) | 10.3 kg (22.7 lb.) |
| Bottom Hole                | 1                 |                     |                    |

#### Features & Benefits

Media

- HDPE drum: Low cost storage solution for media and buffer
- Bottom gate: Allows for bottom drain option
- Smooth scratch-resistant plastic surface: Clean room compatible
- Standard product: Available from stock



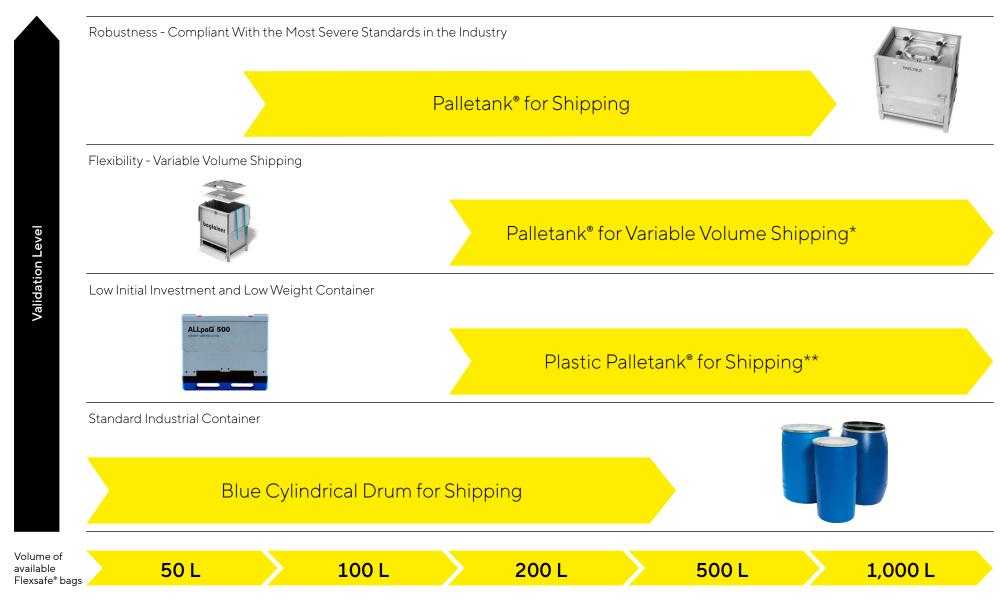


#### Dolly

| Description              | STD Drum Accessory Dolly                     |                        |
|--------------------------|--|------------------------|
|                          | 50 L or 100 L                                | 200 L                  |
| Part Number              | FXA126305                                    | FXA126306              |
| Construction Material    | Stainless steel 304 L and polyamide (wheels) |                        |
| Surface Finish           | Brushed and passivated                       |                        |
| Max. External Dimensions | 502×502×168 mm                               | 594×594×168 mm         |
| W×D×H (Approx.)          | (19.7×19.7×6.6 in)                           | (23.4 × 23.4 × 6.6 in) |
| Wheels                   | 2 with brakes and 2 without brakes           |                        |
| Weight                   | 8.4 kg (19.5 lb.)                            | 10.4 kg (22.9 lb.)     |
| Max. Dynamic Load        | 200 kg                                       | 400 kg                 |

Buffer

# Sartorius 3D Liquid Shipping Overview



# Palletank® for Shipping at Nominal Volume

Buffer

Palletank® for shipping is specifically developed for secure and convenient shipment of sterile media, buffers and high value drug substances. They are available in volumes of 100 L, 200 L and 500 L to fit with 100 L | 200 L and 500 L Flexsafe® 3D Bags. The system is composed of the Palletank® container and the associated shipping kit. The extensive qualification according to ASTM Standard ensures safe & robust liquid shipping for Flexsafe® for Palletank®.

#### Features & Benefits

**ASTM qualification** of Flexsafe® 3D Bags with the Palletank® for shipping ensures safe and robust liquid shipping applications.

**Immobilization** of Flexsafe® Bag by compression assures system integrity Dismountable construction improves space utilization on site before and after usage

#### **Technical Specifications**

| Description                     | Palletank® for Shipping 100 L                       | Palletank® for Shipping 200 L                       | Palletank® for Shipping 500 L                       |
|---------------------------------|---|---|---|
| Part Number                     | FXC106362   | FXC103133   | FXC106609   |
| Bag Volume(s)                   | 100 L   | 200 L   | 500 L   |
| Construction Material           | 304 L Stainless Steel                               | 304 L Stainless Steel                               | 304 L Stainless Steel                               |
| Dimensions (W × D × H) Unfolded | 800 × 600 × 688 mm<br>(31.5 × 23.6 × 27.1 in)       | 800 × 600 × 935 mm<br>(31.5 × 23.6 × 36.8 in)       | 1206 × 806 × 1050 mm<br>(47.5 × 31.7 × 41.33 in)    |
| Folded                          | 800 × 600 × 510 mm (31.5 × 23.6 × 20.1 in)          | 800 × 600 × 510 mm (31.5 × 23.6 × 20.1 in)          | 1206 × 806 × 540 mm (47.5 × 31.7 × 21.26 in)        |
| Weight (incl. Lid)              | 63.5 kg (140 lb)                                    | 82 kg (180.78 lb)                                   | 129 kg (284.4 lb)                                   |
| Bottom Gate                     | 1   | 1   | 1   |
| Unfolded                        | 3   | 3   | 2   |
| Folded                          | 5   | 5   | 3   |
| Description                     | Shipping kit 100 L                                  | Shipping kit 200 L                                  | Shipping kit 500 L                                  |
| Part Number                     | FXC102475   | FXC102477   | FXC102478   |
| Weight                          | 16 kg (35.27 lb)                                    | 16 kg (35.27 lb)                                    | 28 kg (61.8 lb)                                     |
| Shipping Validation             | ASTM D4169 Level 2                                  | ASTM D4169 Level 2                                  | ASTM D4169 Level 2                                  |
| Description                     | Dolly for Palletank® 100 L for Storage and Shipping | Dolly for Palletank® 200 L for Storage and Shipping | Dolly for Palletank® 500 L for Storage and Shipping |
| Part Number                     | FXS102254   | FXS102254   | FXS102256   |
| Construction Material           | 304 L and polyamide (wheels)                        | 304 L and polyamide (wheels)                        | 304 L and polyamide (wheels)                        |
| Surface Finishing               | Glass Bead Blasted                                  | Glass Bead Blasted                                  | Glass Bead Blasted                                  |
| Dimensions (W × D × H)          | 815 × 615 × 188 mm (32.1 × 24.2 × 6.4 in)           | 815 × 615 × 188 mm (32.1 × 24.2 × 6.4 in)           | 1215 × 815 × 161 mm (47.8 × 32.1 × 6.4 in)          |
| Weight (approx.)                | 10 kg (22 lb)                                       | 10 kg (22 lb)                                       | 18 kg (39.7 lb)                                     |
| ·                               |   |   |   |



# Plastic Palletank® for Shipping\* for Sterile Buffer or Media Shipping at Nominal Volume

Plastic Palletank® for Shipping is designed to meet the ever-evolving needs of the pharmaceutical industry, Genesis bioprocess containers presents the ultimate storage and shipment solution. Collapsible, stackable and reusable, the user-friendly range of 200 L up to 1,000 L totes feature smooth surfaces to inhibit bacterial growth, are easy to maintain and ready to customize to any application to protect **sterile** buffer or media.

#### Features & Benefits

Lightweight: Plastic properties reduce shipping charges.

Collapsible: Fold the units to save valuable space in return shipping. Stackable: Maximize warehousing for space and cost optimization.

Reusable: Keep in rotation for years and replace panels as needed, to add to the lifespan

of your fleet.

Hygienic: Spillage control and jet washable. Individual panels can be removed for

cleaning.

# **Technical Specifications**

| Description                     | Plastic Palletank® for Shipping 200 L         | Plastic Palletank® for Shipping 500 L           | Plastic Palletank® for Shipping 1,000 L         |
|---------------------------------|---|---|---|
| Part Number                     | FXC308396                                     | FXC308406                                       | FXC308398                                       |
| Bag Volume(s)                   | 200 L   | 500 L   | 1,000 L   |
| Construction Material           | PP  | HDPE/ABS  | PP  |
| Dimensions (W × D × H) Unfolded | 809 × 609 × 954 mm<br>(31.8 × 23.9 × 37.6 in) | 1200 × 800 × 1070 mm<br>(47.2 × 31.5 × 42.1 in) | 1200 × 995 × 1285 mm<br>(47.2 × 39.2 × 50.6 in) |
| Folded                          | 809 × 609 × 520 mm<br>(31.8 × 23.9 × 20.5 in) | 1200 × 800 × 615 mm<br>(47.2 × 31.5 × 24.2 in)  | 1200 × 995 × 448 mm<br>(47.2 × 39.2 × 17.6 in)  |
| Weight (incl. Lid)              | 24 kg (53 lb)                                 | 90 kg (199 lb)                                  | 113 kg (249 lb)                                 |
| Bottom Gate                     | 1   | 1   | 1   |
| Filled Static Stackability      | 2   | 2   | 2   |
| Shipping Validation             | Real Shipping                                 | Real Shipping                                   | ASTM D4169 Level 3                              |



| Description            | Plastic Palletank® Dolly 200 L              | Plastic Palletank® Dolly 500 L               | Plastic Palletank® Dolly 1,000 L              |
|------------------------|---|--|---|
| Part Number            | FXA116630                                   | FXA116631                                    | FXA116632                                     |
| Construction Material  | 304 L and polyamide (wheels)                | 304 L and polyamide (wheels)                 | 304 L and polyamide (wheels)                  |
| Surface Finishing      | Glass Bead Blasted                          | Glass Bead Blasted                           | Glass Bead Blasted                            |
| Dimensions (W × D × H) | 807 × 607 × 214 mm<br>31.8 × 23.9 × 8.4 in. | 1207 × 807 × 214 mm<br>47.5 × 31.8 × 8.4 in. | 1210 × 1010 × 227 mm<br>47.6 × 39.8 × 8.9 in. |
| Weight (approx.)       | 10 kg (22 lb)                               | 20 kg (44 lb)                                | 35 kg (77 lb)                                 |

# Palletank® for Variable Volume Shipping\*

Palletank® for Variable Volume Shipping prevent the bag from being ripped during transport. The unique bagtainer bag securing system is easy to operate and allows for underfilling the bag down to any level, still securing the liquid during transport.

#### **Features & Benefits**

Variable: unique bagtainer bag securing system which works with intermediate volumes Warehouse Handling: can easily be moved by forklift or with the use of other accessories

Stackable: stackable empty or filled

Collapsible: collapsible alternatives available

# Technical Specifications

| Description                     | Palletank® for Variable Volume Shipping 200 L  | Palletank® for Variable Volume Shipping 500 L   | Palletank® for Variable Volume Shipping 1,000 L  |
|---------------------------------|--|---|--|
| Part Number                     | FXC308400                                      | FXC308401                                       | FXC308402  |
| Bag Volume(s)                   | 200 L  | 500 L   | 1,000 L  |
| Construction Material           | 304 L Stainless Steel                          | 304 L Stainless Steel                           | 304 L Stainless Steel                            |
| Dimensions (W × D × H) Unfolded | 800 × 604 × 1027 mm<br>(31.5 × 23.8 × 40.4 in) | 1186 × 792 × 1078 mm<br>(46.7 × 31.2 × 42.4 in) | 1235 × 1011 × 1492 mm<br>(48.6 × 39.8 × 58.7 in) |
| Folded                          | No   | No  | No   |
| Weight (incl. Lid)              | 92 kg (203 lb)                                 | 190 kg (419 lb)                                 | 270 kg (595 lb)                                  |
| Bottom Gate                     | 1  | 1   | 1  |
| Unfolded                        | 3  | 2   | 2  |
| Folded                          | No   | No  | No   |
| Shipping Validation             | ASTM D4169 Level 2 (150 L and 200 L)           | Real Shipping                                   | ASTM D4169 Level 2                               |

| bagkainer |
|-----------|
|           |

| Description            | Dolly for bagtainer 200 L    | Dolly for bagtainer 500 L    | Dolly for bagtainer 1,000 L        |
|------------------------|------------------------------|------------------------------|------------------------------------|
| Part Number            |                              |                              |                                    |
| Construction Material  | 304 L and polyamide (wheels) | 304 L and polyamide (wheels) | 304 L and polyamide (wheels)       |
| Surface Finishing      | Pickled and Passivated       | Pickled and Passivated       | Pickled and Passivated             |
| Dimensions (W × D × H) | 820 × 620 × 235 mm           | 1205 × 800 × 235 mm          | 1205 × 1020 × 282 mm               |
|                        | 32.3 × 24.4 × 9.3 in.        | 47.4 × 31.5 × 9.3 in.        | $47.4 \times 40.2 \times 11.1$ in. |
| Weight (approx.)       | 12.5 kg (26.5 lb)            | 15 kg (33.1 lb)              | 33 kg (72.8 lb)                    |

\* Schulte bagtainer

# Drum for Shipping

Media

Plastic Drum is designed to meet the ever-evolving needs of the pharmaceutical industry, Genesis bioprocess containers presents the ultimate storage and shipment solution.

Small footprint and reusable, the user-friendly range of 50 L up to 200 L drums feature smooth surfaces to inhibit bacterial growth, are easy to maintain and ready to customize to any application to protect sterile buffer or media.

#### Features & Benefits

**Lightweight:** Plastic properties reduce shipping charges.

Stackable: Non-stackable

Reduced footprint: total floor space used is minimal

Hygienic: Spillage control and jet washable.

# Technical Specifications

| Description            | Plastic Drum 50 L                           | Plastic Drum 100 L     | Plastic Drum 200 L |  |
|------------------------|---|------------------------|--------------------|--|
| Part Number            | Supplier ref.                               | Supplier ref.          | Supplier ref.      |  |
| Bag Volume(s)          | 50 L  | 100 L                  | 200 L              |  |
| Construction Material  | HDPE  | HDPE                   | HDPE               |  |
| Diameter top           | 325 mm (12.8 in)                            | 395 mm (15.6 in)       | 471 mm (18.5 in)   |  |
| Diameter middle        | 400 mm (15.8 in)                            | 492 mm (19.4 in)       | 590 mm (23.2 in)   |  |
| Height                 | 628 mm (24.7 in)                            | 800 mm (31.5 in)       | 975 mm (38.4 in)   |  |
| Weight (empty)         | 3.4 kg (7.5 lb)                             | 5.4 kg (11.9 lb)       | 10 kg (22 lb)      |  |
| Weight (full)          | 55 kg (121 lb)                              | 110 kg (243 lb)        | 210 kg (463 lb)    |  |
| Bottom Gate            | Top drain                                   | Top drain              | Top drain          |  |
| Shipping Validation    | Real Shipping                               | No Shipping Validation | Real Shipping      |  |
| Description            | Dolly for Drum 50-100-200 L                 |                        |                    |  |
| Part Number            | FXA126305                                   |                        |                    |  |
| Construction Material  | 304 L Stainless Steel                       |                        |                    |  |
| Surface Finishing      | Brushed and passivated                      |                        |                    |  |
| Dimensions (W × D × H) | 502 × 502 × 168 mm<br>19.8 × 19.8 × 6.6 in. |                        |                    |  |
| Weight (approx.)       | 8.4 kg (18.5 lb)                            |                        |                    |  |

Buffer

Sartopore® single-use sterilizing-grade filter transfer sets are preassembled, gamma irradiated and ready-to-use for particle removal, bioburden reduction and sterilizing filtration in all process steps.

They are designed with Opta® SFT connectors and C-Flex® tubing to allow either a sterile connection or a sterile weld to other single systems such as Flexsafe® PDS.

Alternatively, MPX quick coupler connectors are available for a sanitary or aseptic connection under laminar air flow

Our Sartopore® family of sterilizing-grade filtration transfer sets offer a large variety of filter types and sizes that can be easily and securily connected to most of SSB single-use solutions

#### Features & Benefits

- Pre-assembled and gamma sterilized: Ready-to-use as standalone filter transfer sets or for connection to single use bag to save time compared to traditional assembly and autoclaving operations
- Qualified C-Flex® tube and Opta® connector engagement: Robust design Allow secured sterile connection or sterile weld to other single use systems
- Large variety of filter types and sizes Flexible design Solution for every process step
- Highest Safety Standards These products are designed with Oetiker® clamp engagements instead of cable ties ensuring highest safety for single-use connections. A comprehensive transport validation in accordance to ASTM D4169-09 has been performed for safe transportation

# Media. Buffer and Harvest & Downstream Intermediates Sterilizing Filtration

| Filter Type                   | Filter                   | Tubing & Outlet Connector                   | Part Number | Lot<br>size |
|-------------------------------|--------------------------|---|-------------|-------------|
| Sartopore® 2<br>0.45   0.2 μm | Midicaps® size 7         | ½" ID Clear C-Flex® 500 mm<br>Opta® male ½" | FFU500214   | 8           |
|                               | Midicaps® size 8         |   | FFU500215   | 8           |
|                               | Midicaps® size 9         |   | FFU500216   | 8           |
|                               | Midicaps® size 0         |   | FFU500217   | 8           |
|                               | Maxicaps® T-style size 1 |   | FFU500249   | 4           |
|                               | Maxicaps® T-style size 2 |   | FFU500250   | 4           |
|                               | Maxicaps® T-style size 3 |   | FFU500251   | 4           |
|                               | Midicaps® size 7         |   | FFU500252   | 8           |
|                               | Midicaps® size 8         |   | FFU500253   | 8           |
|                               | Midicaps® size 9         |   | FFU500254   | 8           |
|                               | Midicaps® size 0         |   | FFU500255   | 8           |
|                               | Maxicaps® T-style size 1 |   | FFU500256   | 4           |
|                               | Maxicaps® T-style size 2 |   | FFU500257   | 4           |
|                               | Maxicaps® T-style size 3 |   | FFU500258   | 4           |

Media

# Media, Buffer and Harvest & Downstream Intermediates Sterilizing Filtration

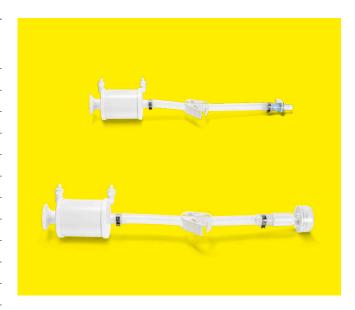
| Filter Type                      | Filter                   | Tubing & Outlet Connector                          | Part Number | Lot<br>size |
|----------------------------------|--------------------------|--|-------------|-------------|
| Sartopore® 2<br>XLG 0.8   0.2 µm | Midicaps® size 7         |  | FFU500268   | 8           |
|                                  | Midicaps® size 8         | <del></del>  | FFU500269   | 8           |
|                                  | Midicaps® size 9         | <br>½" ID Clear C-Flex® 500 mm                     | FFU500270   | 8           |
|                                  | Midicaps® size 0         | Opta® male ½"                                      | FFU500271   | 8           |
|                                  | Maxicaps® T-style size 1 |  | FFU500272   | 4           |
|                                  | Maxicaps® T-style size 2 |  | FFU500273   | 4           |
|                                  | Maxicaps® T-style size 3 |  | FFU500274   | 4           |
|                                  | Midicaps® size 7         |  | FFU500275   | 8           |
|                                  | Midicaps® size 8         |  | FFU500276   | 8           |
|                                  | Midicaps® size 9         | ½" ID Clear C-Flex® 500 mm  MPX male + sealing cap | FFU500277   | 8           |
|                                  | Midicaps® size 0         |  | FFU500278   | 8           |
|                                  | Maxicaps® T-style size 1 | · /a.c · scaling cup                               | FFU500226   | 4           |
|                                  | Maxicaps® T-style size 2 | <del></del>  | FFU500279   | 4           |
|                                  | Maxicaps® T-style size 3 |  | FFU500225   | 4           |

# Media Sterilizing Filtration for Mycoplasma Removal

| Filter Type                   | Filter                   | Tubing & Outlet Connector                   | Part Number | Lot<br>size |
|-------------------------------|--------------------------|---|-------------|-------------|
| Sartopore® 2 XLM 0.2   0.1 μm | Midicaps® size 7         |   | FFU500235   | 8           |
|                               | Midicaps® size 8         | ½" ID Clear C-Flex® 500 mm<br>Opta® male ½" | FFU500236   | 8           |
|                               | Midicaps® size 9         |   | FFU500237   | 8           |
|                               | Midicaps® size 0         |   | FFU500238   | 8           |
|                               | Maxicaps® T-style size 1 |   | FFU500239   | 4           |
|                               | Maxicaps® T-style size 2 |   | FFU500240   | 4           |
|                               | Maxicaps® T-style size 3 |   | FFU500241   | 4           |
|                               | Midicaps® size 7         |   | FFU500242   | 8           |
|                               | Midicaps® size 8         |   | FFU500243   | 8           |
|                               | Midicaps® size 9         |   | FFU500244   | 8           |
|                               | Midicaps® size 0         |   | FFU500245   | 8           |
|                               | Maxicaps® T-style size 1 |   | FFU500246   | 4           |
|                               | Maxicaps® T-style size 2 |   | FFU500247   | 4           |
|                               | Maxicaps® T-style size 3 |   | FFU500248   | 4           |

# Drug Substance and Drug Product Sterilizing Filtration

| Filter Type                          | Filter                       | Tubing & Outlet Connector                          | Part Number | Lot<br>size |
|--------------------------------------|------------------------------|--|-------------|-------------|
| Sartopore° Platinum<br>0.45   0.2 μm | Midicaps <sup>®</sup> size 7 | ½" ID Clear C-Flex® 500 mm<br>Opta® male ½"        | FFU500220   | 8           |
|                                      | Midicaps® size 8             |  | FFU500221   | 8           |
|                                      | Midicaps® size 9             |  | FFU500222   | 8           |
|                                      | Midicaps® size 0             |  | FFU500223   | 8           |
|                                      | Maxicaps® T-style size 1     |  | FFU500259   | 4           |
|                                      | Maxicaps® T-style size 2     |  | FFU500260   | 4           |
|                                      | Maxicaps® T-style size 3     |  | FFU500261   | 4           |
|                                      | Midicaps® size 7             | ½" ID Clear C-Flex® 500 mm  MPX male + sealing cap | FFU500262   | 8           |
|                                      | Midicaps® size 8             |  | FFU500263   | 8           |
|                                      | Midicaps® size 9             |  | FFU500264   | 8           |
|                                      | Midicaps® size 0             |  | FFU500172   | 8           |
|                                      | Maxicaps® T-style size 1     |  | FFU500265   | 4           |
|                                      | Maxicaps® T-style size 2     |  | FFU500266   | 4           |
|                                      | Maxicaps® T-style size 3     |  | FFU500267   | 4           |



# Design, Application Development and Validation Services

#### Configure to Order (CTO) Options

Media

All Flexsafe® 3D Pre-designed Solutions are available in our Sartorius Corporate Configurator for easy selection of the right solution for your process and application requirements.

Should our Pre-designed Solutions need to be adjusted to more specific requirements, they can serve as a base for designing your specific best design.

Our CTO configurator then allows the selection of a larger variety of solutions with added features, lines, manifolds, filters, connectors and sampling systems.

Please contact our sales representatives and application specialist to support you with the selection and design of your best solution for your specific process and application.

#### **Application Support**

Our expert FMT Application Specialists provide global support for:

- Single-use process URS definitions and application development
- Process design with standard and custom solutions
- Filter selection and sizing optimization study
- SOP development, process validation and operator training
- Technology transfer and process optimization

#### Validation Service

Our global validation services network offers:

- Installation start up, FAT, IQ & OQ, calibration and maintenance
- Consultancy service and process specific validation studies including
- Extractables | leachables,
- Chemical compatibility
- Integrity testing
- Bacterial challenge test
- Particle shedding
- Shipping test





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