

Flexsafe® 2D & 3D Pre-Designed Solutions for Storage and Shipping Take Your Facility Into The Future



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Standard Hardware for Storage and Shipping: The Perfect Fit
Palletank for Storage
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Media, Buffer and Harvest & Downstream Intermediates Sterilizing Filtration 104
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Design, Application Development and Validation Services

Flexsafe® 2D bags up to 50 L

Flexsafe® 2D bags in shell 5 L &t 10 L

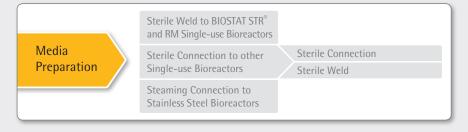
Flexsafe® 3D bags up to 500 L

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



Buffer
Preparation

Sterile Connection
to Downstream Systems
Sanitary or Aseptic Connection
to Downstream Systems
Tri-Clamp Connection

Cell Harvest
Et Downstream
Intermediates

Sterile Connection
to Downstream Systems
Sanitary or Aseptic Connection
to Downstream Systems
Tri-Clamp Connection

Drug
Substance
Purification

Sterile Connection
to Downstream Systems
Sterile Weld

Sanitary or Aseptic Connection
to Downstream Systems

Tri-Clamp Connection

Drug
Product
Formulation

Sterile Connection to
Final Filling

Sterile Weld

Sterile Weld

Flexsafe® 2D bags from 20 mL to 3 L

Flexsafe® 2D bags in shell 5 L & 10 L

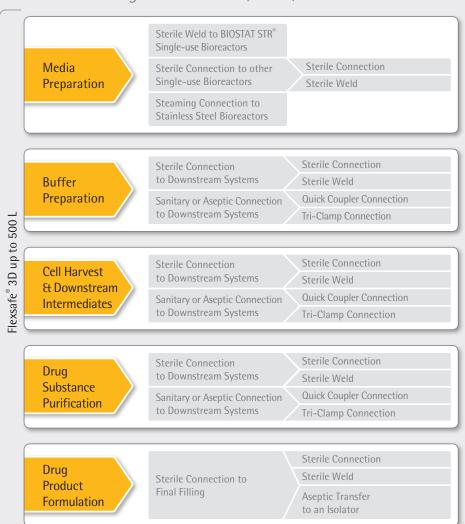




Flexsafe[®] 2D

Digital Selection Map Flexsafe® 3D

Flexsafe® 3D bags for Palletank 100 L, 200 L & 500 L Flexsafe® 3D bags for drum: 50 L, 100 L, 200 L



Flexsafe® 3D bags for Palletank 1,000 L, 1,500 L, 2,000 L, 2,500 L & 3,000 L

0 L (Large)	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 Sterile Connection ½" ID Sterile Weld ½" ID Quick Coupler Connection 1½" ID Tri-Clamp Connection ½" ID
Flexsafe® 3D up to 3,000 L (Large)	Buffer Preparation	Sterile Connection to Downstream Systems Sterile Connection 3/4" ID Sterile Weld 3/4" ID Quick Coupler Connection 3/4" ID Tri-Clamp Connection 3/4" ID
Flexs	Cell Harvest & Downstream Intermediates	Sterile Connection to Downstream Systems Sterile Weld 1/2" ID Sanitary or Aseptic Connection to Downstream Systems Sterile Connection V2" ID Tri-Clamp Connection V2" ID
	Cell Harvest & Downstream Intermediates	Sterile Connection Sterile Connection 3/4" ID to Downstream Systems Sterile Weld 3/4" ID Sanitary or Aseptic Connection to Downstream Systems Tri-Clamp Connection 3/4" ID

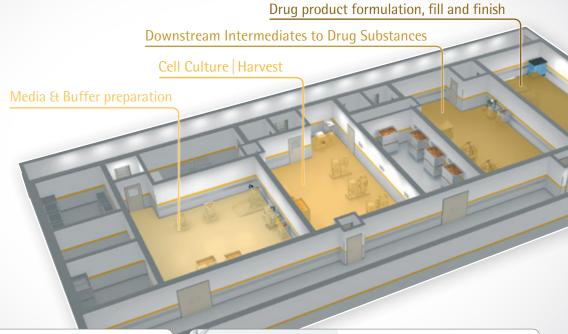
Unprecedented Performance and Assurance of Quality Supply

Flexsafe $^{\circ}$ 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



Cell Harvest & Downstream Intermediates

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



Sampling

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



Buffer

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



Drug Substance

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



Drug Product

Pre-designed Solutions for sterile filtration, hold and transfer of drug products 6

Media
Flexsafe® 2D | Flexsafe® 3D |
Flexsafe® ≥ 1.000 L

Buffer
Flexsafe® 2D | Flexsafe® 3D |
Flexsafe® ≥ 1,000 L

oxidant level

 Use of EP listed antioxidant Cell Harvest & DSP Flexsafe® 2D | Flexsafe® 3D | Flexsafe® ≥ 1,000 L Drug Substance
Flexsafe® 2D |
Flexsafe® 3D

Flexsafe® **2D** Flexsafe® **3D**

Drug Product

Back to Digital Selection Map

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 partnerships ensure a full understanding of the resins formulation and the film manufaturing process.

Following the principles of 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

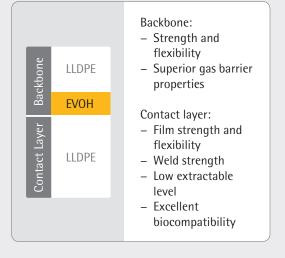
- 400 µm thickness
- Balance between strength, flexibility and gas barrier
- Large sealing window for bag robustness
- Best puncture resistance & elongation at break

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



The lot to lot consistent performance of Flexsafe® bags is ensured by specification and controls of raw materials, the definition of the design space for the film extrusion and the control of the welding and overall bag making process.



Media

Flexsafe® 2D Flexsafe® 3D Flexsafe[®] ≥ 1.000 L

Buffer Flexsafe® 2D Flexsafe® 3D

Flexsafe[®] ≥ 1.000 L

Cell Harvest & DSP Flexsafe[®] **2D** Flexsafe[®] **3D** Flexsafe[®] ≥ 1.000 L

Drug Substance Flexsafe® 2D Flexsafe® 3D

Drug Product Flexsafe® 2D Flexsafe® 3D

> Back to Digital Selection Map

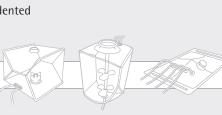
Control of the Entire Manufacturing Process

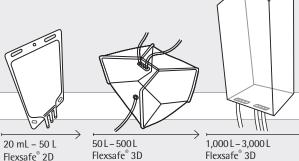
The complete control of the process and our quality management for critical fluid-contact components ensure reliable and consistent performance of our Flexsafe® PDS.

The establishment of long term supply contracts and quality agreements for

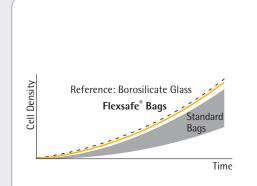
the resins, the film and the fluid-contact components ensure unprecedented assurance of supply.

One for All





Flexsafe® 3D





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
 - 2 year stock of resin & film

▶ 4 year guarantee of unchanged film ▶ 2 year guarantee of unchanged components for our Pre-Designed-Solutions

Components

Long term supply contracts - 2 year change notification

Quality Agreements

- Bioburden, particle & endotoxin
- Extractable characterization

- 2 year last time buy option

Extrusion design space & control

- Lot-to-lot consistent extractable

10 year supply & quality contract

- Consistent cell growth &

Film - S80

robustness

Final PDS Assembly

Business continuity plan - Back up equipment & safety

stocks - Double clean room footprint by 2020

Multiple manufacturing sites

- 7000 m2 of ISO7 clean room WW
- Resin-to-bag process control





Watch Video:

www.sartorius-stedim.com/flexsafe

Cell Growth

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

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.

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.

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.

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Assurance of Quality Supply for Fluid-contact Components

Component Quality, Change Control and Business Continuity

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.

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.

Criteria for Component Selection	Reference
Biological safety (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.

Flexsafe® PDS

Components	Biocompa- tibility USP <87> or USP<88> Class VI	Endotoxin Sub visible particles bioburden	TSE-BSE EMA/410/01 & REACH	Notification period time
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

Media Flexsafe® 2D Flexsafe® 3D Flexsafe[®] ≥ 1.000 L

Buffer Flexsafe® 2D Flexsafe® 3D Flexsafe[®] ≥ 1.000 L

Cell Harvest & DSP Flexsafe® 2D Flexsafe® 3D Flexsafe[®] ≥ 1,000 L

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

Flexsafe® 2D Flexsafe® 3D

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Drug Product

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 and ISO 13485 for Medical Devices. 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, non-pyrogenic fluid path and sterile.

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

Robustness

- ASTM D4169 and D7368: 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

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**
- 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.

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.

Media, Buffer, Harvest & Downstream Intermediates	Drug Substance	Drug Product
Weekly testing of bioburden, on representative finished pr		Lot release testing of bioburden, particles and endotoxin on representative finished product

Certificate of Release

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

^{*} 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

Drug Product

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Assurance of Container Closure 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.

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A 100% bag chamber leak test is then performed in-process before line assembly for all Flexsafe® 2D bags. In addition, we are currently developing a Supplier Integrity Test (SIT) for the complete bag and line assemblies used in critical drug substance and drug product process steps.

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.



Process qualification at supplier

- Robustness validated in the extrusion design space
- Mechanical tests on film and weld
- Microbial immersion test
- 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 test
- 100% bag chamber leak test for 2D bags
- Supplier integrity testing for 2D bags

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

Flexsafe® PDS Benefits

- Full control of manufacturing processes ensure best assurance of supply
- 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 PDS
- Our PoULT with detection limit of 30 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 CCl and safety for patients and operators.

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



Buffer
Flexsafe $^{\circ}$ 2D | Flexsafe $^{\circ}$ 3D |
Flexsafe $^{\circ}$ \geq 1,000 L

Cell Harvest & DSP
Flexsafe® 2D | Flexsafe® 3D |
Flexsafe® ≥ 1,000 L

Drug Substance
Flexsafe® 2D |
Flexsafe® 3D

Drug Product
Flexsafe® 2D |
Flexsafe® 3D

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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 the shipping in single-use systems.

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Flexsafe® 2D Bags in Shell for Liquid Handling & Shipping for 5 L & 10 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.







Watch Videos "Safe and Reliable Handling & Shipping Solutions" and "Robust and Safe Shipping of Your Fluids"



Buffer
Flexsafe® 2D | Flexsafe® 3D |
Flexsafe® ≥ 1,000 L

Cell Harvest & DSP
Flexsafe® 2D | Flexsafe® 3D |
Flexsafe® ≥ 1,000 L

Drug Substance
Flexsafe® 2D |
Flexsafe® 3D

Drug Product
Flexsafe® 2D |
Flexsafe® 3D

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Safe, Self Deploying and Robust Solutions

Flexsafe® 3D for Storage from 100 L to 3,000 L Self Deploying Solution

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The high flexibility of Flexsafe® bags allows self-deployment 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 substance

- 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 F2095-01
- Film flexibility and self-deploying ability whatever the bag size provide safety, ease of use and save operator time





Watch Self Deploying Video:



www.sartorius.com/en/ products/fluid-management/ Iiquid-storage-shipping/ flexsafe-liquid-storageshipping#id-39096



Watch Flexsafe® 3D Large Volume Storage Video:



https://sartorius.wistia.com/ medias/ysr7cw3nxd



Buffer
Flexsafe® 2D | Flexsafe® 3D |
Flexsafe® ≥ 1.000 L

Cell Harvest & DSP
Flexsafe® 2D | Flexsafe® 3D |
Flexsafe® ≥ 1,000 L

Drug Substance
Flexsafe® 2D |
Flexsafe® 3D

Drug Product
Flexsafe® 2D |
Flexsafe® 3D

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Selection Map

Filtration & Storage for All Process Steps

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Outlet Sterile Connections

- Opta[®] SFT male
- C-Flex® tube for sterile weld with Biowelder® TC
- Silicone TuFlux® tube or C-Flex® for sterile disconnection with Clipster®
- STC II Steamthru™ valve

Outlet Sanitary or Aseptic Connections

- CPC Quick coupler male
- Tri-Clamp

Filling and Draining Lines

- Clear C-Flex® tube
- Silicone TuFlux® tube

d Lines tube Peccafe | 5 L

Sampling

Clave needleless sampling port

Inlet Filters

- Sartopore[®] 2 0.45 | 0.2 μm
- Sartopore[®] 2 XLG 0.8 | 0.2 μm
- Sartopore[®] 2 XLM 0.2 | 0.1 μm
- Sartopore[®] Platinum 0.45 | 0.2 μm

Inlet Sanitary or Aseptic Connection

– MPC quick coupler female

Inlet Sterile Connections and Disconnections

- Opta® SFT female
- C-Flex® tube for sterile weld with BioWelder® TC
- Silicone TuFlux® tube or C-Flex® for sterile disconnection with Clipster®





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 $^{\circ}$ 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® 3/8" 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[™] 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 ³/₄" 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

C-Flex® is a registered trademark of Saint-Gobain Performance Plastics Corporation.

Flexsafe® 3D Pre-designed Solutions for 14

> Filtration, Storage & Shipping in All Process Steps

Media Flexsafe® 2D Flexsafe® 3D Flexsafe[®] ≥ 1.000 L

Sampling - Clave needleless sampling port

Buffer Flexsafe® 2D Flexsafe® 3D Flexsafe[®] ≥ 1.000 L

Cell Harvest & DSP Flexsafe® 2D Flexsafe® 3D Flexsafe[®] ≥ 1,000 L

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

Flexsafe® 2D Flexsafe® 3D

Drug Product

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Inlet Filters

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

0.2 | 0.1 μm 0.45 | 0.2 μm

0.45 | 0.2 μm

Inlet Sterile Connections

- Opta[®] SFT female
- C-Flex® tube for sterile weld with BioWelder® TC

Inlet Sanitary or **Aseptic Connection**

- MPX quick coupler female

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

Inlet Filters and Connectors

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™ 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 11/2" 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

Outlet Sterile Connections

- Opta® SFT male
- C-Flex® tube for sterile weld with BioWelder® TC
- STCII Steamthru™ valve

Outlet Sanitary or Aseptic Connections

- CPC Quick coupler male and or female
- Tri-Clamp

Filling and draining

 Clear C-Flex® + Silicone TuFlux® assemblies

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

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

Sterilizing Filtration

Media
Flexsafe® 2D | Flexsafe® 3D |
Flexsafe® ≥ 1,000 L

Buffer
Flexsafe® 2D | Flexsafe® 3D |
Flexsafe® ≥ 1,000 L

Cell Harvest & DSP Flexsafe® 2D | Flexsafe® 3D | Flexsafe® ≥ 1,000 L Drug Substance
Flexsafe® 2D |
Flexsafe® 3D

Drug Product
Flexsafe® 2D |
Flexsafe® 3D

Back to Digital Selection Map

NA L' D

Media Preparation

Sterile W

Media Storage

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.

Media

Preparation

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®.

Media Transfer

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 plug 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™ 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

Back to Digital Selection Map

Media

Preparation

Media Preparation

0 Inlet Line Sterile Weld to BIOSTAT STR® Flexsafe® and RM Single-use Bioreactors Sterile Connection Sterile Connection to other Single-use Bioreactors Sterile Weld **Outlet Line** Steaming Connection to C-Flex® tube with MPC **Stainless Steel Bioreactors** sealing cap for sterile weld with BioWelder® TC 0178D ---3 -00

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

Opta® SFT female

MPC quick coupler female with sealing cap or C-Flex® tube for sterile weld with BioWelder® TC

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

			Inlet ¹		Outlet ²	Sampling	
Bag volume	Part number	Units per box	Filter or distal connector on filling line	Filter type 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	iviluicaps size 4			
	FLS130147	16	3/8" Opta® SFT female	- NA			
	FLS130145	16	3/8" MPC female + sealing cap	NA			
5 L	FLS130018	16	Sartopore® 2 XLG 0.8 0.2 μm	MidiCaps [®] size 4			
	FLS130020	16	Sartopore® 2 XLM 0.2 0.1 μm	- Midicaps Size 4			
	FLS130042	16	3/8" Opta® SFT female	- NA			
	FLS130039	16	3/8" MPC female + sealing cap	- IVA		1/4" ID Silicone TuFlux [®] 100 mm (4") +	
10 L	FLS130025	8	Sartopore® 2 XLG 0.8 0.2 μm	— MidiCaps [®] size 7	2/ 5/ O FI ®		
	FLS130029	8	Sartopore® 2 XLM 0.2 0.1 μm		3/8" × 5/8" C-Flex® + 3/8" MPC male +		
	FLS130043	8	3/8" Opta® SFT female		sealing cap	Luer Lock female +	
	FLS130040	8	3/8" MPC female + sealing cap	- IVA	scannig cap	Clave connector	
20 L	FLS130026	8	Sartopore® 2 XLG 0.8 0.2 μm	- MidiCaps [®] size 7			
	FLS130030	8	Sartopore® 2 XLM 0.2 0.1 μm	iviluicaps size 7			
	FLS130044	8	3/8" Opta® SFT female	- NA			
	FLS130041	8	3/8" MPC female + sealing cap	IVA			
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	iviiuicaps size /			
	FLS130148	8	3/8" Opta® SFT female	- NA			
	FLS130146	8	3/8" MPC female + sealing cap	IVA			

¹ Inlet tubing line from end line to bag: 3/8" × 5/8" Clear C-Flex[®] 500 mm (20") + Clipster[®] in a separate pouch

² Outlet tubing line from bag to end line: 3/8" × 5/8" Clear C-Flex® 500 mm (20")

Flexsafe[®] ≥ 1,000 L

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Selection Map

Media Preparation

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Media

Preparation

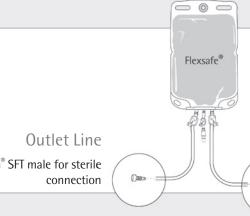
Sterile Weld to BIOSTAT STR® and RM Single-use Bioreactors

> Sterile Connection to other Single-use Bioreactors

Steaming Connection to **Stainless Steel Bioreactors**

Sterile Weld

Opta® SFT male for sterile



Inlet Line

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

Opta® SFT female

MPC quick coupler female with sealing cap or C-Flex® tube for sterile weld with BioWelder® TC

Sterile Connection to other Single-use Bioreactors

			Inlet ¹		Outlet ²	Sampling
Bag	Part number	Units	Filter or distal	Filter type	Distal connector	Sampling line
volume		per box	connector on filling line	and size	on draining line	l
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	3/8" Opta® SFT female	- NA		
	FLS130153	16	3/8" MPC female + sealing cap	- NA		
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	Wildicaps Size 4		
	FLS130054	16	3/8" Opta® SFT female	- NA		1/4" ID Silicone TuFlux [®] 100 mm (4") +
	FLS130051	16	3/8" MPC female + sealing cap	IVA		
10 L	FLS130035	8	Sartopore® 2 XLG 0.8 0.2 μm	MidiCaps [®] size 7	7 — 3/8" Opta [®] SFT male	
	FLS130037	8	Sartopore® 2 XLM 0.2 0.1 µm	wildicaps size /		
	FLS130055	8	3/8" Opta® SFT female	- NA	78 Opta 311 maic	Luer Lock female +
	FLS130052	8	3/8" MPC female + sealing cap	IVA		Clave connector
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	iviiuicaps size /		
	FLS130056	8	3/8" Opta® SFT female	- NA		
	FLS130053	8	3/8" MPC female + sealing cap	N/A		
50 L	FLS130143	8	Sartopore® 2 XLG 0.8 0.2 μm	XLG 0.8 0.2 μm MidiCaps [®] size 7		
	FLS130144	8	Sartopore® 2 XLM 0.2 0.1 μm	iviiuicaps size /		
	FLS130156	8	3/8" Opta® SFT female	- NA		
	FLS130154	8	3/8" MPC female + sealing cap	INA		

¹ Inlet tubing line from end line to bag: 3/8" × 5/8" Clear C-Flex[®] 500 mm (20") + Clipster® in a separate pouch

² Outlet tubing line from bag to end line: 3/8" × 5/8" Clear C-Flex® 500 mm (20")

Flexsafe[®] ≥ 1,000 L

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Selection Map

Media Preparation

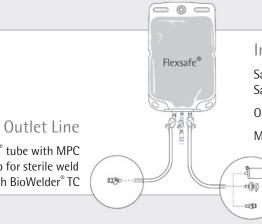
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Sterile Weld to BIOSTAT STR® and RM Single-use Bioreactors Media Sterile Connection to other Preparation Single-use Bioreactors

Sterile Connection

Sterile Weld

C-Flex® tube with MPC sealing cap for sterile weld with BioWelder® TC



Inlet Line

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

Opta® SFT female

MPC quick coupler female with sealing cap or C-Flex® tube for sterile weld with BioWelder® TC

Sterile Weld to other Single-use Bioreactors

Steaming Connection to

Stainless Steel Bioreactors

			Inlet ¹		Outlet ²	Sampling
Bag volume	Part number	Units per box	Filter or distal connector on filling line	Filter type 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	- Wildicaps Size 4		
	FLS130147	16	3/8" Opta® SFT female	– NA		
	FLS130145	16	3/8" MPC female + sealing cap	- NA		
5 L	FLS130018	16	Sartopore® 2 XLG 0.8 0.2 μm	– MidiCaps [®] size 4		
	FLS130020	16	Sartopore [®] 2 XLM 0.2 0.1 μm	- Wildicaps Size 4		
	FLS130042	16	³/8" Opta® SFT female	- NA		
	FLS130039	16	3/8" MPC female + sealing cap	- NA		
10 L	FLS130025	8	Sartopore® 2 XLG 0.8 0.2 μm	- MidiCaps [®] size 7		1/4" ID Silicone TuFlux®
	FLS130029	8	Sartopore® 2 XLM 0.2 0.1 μm		3/8" × 5/8" C-Flex [®] +	100 mm (4") +
	FLS130043	8	3/8" Opta® SFT female	- NA	sealing cap	Luer Lock female +
	FLS130040	8	3/8" MPC female + sealing cap	- NA	scannig cap	Clave connector
20 L	FLS130026	8	Sartopore® 2 XLG 0.8 0.2 μm	– MidiCaps [®] size 7		
	FLS130030	8	Sartopore® 2 XLM 0.2 0.1 μm	- iviiuicaps size /		
	FLS130044	8	3/8" Opta® SFT female	- NA		
	FLS130041	8	3/8" MPC female + sealing cap	- NA		
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	- iviiuicaps size /		
	FLS130148	8	3/8" Opta® SFT female	– NA		
	FLS130146	8	3/8" MPC female + sealing cap	- IVA		

¹ Inlet tubing line from end line to bag: 3/8" × 5/8" Clear C-Flex[®] 500 mm (20") + Clipster[®] in a separate pouch

² Outlet tubing line from bag to end line: 3/8" × 5/8" Clear C-Flex® 500 mm (20")

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Media Preparation

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Media

Preparation

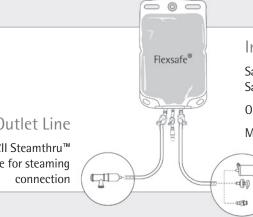
Sterile Weld to BIOSTAT STR® and RM Single-use Bioreactors

> Sterile Connection to other Single-use Bioreactors

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

Outlet Line

STCII Steamthru™ valve for steaming



Inlet Line

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

Opta® SFT female

MPC quick coupler female with sealing cap or C-Flex® tube for sterile weld with BioWelder® TC

Steaming Connection to Stainless Steel Bioreactors

			Inlet ¹		Outlet ²	Sampling	
Bag volume	Part number	Units per box	Filter or distal connector on filling line	Filter type 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	Wildicaps Size 4			
	FLS130151	16	³/8" Opta® SFT female	- NA			
	FLS130149	16	3/8" MPC female + sealing cap	IVA			
5 L	FLS130021	16	Sartopore® 2 XLG 0.8 0.2 μm	- MidiCaps [®] size 4	size 4		
	FLS130022	FLS130022 16 Sartopore® 2 XLM 0	Sartopore® 2 XLM 0.2 0.1 μm	- Midicaps Size 4			
	FLS130048	16	3/8" Opta® SFT female	- NA			
	FLS130045	16	3/8" MPC female + sealing cap	- IVA			
10 L	FLS130031	8	Sartopore [®] 2 XLG 0.8 0.2 μm	- MidiCaps [®] size 7		1/4" ID Silicone TuFlux® 100 mm (4") + Luer Lock female + Clave connector	
	FLS130033	8	Sartopore® 2 XLM 0.2 0.1 μm	Wildicaps Size 7	3/8" STCII 3/4" sanitary flange		
	FLS130049	8	3/8" Opta® SFT female	- NA			
	FLS130046	8	3/8" MPC female + sealing cap	- NA			
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	- Midicaps size 7			
	FLS130050	8	³/8" Opta® SFT female	- NA			
	FLS130047	8	3/8" MPC female + sealing cap	- NA			
50 L	FLS130141	8	Sartopore [®] 2 XLG 0.8 0.2 μm	- MidiCaps [®] size 7			
	FLS130142	8	Sartopore [®] 2 XLM 0.2 0.1 μm	- Midicaps Size 7			
	FLS130152	8	3/8" Opta® SFT female	- NA			
	FLS130150	8	3/8" MPC female + sealing cap	- IVA			

¹ Inlet tubing line from end line to bag: 3/8" × 5/8" Clear C-Flex[®] 500 mm (20") + Clipster® in a separate pouch

² Outlet tubing line from bag to end line: 3/8" × 5/8" Clear C-Flex® 500 mm (20")

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Media

Flexsafe® 2D Flexsafe® 3D Flexsafe[®] ≥ 1.000 L

Buffer Flexsafe® 2D | Flexsafe® 3D Flexsafe[®] ≥ 1.000 L

Cell Harvest & DSP Flexsafe[®] **2D** Flexsafe[®] **3D** Flexsafe[®] ≥ 1,000 L

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

Flexsafe® 2D Flexsafe® 3D

Selection Map

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Drug Product

Media Filtration, Storage and Shipping

Sterile Weld to BIOSTAT STR® Single-use Bioreactors Media Sterile Connection Sterilizing Filtration Media Storage Sterile Connection to other Media Transfer from Mixer and Shipping Single-use Bioreactors Preparation Sterile Weld Steaming Connection to Stainless Steel Bioreactors

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 from mixer

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

Connection for alternative filter transfer set

- Opta[®] SFT female
- C-Flex® tube weld with BioWelder® TC
- MPX guick coupler female



- Clave needleless sampling port

Outlet line

Sterile connection and transfer by pumping or gravity

- C-Flex® with CPC quick coupler and plug 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[™] valve for steaming connection to stainless steel bioreactors

Buffer
Flexsafe® 2D | Flexsafe® 3D |
Flexsafe® ≥ 1,000 L

Cell Harvest & DSP
Flexsafe® 2D | Flexsafe® 3D |
Flexsafe® ≥ 1,000 L

Drug Substance
Flexsafe® 2D |
Flexsafe® 3D

Prug Product
Flexsafe® 2D |
Flexsafe® 3D

Media Eiltration Storage and Chinning

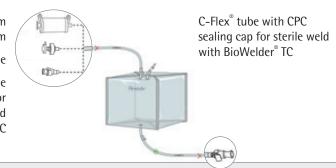
Media Filtration, Storage and Shipping in Palletank

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Media Preparation Sartopore® 2 XLG 0.8 | 0.2 μm Sartopore® 2 XLM 0.2 | 0.1 μm

Opta® SFT female

MPX quick coupler female with sealing cap or C-Flex® tube for sterile weld with BioWelder® TC



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® and BIOSTAT® RM Single-use Bioreactors

			Inlet ¹		Outlet ²
Bag Volume	Part number	Units per box	Filter or distal connector on filling line	Filter type 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	- Midicaps Size 9	
	FIS126706	3	½" Opta® SFT female	- NA	3/8" × 5/8" Clear C-Flex® + 3/8" MPC male + sealing cap
	FIS126243	3	MPX female + sealing cap	- IVA	
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	- Midicaps Size 0	
	FIS126707	3	½" Opta® SFT female	– NA	
	FIS126244	3	MPX female + sealing cap	- NA	
500 L	FIS126680	2	Sartopore® 2 XLG 0.8 0.2 μm	MaxiCaps®	
	FIS126684	2	Sartopore [®] 2 XLM 0.2 0.1 μm	size 1 T-style	¹ / ₂ " × ³ / ₄ " C-Flex [®]
	FIS126708	3	½" Opta [®] SFT female	– NA	+ 1/2" MPX male + sealing cap
	FIS126245	3	MPX female + sealing cap	- IVA	

 $^{^1}$ Inlet tubing line from end line to bag: $\frac{1}{2}$ " \times 3/4" Clear C-Flex $^{\circ}$ 0.5 m (20") + $\frac{1}{2}$ " ID Silicone TuFlux $^{\circ}$ 1 m (40")

²Outlet tubing line from bag to end line: For 100 L & 200 L $\frac{1}{2}$ " ID Silicone TuFlux $^{\circ}$ 1 m (40") + $\frac{3}{8}$ " × $\frac{5}{8}$ " Clear C-Flex $^{\circ}$ 0.5 m (20") For 500 L & 1,000 L: $\frac{1}{2}$ " ID Silicone TuFlux $^{\circ}$ 1 m (40") + $\frac{1}{2}$ " × $\frac{3}{4}$ " Clear C-Flex $^{\circ}$ 0.5 m (20")

Buffer
Flexsafe® 2D | Flexsafe® 3D |
Flexsafe® ≥ 1,000 L

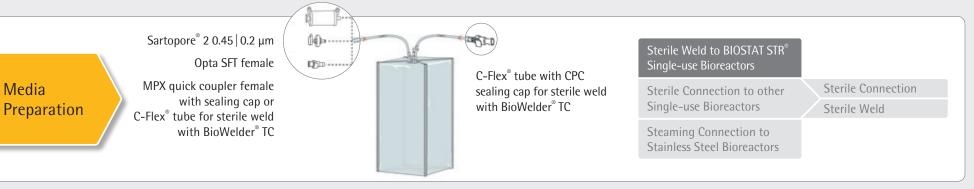
Cell Harvest & DSP
Flexsafe® 2D | Flexsafe® 3D |
Flexsafe® ≥ 1,000 L

Drug Substance
Flexsafe® 2D |
Flexsafe® 3D

Drug Product
Flexsafe® 2D |
Flexsafe® 3D

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Media Filtration and Storage in Drum



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

			Inlet ¹		Outlet ²
Bag Volume	Part number	Units per box	Filter or distal connector on top filling line	Filter type 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	NIA	
	FIS127875	4	MPX female + sealing cap	— NA	
100 L	FIS127862	2	Sartopore® 2 0.45 0.2 μm	MidiCaps® size 9	
	FIS127872	4	½" Opta® SFT female	NIA	3/8" × 5/8" Clear C-Flex [®] + 3/8" MPC male + sealing cap
	FIS127876	4	MPX female + sealing cap	— NA	
200 L	FIS127863	2	Sartopore [®] 2 0.45 0.2 μm	MidiCaps® size 0	
	FIS127873	4	½" Opta® SFT female	NIA	
	FIS127877	4	MPX female + sealing cap	— NA	

 1 Inlet tubing line from end line to bag: $\frac{1}{2}$ " \times $\frac{3}{4}$ " Clear C-Flex $^{\circ}$ 0.5 m (20") + $\frac{1}{2}$ " ID Silicone TuFlux $^{\circ}$ 1 m (40")

²Outlet 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")

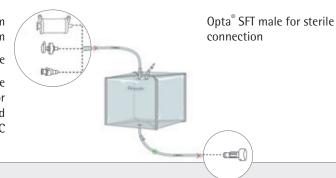
Media Filtration, Storage and Shipping in Palletank

Back to Digital Selection Map

Media Preparation Sartopore[®] 2 XLG 0.8 | 0.2 μm Sartopore[®] 2 XLM 0.2 | 0.1 μm

Opta® SFT female

MPX quick coupler female with sealing cap or C-Flex® tube for sterile weld with BioWelder® TC



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 ¹		Outlet ²	
Bag volume	Part number	Units per box	Filter or distal connector on filling line	Filter type and size	Distal connector on draining line	
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	iviluicaps size 9		
	FIS126718	3	½" Opta® SFT female	- NA	1/2" Opta [®] SFT male	
	FIS126746	3	MPX female + sealing cap	IVA		
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	white caps size o		
	FIS126719	3	½" Opta® SFT female	- NA		
	FIS126747	3	MPX female + sealing cap	IVA		
500 L	FIS126700	2	Sartopore® 2 XLG 0.8 0.2 μm	MaxiCaps® size 1		
	FIS126704	2	Sartopore [®] 2 XLM 0.2 0.1 μm	T-style		
	FIS126720	3	½" Opta® SFT female	- NA		
	FIS126748	3	MPX female + sealing cap	IVA		

 $^{^1}$ 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")

 $^{^{2}}$ Outlet tubing line from bag to end line: $\frac{1}{2}$ " ID Silicone TuFlux $^{\circ}$ 1 m (40") + $\frac{1}{2}$ " \times $\frac{3}{4}$ " Clear C-Flex $^{\circ}$ 0.5 m (20")

Media Flexsafe® 2D Flexsafe® 3D Flexsafe[®] ≥ 1,000 L

Buffer Flexsafe® 2D Flexsafe® 3D Flexsafe[®] ≥ 1,000 L

Cell Harvest & DSP Flexsafe[®] **2D** Flexsafe[®] **3D** Flexsafe[®] ≥ 1,000 L

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

Sterile Connection

Sterile Weld

Drug Product Flexsafe® **2D** Flexsafe® 3D

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Media Filtration, Storage and Shipping in Palletank

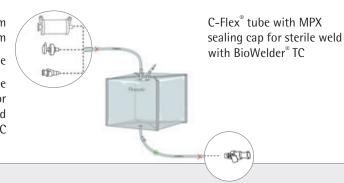
Media Preparation

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Sartopore® 2 XLG 0.8 | 0.2 µm Sartopore[®] 2 XLM 0.2 | 0.1 μm

Opta® SFT female

MPX quick coupler female with sealing cap or C-Flex® tube for sterile weld with BioWelder® TC



Sterile Weld to BIOSTAT STR® Single-use Bioreactors

Sterile Connection to other Single-use Bioreactors

Steaming Connection to Stainless Steel Bioreactors

Sterile Weld to other Single-use Bioreactors

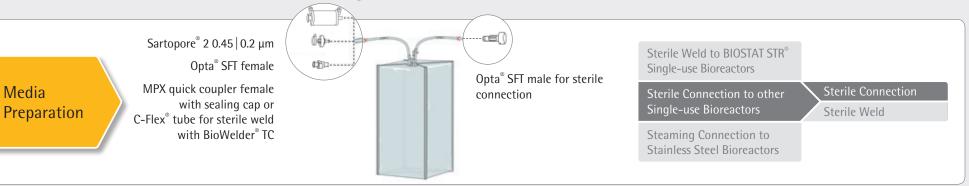
			Inlet ¹		Outlet ²	
Bag volume	Part number	Units per box	Filter or distal connector on filling line	Filter type and size	Distal connector on draining line	
100 L	FIS127159	2	Sartopore® 2 XLG 0.8 0.2 μm	MidiCaps [®] size 9		
	FIS127161	2	Sartopore [®] 2 XLM 0.2 0.1 μm	- Midicaps size 9		
	FIS126722	3	1/2" Opta® SFT female	- NA		
	FIS126247	3	MPX female + sealing cap	- NA		
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	- iviidicaps size o	1/2" × 3/4" C-Flex® + 1/2" MPX male + sealing cap	
	FIS126723	3	1/2" Opta® SFT female	NA		
	FIS126248	3	MPX female + sealing cap			
500 L	FIS126680	2	Sartopore® 2 XLG 0.8 0.2 μm	MaxiCaps [®] size 1		
	FIS126684	2	Sartopore [®] 2 XLM 0.2 0.1 μm	T-style		
	FIS126708	3	1/2" Opta® SFT female	- NA		
	FIS126245	3	MPX female + sealing cap	NA .		

¹Inlet tubing line from end line to bag: $\frac{1}{2}$ " × $\frac{3}{4}$ " Clear C-Flex 0.5 m (20") + $\frac{1}{2}$ " ID Silicone TuFlux 1 m (40")

² Outlet tubing line from bag to end line: ½" ID Silicone TuFlux® 1 m (40") + ½" × ¾" Clear C-Flex® 0.5 m (20")

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Media Filtration and Storage in Drum



Sterile Connection to other Single-use Bioreactors

			Inlet ¹		Outlet ²	
Bag Volume	Part number	Units per box	Filter or distal connector on top filling line	Filter type 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	NΙΔ		
	FIS127909	4	MPX female + sealing cap	— NA		
100 L	FIS127869	2	Sartopore® 2 0.45 0.2 μm	MidiCaps [®] size 9		
	FIS127907	4	½" Opta® SFT female	NIA	½" Opta [®] SFT male	
	FIS127910	4	MPX female + sealing cap	— NA		
200 L	FIS127870	2	Sartopore® 2 0.45 0.2 μm	MidiCaps® size 0		
	FIS127908	4	½" Opta® SFT female	NIA		
	FIS127911	4	MPX female + sealing cap	— NA		

 $^{^{1}}$ Inlet tubing line from end line to bag: $\frac{1}{2}$ " \times $\frac{3}{4}$ " Clear C-Flex $^{\circ}$ 0.5 m (20") + $\frac{1}{2}$ " ID Silicone TuFlux 1 m (40")

 $^{^2}$ Outlet tubing line from bag to end line: 1/2" ID Silicone TuFlux $^{\circ}$ 1 m (40") + 1/2" \times 3/4" Clear C-Flex $^{\circ}$ 0.5 m (20")

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Media

Preparation

Media Filtration and Storage in Drum

(H)=----Sartopore[®] 2 0.45 | 0.2 μm Sterile Weld to BIOSTAT STR® Opta® SFT female Single-use Bioreactors C-Flex® tube with MPX MPX quick coupler female Sterile Connection sealing cap for sterile weld Sterile Connection to other with sealing cap or with BioWelder® TC Single-use Bioreactors Sterile Weld C-Flex® tube for sterile weld with BioWelder® TC Steaming Connection to Stainless Steel Bioreactors

Sterile Weld to other Single-use Bioreactors

			Inlet ¹	Inlet ¹			
Bag volume	Part number	Units per box	Filter or distal connector on top filling line	Filter type 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	NIA	½" × ¾" Clear C-Flex®		
	FIS127903	4	MPX female + sealing cap	— NA			
100 L	FIS127889	2	Sartopore 2 0.45 0.2 μm	MidiCaps® size 8			
	FIS127901	4	½" Opta® SFT female	— NA	+ MPX male + MPX double female		
	FIS127904	4	MPX female + sealing cap	— IVA	+ sealing cap		
200 L	FIS127890	2	Sartopore 2 0.45 0.2 μm	MidiCaps® size 9	3 1		
	FIS127902	4	1/2" Opta® SFT female	NIA			
	FIS127905	4	MPX female + sealing cap	— NA			

 $^{^1}$ Inlet tubing line from end line to bag: 1/2 " \times 3/4 " Clear C-Flex $^{\circ}$ 0.5 m (20") + 1/2 " ID Silicone TuFlux 1 m (40")

² Outlet tubing line from bag to end line: ½" ID Silicone TuFlux® 1 m (40") + ½" × ¾" Clear C-Flex® 0.5 m (20")

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Media Filtration, Storage and Shipping in Palletank

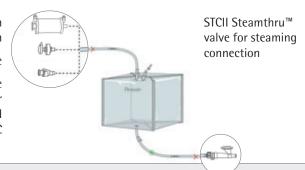
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Sartopore[®] 2 XLG 0.8 | 0.2 μm Sartopore[®] 2 XLM 0.2 | 0.1 μm

Opta® SFT female

MPX quick coupler female with sealing cap or C-Flex® tube for sterile weld with BioWelder® TC



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

Steaming Connection to Stainless Steel Bioreactors

			Inlet ¹		Outlet ²	
Bag Volume	Part number	Units per box	Filter or distal connector on filling line	Filter type and size	Distal connector on draining line	
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	- Midicaps size 9		
	FIS126710	3	½" Opta® SFT female	NΙΛ		
	FIS126714	3	MPX female + sealing cap	– NA	1/2" STCII 11/2" sanitary flange	
200 L	FIS126687	2	Sartopore [®] 2 XLG 0.8 0.2 μm	MidiCone® sine O		
	FIS126691	2	Sartopore® 2 XLM 0.2 0.1 μm	MidiCaps [®] size 0		
	FIS126711	3	½" Opta® SFT female	– NA		
	FIS126715	3	MPX female + sealing cap	- NA		
500 L	FIS126688	2	Sartopore [®] 2 XLG 0.8 0.2 μm	MaxiCaps [®] size 1		
	FIS126692	2	Sartopore® 2 XLM 0.2 0.1 μm	T-style		
	FIS126712	3	½" Opta® SFT female	NΙΔ		
	FIS126716	3	MPX female + sealing cap	– NA		

 $^{^1}$ Inlet tubing line from end line to bag: 1/2" \times 3/4" Clear C-Flex $^{\circ}$ 0.5 m (20") + 1/2" ID Silicone TuFlux $^{\circ}$ 1 m (40")

² 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[®] ≥ 1,000 L

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Media

Preparation

Media Filtration and Storage in Drum

M>----Sartopore[®] 2 0.45 | 0.2 μm Sterile Weld to BIOSTAT STR® Opta® SFT female Single-use Bioreactors STCII Steamthru™ MPX quick coupler female Sterile Connection valve for steaming Sterile Connection to other with sealing cap or Single-use Bioreactors connection Sterile Weld C-Flex® tube for sterile weld with BioWelder® TC Steaming Connection to Stainless Steel Bioreactors

Steaming Connection to Stainless Steel Bioreactors

			Inlet ¹		Outlet ²	
Bag Volume	Part number	Units per box	Filter or distal connector on top filling line	Filter type 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	— NA		
100 L	FIS127865	2	Sartopore® 2 0.45 0.2 μm	MidiCaps [®] size 9		
	FIS127879	4	½" Opta® SFT female	NΙΔ	1/2" STCII 11/2" sanitary flange	
	FIS127882	4	MPX female + sealing cap	— NA		
200 L	FIS127866	2	Sartopore® 2 0.45 0.2 μm	MidiCaps [®] size 0		
	FIS127880	4	½" Opta® SFT female	NΙΔ		
	FIS127883	4	MPX female + sealing cap	— NA		

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

² 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

Flexsafe® 3D Pre-designed Solutions for

Media

Flexsafe® 2D | Flexsafe® 3D | Flexsafe® ≥ 1,000 L Buffer
Flexsafe® 2D | Flexsafe® 3D |
Flexsafe® ≥ 1,000 L

Cell Harvest & DSP
Flexsafe® 2D | Flexsafe® 3D |
Flexsafe® ≥ 1,000 L

Drug Substance
Flexsafe® 2D |
Flexsafe® 3D

Drug Product
Flexsafe® 2D |
Flexsafe® 3D

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Media Filtration and Storage in Palletank

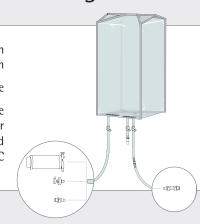
Sartopore® 2 XLG 0.8 | 0.2 µm
Sartopore® 2 XLM 0.2 | 0.1 µm

Opta® SFT female

MPX quick coupler female

with sealing cap or
C-Flex® tube for sterile weld

with BioWelder® TC



C-Flex® tube with CPC sealing cap for sterile weld with BioWelder® TC and MPX quick coupler male &tfemale with cap for sanitary or aseptic connection 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 ¹		Outlet ²
Bag Volume	Part number	Units per box	Filter or distal connector on filling line	Filter type 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	- NA	
1,500 L	FIS500361	2	Sartopore® 2 XLG	MaxiCaps® Size 2	
	FIS500277	2	Sartopore® 2 XLM	MaxiCaps® Size 2	
	FIS500334	2	½" Opta® SFT female		
	FIS302339	2	MPX female + sealing cap		
2,000 L	FIS500362	1	Sartopore® 2 XLG	MaxiCaps [®] Size 3	+ MPX male + MPX double female
	FIS500278	1	Sartopore® 2 XLM	MaxiCaps® Size 3	
	FIS500331	2	½" Opta® SFT female	— NA	
	FIS302340	2	MPX female + sealing cap	- NA	+ sealing cap
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	NΙΛ	
	FIS302341	1	MPX female + sealing cap	— NA	
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	INA	

¹Inlet tubing line from end line to bag: $\frac{1}{2}$ " \times $\frac{3}{4}$ " Clear C-Flex [©] 1.5 m (60")

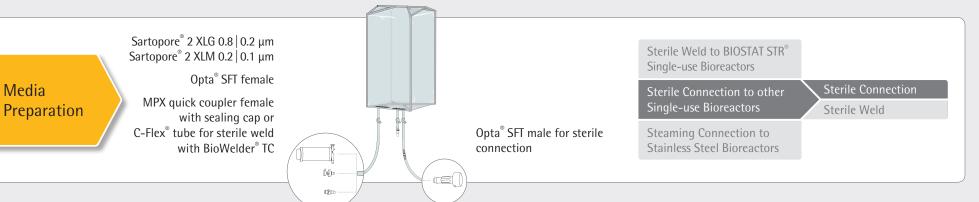
² Outlet tubing line from bag to end line: $\frac{1}{2}$ " ID Silicone TuFlux $^{\circ}$ 2,5 m (98") + $\frac{1}{2}$ " × $\frac{3}{4}$ " Clear C-Flex $^{\circ}$ 0.5 m (20")

Flexsafe[®] ≥ 1,000 L

Media

Media Filtration and Storage in Palletank

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Sterile Connection to other Single-use Bioreactors

			Inlet ¹		Outlet ²
Bag Volume	Part number	Units per box	Filter or distal connector on filling line	Filter type 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	1/2" Opta® SFT female	— NA	
	FIS500300	2	MPX female + sealing cap	— NA	
1,500 L	FIS500281	2	Sartopore® 2 XLG	MaxiCaps [®] Size 2	
	FIS500259	2	Sartopore® XLM	MaxiCaps [®] Size 2	
	FIS500291	2	½" Opta® SFT female		
	FIS500301	2	MPX female + sealing cap		
2,000 L	FIS500282	1	Sartopore® 2 XLG	MaxiCaps® Size 3	
	FIS500262	1	Sartopore® XLM	MaxiCaps® Size 3	½" Opta [®] SFT male
	FIS500292	2	1/2" Opta® SFT female	— NA	72 Opta Sri male
	FIS500302	2	MPX female + sealing cap	— NA	
2,500 L	FIS500283	1	Sartopore® 2 XLG	MaxiCaps® Size 3	
	FIS500263	1	Sartopore® XLM	MaxiCaps [®] Size 3	
	FIS500293	1	½" Opta® SFT female	NΙΛ	
	FIS500303	1	MPX female + sealing cap	— NA	
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	- IVA	

¹Inlet tubing line from end line to bag: 1/2" × 3/4" Clear C-Flex[®] 1.5 m (60")

² Outlet tubing line from bag to end line: 1/2" ID Silicone TuFlux® 2,5 m (98") + $1/2" \times 3/4"$ Clear C-Flex[®] 0.5 m (20")

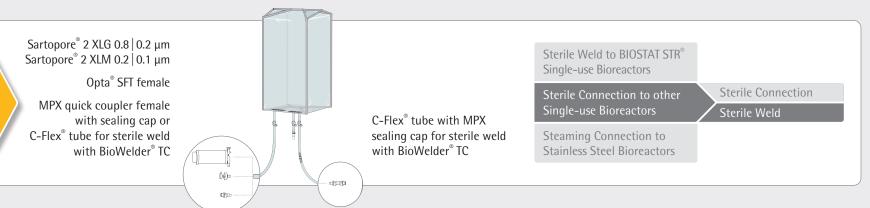
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Media

Preparation

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Media Filtration and Storage in Palletank



Sterile Weld to other Single-use Bioreactors

			Inlet ¹		Outlet ²
Bag Volume	Part number	Units per box	Filter or distal connector on filling line	Filter type 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	1/2" Opta® SFT female	— NA	
	FIS302338	2	MPX female + sealing cap	— IVA	
1,500 L	FIS500361	2	Sartopore® 2 XLG	MaxiCaps [®] Size 2	
	FIS500277	2	Sartopore® XLM	MaxiCaps [®] Size 2	
	FIS500334	2	1/2" Opta® SFT female		
	FIS302339	2	MPX female + sealing cap		
2,000 L	FIS500362	1	Sartopore® 2 XLG	MaxiCaps [®] Size 3	1/2" × 3/4" C-Flex®
	FIS500278	1	Sartopore® XLM	MaxiCaps [®] Size 3	+ MPX male
	FIS500331	2	½" Opta® SFT female	— NA	+ MPX double female
	FIS302340	2	MPX female + sealing cap	IVA	+ sealing cap
2,500 L	FIS500363	1	Sartopore® 2 XLG	MaxiCaps [®] Size 3	
	FIS500279	1	Sartopore® XLM	MaxiCaps [®] Size 3	
	FIS500332	1	1/2" Opta® SFT female	— NA	
	FIS302341	1	MPX female + sealing cap	IVA	
3,000 L	FIS500364	1	Sartopore® 2 XLG	MaxiCaps [®] Size 3	
	FIS500280	1	Sartopore® XLM	MaxiCaps [®] Size 3	
	FIS500333	1	1/2" Opta® SFT female	— NA	
	FIS302342	1	MPX female + sealing cap	IVA	

¹Inlet tubing line from end line to bag: 1/2" × 3/4" Clear C-Flex[®] 1.5 m (60")

² Outlet tubing line from bag to end line: 1/2" ID Silicone TuFlux® 2,5 m (98") + $1/2" \times 3/4"$ Clear C-Flex[®] 0.5 m (20")

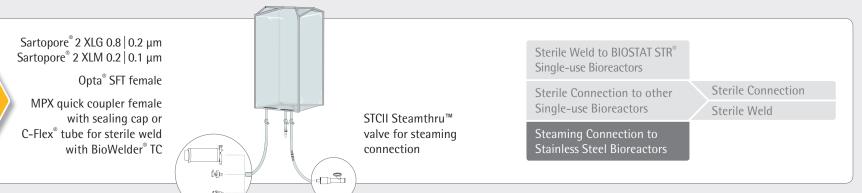
Flexsafe[®] ≥ 1,000 L

Media

Preparation

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Media Filtration and Storage in Palletank



Steaming Connection to Stainless Steel Bioreactors

			Inlet ¹		Outlet ²
Bag Volume	Part number	Units per box	Filter or distal connector on filling line	Filter type 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	1/2" 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	
	FIS500296	2	1/2" Opta® SFT female		
	FIS500306	2	MPX female + sealing cap		
2,000 L	FIS500268	1	Sartopore® 2 XLG	MaxiCaps® Size 3	
	FIS500287	1	Sartopore® XLM	MaxiCaps® Size 3	½" STCII 1½" sanitary flange
	FIS500297	2	1/2" Opta® SFT female	— NA	
	FIS500307	2	MPX female + sealing cap		
2,500 L	FIS500270	1	Sartopore® 2 XLG	MaxiCaps [®] Size 3	
	FIS500288	1	Sartopore® XLM	MaxiCaps [®] Size 3	
	FIS500298	1	1/2" Opta® SFT female	— NA	
	FIS500308	1	MPX female + sealing cap		
3,000 L	FIS500272	1	Sartopore® 2 XLG	MaxiCaps [®] Size 3	
	FIS500289	1	Sartopore® XLM	MaxiCaps® Size 3	
	FIS500299	1	½" Opta® SFT female	NΛ	
	FIS500309	1	MPX female + sealing cap	— NA	

¹Inlet tubing line from end line to bag: $\frac{1}{2}$ " \times $\frac{3}{4}$ " Clear C-Flex $^{\circ}$ 1.5 m (60")

² Outlet tubing line from bag to end line: $\frac{1}{2}$ " ID Silicone TuFlux $^{\circ}$ 2,5 m (98") + $\frac{1}{2}$ " × $\frac{3}{4}$ " Clear C-Flex $^{\circ}$ 0.5 m (20")

Buffer
Flexsafe $^{\circ}$ 2D | Flexsafe $^{\circ}$ 3D |
Flexsafe $^{\circ}$ \geq 1,000 L

Cell Harvest & DSP
Flexsafe® 2D | Flexsafe® 3D |
Flexsafe® ≥ 1,000 L

Drug Substance
Flexsafe® 2D |
Flexsafe® 3D

Drug Product
Flexsafe® 2D |
Flexsafe® 3D

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Buffer Preparation

Buffer Preparation

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Sterilizing Filtration from Mixer

Buffer Storage and Shipping

Buffer Transfer

Sterile Connection to Downstream Systems

Sanitary or Aseptic Connection to Downstream Systems

Sterile Weld

Quick Coupler Connection

Tri-Clamp Connection

Sterile Connection

Flexsafe® 2D solutions for buffer are available with Sartopore® 2 0.45 \mid 0.2 μ m 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.

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 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

Buffer
Flexsafe® 2D | Flexsafe® 3D |
Flexsafe® ≥ 1,000 L

Cell Harvest & DSP
Flexsafe® 2D | Flexsafe® 3D |
Flexsafe® ≥ 1,000 L

Drug Substance
Flexsafe® 2D |
Flexsafe® 3D

Drug Product
Flexsafe® 2D |
Flexsafe® 3D

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Buffer Preparation

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Buffer
Preparation

Sterile Connection
to Downstream Systems
Sanitary or Aseptic Connection
to Downstream Systems
Sterile Connection
Ouick Coupler Connection
Tri-Clamp Connection

Outlet Line
Opta® SFT male for sterile connection

Outlet Line

Opta® SFT male for sterile weld with BioWelder® TC

Sterile Connection to Downstream Systems

			Inlet ¹	Inlet ¹		Sampling
Bag volume	Part number	Units per box	Filter or distal connector on filling line	Filter type 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	3/8" Opta® SFT female	- NA		
	FLS130153	16	3/8" MPC female + sealing cap	- IVA		
5 L	FLS130059	16	Sartopore [®] 2 0.45 0.2 μm	MidiCaps [®] size 4		
	FLS130054	16	3/8" Opta® SFT female	- NA		
	FLS130051	16	3/8" MPC female + sealing cap	- IVA		
10 L	FLS130064	8	Sartopore [®] 2 0.45 0.2 μm	MidiCaps [®] size 7		1/4" ID Silicone TuFlux 100 mm (4") + Luer Lock female +
	FLS130055	8	3/8" Opta® SFT female	- NA	3/8" Opta® SFT male	
	FLS130052	8	3/8" MPC female + sealing cap	- IVA		Clave connector
20 L	FLS130065	8	Sartopore [®] 2 0.45 0.2 μm	MidiCaps [®] size 7		olare connector
	FLS130056	8	3/8" Opta® SFT female	- NA		
	FLS130053	8	3/8" MPC female + sealing cap	- NA		
50 L	FLS130162	8	Sartopore [®] 2 0.45 0.2 μm	MidiCaps [®] size 7		
	FLS130156	8	3/8" Opta® SFT female	- NA		
	FLS130154	8	3/8" MPC female + sealing cap	IN/A		

 $^{^1}$ Inlet tubing line from end line to bag: $3/8"\times5/8"$ Clear C-Flex $^{\circ}$ 500 mm (20") + Clipster $^{\circ}$ in a separate pouch

² Outlet tubing line from bag to end line: 3/8" × 5/8" Clear C-Flex[®] 500 mm (20")

Buffer
Flexsafe® 2D | Flexsafe® 3D |
Flexsafe® ≥ 1,000 L

Cell Harvest & DSP
Flexsafe® 2D | Flexsafe® 3D |
Flexsafe® ≥ 1,000 L

Drug Substance
Flexsafe® 2D |
Flexsafe® 3D

Drug Product
Flexsafe® 2D |
Flexsafe® 3D

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Buffer Preparation

Buffer
Preparation

Sterile Connection
to Downstream Systems

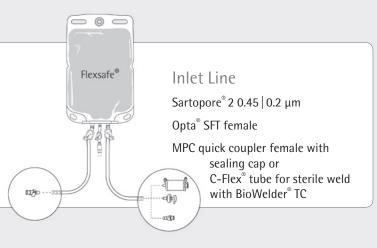
Sterile Connection
Sterile Weld

Quick Coupler Connection
to Downstream Systems

Tri-Clamp Connection

Outlet Line

C-Flex® tube with MPC sealing cap for sterile weld with BioWelder® TC



Sterile Weld to Downstream Systems

			Inlet ¹		Outlet ²	Sampling
Bag volume	Part number	Units per box	Filter or distal connector on filling line	Filter type 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	3/8" 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		
	FLS130042	16	3/8" Opta® SFT female	- NA	³ / ₈ " × ⁵ / ₈ " C-Flex [®] + ³ / ₈ " MPC male + sealing cap	1/4" ID Silicone TuFlux [®] 100 mm (4") + Luer Lock female + Clave connector
	FLS130039	16	3/8" MPC female + sealing cap			
10 L	FLS130060	8	Sartopore [®] 2 0.45 0.2 μm	MidiCaps [®] size 7		
	FLS130043	8	3/8" Opta® SFT female	- NA		
	FLS130040	8	3/8" MPC female + sealing cap			
20 L	FLS130061	8	Sartopore [®] 2 0.45 0.2 μm	MidiCaps [®] size 7		
	FLS130044	8	3/8" Opta® SFT female	- NA		
	FLS130041	8	3/8" MPC female + sealing cap			
50 L	FLS130160	8	Sartopore [®] 2 0.45 0.2 μm	MidiCaps [®] size 7		
	FLS130148	8	3/8" Opta® SFT female	- NA		
	FLS130146	8	3/8" MPC female + sealing cap			

 $^{^1}$ Inlet tubing line from end line to bag: $3/8" \times 5/8"$ Clear C-Flex $^{\circ}$ 500 mm (20") + Clipster $^{\circ}$ in a separate pouch

² Outlet tubing line from bag to end line: 3/8" × 5/8" Clear C-Flex[®] 500 mm (20")

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Buffer Preparation

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Buffer

Preparation

Sterile Connection to Downstream Systems Sterile Weld

Sanitary or Aseptic Connection to Downstream Systems

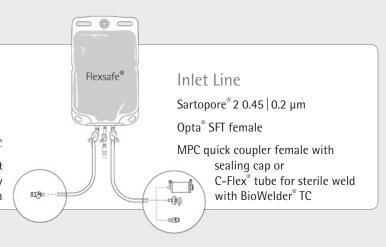
Sterile Weld

Quick Coupler Connection

Tri-Clamp Connection

Outlet Line

MPC quick coupler male & female with cap for sanitary or aseptic connection



Quick Coupler Connection to Downstream Systems

			Inlet ¹		Outlet ²	Sampling
Bag volume	Part number	Units per box	Filter or distal connector on filling line	Filter type 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	3/8" 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		
	FLS130042	16	3/8" Opta® SFT female	- NA		
	FLS130039	16	3/8" MPC female + sealing cap			
10 L	FLS130060	8	Sartopore® 2 0.45 0.2 μm	MidiCaps® size 7	3/8" × 5/8" C-Flex® +	1/4" ID Silicone TuFlux
	FLS130043	8	3/8" Opta® SFT female	- NA	3/8" MPC male + sealing cap	100 mm (4") + Luer Lock female + Clave connector
	FLS130040	8	3/8" MPC female + sealing cap			
20 L	FLS130061	8	Sartopore [®] 2 0.45 0.2 μm	MidiCaps [®] size 7		Gia ve connector
	FLS130044	8	3/8" Opta® SFT female	- NA		
	FLS130041	8	3/8" MPC female + sealing cap			
50 L	FLS130160	8	Sartopore [®] 2 0.45 0.2 μm	MidiCaps [®] size 7		
	FLS130148	8	3/8" Opta® SFT female	- NA		
	FLS130146	8	3/8" MPC female + sealing cap			

 $^{^1}$ Inlet tubing line from end line to bag: $3/8"\times5/8"$ Clear C-Flex $^{\circ}$ 500 mm (20") + Clipster $^{\circ}$ in a separate pouch

² Outlet tubing line from bag to end line: 3/8" × 5/8" Clear C-Flex[®] 500 mm (20")

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Selection Map

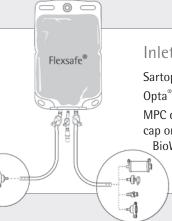
Buffer Preparation

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Sterile Connection Sterile Connection to Downstream Systems Buffer Sterile Weld Preparation **Quick Coupler Connection** Sanitary or Aseptic Connection to Downstream Systems Tri-Clamp Connection

Outlet Line

Tri-Clamp flange for sanitary or aseptic connection



Inlet Line

Sartopore[®] 2 0.45 | 0.2 μm Opta® SFT female

MPC quick coupler female with sealing cap or C-Flex® tube for sterile weld with BioWelder® TC

> Tri-Clamp flange for sanitary or aseptic connection

Tri-Clamp Connection to Downstream Systems

			Inlet ¹		Outlet ²	Sampling
Bag volume	Part number	Units per box	Filter or distal connector on filling line	Filter type 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	3/8" Opta® SFT female			
	FLS130163	16	3/8" MPC female + sealing cap	NA		
	FLS130191	16	3/8" Tri-Clamp 3/4" sanitary flange with gasket, cap & union ³			
5 L	FLS130058	16	Sartopore® 2 0.45 0.2 μm	MidiCaps [®] size 4		
	FLS130069	16	³/8" Opta® SFT female			
	FLS130066	16	3/8" MPC female + sealing cap	NA		
	FLS130108	16	3/8" Tri-Clamp 3/4" sanitary flange with gasket, cap & union ³			
10 L	FLS130062	8	Sartopore® 2 0.45 0.2 μm	MidiCaps [®] size 7	3/8" Tri-Clamp 3/4"	1/4" ID Silicone
	FLS130070	8	³/8" Opta® SFT female		sanitary flange	TuFlux® 100 mm
	FLS130067	8	3/8" MPC female + sealing cap	NA	with gasket,	(4") + Luer Lock female + Clave
	FLS130109	8	3/8" Tri-Clamp 3/4" sanitary flange with gasket, cap & union ³		cap & union	connector
20 L	FLS130063	8	Sartopore® 2 0.45 0.2 μm	MidiCaps [®] size 7		Connector
	FLS130071	8	³/8" Opta® SFT female			
	FLS130068	8	3/8" MPC female + sealing cap	NA		
	FLS130110	8	3/8" Tri-Clamp 3/4" sanitary flange with gasket, cap & union ³			
50 L	FLS130161	8	Sartopore® 2 0.45 0.2 μm	MidiCaps [®] size 7		
	FLS130166	8	³/8" Opta® SFT female			
	FLS130164	8	3/8" MPC female + sealing cap	NA		
	FLS130192	8	3/8" Tri-Clamp 3/4" sanitary flange with gasket, cap & union ³			

¹ Inlet tubing line from end line to bag: 3/8" × 5/8" Clear C-Flex® 500 mm (20") + Clipster[®] in a separate pouch

² Outlet tubing line from bag to end line: 3/8" TuFlux® SIL 300 mm (12")

³ 3/8" TuFlux[®] SIL 300 mm (12") for design with two Tri-Clamps

Media
Flexsafe® 2D | Flexsafe® 3D |
Flexsafe® ≥ 1.000 L

Buffer
Flexsafe® 2D | Flexsafe® 3D |
Flexsafe® ≥ 1,000 L

Cell Harvest & DSP
Flexsafe® 2D | Flexsafe® 3D |
Flexsafe® ≥ 1,000 L

Drug Substance
Flexsafe® 2D |
Flexsafe® 3D

Flexsafe® 2D | Flexsafe® 3D

Drug Product

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D. CC. File 1: C.

Buffer Filtration, Storage and Shipping

Buffer Preparation

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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 $^{\circ}$ 3D solutions for buffer are available with Sartopore $^{\circ}$ 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® 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 sterile buffer transfer to most common single-use and stainless steel downstream purification and formulation systems with a variety of sterile and aseptic connections.

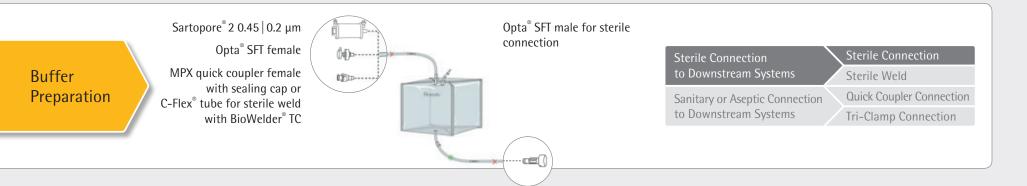


Outlet line

Connection and transfer by pumping or gravity

- Opta® SFT male for sterile connection
- C-Flex[®] tube for sterile weld with BioWelder[®] TC
- 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 Filtration, Storage and Shipping in Palletank



Sterile Connection to Downstream Systems

			Inlet ¹		Outlet ²
Bag volume	Part number	Units per box	Filter or distal connector on filling line	Filter type 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	— NA	
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	— IVA	

 $^{^{1}}$ Inlet tubing line from end line to bag: $\frac{1}{2}$ " \times $\frac{3}{4}$ " Clear C-Flex $^{\circ}$ 0.5 m (20") + $\frac{1}{2}$ " ID Silicone TuFlux $^{\circ}$ 1 m (40")

² 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
Flexsafe® 2D | Flexsafe® 3D |
Flexsafe® ≥ 1,000 L

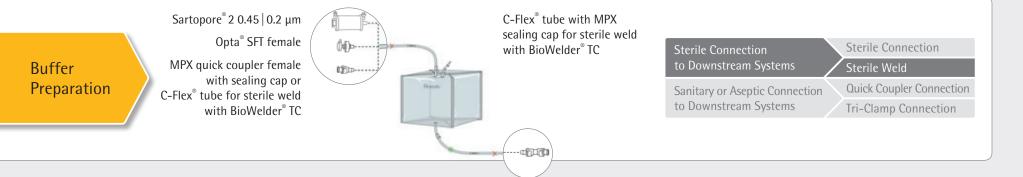
Buffer
Flexsafe® 2D | Flexsafe® 3D |
Flexsafe® ≥ 1,000 L

Cell Harvest & DSP Flexsafe® 2D | Flexsafe® 3D | Flexsafe® ≥ 1,000 L Drug Substance
Flexsafe® 2D |
Flexsafe® 3D

Drug Product
Flexsafe® 2D |
Flexsafe® 3D

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Buffer Filtration, Storage and Shipping in Palletank



Sterile Weld to Downstream Systems

			Inlet ¹		Outlet ²
Bag volume	Part number	Units per 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	1/2" Opta® SFT female	— NA	
	FIS126489	3	MPX female + sealing cap	— IVA	
200 L	FIS126731	2	Sartopore® 2 0.45 0.2 μm	MidiCaps [®] size 9	$\frac{1}{2}$ " × $\frac{3}{4}$ " C-Flex $^{\circ}$ + MPX male
	FIS126743	3	½" Opta® SFT female	NΙΛ	+ MPX double female + sealing cap
	FIS126490	3	MPX female + sealing cap	— NA	
500 L	FIS126732	2	Sartopore [®] 2 0.45 0.2 μm	MaxiCaps [®] size 0	
	FIS126744	3	½" Opta® SFT female	NΙΛ	
	FIS126491	3	MPX female + sealing cap	— NA	

 $^{^{1}}$ Inlet tubing line from end line to bag: $\frac{1}{2}$ " \times $\frac{3}{4}$ " Clear C-Flex $^{\circ}$ 0.5 m (20") + $\frac{1}{2}$ " ID Silicone TuFlux $^{\circ}$ 1 m (40")

² Outlet tubing line from bag to end line: 1/2" ID Silicone TuFlux® 1 m (40") + 1/2" × 3/4" Clear C-Flex® 0.5 m (20")

Buffer

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Buffer Filtration and Storage in Drum



Sterile Connection to Downstream Systems

			Inlet ¹		Outlet ²
Bag volume	Part number	Units per box	Filter or distal connector on top filling line	Filter type 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	NIA	
	FIS127909	4	MPX female + sealing cap	— NA	
100 L	FIS127892	2	Sartopore® 2 0.45 0.2 μm	MidiCaps® size 8	
	FIS127907	4	½" Opta® SFT female	— NA	1/2" Opta® SFT male
	FIS127910	4	MPX female + sealing cap	— NA	
200 L	FIS127893	2	Sartopore [®] 2 0.45 0.2 μm	MidiCaps [®] size 9	
	FIS127908	4	½" Opta® SFT female		
	FIS127911	4	MPX female + sealing cap	— NA	

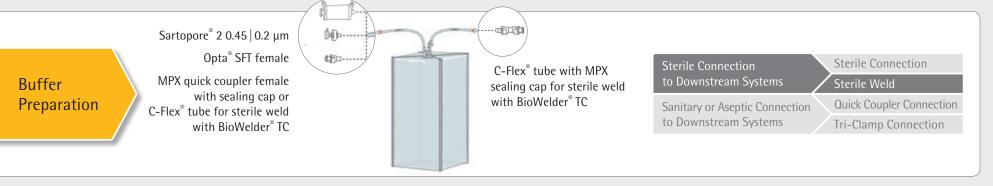
¹Inlet tubing line from end line to bag: ½" × ¾" Clear C-Flex® 0.5 m (20") + ½" ID Silicone TuFlux® 1 m (40")

² Outlet tubing line from bag to end line: 1/2" ID Silicone TuFlux® 1 m (40") + 1/2" × 3/4" Clear C-Flex® 0.5 m (20")

Flexsafe[®] ≥ 1,000 L

Buffer Filtration and Storage in Drum

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Sterile Weld to Downstream Systems

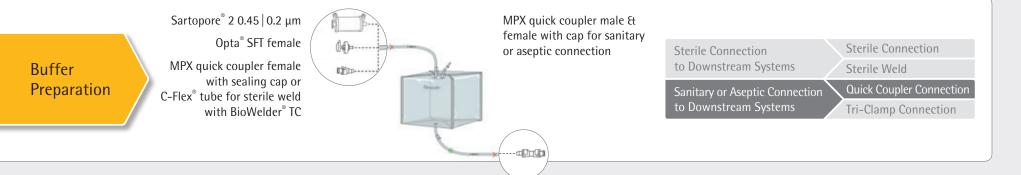
			Inlet ¹		Outlet ²
Bag volume	Part number	Units per box	Filter or distal connector on top filling line	Filter type and size	Distal connector on top draining line
50 L	FIS127888	2	Sartopore 2 0.45 0.2 μm	MidiCaps [®] size 7	
	FIS127900	4	½" Opta® SFT female	NIA	
	FIS127903	4	MPX female + sealing cap	— NA	
100 L	FIS127889	2	Sartopore 2 0.45 0.2 μm	MidiCaps® size 8	1/2" × 3/4" C-Flex® + MPX male
	FIS127901	4	½" Opta® SFT female	— NA	+ MPX double female
	FIS127904	4	MPX female + sealing cap	— IVA	+ sealing cap
200 L	FIS127890	2	Sartopore 2 0.45 0.2 μm	MidiCaps® size 9	
	FIS127902	4	1/2" Opta® SFT female	NΙΔ	
	FIS127905	4	MPX female + sealing cap	— NA	

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

² Outlet tubing line from bag to end line: 1/2" ID Silicone TuFlux® 1 m (40") + 1/2" × 3/4" Clear C-Flex® 0.5 m (20")

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Buffer Filtration, Storage and Shipping in Palletank



Quick Coupler Connection to Downstream Systems

			Inlet ¹		Outlet ²
Bag volume	Part number	Units per 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	1/2" Opta® SFT female	NIA	1/2" MPX male + MPX double female + sealing cap
	FIS126489	3	MPX female + sealing cap	— NA	
200 L	FIS126731	2	Sartopore® 2 0.45 0.2 μm	MidiCaps [®] size 9	
	FIS126743	3	½" Opta® SFT female	NΙΛ	
	FIS126490	3	MPX female + sealing cap	— NA	
500 L	FIS126732	2	Sartopore [®] 2 0.45 0.2 μm	MaxiCaps [®] size 0	
	FIS126744	3	½" Opta® SFT female	NΙΛ	
	FIS126491	3	MPX female + sealing cap	— NA	

 $^{^{1}}$ Inlet tubing line from end line to bag: $\frac{1}{2}$ " \times $\frac{3}{4}$ " Clear C-Flex $^{\circ}$ 0.5 m (20") + $\frac{1}{2}$ " ID Silicone TuFlux $^{\circ}$ 1 m (40")

² Outlet tubing line from bag to end line: 1/2" ID Silicone TuFlux® 1 m (40") + 1/2" × 3/4" Clear C-Flex® 0.5 m (20")

Media
Flexsafe® 2D | Flexsafe® 3D |
Flexsafe® ≥ 1,000 L

Buffer
Flexsafe® 2D | Flexsafe® 3D |
Flexsafe® ≥ 1,000 L

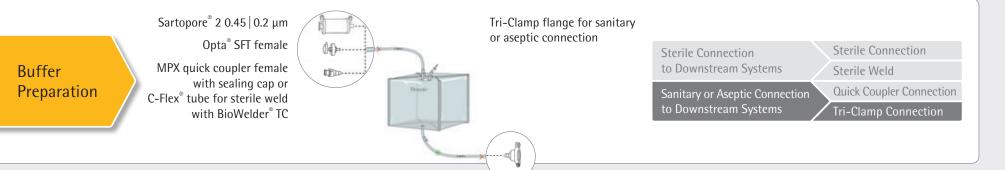
Cell Harvest & DSP
Flexsafe® 2D | Flexsafe® 3D |
Flexsafe® ≥ 1,000 L

Drug Substance
Flexsafe® 2D |
Flexsafe® 3D

Product
Flexsafe® 2D |
Flexsafe® 3D

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Buffer Filtration, Storage and Shipping in Palletank



Tri-Clamp Connection to Downstream Systems

			Inlet ¹		Outlet ²
Bag volume	Part number	Units per 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	NIA	½" Tri-Clamp 1½" sanitary flange with gasket, cap & union
	FIS126255	3	MPX female + sealing cap	— NA	
200 L	FIS126252	2	Sartopore® 2 0.45 0.2 µm	MidiCaps [®] size 9	
	FIS126739	3	½" Opta® SFT female	NΙΛ	
	FIS126256	3	MPX female + sealing cap	— NA	
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	- IVA	

 $^{^1}$ Inlet tubing line from end line to bag: 1/2" \times 3/4" Clear C-Flex $^{\circ}$ 0.5 m (20") + 1/2" ID Silicone TuFlux $^{\circ}$ 1 m (40")

² Outlet tubing line from bag to end line: ½" ID Silicone TuFlux® 1,5 m (60")

Flexsafe[®] ≥ 1,000 L

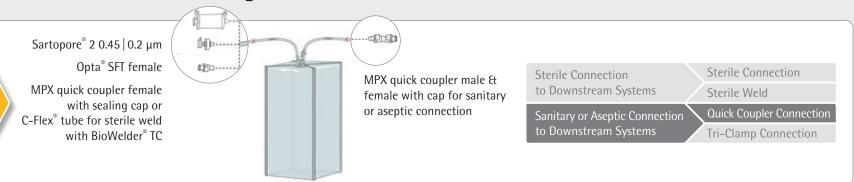
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Buffer

Preparation

Buffer Filtration and Storage in Drum



Quick Coupler Connection to Downstream Systems

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

 $^{^{1}}$ Inlet tubing line from end line to bag: $\frac{1}{2}$ " \times $\frac{3}{4}$ " Clear C-Flex $^{\circ}$ 0.5 m (20") + $\frac{1}{2}$ " ID Silicone TuFlux $^{\circ}$ 1 m (40")

² Outlet tubing line from bag to end line: 1/2" ID Silicone TuFlux® 1 m (40") + 1/2" × 3/4" Clear C-Flex® 0.5 m (20")

Buffer

Media

Flexsafe® 2D Flexsafe® 3D Flexsafe[®] ≥ 1,000 L

Buffer Flexsafe® 2D Flexsafe® 3D Flexsafe[®] ≥ 1,000 L

Cell Harvest & DSP Flexsafe® 2D Flexsafe® 3D Flexsafe[®] ≥ 1,000 L

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

Drug Product Flexsafe® **2D** Flexsafe® 3D

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Buffer Filtration and Storage in Drum



Tri-Clamp Connection to Downstream Systems

			Inlet ¹		Outlet ²
Bag volume	Part number	Units per box	Filter or distal connector on top filling line	Filter type 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		
	FIS127897	4	MPX female + sealing cap	NA	
	FIS127912	4	½" Tri-Clamp 1½" flange ³		1/2" Tri-Clamp 11/2" sanitary flange with gasket, cap & union
100 L	FIS127886	2	Sartopore [®] 2 0.45 0.2 μm	MidiCaps® size 8	
	FIS127895	4	½" Opta® SFT female		
	FIS127898	4	MPX female + sealing cap	— NA	
	FIS127913	4	1/2" Tri-Clamp 11/2" flange ³	— IVA	
200 L	FIS127887	2	Sartopore [®] 2 0.45 0.2 μm	MidiCaps® size 9	
	FIS127896	4	½" Opta® SFT female		
	FIS127899	4	MPX female + sealing cap	NA	
	FIS127914	4	1/2" Tri-Clamp 11/2" flange ³		

 $^{^{1}}$ Inlet tubing line from end line to bag: $\frac{1}{2}$ " \times $\frac{3}{4}$ " Clear C-Flex $^{\circ}$ 0.5 m (20") + $\frac{1}{2}$ " ID Silicone TuFlux $^{\circ}$ 1 m (40")

²Tubing line from bag to end line: ½" ID Silicone TuFlux[®] 1,5 m (60")

Media
Flexsafe® 2D | Flexsafe® 3D |
Flexsafe® ≥ 1,000 L

Buffer
Flexsafe® 2D | Flexsafe® 3D |
Flexsafe® ≥ 1,000 L

Cell Harvest & DSP
Flexsafe® 2D | Flexsafe® 3D |
Flexsafe® ≥ 1,000 L

Drug Substance
Flexsafe® 2D |
Flexsafe® 3D

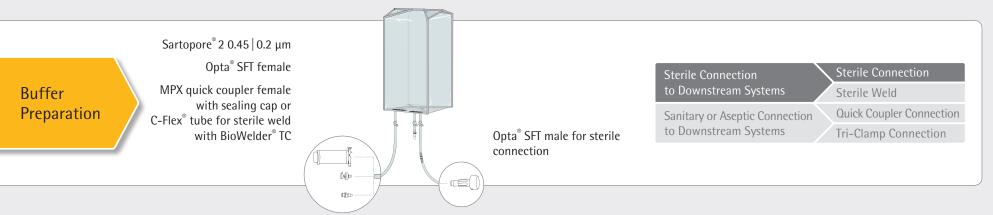
Drug Product
Flexsafe® 2D |
Flexsafe® 3D

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Selection Map

D CC - File - Line - - - - - Classes

Buffer Filtration and Storage in Palletank



Sterile Connection to Downstream Systems

			Inlet ¹		Outlet ²
Bag Volume	Part number	Units per box	Filter or distal connector on filling line	Filter type 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	— NA	
1,500 L	FIS500326	2	Sartopore® 2	MaxiCaps [®] Size 1	
	FIS500291	2	1/2" Opta® SFT female		
	FIS500301	2	MPX female + sealing cap		
2,000 L	FIS500327	1	Sartopore® 2	MaxiCaps [®] Size 2	
	FIS500292	2	½" Opta [®] SFT female	NΙΛ	½" Opta [®] SFT male
	FIS500302	2	MPX female + sealing cap	— NA	
2,500 L	FIS500328	1	Sartopore® 2	MaxiCaps [®] Size 2	
	FIS500293	1	½" Opta® SFT female	— NA	
	FIS500303	1	MPX female + sealing cap	— NA	
3,000 L	FIS500329	1	Sartopore® 2	MaxiCaps [®] Size 2	
	FIS500294	1	½" Opta® SFT female	NΙΛ	
	FIS500304	1	MPX female + sealing cap	— NA	

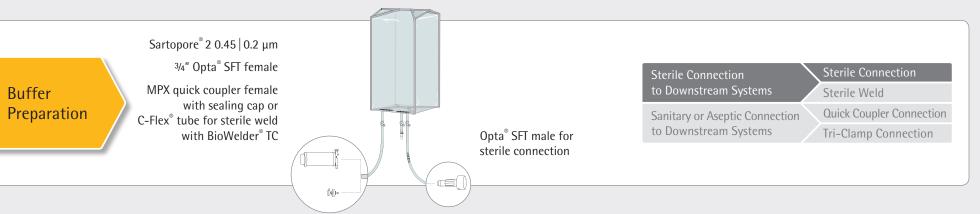
¹Inlet tubing line from end line to bag: $\frac{1}{2}$ " \times $\frac{3}{4}$ " Clear C-Flex [©] 1.5 m (60")

² Outlet tubing line from bag to end line: ¹/₂" ID Silicone TuFlux[®] 2,5 m (98") + ¹/₂" × ³/₄" Clear C-Flex[®] 0.5 m (20")

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Buffer Filtration and Storage in Palletank



Sterile Connection to Downstream Systems – High Flow Rate

				Outlet ²
Part number	Units per box	Filter or distal connector on filling line	Filter type and size	Distal connector on draining line
IS500335	2	Sartopore® 2	MaxiCaps [®] Size 1	
IS302278	2	³/4" Opta® SFT female	NA	
IS500336	2	Sartopore® 2	MaxiCaps [®] Size 1	
IS302279	2	³/4" Opta® SFT female	NA	
IS500337	1	Sartopore® 2	MaxiCaps [®] Size 2	³/4" Opta® SFT male
IS500275	2	³/4" Opta® SFT female	NA	3/4 Opta SFI male
TS500338	1	Sartopore® 2	MaxiCaps [®] Size 2	
IS500276	1	³/4" Opta® SFT female	NA	
TS500339	1	Sartopore® 2	MaxiCaps [®] Size 2	
IS302282	1	³/4" Opta® SFT female	NA	
1	umber IS500335 IS302278 IS500336 IS302279 IS500337 IS500275 IS500338 IS500276 IS500339	umber box IS500335 2 IS302278 2 IS500336 2 IS302279 2 IS500337 1 IS500275 2 IS500338 1 IS500339 1	umber box on filling line IS500335 2 Sartopore® 2 IS302278 2 3/4" Opta® SFT female IS500336 2 Sartopore® 2 IS302279 2 3/4" Opta® SFT female IS500337 1 Sartopore® 2 IS500275 2 3/4" Opta® SFT female IS500338 1 Sartopore® 2 IS500276 1 3/4" Opta® SFT female IS500339 1 Sartopore® 2	umber box on filling line and size IS500335 2 Sartopore® 2 MaxiCaps® Size 1 IS302278 2 3/4" Opta® SFT female NA IS500336 2 Sartopore® 2 MaxiCaps® Size 1 IS302279 2 3/4" Opta® SFT female NA IS500337 1 Sartopore® 2 MaxiCaps® Size 2 IS500275 2 3/4" Opta® SFT female NA IS500338 1 Sartopore® 2 MaxiCaps® Size 2 IS500276 1 3/4" Opta® SFT female NA IS500339 1 Sartopore® 2 MaxiCaps® Size 2

¹Inlet tubing line from end line to bag with filter: $\frac{1}{2}$ " \times $\frac{3}{4}$ " Clear C-Flex $^{\circ}$ 1.5 m (60")

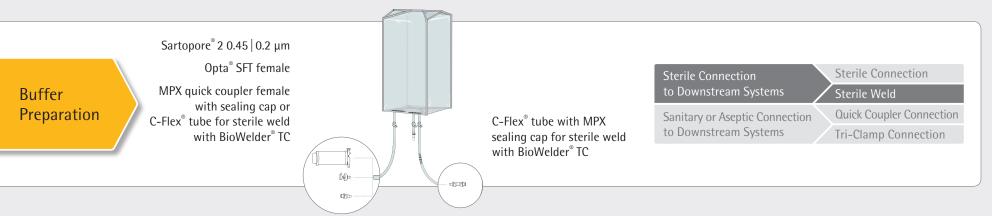
¹Inlet tubing line from connector Opta® to bag: ³/₄" x 1" Clear C-Flex® 1.5 m (60")

 2 Outlet tubing line from bag to end line: 3 /4" ID Silicone TuFlux $^\circ$ 2.5 m (98") + 3 /4" \times 1" Clear C-Flex $^\circ$ 0.5 m (20")

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Duffer Filtretion and Ctars

Buffer Filtration and Storage in Palletank



Sterile Weld to Downstream Systems

			Inlet ¹		Outlet ²
Bag Volume			Units per box	Filter or distal connector on filling line	Filter type and size
1,000 L	FIS500310	2	Sartopore® 2	MaxiCaps [®] Size 1	
	FIS500330	2	½" Opta® SFT female	NΙΛ	
	FIS302338	2	MPX female + sealing cap	— NA	
1,500 L	FIS500311	2	Sartopore® 2	MaxiCaps [®] Size 1	
	FIS500334	2	½" Opta® SFT female		
	FIS302339	2	MPX female + sealing cap		
2,000 L	FIS500312	1	Sartopore® 2	MaxiCaps [®] Size 2	1/2" × 3/4" C-Flex®
	FIS500331	2	½" Opta® SFT female	NΙΔ	+ MPX male + MPX double female
	FIS302340	2	MPX female + sealing cap	— NA	+ sealing cap
2,500 L	FIS500313	1	Sartopore® 2	MaxiCaps [®] Size 2	1 Scaling cup
	FIS500332	1	½" Opta® SFT female	NΙΛ	
	FIS302341	1	MPX female + sealing cap	— NA	
3,000 L	FIS500314	1	Sartopore® 2	MaxiCaps [®] Size 2	
	FIS500333	1	½" Opta® SFT female	NΙΛ	
	FIS302342	1	MPX female + sealing cap	— NA	

¹Inlet tubing line from end line to bag: $\frac{1}{2}$ " \times $\frac{3}{4}$ " Clear C-Flex [©] 1.5 m (60")

² Outlet tubing line from bag to end line: ¹/₂" ID Silicone TuFlux[®] 2,5 m (98") + ¹/₂" × ³/₄" Clear C-Flex[®] 0.5 m (20")

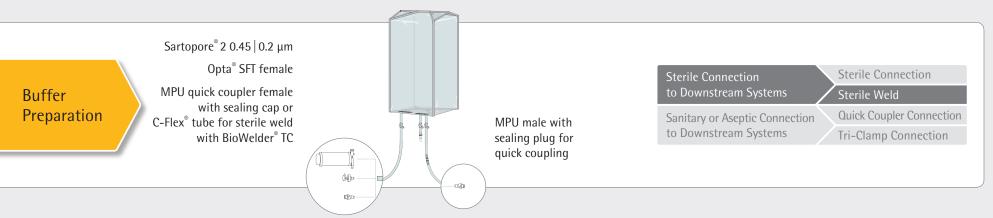
Flexsafe[®] ≥ 1,000 L

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Duffer Filtuation and Ctar

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Buffer Filtration and Storage in Palletank



Sterile Weld to Downstream Systems – High Flow Rate

			Inlet ¹		Outlet ²
Bag Volume	Part number	Units per box	Filter or distal connector on filling line	Filter type and size	Distal connector on draining line
1,000 L	FIS500370	2	Sartopore® 2	MaxiCaps [®] Size 1	
	FIS500375	2	³/4" Opta® SFT female	NΙΛ	
	FIS500365	2	MPX female + sealing cap	— NA	
1,500 L	FIS500371	2	Sartopore® 2	MaxiCaps [®] Size 1	
	FIS500376	2	³/4" Opta® SFT female		
	FIS500366	2	MPX female + sealing cap		
2,000 L	FIS500372	1	Sartopore® 2	MaxiCaps [®] Size 2	3/4" × 1" C-Flex®
	FIS500377	2	³/4" Opta® SFT female	NΙΛ	+ MPU male
	FIS500367	2	MPX female + sealing cap	— NA	+ sealing cap
2,500 L	FIS500373	1	Sartopore® 2	MaxiCaps [®] Size 2	
	FIS500378	1	³/₄" Opta® SFT female	NΙΛ	
	FIS500368	1	MPX female + sealing cap	— NA	
3,000 L	FIS500374	1	Sartopore® 2	MaxiCaps [®] Size 2	
	FIS500379	1	³/4" Opta® SFT female	NΙΛ	
	FIS500369	1	MPX female + sealing cap	— NA	

¹Inlet tubing line from end line to bag with filter: $\frac{1}{2}$ " \times $\frac{3}{4}$ " Clear C-Flex $^{\circ}$ 1.5 m (60")

¹Inlet tubing line from connector to bag: ³/₄" x 1" Clear C-Flex[®] 1.5 m (60")

² Outlet tubing line from bag to end line: $^{3}/^{4}$ " ID Silicone TuFlux $^{\circ}$ 2.5 m (98") + $^{3}/^{4}$ " \times 1" Clear C-Flex $^{\circ}$ 0.5 m (20")

Media
Flexsafe® 2D | Flexsafe® 3D |
Flexsafe® ≥ 1,000 L

Buffer
Flexsafe® 2D | Flexsafe® 3D |
Flexsafe® ≥ 1,000 L

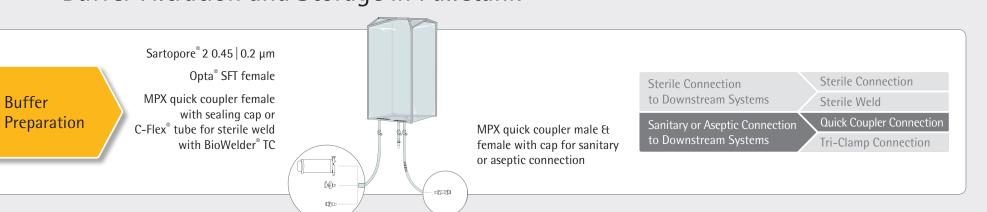
Cell Harvest & DSP
Flexsafe® 2D | Flexsafe® 3D |
Flexsafe® ≥ 1,000 L

Drug Substance
Flexsafe® 2D |
Flexsafe® 3D

Drug Product
Flexsafe® 2D |
Flexsafe® 3D

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Buffer Filtration and Storage in Palletank



Quick Coupler Connection to Downstream Systems

			Inlet ¹		Outlet ²
Bag Volume	Part number	Units per box	Filter or distal connector on filling line	Filter type and size	Distal connector on draining line
1,000 L	FIS500310	2	Sartopore® 2	MaxiCaps [®] Size 1	
	FIS500330	2	1/2" Opta® SFT female	— NA	
	FIS302338	2	MPU female + sealing cap	- NA	
1,500 L	FIS500311	2	Sartopore® 2	MaxiCaps® Size 1	
	FIS500334	2	1/2" Opta® SFT female		
	FIS302339	2	MPU female + sealing cap		
2,000 L	FIS500312	1	Sartopore® 2	MaxiCaps® Size 2	1/2" × 3/4" C-Flex®
	FIS500331	2	1/2" Opta® SFT female		+ MPX male + MPX double female
	FIS302340	2	MPU female + sealing cap	- NA	+ sealing cap
2,500 L	FIS500313	1	Sartopore® 2	MaxiCaps® Size 2	. scannig cap
	FIS500332	1	½" Opta® SFT female	— NA	
	FIS302341	1	MPU female + sealing cap	— NA	
3,000 L	FIS500314	1	Sartopore® 2	MaxiCaps® Size 2	
	FIS500333	1	½" Opta® SFT female	— NA	
	FIS302342	1	MPU female + sealing cap	— IVA	

¹Inlet tubing line from end line to bag: $\frac{1}{2}$ " \times $\frac{3}{4}$ " Clear C-Flex [©] 1.5 m (60")

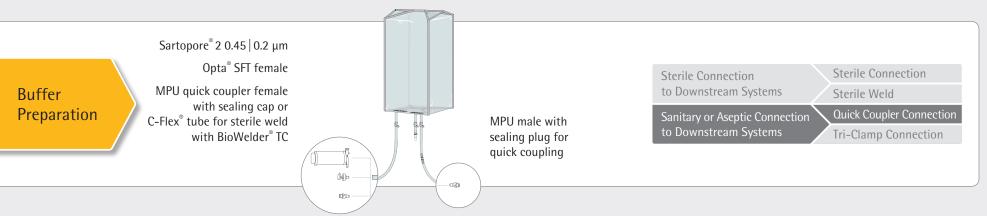
² Outlet tubing line from bag to end line: ½" ID Silicone TuFlux[®] 2,5 m (98") + ½" × ¾" Clear C-Flex[®] 0.5 m (20")

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Buffer Filtration and Storage in Palletank

Flexsafe® 3D Pre-designed Solutions for



Quick Coupler Connection to Downstream Systems - High Flow Rate

			Inlet ¹		Outlet ²
Bag Volume	Part number	Units per box	Filter or distal connector on filling line	Filter type and size	Distal connector on draining line
1,000 L	FIS500370	2	Sartopore® 2	MaxiCaps [®] Size 1	
	FIS500375	2	³/4" Opta® SFT female	— NA	
	FIS500365	2	MPU female + sealing cap	— NA	
1,500 L	FIS500371	2	Sartopore® 2	MaxiCaps [®] Size 1	
	FIS500376	2	³/4" Opta® SFT female		
	FIS500366	2	MPU female + sealing cap		
2,000 L	FIS500372	1	Sartopore® 2	MaxiCaps [®] Size 2	³/4" × 1" C-Flex [®]
	FIS500377	2	³/4" Opta® SFT female	NΙΛ	+ MPU male
	FIS500367	2	MPU female + sealing cap	— NA	+ sealing cap
2,500 L	FIS500373	1	Sartopore® 2	MaxiCaps [®] Size 2	
	FIS500378	1	³/4" Opta® SFT female	NΙΛ	
	FIS500368	1	MPU female + sealing cap	— NA	
3,000 L	FIS500374	1	Sartopore® 2	MaxiCaps [®] Size 2	
	FIS500379	1	³/4" Opta® SFT female	— NA	
	FIS500369	1	MPU female + sealing cap	IVA	

¹Inlet tubing line from end line to bag with filter: $\frac{1}{2}$ " \times $\frac{3}{4}$ " Clear C-Flex $^{\circ}$ 1.5 m (60")

¹Inlet tubing line from connector to bag: ³/₄" x 1" Clear C-Flex[®] 1.5 m (60")

 2 Outlet tubing line from bag to end line: 3 /4" ID Silicone TuFlux $^{\circ}$ 2.5 m (98") + 3 /4" \times 1" Clear C-Flex $^{\circ}$ 0.5 m (20")

xsafe 2D | xsafe[®] 3D

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Buffer Filtration and Storage in Palletank



Tri-Clamp Connection to Downstream Systems

			Inlet ¹		Outlet ²
Bag Volume	Part number	Units per box	Filter or distal connector on filling line	Filter type 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	1/2" Opta® SFT female	NA	WILLIAM IN
2,000 L	FIS500317	1	Sartopore® 2	MaxiCaps® Size 2	1/2" ID tubing,
	FIS500352	2	1/2" Opta® SFT female	NA	Tri-Clamp 1 ½ sanitary flange with gasket, cap & union
2,500 L	FIS500318	1	Sartopore® 2	MaxiCaps® Size 2	with gasker, cap et amon
	FIS500353	1	1/2" Opta® SFT female	NA	
3,000 L	FIS500319	1	Sartopore® 2	MaxiCaps® Size 2	
	FIS500354	1	½" Opta® SFT female	NA	

¹Inlet tubing line from end line to bag: $\frac{1}{2}$ " \times $\frac{3}{4}$ " Clear C-Flex $^{\circ}$ 1.5 m (60")

² Outlet tubing line from bag to end line: $\frac{1}{2}$ " ID Silicone TuFlux 3 m (118")

Media

Flexsafe[®] 2D | Flexsafe[®] 3D |
Flexsafe[®] ≥ 1,000 L

Buffer
Flexsafe® 2D | Flexsafe® 3D |
Flexsafe® ≥ 1,000 L

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

Flexsafe[®] ≥ 1,000 L

Drug Substance
Flexsafe® 2D |
Flexsafe® 3D

Drug Product
Flexsafe® 2D |
Flexsafe® 3D

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Buffer Filtration and Storage in Palletank



Tri-Clamp Connection to Downstream Systems – High Flow Rate

			Inlet ¹		Outlet ²
Bag Volume	Part number	Units per box	Filter or distal connector on filling line	Filter type and size	Distal connector on draining line
1,000 L	FIS500320	2	Sartopore® 2	MaxiCaps [®] Size 1	
	FIS500355	2	³/4" Opta® SFT female	NA	
1,500 L	FIS500321	2	Sartopore® 2	MaxiCaps [®] Size 1	
	FIS500356	2	³/4" Opta® SFT female	NA	
2,000 L	FIS500322	1	Sartopore® 2	MaxiCaps [®] Size 2	3/4" ID tubing,
	FIS500357	2	³/4" Opta® SFT female	NA	Tri-Clamp 1 ½ sanitary flange with gasket, cap & union
2,500 L	FIS500323	1	Sartopore® 2	MaxiCaps [®] Size 2	with gasket, cap et union
	FIS500358	1	³/4" Opta® SFT female	NA	
3,000 L	FIS500324	1	Sartopore® 2	MaxiCaps [®] Size 2	
	FIS500359	1	³/4" Opta® SFT female	NA	

¹Inlet tubing line from end line to bag with filter: $\frac{1}{2}$ " \times $\frac{3}{4}$ " Clear C-Flex $^{\circ}$ 1.5 m (60")

¹Inlet tubing line from connector to bag: ³/₄" x 1" Clear C-Flex[®] 1.5 m (60")

² Outlet tubing line from bag to end line: ³/₄" ID Silicone TuFlux[®] 3 m (118")

Drug Product

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Trexpare 25 fre designed 3014 doins for

Cell Harvest & Downstream Intermediates

Cell Harvest & Downstream Intermediates

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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

Connection for Alternative Filter Line

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

Media

Flexsafe[®] 2D | Flexsafe[®] 3D | Flexsafe[®] ≥ 1,000 L Buffer
Flexsafe® 2D | Flexsafe® 3D |
Flexsafe® ≥ 1,000 L

Cell Harvest & DSP
Flexsafe® 2D | Flexsafe® 3D |
Flexsafe® ≥ 1,000 L

Drug Substance
Flexsafe® 2D |
Flexsafe® 3D

Drug Product
Flexsafe® 2D |
Flexsafe® 3D

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Cell Harvest & Downstream Intermediates

Cell Harvest
Et Downstream Intermediates

Sterile Connection to Downstream Systems

Sterile Connection Sterile Weld

Ouick Coupler Connection Tri-Clamp Connection

Tri-Clamp Connection

Outlet Line
Opta® SFT male for sterile connection

Inlet Line

Sartopore® 2 XLG 0.8 | 0.2 µm

Opta® SFT female

MPC quick coupler female with sealing cap or C-Flex® tube for sterile weld with BioWelder® TC

Sterile Connection to Downstream Systems

			Inlet ¹		Outlet ²	Sampling
Bag volume	Part number	Units per box	Filter or distal connector on filling line	Filter type 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	3/8" Opta® SFT female	- NA		
	FLS130153	16	3/8" MPC female + sealing cap	- NA		
5 L	FLS130023	16	Sartopore® 2 XLG 0.8 0.2 μm	MidiCaps [®] size 4		
	FLS130054	16	3/8" Opta® SFT female	- NA		1/4" ID Silicone TuFlux® 100 mm (4") + Luer Lock female +
	FLS130051	16	3/8" MPC female + sealing cap	- NA		
10 L	FLS130035	8	Sartopore® 2 XLG 0.8 0.2 μm	MidiCaps [®] size 7		
	FLS130055	8	3/8" Opta® SFT female	- NA	3/8" Opta® SFT male	
	FLS130052	8	3/8" MPC female + sealing cap	- NA		Clave connector
20 L	FLS130036	8	Sartopore® 2 XLG 0.8 0.2 μm	MidiCaps [®] size 7		Giave connector
	FLS130056	8	3/8" Opta® SFT female	- NA		
	FLS130053	8	3/8" MPC female + sealing cap	- NA	_	
50 L	FLS130143	8	Sartopore® 2 XLG 0.8 0.2 μm	MidiCaps [®] size 7		
	FLS130156	8	³/8" Opta® SFT female	- NA		
	FLS130154	8	3/8" MPC female + sealing cap	IVA		

 $^{^1}$ Inlet tubing line from end line to bag: $3/8"\times5/8"$ Clear C-Flex $^{\circ}$ 500 mm (20") + Clipster $^{\circ}$ in a separate pouch

² Outlet tubing line from bag to end line: 3/8" × 5/8" Clear C-Flex[®] 500 mm (20")

Media

Flexsafe® 2D Flexsafe® 3D Flexsafe[®] ≥ 1,000 L

Buffer Flexsafe® 2D Flexsafe® 3D Flexsafe[®] ≥ 1,000 L

Cell Harvest & DSP Flexsafe® 2D Flexsafe® 3D Flexsafe[®] ≥ 1,000 L

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

Drug Product Flexsafe® **2D** Flexsafe® 3D

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Selection Map

Cell Harvest & Downstream Intermediates

Cell Harvest & Downstream Intermediates

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Sterile Connection to Downstream Systems

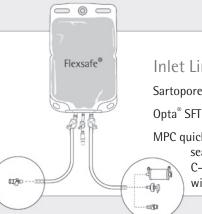
Sanitary or Aseptic Connection to Downstream Systems

Sterile Connection Sterile Weld

Quick Coupler Connection Tri-Clamp Connection

Outlet Line

C-Flex® tube with MPC sealing cap for sterile weld with BioWelder® TC



Inlet Line

Sartopore® 2 XLG 0.8 | 0.2 µm

Opta® SFT female

MPC quick coupler female with sealing cap or C-Flex® tube for sterile weld with BioWelder® TC

Sterile Weld to Downstream Systems

			Inlet ¹		Outlet ²	Sampling
Bag volume	Part number	Units per box	Filter or distal connector on filling line	Filter type 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	3/8" Opta® SFT female			
	FLS130145	16	3/8" MPC female + sealing cap			
5 L	FLS130018	16	Sartopore® 2 XLG 0.8 0.2 μm	MidiCaps [®] size 4		
	FLS130042	16	3/8" Opta® SFT female	- NA		¹ / ₄ " ID Silicone TuFlux [®] 100 mm (4") + Luer Lock female +
	FLS130039	16	3/8" MPC female + sealing cap	NA .		
10 L	FLS130025	8	Sartopore® 2 XLG 0.8 0.2 μm	MidiCaps [®] size 7	3/8" × 5/8" C-Flex® +	
	FLS130043	8	3/8" Opta® SFT female	- NA	3/8" MPC male +	
	FLS130040	8	3/8" MPC female + sealing cap	- NA	sealing cap	Clave connector
20 L	FLS130026	8	Sartopore [®] 2 XLG 0.8 0.2 μm	MidiCaps [®] size 7		
	FLS130044	8	3/8" 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		
	FLS130148	8	3/8" Opta® SFT female	- NA		
	FLS130146	8	3/8" MPC female + sealing cap	- IVA		

 $^{^1}$ Inlet tubing line from end line to bag: $3/8" \times 5/8"$ Clear C-Flex $^{\circ}$ 500 mm (20") + Clipster $^{\circ}$ in a separate pouch

² Outlet tubing line from bag to end line: 3/8" × 5/8" Clear C-Flex® 500 mm (20")

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Selection Map

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Cell Harvest & Downstream Intermediates

Flexsafe®

000

Inlet Line

Sartopore® 2 XLG 0.8 | 0.2 µm

Opta® SFT female

MPC quick coupler female with sealing cap or C-Flex® tube for sterile weld with BioWelder® TC

Quick Coupler Connection to Downstream Systems

			Inlet ¹		Outlet ²	Sampling
Bag volume	Part number	Units per box	Filter or distal connector on filling line	Filter type 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	³/8" Opta® SFT female	– NA		
	FLS130145	16	3/8" MPC female + sealing cap	- NA		
5 L	FLS130018	16	Sartopore® 2 XLG 0.8 0.2 μm	MidiCaps [®] size 4		
	FLS130042	16	3/8" Opta® SFT female	– NA		1/4" ID Silicone TuFlux [®] 100 mm (4") + Luer Lock female +
	FLS130039	16	3/8" MPC female + sealing cap	- NA		
10 L	FLS130025	8	Sartopore® 2 XLG 0.8 0.2 μm	MidiCaps [®] size 7	3/8" × 5/8" C-Flex® +	
	FLS130043	8	3/8" Opta® SFT female	- NA	3/8" MPC male +	
	FLS130040	8	3/8" MPC female + sealing cap	- NA	sealing cap	Clave connector
20 L	FLS130026	8	Sartopore® 2 XLG 0.8 0.2 μm	MidiCaps [®] size 7		
	FLS130044	8	³/8" Opta [®] SFT female	– NA		
	FLS130041	8	3/8" MPC female + sealing cap	- NA		
50 L	FLS130138	8	Sartopore® 2 XLG 0.8 0.2 μm	MidiCaps [®] size 7		
	FLS130148	8	3/8" Opta® SFT female	– NA		
	FLS130146	8	3/8" MPC female + sealing cap	IVA		

 $^{^{1}}$ Inlet tubing line from end line to bag: $3/8" \times 5/8"$ Clear C-Flex $^{\circ}$ 500 mm (20") + Clipster $^{\circ}$ in a separate pouch

 $^{^2}$ Outlet tubing line from bag to end line: $3/8" \times 5/8"$ Clear C-Flex $^{\circ}$ 500 mm (20")

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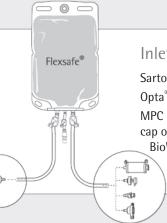
Cell Harvest & Downstream Intermediates

Sterile Connection Cell Harvest to Downstream Systems Sterile Weld & Downstream Sanitary or Aseptic Connection Intermediates to Downstream Systems Tri-Clamp Connection

Sterile Connection **Quick Coupler Connection**

Outlet Line

Tri-Clamp flange for sanitary or aseptic connection



Inlet Line

Sartopore[®] 2 0.45 | 0.2 μm Opta® SFT female

MPC quick coupler female with sealing cap or C-Flex® tube for sterile weld with BioWelder® TC

> Tri-Clamp flange for sanitary or aseptic connection

Tri-Clamp Connection to Downstream Systems

		Inlet ¹		Outlet ²	Sampling
Part	Units	Filter or distal	Filter type	Distal connector	Sampling line
number	per box			on draining line	
FLS130132	16		MidiCaps [®] size 4		
FLS130165	16	3/8" Opta® SFT female	_		
FLS130163	16	3/8" MPC female + sealing cap	NA		
FLS130191	16	3/8" Tri-Clamp 3/4" sanitary flange with gasket, cap & union ³			
FLS130019	16	Sartopore [®] 2 XLG 0.8 0.2 μm	MidiCaps [®] size 4		
FLS130069	16	3/8" Opta® SFT female			
FLS130066	16	3/8" MPC female + sealing cap	NA		
FLS130108	16	3/8" Tri-Clamp 3/4" sanitary flange with gasket, cap & union ³			
FLS130027	8	Sartopore [®] 2 XLG 0.8 0.2 μm	MidiCaps® size 7	3/8" Tri-Clamp	1/4" ID Silicone
FLS130070	8	3/8" Opta® SFT female		³/4" sanitary flange	TuFlux® 100 mm (4") +
FLS130067	8	3/8" MPC female + sealing cap	NA	with gasket,	Luer Lock female +
FLS130109	8	3/8" Tri-Clamp 3/4" sanitary flange with gasket, cap & union ³		cap & union	Clave connector
FLS130028	8	Sartopore [®] 2 XLG 0.8 0.2 μm	MidiCaps [®] size 7		olare connector
FLS130071	8	³/8" Opta® SFT female			
FLS130068	8	3/8" MPC female + sealing cap	NA		
FLS130110	8	3/8" Tri-Clamp 3/4" sanitary flange with gasket, cap & union ³			
FLS130139	8	Sartopore [®] 2 XLG 0.8 0.2 μm	MidiCaps [®] size 7		
FLS130166	8	3/8" Opta® SFT female			
FLS130164	8	3/8" MPC female + sealing cap	NA		
FLS130192	8	3/8" Tri-Clamp 3/4" sanitary flange with gasket, cap & union3	_		
	FLS130165 FLS130165 FLS130163 FLS130191 FLS130069 FLS130066 FLS130027 FLS130070 FLS130067 FLS130028 FLS130071 FLS130068 FLS130110 FLS130139 FLS130166 FLS130164	number per box FLS130132 16 FLS130165 16 FLS130163 16 FLS130191 16 FLS130019 16 FLS130066 16 FLS130108 16 FLS130027 8 FLS130067 8 FLS130069 8 FLS130070 8 FLS130067 8 FLS130109 8 FLS130068 8 FLS130110 8 FLS130139 8 FLS130166 8 FLS130164 8	Part number Units per box Filter or distal connector on filling line FLS130132 16 Sartopore® 2 XLG 0.8 0.2 μm FLS130165 16 ¾8" Opta® SFT female FLS130163 16 ¾8" MPC female + sealing cap FLS130191 16 ¾8" MPC female + sealing with gasket, cap & union³ FLS130019 16 Sartopore® 2 XLG 0.8 0.2 μm FLS130069 16 ¾8" Opta® SFT female FLS130108 16 ¾8" MPC female + sealing cap FLS130108 16 ¾8" Tri-Clamp ¾4" sanitary flange with gasket, cap & union³ FLS130070 8 Sartopore® 2 XLG 0.8 0.2 μm FLS130070 8 ¾8" Opta® SFT female FLS130109 8 ¾8" MPC female + sealing cap FLS130028 8 Sartopore® 2 XLG 0.8 0.2 μm FLS130071 8 ¾8" Opta® SFT female FLS130110 8 ¾8" Opta® SFT female FLS130110 8 ¾8" Opta® SFT female FLS130166 8 ¾8" Opta® SFT female FLS130164 8 ¾8" Opta® SFT female	Part number Units per box per box Filter or distal connector on filling line Filter type and size FLS130132 16 Sartopore® 2 XLG 0.8 0.2 μm MidiCaps® size 4 FLS130165 16 ¾8" Opta® SFT female NA FLS130163 16 ¾8" MPC female + sealing cap NA FLS130191 16 ¾8" Tri-Clamp ¾4" sanitary flange with gasket, cap & union³ MidiCaps® size 4 FLS130069 16 ¾8" Opta® SFT female NA FLS130060 16 ¾8" MPC female + sealing cap NA FLS130108 16 ¾8" Tri-Clamp ¾4" sanitary flange with gasket, cap & union³ NA FLS130070 8 Sartopore® 2 XLG 0.8 0.2 μm MidiCaps® size 7 FLS130070 8 ¾8" Opta® SFT female NA FLS130090 8 ¾8" MPC female + sealing cap NA FLS130010 8 ¾8" Tri-Clamp ¾4" sanitary flange with gasket, cap & union³ NA FLS130071 8 ¾8" Opta® SFT female NA FLS130110 8 ¾8" MPC female + sealing cap NA FLS130116	Part number per box Filter or distal connector on filling line Sartopore* 2 XLG 0.8 0.2 μm MidiCaps* size 4 FLS130165 16 3/8 " Opta* SFT female FLS130163 16 3/8 " MPC female + sealing cap NA FLS130191 16 Sartopore* 2 XLG 0.8 0.2 μm MidiCaps* size 4 FLS130019 16 Sartopore* 2 XLG 0.8 0.2 μm MidiCaps* size 4 FLS130069 16 3/8 " MPC female + sealing cap NA FLS130060 16 3/8 " MPC female + sealing cap NA FLS130070 8 Sartopore* 2 XLG 0.8 0.2 μm MidiCaps* size 7 FLS130070 8 Sartopore* 2 XLG 0.8 0.2 μm MidiCaps* size 7 FLS130070 8 3/8 " Opta* SFT female FLS130070 8 3/8 " MPC female + sealing cap NA FLS130070 8 3/8 " MPC female + sealing cap NA FLS130070 8 3/8 " Tri-Clamp 3/4" sanitary flange with gasket, cap & union NA FLS130070 8 3/8 " MPC female + sealing cap NA FLS130071 8 3/8 " Tri-Clamp 3/4" sanitary flange with gasket, cap & union NA FLS130071 8 3/8 " MPC female + sealing cap NA FLS130071 8 3/8 " MPC female + sealing cap NA FLS130071 8 3/8 " MPC female + sealing cap NA FLS130071 8 3/8 " MPC female + sealing cap NA FLS130071 8 3/8 " MPC female + sealing cap NA FLS130071 8 3/8 " MPC female + sealing cap NA FLS130108 8 Sartopore* 2 XLG 0.8 0.2 μm MidiCaps* size 7 FLS130108 8 Sartopore* 2 XLG 0.8 0.2 μm MidiCaps* size 7 FLS130108 8 Sartopore* 2 XLG 0.8 0.2 μm MidiCaps* size 7 FLS130166 8 3/8 " Opta* SFT female MidiCaps* size 7 FLS130166 8 3/8 " MPC female + sealing cap NA FLS130166 8 3/8 " Opta* SFT female MidiCaps* size 7 FLS130166 8 3/8 " Opta* SFT female MidiCaps* size 7 FLS130166 8 3/8 " Opta* SFT female MidiCaps* size 7 FLS130166 8 3/8 " Opta* SFT female MidiCaps* size 7 FLS130166 8 3/8 " Opta* SFT female MidiCaps* size 7 FLS130166 8 3/8 " Opta* SFT female MidiCaps* size 7 FLS130166

¹ Inlet tubing line from end line to bag: 3/8" × 5/8" Clear C-Flex® 500 mm (20") + Clipster[®] in a separate pouch

² Outlet tubing line from bag to end line: 3/8" TuFlux® SIL 300 mm (12")

³ 3/8" TuFlux[®] SIL 300 mm (12") for design with two Tri-Clamps

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Cell Harvest & Downstream Intermediates Filtration, Storage and Shipping

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Cell Harvest & Downstream Intermediates

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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 Weld

Quick Coupler Connection

Tri-Clamp Connection

Sterile Connection

Flexsafe® 3D solutions for cell harvest & downstream intermediates are available with Sartopore® 2 XLG $0.8 \mid 0.2 \mu m$ 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



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 single-use system
- Tri-Clamp flange for sanitary or aseptic connection to stainless steel system

Inlet line

 C-Flex[®] tube for sterile weld with BioWelder[®] TC

Clarification and sterile filtration

from bioreactor or any downstream

purification step before cross-flow

- Sartopore[®] 2 XLG 0.8 | 0.2 μm

Connection for alternative filter

- MPX quick coupler female

Buffer Flexsafe® 2D | Flexsafe® 3D Flexsafe[®] ≥ 1,000 L

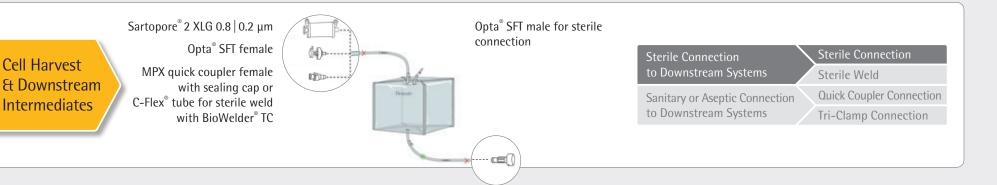
Cell Harvest & DSP Flexsafe[®] **2D** Flexsafe[®] **3D** Flexsafe[®] ≥ 1,000 L

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

Drug Product Flexsafe® **2D** Flexsafe® 3D

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



Sterile Connection to Downstream Systems

			Inlet ¹	Inlet ¹	
Bag volume	Part number	Units per box	Filter or distal connector on filling line	Filter type and size	Distal connector on outlet line
100 L	FIS126698	2	Sartopore [®] 2 XLG 0.8 0.2 μm	MidiCaps [®] size 9	
	FIS126718	3	½" Opta® SFT female	- NA	
	FIS126746	3	MPX female + sealing cap	- NA	
200 L	FIS126699	2	Sartopore® 2 XLG 0.8 0.2 µm	MidiCaps [®] size 0	
	FIS126719	3	½" Opta® SFT female	- NA	½" Opta® SFT male
	FIS126747	3	MPX female + sealing cap	- NA	
500 L	FIS126700	2	Sartopore® 2 XLG 0.8 0.2 µm	MaxiCaps [®] size 1 T-style	
	FIS126720	3	½" Opta® SFT female	- NA	
	FIS126748	3	MPX female + sealing cap	IVA	

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

² 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 Flexsafe® 2D Flexsafe® 3D Flexsafe[®] ≥ 1,000 L

Buffer Flexsafe® 2D | Flexsafe® 3D Flexsafe[®] ≥ 1,000 L

Cell Harvest & DSP Flexsafe[®] **2D** Flexsafe[®] **3D** Flexsafe[®] ≥ 1,000 L

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

Drug Product Flexsafe® **2D** Flexsafe® 3D

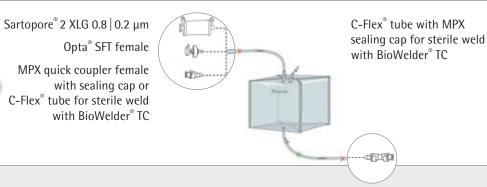
Cell Harvest & Downstream Intermediates Filtration, Storage and Shipping in Palletank

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Opta® SFT female MPX quick coupler female with sealing cap or C-Flex® tube for sterile weld with BioWelder® TC



Sterile Connection Sterile Connection Sterile Weld **Quick Coupler Connection** Sanitary or Aseptic Connection to Downstream Systems Tri-Clamp Connection

Sterile Weld to Downstream Systems

			Inlet ¹		Outlet ²	
Bag volume	Part number	Units per box	Filter or distal connector on filling line	Filter type and size	Distal connector on outlet line	
100 L	FIS126767	2	Sartopore®XLG 0.8 0.2 µm	MidiCaps [®] size 9		
	FIS126742	3	½" Opta® SFT female	NΙΔ		
	FIS126489	3	MPX female + sealing cap	— NA		
200 L	FIS126768	2	Sartopore® XLG 0.8 0.2 µm	MidiCaps [®] size 0	1/2" × 3/4" Clear C-Flex® + MPX male	
	FIS126743	3	½" Opta® SFT female	NΙΛ	+ MPX double female	
	FIS126490	3	MPX female + sealing cap	— NA	+ sealing cap	
500 L	FIS126769	2	Sartopore® XLG 0.8 0.2 µm	MaxiCaps [®] size 1 T-style		
	FIS126744	3	½" Opta® SFT female	— NA		
	FIS126491	3	MPX female + sealing cap	— IVA		

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

² 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

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Sartopore® 2 XLG 0.8 | 0.2 µm

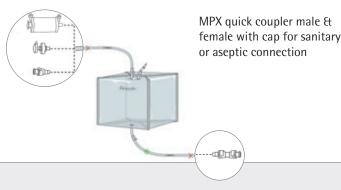
Opta® SFT female

MPX quick coupler female

with sealing cap or

C-Flex® tube for sterile weld

with BioWelder® TC



Sterile Connection
to Downstream Systems

Sterile Connection
Sterile Weld

Ouick Coupler Connection
to Downstream Systems

Tri-Clamp Connection

Quick Coupler Connection to Downstream Systems

			Inlet ¹	Inlet ¹	
Bag volume	Part number	Units per box	Filter or distal connector on filling line	Filter type and size	Distal connector on draining line
100 L	FIS126767	2	Sartopore® 2 XLG 0.8 0.2 µm	MidiCaps [®] size 9	
	FIS126742	3	½" Opta® SFT female	NIA	
	FIS126489	3	MPX female + sealing cap	— NA	1/2" MPX male
200 L	FIS126768	2	Sartopore® 2 XLG 0.8 0.2 µm	MidiCaps [®] size 0	
	FIS126743	3	½" Opta® SFT female	NIA	+ MPX double female + sealing cap
	FIS126490	3	MPX female + sealing cap	— NA	+ scaling cap
500 L	FIS126769	2	Sartopore® 2 XLG 0.8 0.2 µm	MaxiCaps [®] size 1 T-style	
	FIS126744	3	1/2" Opta® SFT female	— NA	
	FIS126491	3	MPX female + sealing cap	— IVA	

 $^{^{1}}$ Inlet tubing line from end line to bag: $\frac{1}{2}$ " × $\frac{3}{4}$ " C-Flex $^{\circ}$ 0.5 m (20") + $\frac{1}{2}$ " ID Silicone TuFlux $^{\circ}$ 1 m (40")

² 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[®] ≥ 1,000 L

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

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Cell Harvest & Downstream Intermediates Sartopore® 2 XLG 0.8 | 0.2 µm

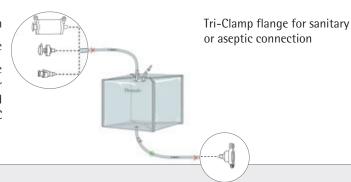
Opta® SFT female

MPX quick coupler female

with sealing cap or

C-Flex® tube for sterile weld

with BioWelder® TC



Sterile Connection
to Downstream Systems

Sterile Connection
Sterile Weld

Quick Coupler Connection
to Downstream Systems

Tri-Clamp Connection

Tri-Clamp Connection to Downstream Systems

			Inlet ¹		Outlet ²
Bag volume	Part number	Units per box	Filter or distal connector on filling line	Filter type and size	Distal connector on draining line
100 L	FIS126759	2	Sartopore®XLG 0.8 0.2 µm	MidiCaps [®] size 9	- ½" Tri-Clamp 1½" - sanitary flange with gasket, cap & union
	FIS126738	3	½" Opta® SFT female	— NA	
	FIS126255	3	MPX female + sealing cap		
200 L	FIS126760	2	Sartopore® XLG 0.8 0.2 µm	MidiCaps [®] size 0	
	FIS126739	3	½" Opta® SFT female	— NA	
	FIS126256	3	MPX female + sealing cap		
500 L	FIS126761	2	Sartopore® XLG 0.8 0.2 µm	MaxiCaps [®] size 1 T-style	
	FIS126740	3	½" Opta® SFT female	NΛ	
	FIS126257	3	MPX female + sealing cap	— NA	

 $^{^{1}}$ Inlet tubing line from end line to bag: $\frac{1}{2}$ " \times $\frac{3}{4}$ " Clear C-Flex $^{\circ}$ 0.5 m (20") + $\frac{1}{2}$ " ID Silicone TuFlux $^{\circ}$ 1 m (40")

² Outlet tubing line from bag to end line: ½" ID Silicone TuFlux® 1,5 m (60")

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Cell Harvest

Cell Harvest & Downstream Intermediates Filtration and Storage in Palletank

Sartopore® 2 XLG 0.8 | 0.2 μm Opta® SFT female **Sterile Connection** Sterile Connection MPX quick coupler female to Downstream Systems Sterile Weld & Downstream with sealing cap or **Quick Coupler Connection** Sanitary or Aseptic Connection C-Flex® tube for sterile weld Intermediates to Downstream Systems Tri-Clamp Connection Opta® SFT male for sterile with BioWelder® TC connection (14)n

Sterile Connection to Downstream Systems

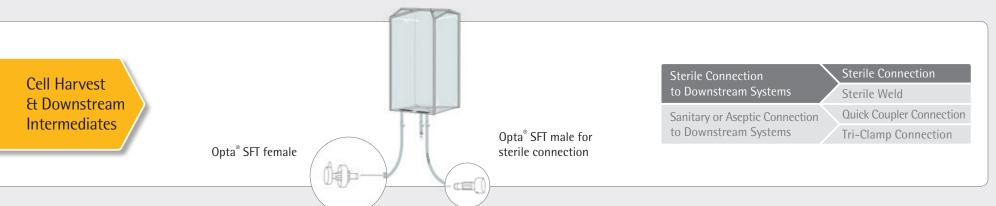
			Inlet ¹		Outlet ²
Bag Volume	Part number	Units per box	Filter or distal connector on filling line	Filter type and size	Distal connector on draining line
1,000 L	FIS500273	2	Sartopore® 2 XLG	MaxiCaps [®] Size 2	
	FIS500290	2	½" Opta® SFT female	NΙΛ	
	FIS500300	2	MPX female + sealing cap	— NA	
1,500 L	FIS500281	2	Sartopore® 2 XLG	MaxiCaps [®] Size 2	
	FIS500291	2	½" Opta® SFT female		
	FIS500301	2	MPX female + sealing cap		
2,000 L	FIS500282	1	Sartopore® 2 XLG	MaxiCaps [®] Size 3	
	FIS500292	2	1/2" Opta® SFT female	- NA	½" Opta® SFT male
	FIS500302	2	MPX female + sealing cap		
2,500 L	FIS500283	1	Sartopore® 2 XLG	MaxiCaps [®] Size 3	
	FIS500293	1	½" Opta® SFT female	NΙΛ	
	FIS500303	1	MPX female + sealing cap	— NA	
3,000 L	FIS500284	1	Sartopore® 2 XLG	MaxiCaps [®] Size 3	
	FIS500294	1	½" Opta® SFT female	NΙΛ	
	FIS500304	1	MPX female + sealing cap	— NA	

¹Inlet tubing line from end line to bag: 1/2" × 3/4" Clear C-Flex[®] 1.5 m (60")

² Outlet tubing line from bag to end line: 1/2" ID Silicone TuFlux® 2,5 m (98") + $1/2" \times 3/4"$ Clear C-Flex[®] 0.5 m (20")

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Cell Harvest & Downstream Intermediates Filtration and Storage in Palletank



Sterile Connection to Downstream Systems – High Flow Rate

		Inlet ¹		Outlet ²	
Bag Volume	Part number	Units per box	Filter or distal connector on filling line	Filter type and size	Distal connector on draining line
1,000 L	FIS302278	2	³/4" Opta® SFT female	NA	
1,500 L	FIS302279	2	³/4" Opta® SFT female	NA	
2,000 L	FIS500275	2	³/4" Opta® SFT female	NA	3/4" Opta [®] SFT male
2,500 L	FIS500276	1	³/4" Opta® SFT female	NA	
3,000 L	FIS302282	1	³/4" Opta® SFT female	NA	

¹Inlet tubing line from connector Opta® to bag: ³/₄" x 1" Clear C-Flex® 1.5 m (60")

² 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")

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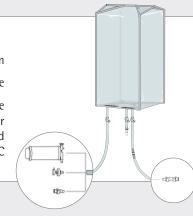
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Cell Harvest & Downstream Intermediates Filtration and Storage in Palletank

Sterile Connection

Cell Harvest & Downstream Intermediates

Sartopore® 2 XLG 0.8 | 0.2 μm Opta® SFT female MPX quick coupler female with sealing cap or C-Flex® tube for sterile weld with BioWelder® TC



C-Flex® tube with MPX sealing cap for sterile weld with BioWelder® TC

to Downstream Systems Sanitary or Aseptic Connection to Downstream Systems

Sterile Connection

Quick Coupler Connection Tri-Clamp Connection

Sterile Weld

Sterile Weld to Downstream Systems

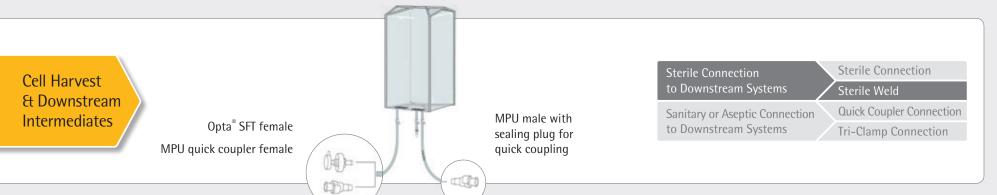
			Inlet ¹		Outlet ²
Bag Volume	Part number	Units per box	Filter or distal connector on filling line	Filter type and size	Distal connector on draining line
1,000 L	FIS500360	2	Sartopore® 2 XLG	MaxiCaps [®] Size 2	
	FIS500330	2	½" Opta [®] SFT female	NΙΔ	
	FIS302338	2	MPX female + sealing cap	— NA	
1,500 L	FIS500361	2	Sartopore® 2 XLG	MaxiCaps [®] Size 2	
	FIS500334	2	1/2" Opta® SFT female		
	FIS302339	2	MPX female + sealing cap		
2,000 L	FIS500362	1	Sartopore® 2 XLG	MaxiCaps [®] Size 3	1/2" × 3/4" C-Flex®
	FIS500331	2	½" Opta [®] SFT female	— NA	+ MPX male + MPX double female - + sealing cap
	FIS302340	2	MPX female + sealing cap		
2,500 L	FIS500363	1	Sartopore® 2 XLG	MaxiCaps [®] Size 3	1 Scannig Cap
	FIS500332	1	½" Opta® SFT female	NΙΛ	
	FIS302341	1	MPX female + sealing cap	— NA	
3,000 L	FIS500364	1	Sartopore® 2 XLG	MaxiCaps [®] Size 3	
	FIS500333	1	1/2" Opta® SFT female	NΙΔ	
	FIS302342	1	MPX female + sealing cap	— NA	

¹Inlet tubing line from end line to bag: $1/2" \times 3/4"$ Clear C-Flex[®] 1.5 m (60")

² Outlet tubing line from bag to end line: 1/2" ID Silicone TuFlux® 2,5 m (98") + $1/2" \times 3/4"$ Clear C-Flex[®] 0.5 m (20")

Back to Digital Selection Map

Cell Harvest & Downstream Intermediates Filtration and Storage in Palletank



Sterile Weld to Downstream Systems – High Flow Rate

			Inlet ¹		Outlet ²
Bag Volume	Part number	Units per box	Filter or distal connector on filling line	Filter type and size	Distal connector on draining line
1,000 L	FIS500375	2	³/4" Opta® SFT female	NA	
	FIS500365	2	MPU female + sealing cap		
1,500 L	FIS500376	2	³/4" Opta® SFT female	NA	
	FIS500366	2	MPU female + sealing cap		⁻ ³ /4" × 1" C-Flex [®] + MPU male
2,000 L	FIS500377	2	³/₄" Opta® SFT female	NA	
	FIS500367	2	MPU female + sealing cap		+ sealing cap
2,500 L	FIS500378	1	³/₄" Opta® SFT female	NA	– + scaming caρ
	FIS500368	1	MPU female + sealing cap		
3,000 L	FIS500379	1	³/₄" Opta® SFT female	NA	
	FIS500369	1	MPU female + sealing cap		

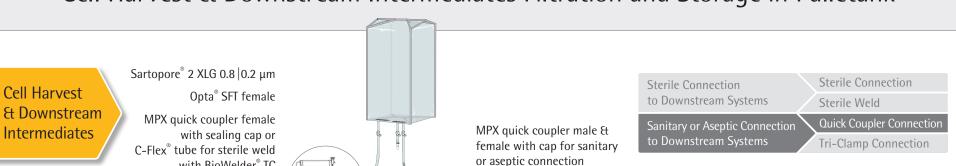
¹Inlet tubing line from connector to bag: ³/₄" x 1" Clear C-Flex[®] 1.5 m (60")

² Outlet tubing line from bag to end line: 3 /4" ID Silicone TuFlux $^{\circ}$ 2.5 m (98") + 3 /4" \times 1" Clear C-Flex $^{\circ}$ 0.5 m (20")

Back to Digital Selection Map

Cell Harvest & Downstream Intermediates Filtration and Storage in Palletank

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Quick Coupler Connection to Downstream Systems

with BioWelder® TC

			Inlet ¹		Outlet ²
Bag Volume	Part number	Units per box	Filter or distal connector on filling line	Filter type 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	
	FIS500334	2	1/2" Opta® SFT female		
	FIS302339	2	MPX female + sealing cap		
2,000 L	FIS500362	1	Sartopore® 2 XLG	MaxiCaps® Size 3	1/2" × 3/4" C-Flex®
	FIS500362	2	1/2" Opta® SFT female	NIA	+ MPX male + MPX double female + sealing cap
	FIS302340	2	MPX female + sealing cap	— NA	
2,500 L	FIS500363	1	Sartopore® 2 XLG	MaxiCaps [®] Size 3	r scannig cap
	FIS500332	1	½" Opta® SFT female	— NA	
	FIS302341	1	MPX female + sealing cap	- NA	
3,000 L	FIS500364	1	Sartopore® 2 XLG	MaxiCaps [®] Size 3	
	FIS500333	1	1/2" Opta® SFT female	NΛ	
	FIS302342	1	MPX female + sealing cap	— NA	

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¹Inlet tubing line from end line to bag: $1/2" \times 3/4"$ Clear C-Flex[®] 1.5 m (60")

² Outlet tubing line from bag to end line: 1/2" ID Silicone TuFlux® 2,5 m (98") + $1/2" \times 3/4"$ Clear C-Flex[®] 0.5 m (20")

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Cell Harvest & Downstream Intermediates Filtration and Storage in Palletank

Sterile Connection Sterile Connection Cell Harvest Opta® SFT female to Downstream Systems Sterile Weld & Downstream MPU quick coupler female Quick Coupler Connection Sanitary or Aseptic Connection MPU male with Intermediates with sealing cap or C-Flex® to Downstream Systems Tri-Clamp Connection sealing plug for tube for sterile weld with

quick coupling

Quick Coupler Connection to Downstream Systems - High Flow Rate

OF-

BioWelder® TC

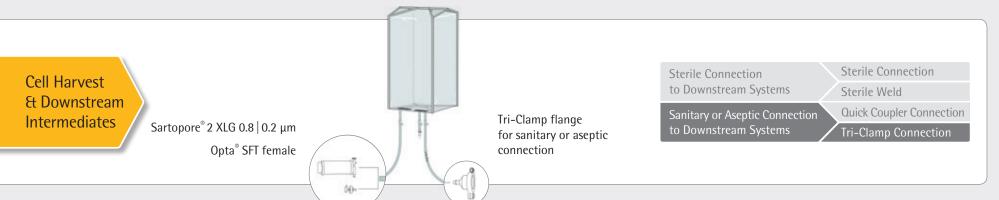
			Inlet ¹		Outlet ²
Bag Volume	Part number	Units per box	Filter or distal connector on filling line	Filter type and size	Distal connector on draining line
1,000 L	FIS500375	2	³/4" Opta® SFT female	NA	
	FIS500365	2	MPU female + sealing cap		
1,500 L	FIS500376	2	³/4" Opta® SFT female	NA	
	FIS500366	2	MPU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

¹Inlet tubing line from connector Opta® to bag: ³/₄" x 1" Clear C-Flex® 1.5 m (60")

² Outlet tubing line from bag to end line: 3 /4" ID Silicone TuFlux $^{\circ}$ 2.5 m (98") + 3 /4" \times 1" Clear C-Flex $^{\circ}$ 0.5 m (20")

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Cell Harvest & Downstream Intermediates Filtration and Storage in Palletank



Tri-Clamp Connection to Downstream Systems

			Inlet ¹		Outlet ²
Bag Volume	Part number	Units per box	Filter or distal connector on filling line	Filter type 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	W. II. ID. v. 1.3
2,000 L	FIS500342	1	Sartopore® 2 XLG	MaxiCaps® Size 3	1/2" ID tubing,
	FIS500352	2	½" Opta® SFT female	NA	Tri-Clamp 1 1/2 sanitary flange with gasket, cap & union
2,500 L	FIS500343	1	Sartopore® 2 XLG	MaxiCaps® Size 3	With gasket, cap et amon
	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	

¹Inlet tubing line from end line to bag: 1/2" × 3/4" Clear C-Flex[®] 1.5 m (60")

² Outlet tubing line from bag to end line: 1/2" ID Silicone TuFlux® 2,5 m (98") + $1/2" \times 3/4"$ Clear C-Flex[®] 0.5 m (20")

Flexsafe[®] ≥ 1,000 L

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Cell Harvest & Downstream Intermediates Filtration and Storage in Palletank



Tri-Clamp Connection to Downstream Systems – High Flow Rate

			Inlet ¹		Outlet ²
Bag Volume	Part number	Units per box	Filter or distal connector on filling line	Filter type and size	Distal connector on draining line
1,000 L	FIS500345	2	Sartopore® 2 XLG	MaxiCaps [®] Size 2	
	FIS500355	2	³/4" Opta® SFT female	NA	
1,500 L	FIS500346	2	Sartopore® 2 XLG	MaxiCaps [®] Size 2	
	FIS500356	2	³/4" Opta® SFT female	NA	
2,000 L	FIS500347	1	Sartopore® 2 XLG	MaxiCaps [®] Size 3	3/4" ID tubing,
	FIS500357	2	³/4" Opta® SFT female	NA	Tri-Clamp 1 1/2 sanitary flange with gasket, cap & union
2,500 L	FIS500348	1	Sartopore® 2 XLG	MaxiCaps [®] Size 3	with gasket, cap et umon
	FIS500358	1	³/4" Opta® SFT female	NA	
3,000 L	FIS500349	1	Sartopore® 2 XLG	MaxiCaps [®] Size 3	
	FIS500359	1	³/4" Opta® SFT female	NA	

¹Inlet tubing line from end line to bag with filter: $\frac{1}{2}$ " \times $\frac{3}{4}$ " Clear C-Flex $^{\circ}$ 1.5 m (60")

¹Inlet tubing line from connector to bag: ³/₄" x 1" Clear C-Flex[®] 1.5 m (60")

² Outlet tubing line from bag to end line: ³/₄" ID Silicone TuFlux[®] 3 m (118")

Media Flexsafe® 2D Flexsafe® 3D Flexsafe[®] ≥ 1.000 L

Buffer Flexsafe® 2D | Flexsafe® 3D Flexsafe[®] ≥ 1.000 L

Cell Harvest & DSP Flexsafe[®] **2D** Flexsafe[®] **3D** Flexsafe[®] ≥ 1,000 L

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

Drug Product Flexsafe® 2D Flexsafe® 3D

> Back to Digital Selection Map

Drug Substances

Drug Substance **Purification**

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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 Weld **Quick Coupler Connection**

Tri-Clamp Connection

Sterile 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 filter is installed on the inlet line to allow sterile 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.

Outlet Line

Connection and transfer by pumping or gravity

- Opta® SFT male for sterile connection
- C-Flex® tube for sterile weld with BioWelder® TC

Sampling

Clave needleless sampling port

- 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

- C-Flex[®] tube for sterile weld with
- BioWelder® TC

Inlet Line

Sterilizing Filtration

Sartopore® Platinum 0.45 | 0.2 μm

Connection for Alternative Filter Line

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

Media
Flexsafe® 2D | Flexsafe® 3D |
Flexsafe® ≥ 1,000 L

Buffer
Flexsafe® 2D | Flexsafe® 3D |
Flexsafe® ≥ 1,000 L

Cell Harvest & DSP
Flexsafe® 2D | Flexsafe® 3D |
Flexsafe® ≥ 1,000 L

Drug Substance
Flexsafe® 2D |
Flexsafe® 3D

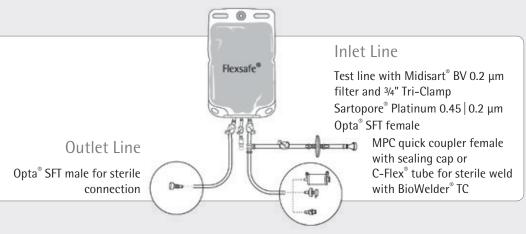
Drug Product
Flexsafe® 2D |
Flexsafe® 3D

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Drug Substances

Drug
Substance
Purification

Sterile Connection
to Downstream Systems
Sterile Weld
Sanitary or Aseptic Connection
to Downstream Systems
Tri-Clamp Connection



Sterile Connection to Downstream Systems

			Inlet ¹		Outlet ²	Sampling
Bag volume	Part number	Units per box	Filter or distal connector on filling line	Filter type 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	³/8" Opta® SFT female	- NA		
	FLS130181	16	3/8" MPC female + sealing cap			
5 L	FLS130074	16	Sartopore® Platinum 0.45 0.2 μm	MidiCaps [®] size 4		
	FLS130096	16	³/8" Opta® SFT female	NΙΛ		1/4" ID Silicone TuFlux® 100 mm (4") + Luer Lock female + Clave connector
	FLS130093	16	3/8" MPC female + sealing cap	– NA		
10 L	FLS130079	8	Sartopore [®] Platinum 0.45 0.2 μm	MidiCaps [®] size 7		
	FLS130097	8	³/8" Opta® SFT female	- NA	3/8" Opta® SFT male	
	FLS130094	8	3/8" MPC female + sealing cap	- NA		
20 L	FLS130080	8	Sartopore® Platinum 0.45 0.2 μm	MidiCaps [®] size 7		Giare connector
	FLS130098	8	³/8" Opta® SFT female	- NA		
	FLS130095	8	3/8" MPC female + sealing cap	- NA		
50 L	FLS130172	8	Sartopore® Platinum 0.45 0.2 μm	MidiCaps [®] size 7		
	FLS130184	8	³/8" Opta® SFT female	- NA		
	FLS130182	8	3/8" MPC female + sealing cap	- IVA		

1 Inlet tubing line from end line to bag: $3/8"\times5/8"$ Clear C-Flex $^{\circ}$ 500 mm (20") + Clipster $^{\circ}$ in a separate pouch

Leak Test Line

- ½" × ½" Clear C-Flex® 300 mm (12") + Midisart® BV 0.2 µm + ½" ID Silicone TuFlux® 100 mm (4") + ½" Tri-Clamp with gasket, cap & union

 $^{^2}$ Outlet tubing line from bag to end line: $3/8" \times 5/8"$ Clear C-Flex $^{\circ}$ 500 mm (20")

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Selection Map

Drug Substances

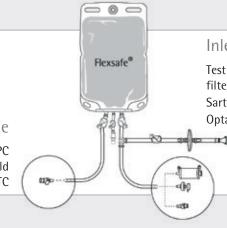
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Drug

Sterile Connection Sterile Connection to Downstream Systems Sterile Weld Substance **Quick Coupler Connection** Sanitary or Aseptic Connection Purification to Downstream Systems Tri-Clamp Connection

Outlet Line

C-Flex® tube with MPC sealing cap for sterile weld with BioWelder® TC



Inlet Line

Test line with Midisart® BV 0.2 μm filter and 3/4" Tri-Clamp Sartopore® Platinum 0.45 | 0.2 μm Opta® SFT female

> MPC quick coupler female with sealing cap or C-Flex® tube for sterile weld with BioWelder® TC

Sterile Weld to Downstream Systems

			Inlet ¹		Outlet ²	Sampling
Bag volume	Part number	Units per box	Filter or distal connector on filling line	Filter type 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	3/8" Opta® SFT female	- NA		
	FLS130177	16	3/8" MPC female + sealing cap	- NA		
5 L	FLS130072	16	Sartopore® Platinum 0.45 0.2 μm	MidiCaps [®] size 4		
	FLS130090	16	3/8" Opta® SFT female	- NA		1/4" ID Silicone TuFlux [®] 100 mm (4") + Luer Lock female + Clave connector
	FLS130087	16	3/8" MPC female + sealing cap	IVA		
10 L	FLS130075	8	Sartopore® Platinum 0.45 0.2 μm	MidiCaps [®] size 7	3/8" × 5/8" C-Flex® +	
	FLS130091	8	3/8" Opta® SFT female	- NA	3/8" MPC male + sealing cap	
	FLS130088	8	3/8" MPC female + sealing cap	- NA		
20 L	FLS130076	8	Sartopore® Platinum 0.45 0.2 μm	MidiCaps [®] size 7		
	FLS130092	8	3/8" Opta® SFT female	- NA		
	FLS130089	8	3/8" MPC female + sealing cap	- NA		
50 L	FLS130170	8	Sartopore® Platinum 0.45 0.2 μm	MidiCaps [®] size 7		
	FLS130180	8	³/8" Opta® SFT female	- NA		
	FLS130178	8	³ / ₈ " MPC female + sealing cap	IVA		

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

Leak Test Line

 $-1/4" \times 3/8"$ 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

² Outlet tubing line from bag to end line: 3/8" × 5/8" Clear C-Flex[®] 500 mm (20")

Media
Flexsafe® 2D | Flexsafe® 3D |

Flexsafe[®] ≥ 1,000 L

Buffer
Flexsafe® 2D | Flexsafe® 3D |
Flexsafe® ≥ 1,000 L

Cell Harvest & DSP
Flexsafe® 2D | Flexsafe® 3D |
Flexsafe® ≥ 1,000 L

Drug Substance
Flexsafe® 2D |
Flexsafe® 3D

Drug Product
Flexsafe® 2D |
Flexsafe® 3D

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Drug Cubstances

Drug Substances

Drug Substance Purification

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Sterile Connection to Downstream Systems

Sanitary or Aseptic Connection to Downstream Systems

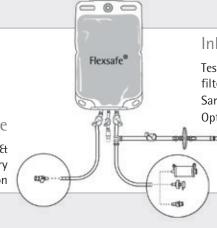
Sterile Connection
Sterile Weld

Quick Coupler Connection

Tri-Clamp Connection

Outlet Line

MPC quick coupler male & female with cap for sanitary or aseptic connection



Inlet Line

Test line with Midisart $^{\circ}$ BV 0.2 μ m filter and 3/4" Tri-Clamp Sartopore $^{\circ}$ Platinum 0.45 | 0.2 μ m Opta $^{\circ}$ SFT female

MPC quick coupler female with sealing cap or C-Flex® tube for sterile weld with BioWelder® TC

Quick Coupler Connection to Downstream Systems

			Inlet ¹		Outlet ²	Sampling
Bag volume	Part number	Units per box	Filter or distal connector on filling line	Filter type 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	³/8" Opta® SFT female	- NA		
	FLS130177	16	3/8" MPC female + sealing cap	- NA		
5 L	FLS130072	16	Sartopore® Platinum 0.45 0.2 μm	MidiCaps [®] size 4		
	FLS130090	16	³/8" Opta® SFT female	- NA		1/4" ID Silicone TuFlux® 100 mm (4") + Luer Lock female + Clave connector
	FLS130087	16	³ / ₈ " MPC female + sealing cap	IVA		
10 L	FLS130075	8	Sartopore® Platinum 0.45 0.2 μm	MidiCaps [®] size 7	3/8" × 5/8" C-Flex® +	
	FLS130091	8	³/8" Opta® SFT female	- NA	3/8" MPC male +	
	FLS130088	8	3/8" MPC female + sealing cap	IVA	sealing cap	
20 L	FLS130076	8	Sartopore® Platinum 0.45 0.2 μm	MidiCaps® size 7		
	FLS130092	8	³/8" Opta® SFT female	- NA		
	FLS130089	8	³ / ₈ " MPC female + sealing cap			
50 L	FLS130170	8	Sartopore® Platinum 0.45 0.2 μm	MidiCaps® size 7		
	FLS130180	8	3/8" Opta® SFT female	- NA		
	FLS130178	8	3/8" MPC female + sealing cap	IVA		

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

Leak Test Line

- ½" × ½" Clear C-Flex® 300 mm (12") + Midisart® BV 0.2 µm + ½" ID Silicone TuFlux® 100 mm (4") + ½" Tri-Clamp with gasket, cap & union

 $^{^2}$ Outlet tubing line from bag to end line: $3/8"\times5/8"$ Clear C-Flex $^{\circ}$ 500 mm (20")

Flexsafe[®] 2D | Flexsafe[®] 3D | Flexsafe[®] ≥ 1,000 L Buffer
Flexsafe® 2D | Flexsafe® 3D |
Flexsafe® ≥ 1,000 L

Cell Harvest & DSP
Flexsafe® 2D | Flexsafe® 3D |
Flexsafe® ≥ 1,000 L

Drug Substance
Flexsafe® 2D |
Flexsafe® 3D

Drug Product
Flexsafe® 2D |
Flexsafe® 3D

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Drug Substances

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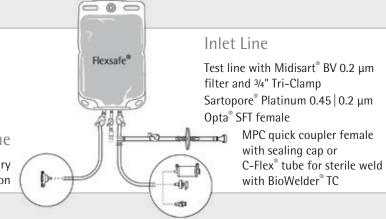
Drug
Substance
Purification

Sterile Connection
to Downstream Systems
Sterile Connection
Sterile Weld

Ouick Coupler Connection
to Downstream Systems
Tri-Clamp Connection

Outlet Line

Tri-Clamp flange for sanitary or aseptic connection



Tri-Clamp Connection to Downstream Systems

			Inlet ¹		Outlet ²	Sampling
Bag	Part	Units	Filter or distal	Filter type	Distal connector	Sampling line
volume	number	per box	connector on filling line	and size	on draining line	
3 L	FLS130168	16	Sartopore® Platinum 0.45 0.2 μm	MidiCaps [®] size 4		
	FLS130175	16	³/8" Opta® SFT female	- NA		
	FLS130173	16	³ / ₈ " MPC female + sealing cap			
5 L	FLS130073	16	Sartopore® Platinum 0.45 0.2 μm	MidiCaps [®] size 4		
	FLS130084	16	³/8" Opta® SFT female	- NA		¹ / ₄ " ID Silicone TuFlux [®] 100 mm (4") + Luer Lock female +
	FLS130081	16	³ / ₈ " MPC female + sealing cap			
10 L	FLS130077	8	Sartopore® Platinum 0.45 0.2 μm	MidiCaps [®] size 7	3/8" Tri-Clamp	
	FLS130085	8	3/8" Opta® SFT female	- NA	3/4" sanitary flange with gasket,	
	FLS130082	8	³ / ₈ " MPC female + sealing cap	IVA	cap & union	Clave connector
20 L	FLS130078	8	Sartopore® Platinum 0.45 0.2 μm	MidiCaps [®] size 7	P	
	FLS130086	8	³/8" Opta® SFT female	- NA		
	FLS130083	8	³ / ₈ " MPC female + sealing cap	IVA		
50 L	FLS130171	8	Sartopore® Platinum 0.45 0.2 μm	MidiCaps [®] size 7		
	FLS130176	8	³ / ₈ " Opta [®] SFT female	- NA		
	FLS130174	8	3/8" MPC female + sealing cap	INA		

 $^{^1}$ Inlet tubing line from end line to bag: $3/8"\times5/8"$ Clear C-Flex $^{\circ}$ 500 mm (20") + Clipster $^{\circ}$ in a separate pouch

Leak Test Line

- ½" × ½" Clear C-Flex® 300 mm (12") + Midisart® BV 0.2 µm + ½" ID Silicone TuFlux® 100 mm (4") + ½" Tri-Clamp with gasket, cap & union

 $^{^2}$ Outlet tubing line from bag to end line: $3/8" \times 5/8"$ TuFlux $^{\circ}$ SIL 300 mm (12")

Media
Flexsafe® 2D | Flexsafe® 3D |
Flexsafe® ≥ 1.000 L

Buffer

Flexsafe® 2D | Flexsafe® 3D |

Flexsafe® ≥ 1,000 L

Cell Harvest & DSP
Flexsafe® 2D | Flexsafe® 3D |
Flexsafe® ≥ 1,000 L

Drug Substance
Flexsafe® 2D |
Flexsafe® 3D

Flexsafe® 2D | Flexsafe® 3D

Drug Product

Duran Carlostonese Filturations Cto

Drug Substance Filtration, Storage and Shipping

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Drug Substance Purification

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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

- Needleless sampling port

Sampling

2×20" Filters | 1×20" Sartopore Platinum | 1×20 L Flushing Bag

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

Flexsafe® PDS for drug substance feature the Sartopore® Platinum 0.45 \mid 0.2 μ m 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® 1/2" 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 single-use system
- Tri-Clamp flange for sanitary or aseptic connection to stainless steel system

Drug

Substance

Purification

Media
Flexsafe® 2D | Flexsafe® 3D |
Flexsafe® ≥ 1,000 L

Buffer
Flexsafe® 2D | Flexsafe® 3D |
Flexsafe® ≥ 1,000 L

Cell Harvest & DSP
Flexsafe® 2D | Flexsafe® 3D |
Flexsafe® ≥ 1,000 L

Drug Substance
Flexsafe® 2D |
Flexsafe® 3D

Drug Product
Flexsafe® 2D |
Flexsafe® 3D

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Drug Substance Filtration, Storage and Shipping in Palletank

Sartopore® Platinum Test line with Sartopore® Air 0.45 | 0.2 μm filter 0.2 µm allowing the **Sterile Connection** connection to the Sartocheck® 4 Sterile Connection Opta® SFT female + bag tester up to 500 L to Downstream Systems Sterile Weld MPX quick coupler female **Quick Coupler Connection** Sanitary or Aseptic Connection with sealing cap or Opta® SFT male for sterile to Downstream Systems Tri-Clamp Connection C-Flex® tube for sterile weld connection with BioWelder® TC <E()

Sterile Connection to Downstream Systems

			Inlet ¹		Outlet ²	
Bag volume	Part number	Units per box	Filter or distal connector on filling line	Filter type 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	NIA		
	FIS301531	3	MPX female + sealing cap	— NA		
200 L	FIS126793	2	Sartopore® Platinum 0.45 0.2 μm	MidiCaps [®] size 8		
	FIS301535	3	½" Opta® SFT female	NIA	½" Opta [®] SFT male	
	FIS301536	3	MPX female + sealing cap	— NA		
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	IVA		

 1 Inlet tubing line from end line to bag: $\frac{1}{2}$ " \times $\frac{3}{4}$ " Clear C-Flex $^{\circ}$ 0.5 m (20") + $\frac{1}{2}$ " ID Silicone TuFlux $^{\circ}$ 1 m (40")

Leak Test Line

 $- \frac{1}{2}$ " $\times \frac{3}{4}$ " Clear C-Flex $^{\circ}$ 1,500 mm (59") + Sartopore $^{\circ}$ Air filter 0.2 μ m size 7 (Inlet 1 $\frac{1}{2}$ " tri-clamp) up to 500 L



² 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[®] ≥ 1,000 L

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Drug Substance Filtration, Storage and Shipping in Palletank

Drug Substance Purification

Sartopore® Platinum 0.45 | 0.2 μm Opta® SFT female MPX quick coupler female

with sealing cap or C-Flex® tube for sterile weld with BioWelder® TC

Test line with Sartopore® Air filter 0.2 µm allowing the connection to the Sartocheck® 4 + bag tester up to 500 L

C-Flex® tube with MPX sealing cap for sterile weld with BioWelder® TC

Sterile Connection to Downstream Systems

Sanitary or Aseptic Connection to Downstream Systems

Sterile Connection Sterile Weld

Quick Coupler Connection Tri-Clamp Connection

Sterile Weld to Downstream Systems

			Inlet ¹		Outlet ²
Bag volume	Part number	Units per box	Filter or distal connector on filling line	Filter type 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	— IVA	
200 L	FIS126789	2	Sartopore® Platinum 0.45 0.2 μm	MidiCaps [®] size 8	1/2" × 3/4" C-Flex® + MPX male
	FIS301537	3	½" Opta® SFT female	NIA	+ MPX double female
	FIS300132	3	MPX female + sealing cap	— NA	+ sealing cap
500 L	FIS126790	2	Sartopore® Platinum 0.45 0.2 μm	MidiCaps [®] size 9	
	FIS301544	3	1/2" Opta® SFT female	— NA	
	FIS300133	3	MPX female + sealing cap	— IVA	

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



² 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

Purification

Media
Flexsafe® 2D | Flexsafe® 3D |
Flexsafe® ≥ 1,000 L

Buffer
Flexsafe® 2D | Flexsafe® 3D |
Flexsafe® ≥ 1,000 L

Cell Harvest & DSP
Flexsafe® 2D | Flexsafe® 3D |
Flexsafe® ≥ 1,000 L

Drug Substance
Flexsafe® 2D |
Flexsafe® 3D

Sterile Connection

Quick Coupler Connection

Tri-Clamp Connection

Sterile Weld

Drug Product
Flexsafe® 2D |
Flexsafe® 3D

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Drug Substance Filtration, Storage and Shipping in Palletank

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

Quick Coupler Connection to Downstream Systems

			Inlet ¹		Outlet ²	
Bag volume	Part number	Units per box	Filter or distal connector on filling line	Filter type 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	- IVA		
200 L	FIS126789	2	Sartopore® Platinum 0.45 0.2 μm	MidiCaps [®] size 8	1/2" × 3/4" C-Flex® + MPX male	
	FIS301537	3	½" Opta® SFT female	NΙΛ	+ MPX double female	
	FIS300132	3	MPX female + sealing cap	— NA	+ sealing cap	
500 L	FIS126790	2	Sartopore® Platinum	MidiCaps®		
			0.45 0.2 μm	size 9		
	FIS301544	3	1/2" Opta® SFT female	— NA		
	FIS300133	3	MPX female + sealing cap	IVA		

 1 Inlet tubing line from end line to bag: $\frac{1}{2}$ " \times $\frac{3}{4}$ " Clear C-Flex $^{\circ}$ 0.5 m (20") + $\frac{1}{2}$ " ID Silicone TuFlux $^{\circ}$ 1 m (40")



 $^{^2}$ Outlet tubing line from bag to end line: $\frac{1}{2}$ " ID Silicone TuFlux $^{\circ}$ 1 m (40") + $\frac{1}{2}$ " \times $\frac{3}{4}$ " Clear C-Flex $^{\circ}$ 0.5 m (20")

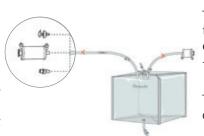
Drug Substance Filtration, Storage and Shipping in Palletank

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Drug Substance Purification Sartopore® Platinum $0.45\,|\,0.2~\mu m$

Opta® SFT female

MPX quick coupler female with sealing cap or C-Flex® tube for sterile weld with BioWelder® TC



Test line with Sartopore® Air filter 0.2 µm allowing the connection to the Sartocheck® 4 + bag tester up to 500 L

Tri-Clamp flange for sanitary or aseptic connection

Sterile Connection to Downstream Systems

Sanitary or Aseptic Connection to Downstream Systems

Sterile Weld **Quick Coupler Connection**

Tri-Clamp Connection

Sterile Connection

Tri-Clamp Connection to Downstream Systems

			Inlet ¹		Outlet ²
Bag volume	Part number	Units per box	Filter or distal connector on filling line	Filter type 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	NΙΛ	
	FIS301534	3	MPX female + sealing cap	— NA	
200 L	FIS126781	2	Sartopore® Platinum 0.45 0.2 μm	MidiCaps [®] size 8	1/2" Tri-Clamp 11/2"
	FIS301538	3	½" Opta® SFT female	NΙΛ	sanitary flange with gasket, cap & union
	FIS301539	3	MPX female + sealing cap	— NA	cap ct union
500 L	FIS126782	2	Sartopore® Platinum 0.45 0.2 μm	MidiCaps [®] size 9	
	FIS301545	3	½" Opta® SFT female	NΛ	
	FIS301546	3	MPX female + sealing cap	— NA	

¹ Inlet tubing line from end line to bag: ½2" × ¾4" Clear C-Flex® 0.5 m (20") + ½2" ID Silicone TuFlux® 1 m (40")



² Outlet tubing line from bag to end line: ½" ID Silicone TuFlux® 1,5 m (60")

Media
Flexsafe® 2D | Flexsafe® 3D |
Flexsafe® ≥ 1,000 L

Buffer
Flexsafe® 2D | Flexsafe® 3D |
Flexsafe® ≥ 1,000 L

Cell Harvest & DSP Flexsafe® 2D | Flexsafe® 3D | Flexsafe® ≥ 1,000 L Drug Substance
Flexsafe® 2D |
Flexsafe® 3D

Drug Product
Flexsafe® 2D |
Flexsafe® 3D

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Drug Product Formulation

Drug Product Formulation

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Sterilizing Filtration

Drug Product Storage Drug Product Transfer Sterile Connection to Final Filling

Sterile Connection
Sterile Weld

Flexsafe $^{\circ}$ 2D advanced solutions for drug product feature the Sartopore $^{\circ}$ 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.

Test line with Midisart® BV 0.2 μm filter are 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 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.

Outlet Line

Connection and transfer by pumping or gravity

- Opta® SFT male for sterile connection
- C-Flex® tube for sterile weld with BioWelder® TC



Clave needleless sampling port

 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

use leak test with FlexAct® BT

- C-Flex® tube for sterile weld with
BioWelder® TC

filter and 1/4" Tri-Clamp for point of

Inlet Line

Sterilizing Filtration

- Sartopore® Platinum 0.45 | 0.2 μm

Connection for Alternative Filter Line

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



Flexsafe[®] 2D | Flexsafe[®] 3D | Flexsafe[®] ≥ 1,000 L Buffer
Flexsafe® 2D | Flexsafe® 3D |
Flexsafe® ≥ 1,000 L

Cell Harvest & DSP
Flexsafe® 2D | Flexsafe® 3D |
Flexsafe® ≥ 1,000 L

Drug Substance
Flexsafe® 2D |
Flexsafe® 3D

Drug Product
Flexsafe® 2D |
Flexsafe® 3D

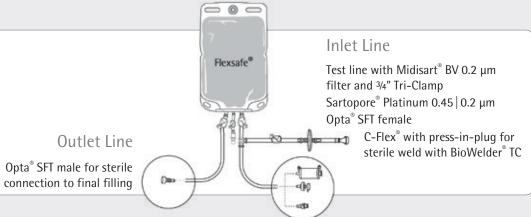
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Drug Product Formulation

Drug Product
Formulation

Sterile Connection
to Final Filling

Sterile Weld



Sterile Connection to Final Formulation & Filling

			Inlet ¹		Outlet ²	Sampling	
Bag volume	Part number	Units per box	Filter or distal connector on filling line	Filter type 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	³/8" Opta® SFT female	NA			
5 L	FLS130099	16	Sartopore [®] Platinum 0.45 0.2 μm	MidiCaps [®] size 4			
	FLS130102	16	³/8" Opta® SFT female	NA		1/4" ID Silicone TuFlux®	
10 L	FLS130100	8	Sartopore [®] Platinum 0.45 0.2 μm	MidiCaps [®] size 7	3/8" Opta [®] SFT male	100 mm (4") +	
	FLS130103	8	³/8" Opta® SFT female	NA	3/8 Opta SFI male	Luer Lock female +	
20 L	FLS130101	8	Sartopore [®] Platinum 0.45 0.2 μm	MidiCaps [®] size 7		Clave connector	
	FLS130104	8	³/8" Opta® SFT female	NA			
50 L	FLS130186	8	Sartopore [®] Platinum 0.45 0.2 μm	MidiCaps [®] size 7			
	FLS130188	8	3/8" Opta® SFT female	NA			

1 Inlet tubing line from end line to bag: $3/8"\times5/8"$ Clear C-Flex $^{\circ}$ 500 mm (20") + Clipster $^{\circ}$ in a separate pouch

Leak Test Line

- ½" × ½" Clear C-Flex® 300 mm (12") + Midisart® BV 0.2 µm + ½" ID Silicone TuFlux® 100 mm (4") + ½" Tri-Clamp with gasket, cap & union

 $^{^2}$ Outlet tubing line from bag to end line: $3/8"\times5/8"$ Clear C-Flex $^{\!\circ}$ 500 mm (20")

Flexsafe[®] 2D | Flexsafe[®] 3D | Flexsafe[®] ≥ 1,000 L Buffer
Flexsafe® 2D | Flexsafe® 3D |
Flexsafe® ≥ 1,000 L

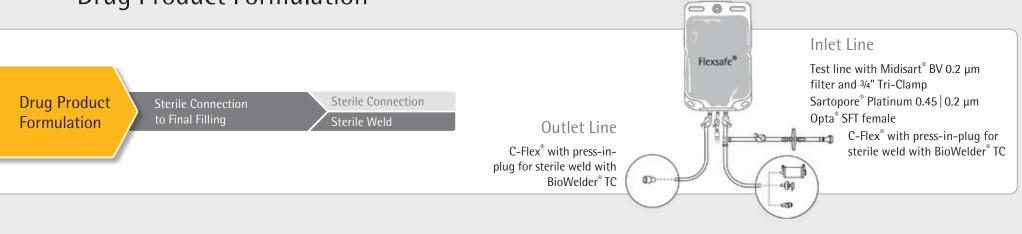
Cell Harvest & DSP
Flexsafe® 2D | Flexsafe® 3D |
Flexsafe® ≥ 1,000 L

Drug Substance
Flexsafe® 2D |
Flexsafe® 3D

Drug Product
Flexsafe® 2D |
Flexsafe® 3D

Back to Digital Selection Map

Drug Product Formulation



Sterile Weld to Final Formulation & Filling

			Inlet ¹	Outlet ²	Sampling
Bag volume	Part number	Units per box	Distal connector on filling line	Distal connector on draining line	Sampling line
3 L	FLS130189	16	3/8" ID C-Flex® + 3/8" press-in-plug	on araning mic	
5 L	FLS130105	16	3/8" ID C-Flex® + 3/8" press-in-plug		1/4" ID Silicone TuFlux®
10 L	FLS130106	8	³ / ₈ " ID C-Flex [®] + ³ / ₈ " press-in-plug	3/8" ID C-Flex® + 3/8"	100 mm (4") +
20 L	FLS130107	8	³ / ₈ " ID C-Flex [®] + ³ / ₈ " press-in-plug	press-in-plug	Luer Lock female + Clave connector
50 L	FLS130190	8	³ / ₈ " ID C-Flex [®] + ³ / ₈ " press-in-plug		Clave connector

 $^{^1}$ Inlet tubing line from end line to bag: $3/8"\times5/8"$ Clear C-Flex $^{\circ}$ 500 mm (20") + Clipster $^{\circ}$ in a separate pouch

Leak Test Line

- ½" \times ½" Clear C-Flex $^{\circ}$ 300 mm (12") + Midisart $^{\circ}$ BV 0.2 μm + ½" ID Silicone TuFlux $^{\circ}$ 100 mm (4") + ½" Tri-Clamp with gasket, cap & union

² Outlet tubing line from bag to end line: 3/8" × 5/8" Clear C-Flex[®] 500 mm (20")

Media
Flexsafe® 2D | Flexsafe® 3D |
Flexsafe® ≥ 1,000 L

Buffer
Flexsafe® 2D | Flexsafe® 3D |
Flexsafe® ≥ 1,000 L

Cell Harvest & DSP
Flexsafe® 2D | Flexsafe® 3D |
Flexsafe® ≥ 1,000 L

Drug Substance
Flexsafe® 2D |
Flexsafe® 3D

Drug Product
Flexsafe® 2D |
Flexsafe® 3D

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Drug Product Filtration, Storage and Filling

Drug Product Formulation

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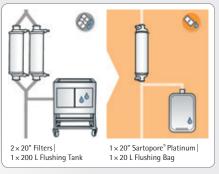
Sterilizing Filtration

Drug Product Storage Drug Product Transfer Sterile Connection to Final Filling

Sterile Weld

Aseptic Transfer to an Isolator

Sterile Connection



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

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.



Opta® SFT female

C-Flex® tube weld with BioWelder® TC

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



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

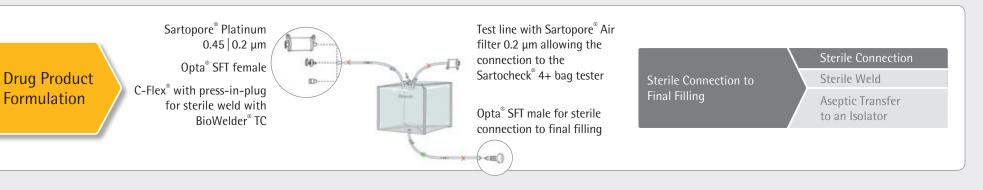
Connection and transfer by pumping

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

Flexsafe[®] ≥ 1,000 L

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Drug Product Filtration and Storage in Palletank



Sterile Connection to Final Filling

Formulation

			Inlet ¹	Outlet ²			
Bag volume	Part number	Units per box	Filter or distal connector on filling line	Filter type 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	- ½" Opta [®] SFT male		
	FIS126821	3	Press in plug	— NA			
200 L	FIS127158	2	Sartopore® Platinum 0.45 0.2 µm	MidiCaps [®] size 8	- ½ Opta Sri male		
	FIS301540	3	½" Opta® SFT female	NA			
	FIS126822	3	Press in plug	— NA			

¹ Inlet tubing line from end line to bag: $\frac{1}{2}$ " × $\frac{3}{4}$ " Clear C-Flex 0.5 m (20") + $\frac{1}{2}$ " ID Silicone TuFlux 1 m (40")

Leak Test Line

 $- \frac{1}{2}$ " × $\frac{3}{4}$ " Clear C-Flex $^{\circ}$ 1,500 mm (59") + Sartopore® Air filter 0.2 µm size 7 (Inlet 11/2" tri-clamp)



² Outlet tubing line from bag to end line: 1/2" ID Silicone TuFlux® 1 m (40") + 1/2" × 3/4" Clear C-Flex® 0.5 m (20")

Media Flexsafe® 2D Flexsafe® 3D Flexsafe[®] ≥ 1,000 L

Buffer Flexsafe® 2D Flexsafe® 3D Flexsafe[®] ≥ 1,000 L

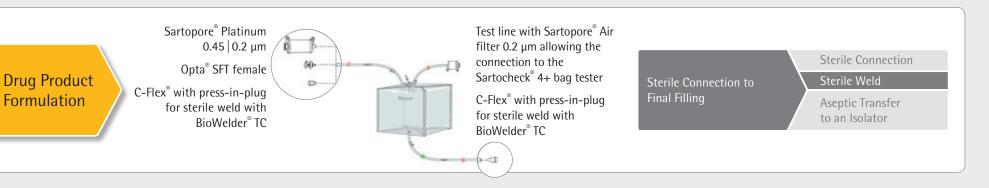
Cell Harvest & DSP Flexsafe[®] **2D** Flexsafe[®] **3D** Flexsafe[®] ≥ 1,000 L

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

Drug Product Flexsafe® **2D** Flexsafe® 3D

> Back to Digital Selection Map

Drug Product Filtration and Storage in Palletank



Sterile Weld to Final Filling

Formulation

			Inlet ¹	Outlet ²		
Bag volume	Part number	Units per box	Filter or distal connector on filling line	Filter type and size	Distal connector on outlet line	
100 L	FIS126879	2	Sartopore [®] Platinum 0.45 0.2 μm	MidiCaps [®] size 7	½"׳/4" C−Flex [®]	
	FIS126823	3	½" Opta® SFT female	— NA		
	FIS126825	3	Press in plug	— IVA		
200 L	FIS126880	2	Sartopore® Platinum 0.45 0.2 µm	MidiCaps [®] size 8	+ Press-in-plug	
	FIS126824	3	½" Opta® SFT female	NIA		
	FIS126826	3	Press in plug	— NA		

¹ Inlet tubing line from end line to bag: 1/2" × 3/4" Clear C-Flex® 0.5 m (20") + 1/2" ID Silicone TuFlux® 1 m (40")

Leak Test Line

 $-\frac{1}{2}$ " $\times \frac{3}{4}$ " Clear C-Flex 1,500 mm (59") + Sartopore® Air filter 0.2 µm size 7 (Inlet 11/2" tri-clamp)



² Outlet tubing line from bag to end line: 1/2" ID Silicone TuFlux® 1 m (40") + 1/2" × 3/4" Clear C-Flex® 0.5 m (20")

Drug Product

Formulation

Flexsafe® 3D Pre-designed Solutions for

Media

Flexsafe[®] **2D** | Flexsafe[®] **3D** | Flexsafe[®] ≥ **1,000** L

Buffer
Flexsafe® 2D | Flexsafe® 3D |
Flexsafe® ≥ 1,000 L

Cell Harvest & DSP
Flexsafe® 2D | Flexsafe® 3D |
Flexsafe® ≥ 1,000 L

Drug Substance
Flexsafe® 2D |
Flexsafe® 3D

Flexsafe® 2D | Flexsafe® 3D

Drug Product

Back to Digital Selection Map

Drug Product Filtration and Storage in Palletank

Sartopore® Platinum
0.45 | 0.2 µm
Opta® SFT female
C-Flex® with press-in-plug
for sterile weld with
BioWelder® TC

Test line with Sartopore® Air filter 0.2 µm allowing the connection to the Sartocheck® 4+ bag tester

GammaSart® sterile connection for aseptic transfer to an isolator

Sterile Connection to Final Filling

Sterile Weld
Aseptic Transfer

to an Isolator

Sterile Connection

Sterile Connection to an Isolator for Final Filling

			Inlet ¹	Inlet ¹	
Bag volume	Part number	Units per box	Filter or distal connector on filling line	Filter type and size	Distal connector on outlet line
100 L	FIS126817	2	Sartopore® Platinum 0.45 0.2 μm	MidiCaps [®] size 7	
	FIS126827	3	1/2" Opta® SFT female	NΙΔ	
	FIS126829	3	Press in plug	— NA	3/8" 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	NIA	
	FIS301541	3	Press in plug	— NA	

 $^{^{1}}$ Inlet tubing line from end line to bag: $\frac{1}{2}$ " \times $\frac{3}{4}$ " Clear C-Flex $^{\circ}$ 0.5 m (20") + $\frac{1}{2}$ " ID Silicone TuFlux $^{\circ}$ 1 m (40")

Leak Test Line

 $- \frac{1}{2}$ " \times $\frac{3}{4}$ " Clear C-Flex $^{\circ}$ 1,500 mm (59") + Sartopore $^{\circ}$ Air filter 0.2 μ m size 7 (Inlet 1 $\frac{1}{2}$ " tri-clamp)



² Outlet tubing line from bag to end line: ³/₈" ID Clear C-Flex[®] 0.5 m (20") + ¹/₂" × ³/₄" Silicone TuFlux[®] 2 m (80")

Flexsafe[®] ≥ 1,000 L

Selection Map

Sampling in Flexsafe® 2D Bags

			Inlet ¹	Outlet ¹
Bag Volume	Part Number	Units per box	Distal Connector on Filling Line	Distal Connector on Draining Line
20 mL	FLS130111	20		
50 mL	FLS130112	20		
150 mL	FLS130000	20		
250 mL	FLS130001	20	1/4" MPC male + sealing cap	1/4" MPC male + sealing cap
500 mL	FLS130002	20		
1,000 mL ²	FLS130123	20		
3,000 mL ²	FLS130124	16		
20 mL	FLS130113	20		
50 mL	FLS130114	20		1/4" MPC male + sealing cap
150 mL	FLS130003	20		
250 mL	FLS130004	20	1/4" MPC female + sealing cap	
500 mL	FLS130005	20		
1,000 mL ²	FLS130125	20		
3,000 mL ²	FLS130126	16		
20 mL	FLS130115	20		
50 mL	FLS130116	20		
150 mL	FLS130006	20	1/4" MPC female + sealing cap	Luer Lock female + Clave connector
250 mL	FLS130007	20		
500 mL	FLS130008	20		
20 mL	FLS130117	20		
50 mL	FLS130118	20		
150 mL	FLS130009	20	Luer Lock female + cap	Luer Lock female + Clave connector
250 mL	FLS130010	20		
500 mL	FLS130011	20		

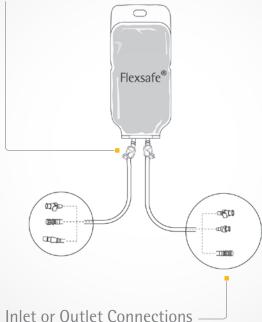
 $^{^{1}}$ Inlet and outlet tubing: $1/4" \times 3/8"$ Silicone 150 mm (6")

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.

Filling or Draining Lines

- Silicone TuFlux® tube
- Clear C-Flex® tube



- MPC quick coupler male or female
- Luer lock male or female
- Luer lock and needleless sampling port

² Third line with Silicone tubing and needleless Clave connecteur for 1 L and 3 L bags

Media
Flexsafe® 2D | Flexsafe® 3D |
Flexsafe® ≥ 1,000 L

Buffer
Flexsafe® 2D | Flexsafe® 3D |
Flexsafe® ≥ 1,000 L

Cell Harvest & DSP
Flexsafe® 2D | Flexsafe® 3D |
Flexsafe® ≥ 1,000 L

Drug Substance
Flexsafe® 2D |
Flexsafe® 3D

Drug Product
Flexsafe® 2D |
Flexsafe® 3D

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Sampling in Flexsafe® 2D Bags

			Inlet ¹	Outlet ¹
Bag Volume	Part Number	Units per box	Distal Connector on Filling Line	Distal Connector on Draining Line
20 mL	FLS130119	20		
50 mL	FLS130120	20		
150 mL	FLS130012	20		
250 mL	FLS130013	20	Luer Lock female + cap	Luer Lock male + cap
500 mL	FLS130014	20		
1,000 mL ²	FLS130127	20		
3,000 mL ²	FLS130128	16		

 $^{^{1}}$ Inlet and outlet tubing: $1/4" \times 3/8"$ Silicone 150 mm (6")

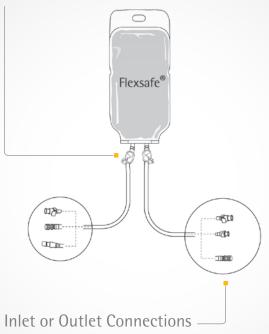
² Third line with Silicone tubing and needleless Clave connecteur for 1L and 3L bags

			Inlet ²	Outlet ²
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 female + sealing cap	1/4" MPC male + sealing cap
500 mL	FLS130017	10		
1,000 mL ³	FLS130129	10		
3,000 mL ³	FLS130130	16		

 $^{^2}$ Inlet and outlet tubing: $^{1/4}$ " \times $^{3/8}$ " Clear C-Flex $^{\circ}$ 500 mm (20")

Filling or Draining Lines

- Silicone TuFlux® tube
- Clear C-Flex® tube



- MPC quick coupler male or female
- Luer lock male or female
- Luer lock and needleless sampling port

³ 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



Bag Volume	Part Number	Units per box	Description	Inlet ¹	Outlet
5 L	FLS303106	2	Flexsafe® 5 L (Shell, MPC, TC)		Tri-clamp 3/4" flange with gasket, union & cap ²
5 L	FLS303107	2	Flexsafe® 5 L (Shell, MPC, LT/MPC)³	3/8" MPC female + sealing cap	3/8" MPC male + sealing cap ¹
10 L	FLS303108	1	Flexsafe® 10 L (Shell, MPC, TC)		Tri-clamp ³ / ₄ " flange with gasket, union & cap ²
10 L	FLS303109	1	Flexsafe® 10 L (Shell, MPC, LT/MPC)³		³ / ₈ " MPC male + sealing cap ¹



Shippers & Standalone Shells

Bag Volume	Part Number	Units per box	Description
5 L	FLA302721	10 units shippers 20 units PE overpouches	Standard Shipper for 5 L shell with double PE overpouches per shipper
10 L	FLA300318	10 units shippers 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



¹ Inlet & outlet tubing: ³/₈" Clear C-Flex ⁶ 500 mm (20"). Third line with Silicon tubing & needleless clave connector.

² Outlet tubing: 3/8" Silicone TuFlux® 500 mm (20")

³Leak 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

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Point-of-Use Leak Test for Flexsafe® 2D and 3D Bags



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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

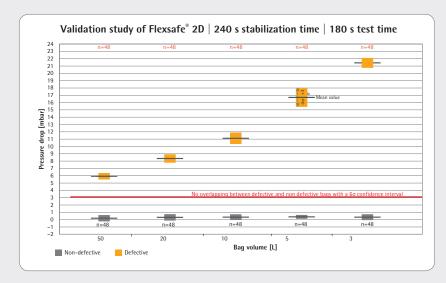
Fast & Easy to Use

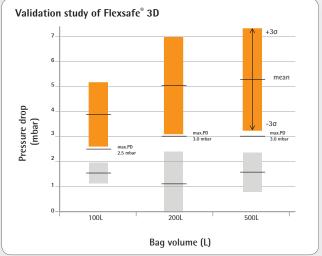
- The well-known ASTM F2095-07 standard pressure decay leak test at point of use and the well-established Sartocheck® technology make it easy to implement -The restraining plates allow a small inflation volume thus reduce the total test time to less than 10 minutes
- The 3D bags are tested in their container. 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







Buffer
Flexsafe® 2D | Flexsafe® 3D |
Flexsafe® ≥ 1,000 L

Cell Harvest & DSP
Flexsafe® 2D | Flexsafe® 3D |
Flexsafe® ≥ 1,000 L

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

Standard Hardware for Storage and Shipping: The Perfect Fit





Palletank for Storage



Palletank for In-process Fluid Handling



Palletank for Large Volume Storage



Palletank for Shipping



Plastic Palletank for Storage



Plastic Drum for Storage

Cell Harvest & DSP Flexsafe® 2D Flexsafe® 3D Flexsafe[®] ≥ **1,000 L**

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

Flexsafe® **2D** Flexsafe® 3D

Drug Product

Back to Digital Selection Map

Palletank for Storage

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

Features & Benefits

Qualified System

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

Stackable Version

Space saving containment system

Optimal Bag Unfolding

without operator manipulation with the self-deploying accessory



Palletank for storage

Description	Palletank 200 L for storage	Palletank 500 L for storage
Part Number	FXC110888	FXC110889
Bag Volume(s)	100 L or 200 L	500 L
Construction Material	304 L Stainless Steel	304 L Stainless Steel
Surface Finishing	Bead Blasted	Bead Blasted
Dimensions (W \times D \times H)	792 × 592 × 892 mm (31 × 23 × 35 in)	1192 × 792 × 1008 mm (46 × 31 × 39 in)
Weight	48 kg (106 lb)	100 kg (220 lb)
Bottom Gate	1	1
Stackability	No	No

Palletank for storage stackable

Description	Palletank 200 L for storage stackable	Palletank 500 L for storage stackable
Part Number	FXC110733	FXC110734
Bag Volume(s)	100 L or 200 L	500 L
Construction Material	304 L Stainless Steel	304 L Stainless Steel
Surface Finishing	Bead Blasted	Bead Blasted
Dimensions (W \times D \times H)	792 × 592 × 929 mm (31 × 23 × 36 in)	1135 × 792 × 1044 mm (44 × 31 × 41 in)
Weight	70 kg (154.3 lb)	110 kg (242 lb)
Bottom Gate Sliding Gate	1	1
Stackability (Static)	3 high	2 high

Dolly

Description	Dolly for Palletank 200 L for Storage and Shipping	Dolly for Palletank 500 L for Storage and Shipping
Part Number	FXS102254	FXS102256
Construction Material	304L and polyamide (wheels)	304L and polyamide (wheels)
Surface Finishing	Glass Bead blasted	Glass Bead blasted
Dimensions (W \times D \times H)	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)	18 kg (39.7 lb)

Media

Flexsafe[®] 2D | Flexsafe[®] 3D | Flexsafe[®] ≥ 1,000 L Buffer
Flexsafe® 2D | Flexsafe® 3D |
Flexsafe® ≥ 1,000 L

Cell Harvest & DSP Flexsafe® 2D | Flexsafe® 3D | Flexsafe® ≥ 1,000 L Drug Substance
Flexsafe® 2D |
Flexsafe® 3D

Flexsafe® 2D | Flexsafe® 3D

Drug Product

Back to Digital Selection Map

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





Media
Flexsafe® 2D | Flexsafe® 3D |
Flexsafe® ≥ 1,000 L

Buffer
Flexsafe® 2D | Flexsafe® 3D |
Flexsafe® ≥ 1,000 L

Cell Harvest & DSP
Flexsafe® 2D | Flexsafe® 3D |
Flexsafe® ≥ 1,000 L

Drug Substance
Flexsafe® 2D |
Flexsafe® 3D

Drug Product
Flexsafe® 2D |
Flexsafe® 3D

Palletank for Large Volume Storage

Back to Digital Selection Map

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 \times D \times H)			
w/ ergonomic module	1603 × 1076 × 2011 mm (63 × 42 × 79 in)	1603×1076×2511 mm (63×42×99 in)	1603 × 1076 × 3012 mm (63 × 42 × 118 in)
w/o ergonomic module	1603 × 1076 × 1700 mm (63 × 42 × 67 in)	1603×1076×2200 mm (63×42×87 in)	1603 × 1076 × 2701 mm (63 × 42 × 106 in)
Built on wheels	1603 × 1076 × 1790 mm (63 × 42 × 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 \times D \times H)		
w/ ergonomic module	$1603 \times 1076 \times 3512 \text{ mm } (63 \times 42 \times 138 \text{ in})$	1603 × 1076 × 4013 mm (63 × 42 × 158 in)
w/o ergonomic module	1603×1076×3201 mm (63×42×126 in)	1603 × 1076 × 3702 mm (63 × 42 × 146 in)
Built on wheels	N A	N A
Bottom gate Sliding gate	2	2
Stackability	No	No

Volume	Max net Weighing Capacty in kg	Resolution in g	Accuracy in g
50 L	60	20	60
100 L	110	20	60
200 L	220	20	60
400 L	450	50	150
650 L	750	50	150
1,000 L	1100	100	300
1,500 L	1750	100	300
2,000 L	2200	200	600
2,500 L	2750	200	600
3,000 L	3300	200	600

Palletank for Large Volume Storage

Back to Digital Selection Map

Palletank for Large Volume Storage

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	Part Number				
Description	Palletank Storage 1,000L	Palletank Storage 1,500L	Palletank Storage 2,000L	Palletank Storage 2,500L	Palletank Storage 3,000L
w/ ergonomic module	FXC302072	FXC302073	FXC302074	FXC302075	FXC302076
w/ ergonomic module and w/ weighing	FXC304053	FXC304054	FXC304055	FXC304056	FXC304057
w/o ergonomic module	FXC304027	FXC301928	FXC301929	FXC302070	FXC302071
w/o ergonomic module 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





Tubing holder Bag Lifting Kit Without Base module Weighing Kit or with Weighing Kit Built-on Wheels or Height Short Frame Adjustable Legs

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

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

Palletank Storage 1,000L Built-on wheels

Standard Hardware for Storage and Shipping

Media

Flexsafe[®] 2D | Flexsafe[®] 3D | Flexsafe[®] ≥ 1,000 L Buffer
Flexsafe® 2D | Flexsafe® 3D |
Flexsafe® ≥ 1,000 L

Cell Harvest & DSP
Flexsafe® 2D | Flexsafe® 3D |
Flexsafe® ≥ 1,000 L

Drug Substance
Flexsafe® 2D |
Flexsafe® 3D

Flexsafe® 2D | Flexsafe® 3D

Drug Product

Palletank for Large Volume Storage

Back to Digital Selection Map

Tubing and filters holders

Part Number PXC301562 STD tubing holder single 5/8" FXC301563 STD tubing holder triple 5/8" FXC301564 STD tubing holder triple 5/8" FXC301565 STD tubing holder quattro 5/8" FXC301566 STD tubing holder single 3/4" FXC301567 STD tubing holder single 3/4" FXC301568 STD tubing holder triple 3/4" FXC301569 STD tubing holder quattro 3/4" FXC301570 STD tubing holder quattro 3/4" FXC301571 STD tubing holder single 1" FXC301572 STD tubing holder triple 1" FXC301573 STD tubing holder triple 1" FXC301574 STD tubing holder quattro 1" FXC301575 STD tubing holder single 1-1/8" FXC301576 STD tubing holder triple 1-1/8" FXC301577 STD tubing holder triple 1-3/8" FXC301578 STD tubing holder single 1-3/8" FXC301579 STD tubing holder triple 1-3/8" FXC301580 STD tubing holder triple 1-3/8" FXC301580 STD filter holder short 100 mm	ruonig una micro notacio	
FXC301563 STD tubing holder twin 5/8" FXC301564 STD tubing holder triple 5/8" FXC301565 STD tubing holder quattro 5/8" FXC301566 STD tubing holder single 3/4" FXC301567 STD tubing holder twin 3/4" FXC301568 STD tubing holder triple 3/4" FXC301569 STD tubing holder quattro 3/4" FXC301570 STD tubing holder single 1" FXC301571 STD tubing holder single 1" FXC301572 STD tubing holder twin 1" FXC301573 STD tubing holder triple 1" FXC301574 STD tubing holder single 1 -1/8" FXC301575 STD tubing holder single 1 -1/8" FXC301576 STD tubing holder twin 1 -1/8" FXC301577 STD tubing holder triple 1 -1/8" FXC301578 STD tubing holder single 1 -1/8" FXC301579 STD tubing holder single 1 -3/8" FXC301579 STD tubing holder twin 1 -3/8" FXC301579 STD tubing holder twin 1 -3/8"	Part Number	Description
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FXC301566 STD tubing holder single 3/4" FXC301567 STD tubing holder twin 3/4" FXC301568 STD tubing holder triple 3/4" FXC301569 STD tubing holder quattro 3/4" 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 1-1/8" FXC301575 STD tubing holder twin 1-1/8" FXC301576 STD tubing holder triple 1-1/8" FXC301577 STD tubing holder quattro 1-1/8" FXC301578 STD tubing holder quattro 1-1/8" FXC301579 STD tubing holder single 1-3/8" FXC301580 STD tubing holder twin 1-3/8" FXC301580	FXC301564	STD tubing holder triple 5/8"
FXC301567 STD tubing holder twin 3/4" FXC301568 STD tubing holder triple 3/4" FXC301569 STD tubing holder quattro 3/4" 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 1-1/8" FXC301575 STD tubing holder twin 1-1/8" FXC301576 STD tubing holder triple 1-1/8" FXC301577 STD tubing holder quattro 1-1/8" FXC301578 STD tubing holder single 1-3/8" FXC301579 STD tubing holder twin 1-3/8" FXC301580 STD tubing holder triple 1-3/8"	FXC301565	STD tubing holder quattro 5/8"
FXC301568 STD tubing holder triple 3/4" 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 1-1/8" FXC301575 STD tubing holder single 1-1/8" FXC301576 STD tubing holder twin 1-1/8" FXC301577 STD tubing holder triple 1-1/8" FXC301578 STD tubing holder quattro 1-1/8" FXC301579 STD tubing holder single 1-3/8" FXC301580 STD tubing holder twin 1-3/8" FXC301580	FXC301566	STD tubing holder single 3/4"
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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 1–1/8" FXC301575 STD tubing holder twin 1–1/8" FXC301576 STD tubing holder triple 1–1/8" FXC301577 STD tubing holder quattro 1–1/8" FXC301578 STD tubing holder single 1–3/8" FXC301579 STD tubing holder twin 1–3/8" FXC301580 STD tubing holder triple 1–3/8"	FXC301568	STD tubing holder triple 3/4"
FXC301571 STD tubing holder twin 1" FXC301572 STD tubing holder triple 1" FXC301573 STD tubing holder quattro 1" FXC301574 STD tubing holder single 1–1/8" FXC301575 STD tubing holder twin 1–1/8" FXC301576 STD tubing holder triple 1–1/8" FXC301577 STD tubing holder quattro 1–1/8" FXC301578 STD tubing holder single 1–3/8" FXC301579 STD tubing holder twin 1–3/8" FXC301580 STD tubing holder triple 1–3/8"	FXC301569	STD tubing holder quattro 3/4"
FXC301572 STD tubing holder triple 1" FXC301573 STD tubing holder quattro 1" FXC301574 STD tubing holder single 1–1/8" FXC301575 STD tubing holder twin 1–1/8" FXC301576 STD tubing holder triple 1–1/8" FXC301577 STD tubing holder quattro 1–1/8" FXC301578 STD tubing holder single 1–3/8" FXC301579 STD tubing holder twin 1–3/8" FXC301580 STD tubing holder triple 1–3/8"	FXC301570	STD tubing holder single 1"
FXC301573 STD tubing holder quattro 1" FXC301574 STD tubing holder single 1–1/8" FXC301575 STD tubing holder twin 1–1/8" FXC301576 STD tubing holder triple 1–1/8" FXC301577 STD tubing holder quattro 1–1/8" FXC301578 STD tubing holder single 1–3/8" FXC301579 STD tubing holder twin 1–3/8" FXC301580 STD tubing holder triple 1–3/8"	FXC301571	STD tubing holder twin 1"
FXC301574 STD tubing holder single 1–1/8" FXC301575 STD tubing holder twin 1–1/8" FXC301576 STD tubing holder triple 1–1/8" FXC301577 STD tubing holder quattro 1–1/8" FXC301578 STD tubing holder single 1–3/8" FXC301579 STD tubing holder twin 1–3/8" FXC301580 STD tubing holder triple 1–3/8"	FXC301572	STD tubing holder triple 1"
FXC301575 STD tubing holder twin 1–1/8" FXC301576 STD tubing holder triple 1–1/8" FXC301577 STD tubing holder quattro 1–1/8" FXC301578 STD tubing holder single 1–3/8" FXC301579 STD tubing holder twin 1–3/8" FXC301580 STD tubing holder triple 1–3/8"	FXC301573	STD tubing holder quattro 1"
FXC301576 STD tubing holder triple 1–1/8" FXC301577 STD tubing holder quattro 1–1/8" FXC301578 STD tubing holder single 1–3/8" FXC301579 STD tubing holder twin 1–3/8" FXC301580 STD tubing holder triple 1–3/8"	FXC301574	STD tubing holder single 1–1/8"
FXC301577 STD tubing holder quattro 1–1/8" FXC301578 STD tubing holder single 1–3/8" FXC301579 STD tubing holder twin 1–3/8" FXC301580 STD tubing holder triple 1–3/8"	FXC301575	STD tubing holder twin 1–1/8"
FXC301578 STD tubing holder single 1–3/8" FXC301579 STD tubing holder twin 1–3/8" FXC301580 STD tubing holder triple 1–3/8"	FXC301576	STD tubing holder triple 1–1/8"
FXC301579 STD tubing holder twin 1–3/8" FXC301580 STD tubing holder triple 1–3/8"	FXC301577	STD tubing holder quattro 1–1/8"
FXC301580 STD tubing holder triple 1–3/8"	FXC301578	STD tubing holder single 1–3/8"
	FXC301579	STD tubing holder twin 1–3/8"
FXC301586 STD filter holder short 100 mm	FXC301580	STD tubing holder triple 1–3/8"
	FXC301586	STD filter holder short 100 mm



Media Flexsafe[®] **2D** Flexsafe[®] **3D** Flexsafe[®] ≥ 1,000 L

Buffer Flexsafe® 2D Flexsafe® 3D Flexsafe[®] ≥ 1,000 L

Cell Harvest & DSP Flexsafe® 2D Flexsafe® 3D Flexsafe[®] ≥ 1,000 L

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

Drug Product Flexsafe® **2D** Flexsafe® 3D

> Back to Digital Selection Map

Plastic Palletank for Storage

Plastic Palletank for Storage in 200 L and 500 L represents a cost-effective containment solution for the storage and processing of biopharmaceutical fluids 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



Palletank for storage

Description	STD Plastic Palletank 200 L for storage	STD Plastic Palletank 500 L for storage
Part Number	FXC116215	FXC116216
Bag Volume(s)	100 L 200 L	500 L ¹
Main Constrution Material	PP	ABS
Dimensions (W \times D \times H) Approx.		
Unfolded	$805 \times 607 \times 969 \text{ mm}$ $32 \times 24 \times 38 \text{ in.}$	1215 × 805 × 1086 mm 48 × 31 × 43 in.
Folded	$805 \times 607 \times 510 \text{ mm}$ $32 \times 24 \times 20 \text{ in.}$	1215 × 805 × 572 mm 48 × 31 × 22 in.
Bottom Gate	1	1
Stackability – Static		
Folded	5	3
Unfolded and Full	3	2

Dolly

Description	Dolly for STD Palletank 200 L	Dolly for STD Palletank 500 L
Part Number	FXA116630	FXA116631
Construction Material	304L and polyamide (wheels)	304L and polyamide (wheels)
Surface Finishing	Glass Bead blasted	Glass Bead blasted
Dimensions (W \times D \times H)	$807 \times 607 \times 214 \text{ mm}$ $32 \times 24 \times 8 \text{ in.}$	1207 × 807 × 214 mm 47 × 32 × 8 in.
Weight (approx.)	10 kg (22 lb)	20 kg (44 lb)

¹ The maximum filling volume of the Flexel ⁹ 3D Bag in the 500 L Plastic Palletank for storage is 490 L.

Media

Flexsafe® 2D Flexsafe® 3D Flexsafe[®] ≥ 1,000 L

Buffer Flexsafe® 2D Flexsafe® 3D Flexsafe[®] ≥ 1,000 L

Cell Harvest & DSP Flexsafe® 2D Flexsafe® 3D Flexsafe[®] ≥ 1,000 L

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

Drug Product Flexsafe® **2D** Flexsafe® 3D

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Palletank for In-process Fluid Handling

Palletank for in-process fluid handling are specifically developed for users who wish to leave the containers in close proximity to process equipment. Palletank for in-process fluid handling are available in 200 L, 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

Easy operation due to continuous processing without movement of the containers

Easy access through double hinged front doors with safety latches

Optimal bag unfolding without operator manipulation with the selfdeploying accessory

Palletank for in-process fluid handling

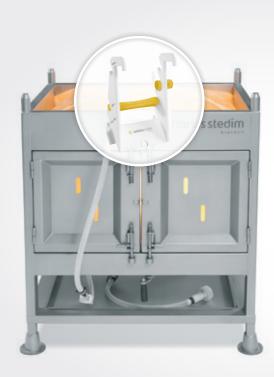
Description	Palletank 200 L for in-process fluid handling	Palletank 500 L for in-process fluid handling
Part Number	FXC106230	FXC106235
Bag Volume(s)	100 L or 200 L	500 L
Construction Material	304L Stainless Steel	304L Stainless Steel
Surface Finishing	Glass Bead Blasted	Glass Bead Blasted
Dimensions (W \times D \times H)	$860 \times 660 \times 929 \text{ mm}$ (33.9 × 26 × 36.6 in)	1260 × 860 × 989 mm (49.6 × 33.9 × 38.9 in)
Weight (approx.)	50 kg (110.2 lb)	89 kg (196.2 lb)
Bottom Gate	1	1
Stackability	3 high	3 high
Total Weight (approx.)	68 kg (150.2 lb)	111 kg (244.7 lb)

Dolly

Description	Dolly for Palletank 200 L for in-process fluid handling	Dolly for Palletank 500 L for in-process fluid handling
Part Number	FXS102255	FXS102257
Weight	18 kg (40 lb)	22 kg (48.5 lb)

Accessories

Description	Self-Deploying accessory for Palletank storage and in-process fluid handling
Part Number	FXA127314





Standard Hardware for Storage and Shipping

Media Flexsafe[®] **2D** Flexsafe[®] **3D** Flexsafe[®] ≥ 1,000 L

Buffer Flexsafe® 2D Flexsafe® 3D Flexsafe[®] ≥ 1,000 L

Cell Harvest & DSP Flexsafe® 2D Flexsafe® 3D Flexsafe[®] ≥ 1,000 L

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

Flexsafe® 2D Flexsafe® 3D

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Drug Product

Standard Palletank for Storage, Processing and Shipping

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.

Immobilisation of Flexsafe[®] | Flexel[®] 3D Bag by compression assures system integrity

Dismountable construction improves space utilization on site before and after usage



Palletank for in-process fluid handling

Description	Palletank 100 L for shipping	Palletank 200 L for shipping	Palletank 500 L for shipping
Part Number	FXC106362	FXC103133	FXC106609
Bag Volume(s)	100 L	200 L	500 L
Construction Material	304L Stainless Steel	304L Stainless Steel	304L Stainless Steel
Dimensions (W \times D \times H)			
Unfolded	800 × 600 × 688 mm (31.5 × 23.6 × 27.1 in)	800 × 600 × 935 mm (31.5 × 23.6 × 36.8 in)	1206 × 806 × 1050 mm (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)	84 kg (185.18 lb)	129 kg (284.4 lb)
Bottom Gate	1	1	1
Unfolded	3	3	2
Folded	5	5	3

Accessories

Description	Shipping kit 100L	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)

Media
Flexsafe® 2D | Flexsafe® 3D |

Flexsafe[®] ≥ 1,000 L

Buffer
Flexsafe® 2D | Flexsafe® 3D |
Flexsafe® ≥ 1,000 L

Cell Harvest & DSP
Flexsafe® 2D | Flexsafe® 3D |
Flexsafe® ≥ 1,000 L

Drug Substance
Flexsafe® 2D |
Flexsafe® 3D

Drug Product
Flexsafe® 2D |
Flexsafe® 3D

Standard Drum for Storage and Processing

The plastic drum containers offer a costeffective 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 $^{\circ}$ 3D Bags can be moved safely with a stainless steel dolly available in two sizes 50 L | 100 L and 200 L.

Features & Benefits

- 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

Drum

Description	STD Drum		
	50 L	100 L	200 L
Part Number	FBC125627	FBC125628	FBC125629
Construction Material		HDPE	
Internal Diameter (Approx.)	346 mm (13.6 in)	467 mm (18.4 in)	559 mm (22 in)
Internal 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	



Dolly

Description	STD Drum Accessory Dolly		
	50 L 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 W×D×H (Approx.)	502×502×168 mm (19.7×19.7×6.6 in)	594×594×168 mm (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	



Back to Digital Selection Map Media
Flexsafe® 2D | Flexsafe® 3D |
Flexsafe® ≥ 1,000 L

Buffer
Flexsafe® 2D | Flexsafe® 3D |
Flexsafe® ≥ 1,000 L

Cell Harvest & DSP
Flexsafe® 2D | Flexsafe® 3D |
Flexsafe® ≥ 1,000 L

Drug Substance
Flexsafe® 2D |
Flexsafe® 3D

Drug Product
Flexsafe® 2D |
Flexsafe® 3D

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Sterilizing-Grade Filtration for all Process Steps

Sartopore single-use sterilizing-grade filter transfer sets are pre-assembled, 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 size
Sartopore® 2	MidiCaps [®] size 7		FFU500214	8
0.45 0.2 μm	MidiCaps [®] size 8		FFU500215	8
	MidiCaps [®] size 9		FFU500216	8
	MidiCaps [®] size 0	1/2" ID Clear C-Flex® 500 mm Opta® male 1/2"	FFU500217	8
	MaxiCaps [®] T-style size 1	Opta maic 72	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	½" ID Clear C-Flex® 500 mm	FFU500254	8
	MidiCaps [®] size 0	MPX male + sealing cap	FFU500255	8
	MaxiCaps [®] T-style size 1		FFU500256	4
	MaxiCaps [®] T-style size 2		FFU500257	4
	MaxiCaps [®] T-style size 3		FFU500258	4
Sartopore® 2 XLM	MidiCaps [®] size 7		FFU500268	8
0.8 0.2 μm	MidiCaps [®] size 8		FFU500269	8
	MidiCaps [®] size 9	1/2" 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		FFU500277	8
	MidiCaps [®] size 0	1/2" ID Clear C-Flex® 500 mm MPX male + sealing cap	FFU500278	8
	MaxiCaps® T-style size 1	INI A maic + scanny cap	FFU500226	4
	MaxiCaps® T-style size 2		FFU500279	4
	MaxiCaps® T-style size 3		FFU500225	4

Media Flexsafe® 2D Flexsafe® 3D Flexsafe[®] ≥ 1,000 L

Buffer Flexsafe[®] **2D** Flexsafe[®] **3D** Flexsafe[®] ≥ 1,000 L

Cell Harvest & DSP Flexsafe® 2D Flexsafe® 3D Flexsafe[®] ≥ **1,000 L**

Drug Substance Flexsafe[®] **2D** Flexsafe® 3D

Drug Product Flexsafe® **2D** Flexsafe® 3D

Sterilizing-Grade Filtration for all Process Steps

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Media Sterilizing Filtration for Mycoplasma Removal

Filter Type	Filter	Tubing & Outlet Connector	Part Number	Lot size
Sartopore® 2 XLM 0.2 0.1 μm	MidiCaps [®] size 7	1/2" ID Clear C-Flex® 500 mm Opta® male 1/2"	FFU500235	8
	MidiCaps [®] size 8		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	1/2" ID Clear C-Flex® 500 mm MPX male + sealing cap	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 size
Sartopore® Platinum 0.45 0.2 μm	MidiCaps [®] size 7	1/2" ID Clear C-Flex® 500 mm Opta® male 1/2"	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	1/2" 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



Drug Product

Design, Application Development and Validation Services

Configure to Order (CTO) Options

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

Please contact

www.sartorius-stedim.com

or your local sales representative for more information.



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