

Flexboy® 2D Pre-designed Solutions for Storage

Best Performance, Assurance of Supply and Closure Integrity for All Process Steps



Table of Contents

Please click on the headline to go to the selected topic

Unprecedented Performance and Assurance of Supply	3
Material Science and Film Extrusion Expertise	4
Control of the Entire Manufacturing Process	5
Assurance of Supply for Fluid-contact Components	6
Validation and Quality Assurance	7
Assurance of Container Closure Integrity	8

Flexboy® 2D Pre-designed Solutions for Filtration & Storage for All Process Steps	9
--	---

Media Formulation	10
-------------------------	----

Buffer Formulation	15
--------------------------	----

Cell Harvest & Downstream Intermediates	20
---	----

Drug Substance Purification	25
-----------------------------------	----

Drug Product Formulation	30
--------------------------------	----

Standard Flexboy® 2D Other Bag Configurations for Storage and Sampling	33
---	----

FlexAct® BT (Bag Tester) Point of Use Leak test for Flexboy® 2D	34
--	----

Accessories Flexboy® 2D Tray and Rack Systems	35
--	----

Design, Application Development and Validation Services	36
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Digital Selection Map

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

Media Formulation

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

Buffer Formulation

Sterile Connection
to Downstream Systems

Sanitary or Aseptic Connection
to Downstream Systems

Sterile Connection
Sterile Weld

Quick Coupler Connection
Tri-Clamp Connection

Cell Harvest & Downstream Intermediates

Sterile Connection
to Downstream Systems

Sanitary or Aseptic Connection
to Downstream Systems

Sterile Connection
Sterile Weld

Quick Coupler Connection
Tri-Clamp Connection

Drug Substance Purification

Sterile Connection
to Downstream Systems

Sanitary or Aseptic Connection
to Downstream Systems

Sterile Connection
Sterile Weld

Quick Coupler Connection
Tri-Clamp Connection

Drug Product Formulation

Sterile Connection
to Final Filling

Sterile Connection
Sterile Weld

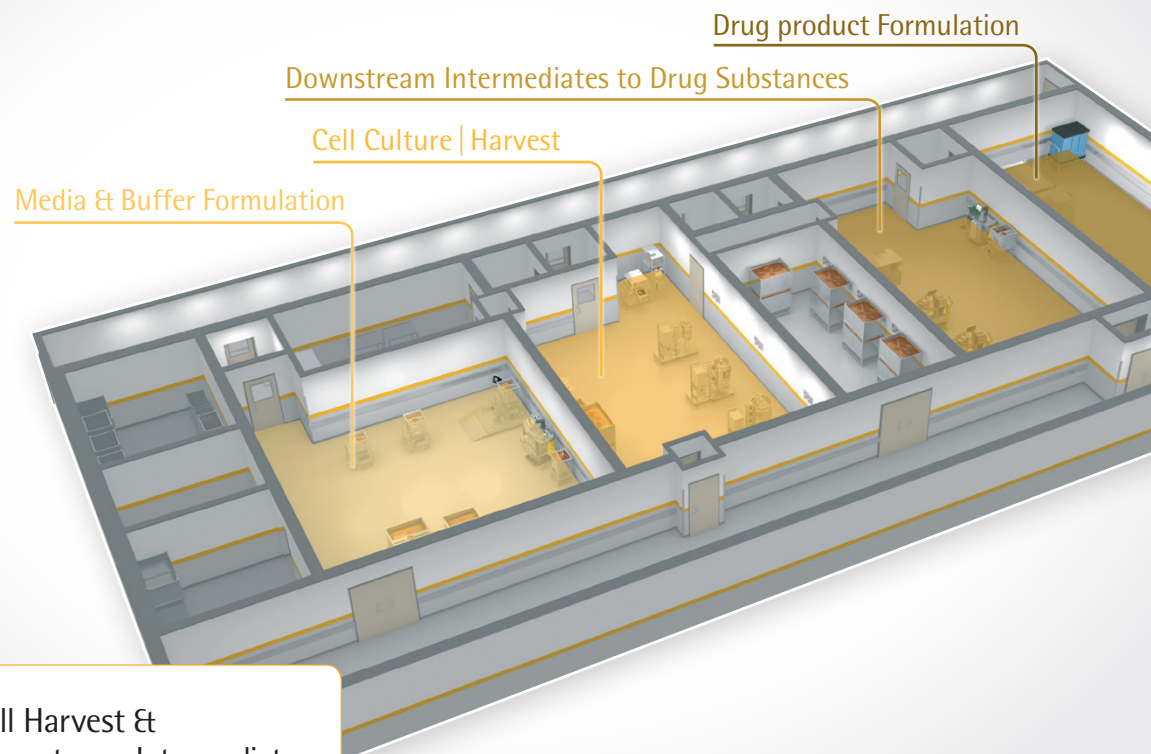
Unprecedented Performance and Assurance of Supply

Flexboy® 2D Storage 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 Flexboy® PDS are based on the complete control of our manufacturing process for the resins, the film, the bags, the filters and the assembly. 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 Flexboy® PDS, you get the assurance of consistent quality and robust change control for every process step of your bioproduction. Business continuity is guaranteed at any time with at least 24 months of change notification.



Media Formulation

Pre-designed Solutions for media storage and feeding of bioreactors



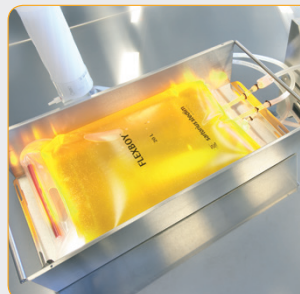
Cell Harvest & Downstream Intermediates

Pre-designed Solutions for harvesting cell cultures and for handling all the process intermediates



Buffer Formulation

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



Drug Substance Purification

Pre-designed Solutions for storage of drug substance



Drug Product Formulation

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

Material Science and Film Extrusion Expertise

The S71 EVA film of Flexboy® 2D 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 manufacturing process.

Following the principles of QbD, we have selected the raw materials to achieve best quality attributes and superior assurance of supply.

We have established the resin specification, extrusion design space and process controls that provide consistent quality and reproducible characteristics of the S71 film.

The resins and additive package formulation and the film extrusion are optimized to achieve outstanding robustness, provide excellent cell growth and generate low and consistent extractable profiles.

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

Heat-laminated EVA | EVOH | EVA Structure

- 300 µm thickness from 5mL to 20L bags and 360 µm thickness for 50L bags
- Balance between strength, flexibility and gas barrier
- Large sealing window for bag robustness
- Best puncture resistance & elongation at break

S71 Film Features & Benefits

- Superior robustness: Strength and flexibility. The film strength offers safety during handling while flexibility ensures integrity during storage and shipping
- High gas and water barrier properties: Suitable for long term storage of media, buffers and drug substances
- Low and consistent extractable profile: Ideal for drug substance and drug product process steps
- Excellent biocompatibility: Ideal for media storage and cell culture

Resins + Additives

Film Extrusion and Welding

Bag Making

Specifications & Controls

- Optimized resin & additives
- Minimized anti-oxidant level
- Use of EP listed antioxidant

Design Space, Operating Ranges & Controls

- No slipping agents
- Mechanical anti-blocking (SiO₂)

Robustness testing in process qualification

Benefits

- Superior assurance of supply
- Proven film robustness
- Container closure integrity
- Excellent and reproducible cell growth
- Consistent extractable profile

The lot to lot consistent performance of Flexboy® 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.

 Backbone
 Contact Layer

EVA

EVOH

EVA

Backbone:

- Superior strength and flexibility
- High gas barrier properties

Contact layer:

- Superior strength and flexibility
- Weld strength
- Low extractable level
- Excellent biocompatibility

Control of the Entire Manufacturing Process

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

We have optimized the film extrusion process, defined the design space and established the critical process controls to guarantee the lot to lot consistency of Flexboy® quality attributes.

Resins for S71 Film
Resin specification & control
 - Resin & additives traceability
 - Lot-to-lot raw material consistency
Long term contract
 - 2 year last time buy option
 - 2 year stock of resin & film

Film – S71
Extrusion design space & control
 - Consistent cell growth & robustness
 - Lot-to-lot consistent extractable
10 year supply & quality contract
 - 2 year last time buy option
 - 2 year stock of resin & film

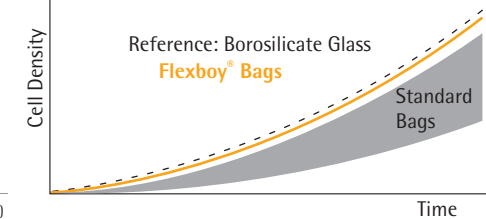
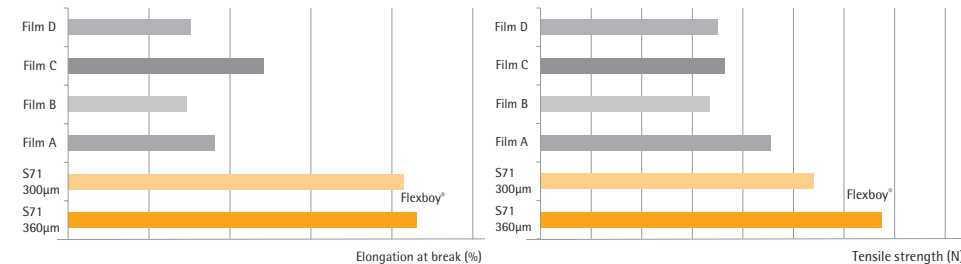
▶ 4 year guarantee of unchanged film
 ▶ 2 year guarantee of unchanged components for our Pre-Designed-Solutions

Components
Long term supply contracts
 - 2 year change notification
Quality Agreements
 - Bioburden, particle & endotoxin
 - Extractable characterization

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

Maximum Robustness

20 million bags produced in S71 since 1995



Assurance of 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.

Proven Robustness

The strength and flexibility of Flexboy® bags make them robust and suitable for all process steps.

Combining material science and film expertise in partnership with our suppliers, we have selected the best raw materials and extrusion process parameters to obtain consistent robustness in the entire film extrusion design space.

Assurance of Integrity

For the last 2 decades, Sartorius Stedim Biotech has been ensuring the closure integrity of Flexboy® 2D bags using multiple qualification tests, process controls and a 100% in-process leak test resulting in 20 million 2D bags safely used worldwide in the biopharmaceutical industry.

The assurance of integrity is the result of the control of the manufacturing process along the entire product lifecycle.

Cell Growth

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

Assurance of Supply for Fluid-contact Components

Component Quality, Change Control and Business Continuity

Critical fluid-contact components used for Flexboy® PDS are secured by long term contracts and quality agreements to offer the best assurance of supply.

We guaranty at least a 24-month change notification on critical fluid-contact components thus providing robust change control and business continuity.

Critical fluid-contact components are also available off-the-shelf to offer the best delivery reliability.

Material Qualification

Flexboy® 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
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 Flexboy® Pre-designed Solutions in all your process steps provide you with the best quality, change control, business continuity and delivery performances.

Flexboy® PDS

Components	Biocompatibility USP <87> or USP<88> Class VI	Endotoxin Sub visible particles bioburden	TSE-BSE EMA/410/01 & REACH	Notification period time
Flexboy® 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
Midisart® BV filters	Yes	Yes	Yes	24 months
Connectors	Yes	Yes	Yes	24 months

7 Flexboy® 2D Pre-designed Solutions Validation and Quality Assurance

Flexboy® 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 Flexboy® PDS are conducted under conditions that mirror biopharmaceutical operations and meet cGMP like requirements to ensure they are supplied clean, pure, endotoxin free and sterile.

Flexboy® 2D PDS are validated and routinely controlled to provide consistent performance for:

Robustness

- ASTM D882 and ISO527, ASTM D1004, F392 for tensile properties, tear resistance and flex durability
- Qualification of the bag manufacturing process capabilities following recommendations from standards (ASTM F-2097, ISO15747) and other publications (PDA, FDA-CBER)
- Internal standardized methods for connection tests and functional qualification in real process conditions
- 100% bag chamber leak test by pressure decay (ASTM F2095-01)
- 100% finished product Helium integrity test for critical process steps (2017)

Gas Transmission

- ASTM D3985, ISO15106-3, ASTM F2476: Oxygen, Water Vapor and Carbon Dioxide Transmission Rate

Biocompatibility & Chemical Compatibility

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

Cleanliness, Particulates and Sterilization

- TSE/BSE: EMA/410/01 and EP 5.2.8
- USP<788> and EP 2.9.19: Particulate Matter in Injections
- USP<71> and E.P. 2.6.1: Sterility test
- USP<85> and E.P. 2.6.14: Bacterial endotoxins sterility
- Other tests listed in section "Sterile Water for Injection" of USP and EP
- 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 radiation dose mapping

Flexboy® 2D 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 actual product samples for every production batch.

Media, Buffer, Harvest & Downstream Intermediates	Drug Substance	Drug Product ¹
Weekly testing of bioburden, particles and endotoxin on representative sample		Lot release testing of bioburden, particles and endotoxin on actual product sample

¹ None of the Flexboy® PDS for Drug Product are yet released on the basis of a lot release testing

Certificate of Release

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

² performed weekly on representative samples for buffer, media, harvest, drug substance and drug product process step

8 Flexboy® 2D Pre-designed Solutions Assurance of Container Closure Integrity

[Back to Table of Contents](#)

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

A 100% bag chamber leak test is then performed in-process before line assembly for all Flexboy® 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 handing of single-use 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
- Supplier integrity testing

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

Flexboy® PDS Features & Benefits

- Full control of manufacturing processes ensure best assurance of supply
- Long term contract and stocks of raw materials, films and components ensure best assurance of supply 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
- Best assurance of integrity of high value drug substances and drug products according to ASTM F2095



9 Flexboy® 2D Pre-designed Solutions for
Filtration & Storage for All Process Steps

Media

Buffer

Cell Harvest & DSP

Drug Substance

Drug Product

Back to Table of Contents

Filling and draining lines

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

Sampling

- Clave needleless sampling port

Outlet Sterile Connections

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

Outlet Sanitary or Aseptic Connections

- CPC Quick coupler male
- Tri-Clamp



- EVA tube for sterile weld with Vante™ sealer

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 for sterile disconnection with Clipster®



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

Inlet Filters and Connectors

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

- Sartopore® 2 sterilizing-grade filter with 0.45 | 0.2 µm membranes optimized for buffer filtration
- Sartopore® 2 XLG sterilizing-grade filter with 0.8 | 0.2 µm membranes optimized for media filtration, cell harvest & downstream intermediates
- Sartopore® 2 XLM filter with advanced 0.2 | 0.1 µm pore size distribution and asymmetric prefilter membrane optimized for mycoplasma retention in media
- Sartopore® Platinum sterilizing-grade filter with 0.45 | 0.2 µm membranes optimized for drug substance and drug product filtration. The outstanding wetting properties of the modified membrane reduce by ten times the flushing volumes required prior to integrity testing.

Silicone TuFlux® tube enables 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® 1/4" and 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 1 1/2" 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

Tubes

- TuFlux® silicone tubing enables sterile disconnection with Clipster®
- Clear C-Flex® tubing allows for sterile weld connection with BioWelder® TC and sterile seal disconnection with BioSealer®
- EVA tubing enables sterile seal disconnection with Vante™ sealer

All fluid-contact components of Flexboy® 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

10 Flexboy® 2D Pre-designed Solutions for Media Formulation

[Back to Table of Contents](#)

Media Formulation

Sterilizing Filtration

Media Storage

Media Transfer

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

Sterile Connection to other Single-use Bioreactors

Steaming Connection to Stainless Steel Bioreactors

Sterile Connection
Sterile Weld

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

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

- Sterile connection to alternative Sartopore® filter line using Opta® 1/4" or 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 disconnection using Clipster®.

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

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

Sampling

- Clave needless 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
- STCI Steamthru™ valve for steaming connection to stainless steel bioreactors

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



11 Flexboy® 2D Pre-designed Solutions for Media Formulation

[Back to Table of Contents](#)

Media Formulation

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

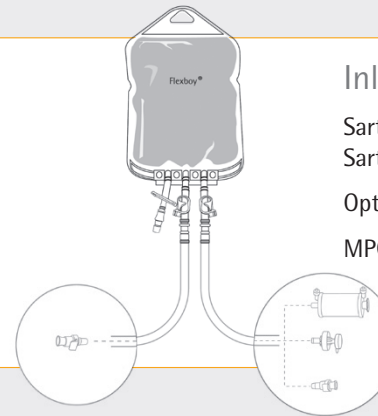
Sterile Connection to other Single-use Bioreactors

Steaming Connection to Stainless Steel Bioreactors

Sterile Connection

Sterile Weld

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
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

Bag volume	Part number	Units per box	Inlet ¹		Outlet ²	Sampling
			Filter or distal connector on filling line	Filter type and size	Distal connector on draining line	Sampling line
3 L	FFB128255	20	Sartopore® 2 XLG 0.8 0.2 µm	MidiCaps® size 4	1/4" ID C-Flex® + 1/4" MPC male + sealing cap	
	FFB128240	20	Sartopore® 2 XLM 0.2 0.1 µm			
	FFB128275	20	1/4" Opta® SFT female	NA		
	FFB128265	20	MPC female + sealing cap			
5 L	FFB128256	20	Sartopore® 2 XLG 0.8 0.2 µm	MidiCaps® size 4		
	FFB128241	20	Sartopore® 2 XLM 0.2 0.1 µm			
	FFB128276	20	3/8" Opta® SFT female	NA		
	FFB128266	20	MPC female + sealing cap			
10 L	FFB128257	10	Sartopore® 2 XLG 0.8 0.2 µm	MidiCaps® size 7	3/8" ID C-Flex® + 3/8" MPC male + sealing cap	3/16" ID EVA 50 mm (2") + 3/16" Luer Lock female + Clave connector
	FFB128242	10	Sartopore® 2 XLM 0.2 0.1 µm			
	FFB128277	10	3/8" Opta® SFT female	NA		
	FFB128267	10	MPC female + sealing cap			
20 L	FFB128258	10	Sartopore® 2 XLG 0.8 0.2 µm	MidiCaps® size 7		
	FFB128243	10	Sartopore® 2 XLM 0.2 0.1 µm			
	FFB128278	10	3/8" Opta® SFT female	NA		
	FFB128268	10	MPC female + sealing cap			
50 L	FFB128259	10	Sartopore® 2 XLG 0.8 0.2 µm	MidiCaps® size 7		
	FFB128244	10	Sartopore® 2 XLM 0.2 0.1 µm			
	FFB128279	10	3/8" Opta® SFT female	NA		
	FFB128269	10	MPC female + sealing cap			

¹ Inlet tubing line from end line to bag:

For 3 L Sartopore® 2 filters and Opta®
– 1/4" ID Silicone TuFlux® 300 mm (12") + 1/4" ID EVA 100 mm (4") + Clipster® in a separate pouch

For 5 L – 50 L Sartopore® 2 filters and Opta®
– 3/8" ID Silicone TuFlux® 300 mm (12") + 3/8" ID EVA 100 mm (4") + Clipster® in a separate pouch

For 3 L MPC
– 1/4" ID Clear C-Flex® 500 mm (20") + 4" ID EVA 100 mm (4")

For 5 L – 50 L MPC
– 3/8" ID Clear C-Flex® 500 mm (20") + 3/8" ID EVA 100 mm (4")

² Outlet tubing line from bag to end line:

For 3 L
– 1/4" ID EVA 100 mm (4") + 1/4" ID C-Flex® 500 mm (20")

For 5 L – 50 L
– 3/8" ID EVA 100 mm (4") + 3/8" ID C-Flex® 500 mm (20")

12 Flexboy® 2D Pre-designed Solutions for Media Formulation

[Back to Table of Contents](#)

Media Formulation

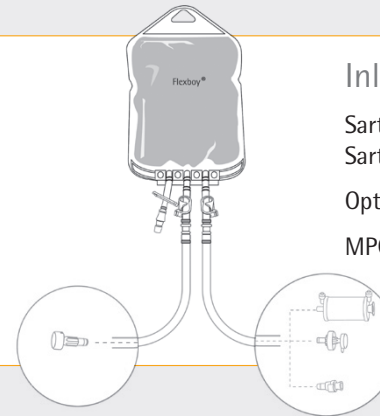
Sterile Weld to BIOSTAT STR® and RM Single-use Bioreactor

Sterile Connection to other Single-use Bioreactors

Steaming Connection to Stainless Steel Bioreactors

Sterile Connection
Sterile Weld

Outlet Line
Opta® SFT male for sterile connection



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

Bag volume	Part number	Units per box	Inlet ¹		Outlet ²	Sampling
			Filter or distal connector on filling line	Filter type and size	Distal connector on draining line	Sampling line
3 L	FFB128260	20	Sartopore® 2 XLG 0.8 0.2 µm	MidiCaps® size 4	1/4" Opta® SFT male	
	FFB128245	20	Sartopore® 2 XLM 0.2 0.1 µm			
	FFB128280	20	1/4" Opta® SFT female	NA		
	FFB128270	20	MPC female + sealing cap			
5 L	FFB128261	20	Sartopore® 2 XLG 0.8 0.2 µm	MidiCaps® size 4		
	FFB128246	20	Sartopore® 2 XLM 0.2 0.1 µm			
	FFB128281	20	3/8" Opta® SFT female	NA		
	FFB128271	20	MPC female + sealing cap			
10 L	FFB128262	10	Sartopore® 2 XLG 0.8 0.2 µm	MidiCaps® size 7	3/8" Opta® SFT male	3/16" ID EVA 50 mm (2") + 3/16" Luer Lock female + Clave connector
	FFB128247	10	Sartopore® 2 XLM 0.2 0.1 µm			
	FFB128282	10	3/8" Opta® SFT female	NA		
	FFB128272	10	MPC female + sealing cap			
20 L	FFB128263	10	Sartopore® 2 XLG 0.8 0.2 µm	MidiCaps® size 7		
	FFB128248	10	Sartopore® 2 XLM 0.2 0.1 µm			
	FFB128283	10	3/8" Opta® SFT female	NA		
	FFB128273	10	MPC female + sealing cap			
50 L	FFB128264	10	Sartopore® 2 XLG 0.8 0.2 µm	MidiCaps® size 7		
	FFB128249	10	Sartopore® 2 XLM 0.2 0.1 µm			
	FFB128284	10	3/8" Opta® SFT female	NA		
	FFB128274	10	MPC female + sealing cap			

¹ Inlet tubing line from end line to bag:

For 3 L Sartopore® 2 filters and Opta®
– 1/4" ID Silicone TuFlux® 300 mm (12") + 1/4" ID EVA 100 mm (4") +
Clipster® in a separate pouch

For 5 L – 50 L Sartopore® 2 filters and Opta®
– 3/8" ID Silicone TuFlux® 300 mm (12") + 3/8" ID EVA 100 mm (4") +
Clipster® in a separate pouch

For 3 L MPC 1/4" ID Clear C-Flex®
– 500 mm (20") + 1/4" ID EVA 100 mm (4")

For 5 L – 50 L MPC 3/8" ID Clear C-Flex®
– 500 mm (20") + 3/8" ID EVA 100 mm (4")

² Outlet tubing line from bag to end line:

For 3 L
– 1/4" ID EVA 100 mm (4") + 1/4" ID Silicone TuFlux® 300 mm (12")

For 5 L – 50 L
– 3/8" ID EVA 100 mm (4") + 3/8" ID Silicone TuFlux® 300 mm (12")

13 Flexboy® 2D Pre-designed Solutions for Media Formulation

[Back to Table of Contents](#)

Media Formulation

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

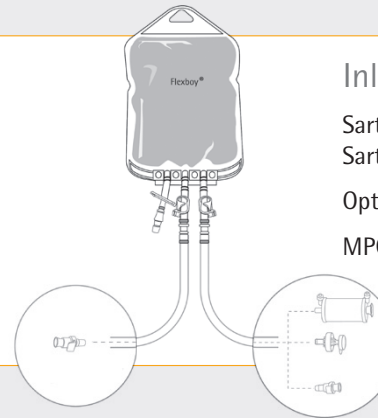
Sterile Connection to other Single-use Bioreactors

Steaming Connection to Stainless Steel Bioreactors

Sterile Connection

Sterile Weld

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
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

Bag volume	Part number	Units per box	Inlet ¹		Outlet ²	Sampling
			Filter or distal connector on filling line	Filter type and size	Distal connector on draining line	Sampling line
3 L	FFB128255	20	Sartopore® 2 XLG 0.8 0.2 µm	MidiCaps® size 4	1/4" ID C-Flex® + 1/4" MPC male + sealing cap	
	FFB128240	20	Sartopore® 2 XLM 0.2 0.1 µm			
	FFB128275	20	1/4" Opta® SFT female	NA		
	FFB128265	20	MPC female + sealing cap			
5 L	FFB128256	20	Sartopore® 2 XLG 0.8 0.2 µm	MidiCaps® size 4		
	FFB128241	20	Sartopore® 2 XLM 0.2 0.1 µm			
	FFB128276	20	3/8" Opta® SFT female	NA		
	FFB128266	20	MPC female + sealing cap			
10 L	FFB128257	10	Sartopore® 2 XLG 0.8 0.2 µm	MidiCaps® size 7	3/8" ID C-Flex® + 3/8" MPC male + sealing cap	3/16" ID EVA 50 mm (2") + 3/16" Luer Lock female + Clave connector
	FFB128242	10	Sartopore® 2 XLM 0.2 0.1 µm			
	FFB128277	10	3/8" Opta® SFT female	NA		
	FFB128267	10	MPC female + sealing cap			
20 L	FFB128258	10	Sartopore® 2 XLG 0.8 0.2 µm	MidiCaps® size 7		
	FFB128243	10	Sartopore® 2 XLM 0.2 0.1 µm			
	FFB128278	10	3/8" Opta® SFT female	NA		
	FFB128268	10	MPC female + sealing cap			
50 L	FFB128259	10	Sartopore® 2 XLG 0.8 0.2 µm	MidiCaps® size 7		
	FFB128244	10	Sartopore® 2 XLM 0.2 0.1 µm			
	FFB128279	10	3/8" Opta® SFT female	NA		
	FFB128269	10	MPC female + sealing cap			

¹ Inlet tubing line from end line to bag:

For 3 L Sartopore® 2 filters and Opta®
– 1/4" ID Silicone TuFlux® 300 mm (12") + 1/4" ID EVA 100 mm (4") +
Clipster® in a separate pouch

For 5 L – 50 L Sartopore® 2 filters and Opta®
– 3/8" ID Silicone TuFlux® 300 mm (12") + 3/8" ID EVA 100 mm (4") +
Clipster® in a separate pouch

For 3 L MPC
– 1/4" ID Clear C-Flex® 500 mm (20") + 1/4" ID EVA 100 mm (4")

For 5 L – 50 L MPC
– 3/8" ID Clear C-Flex® 500 mm (20") + 3/8" ID EVA 100 mm (4")

² Outlet tubing line from bag to end line:

For 3 L
– 1/4" ID EVA 100 mm (4") + 1/4" ID C-Flex® 500 mm (20")

For 5 L – 50 L
– 3/8" ID EVA 100 mm (4") + 3/8" ID C-Flex® 500 mm (20")

14 Flexboy® 2D Pre-designed Solutions for Media Formulation

[Back to Table of Contents](#)

Media Formulation

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

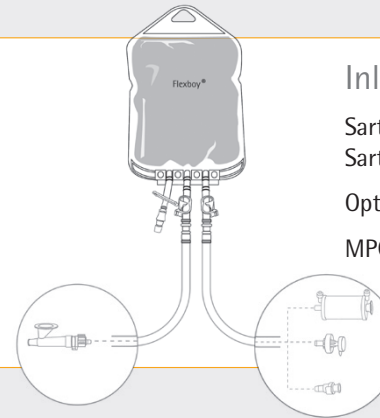
Sterile Connection to other Single-use Bioreactors

Steaming Connection to Stainless Steel Bioreactors

Sterile Connection

Sterile Weld

Outlet Line
STCII Steamthru™ valve for steaming connection



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

Bag volume	Part number	Units per box	Inlet ¹		Outlet ²	Sampling				
			Filter or distal connector on filling line	Filter type and size	Distal connector on draining line	Sampling line				
3 L	FFB128250	20	Sartopore® 2 XLG 0.8 0.2 µm	MidiCaps® size 4	3/8" STCII 3/4" sanitary flange	3/16" ID EVA 50 mm (2") + 3/16" Luer Lock female + Clave connector				
	FFB128235	20	Sartopore® 2 XLM 0.2 0.1 µm							
	FFB128230	20	1/4" Opta® SFT female	NA						
	FFB128225	20	MPC female + sealing cap	NA						
5 L	FFB128251	20	Sartopore® 2 XLG 0.8 0.2 µm	MidiCaps® size 4			3/8" STCII 3/4" sanitary flange	3/16" ID EVA 50 mm (2") + 3/16" Luer Lock female + Clave connector		
	FFB128236	20	Sartopore® 2 XLM 0.2 0.1 µm							
	FFB128231	20	3/8" Opta® SFT female	NA						
	FFB128226	20	MPC female + sealing cap	NA						
10 L	FFB128252	10	Sartopore® 2 XLG 0.8 0.2 µm	MidiCaps® size 7					3/8" STCII 3/4" sanitary flange	3/16" ID EVA 50 mm (2") + 3/16" Luer Lock female + Clave connector
	FFB128237	10	Sartopore® 2 XLM 0.2 0.1 µm							
	FFB128232	10	3/8" Opta® SFT female	NA						
	FFB128227	10	MPC female + sealing cap	NA						
20 L	FFB128253	10	Sartopore® 2 XLG 0.8 0.2 µm	MidiCaps® size 7	3/8" STCII 3/4" sanitary flange	3/16" ID EVA 50 mm (2") + 3/16" Luer Lock female + Clave connector				
	FFB128238	10	Sartopore® 2 XLM 0.2 0.1 µm							
	FFB128233	10	3/8" Opta® SFT female	NA						
	FFB128228	10	MPC female + sealing cap	NA						
50 L	FFB128254	10	Sartopore® 2 XLG 0.8 0.2 µm	MidiCaps® size 7			3/8" STCII 3/4" sanitary flange	3/16" ID EVA 50 mm (2") + 3/16" Luer Lock female + Clave connector		
	FFB128239	10	Sartopore® 2 XLM 0.2 0.1 µm							
	FFB128234	10	3/8" Opta® SFT female	NA						
	FFB128229	10	MPC female + sealing cap	NA						

¹ Inlet tubing line from end line to bag:

For 3 L Sartopore® 2 filters and Opta®
– 1/4" ID Silicone TuFlux® 300 mm (12") + 1/4" ID EVA 100 mm (4") +
Clipster® in a separate pouch

For 5 L–50 L Sartopore® 2 filters and Opta®
– 3/8" ID Silicone TuFlux® 300 mm (12") + 3/8" ID EVA 100 mm (4") +
Clipster® in a separate pouch

For 3 L MPC

– 1/4" ID Clear C-Flex® 500 mm (20") + 1/4" ID EVA 100 mm (4")

For 5 L–50 L MPC

– 3/8" ID Clear C-Flex® 500 mm (20") + 3/8" ID EVA 100 mm (4")

² Outlet tubing line from bag to end line:

For 3 L

– 1/4" ID EVA 100 mm (4") + 3/8" ID Silicone TuFlux® 300 mm (12")

For 5 L–50 L

– 3/8" ID EVA 100 mm (4") + 3/8" ID Silicone TuFlux® 300 mm (12")

15 Flexboy® 2D Pre-designed Solutions for Buffer Formulation

[Back to Table of Contents](#)

Buffer Formulation

Sterilizing Filtration from Mixer

Buffer Storage and Shipping

Buffer Transfer

Sterile Connection to Downstream Systems

Sterile Connection

Sterile Weld

Sanitary or Aseptic Connection to Downstream Systems

Quick Coupler Connection

Tri-Clamp Connection

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

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

- Sterile connection to alternative Sartopore® filter line using Opta® 1/2" or welding with BioWelder® TC
- Aseptic connection to alternative Sartopore® filter line with MPC quick coupler

Sartopore® filters for sterile disconnection with Clipster® are available with Silicone TuFlux® tubing.

Inlet and outlet lines are made of EVA + Silicone TuFlux® or EVA + C-Flex® tubing for welding and sealing.

Flexboy® 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.

Sampling

- Clave needleless sampling port

Outlet Line

Connection and transfer by pumping or gravity

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

- MPC quick coupler male & female for sanitary or aseptic connection to single-use systems
- Tri-Clamp flange for sanitary or aseptic connection to stainless steel systems



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

16 Flexboy® 2D Pre-designed Solutions for Buffer Formulation

[Back to Table of Contents](#)

Buffer Formulation

Sterile Connection to Downstream Systems

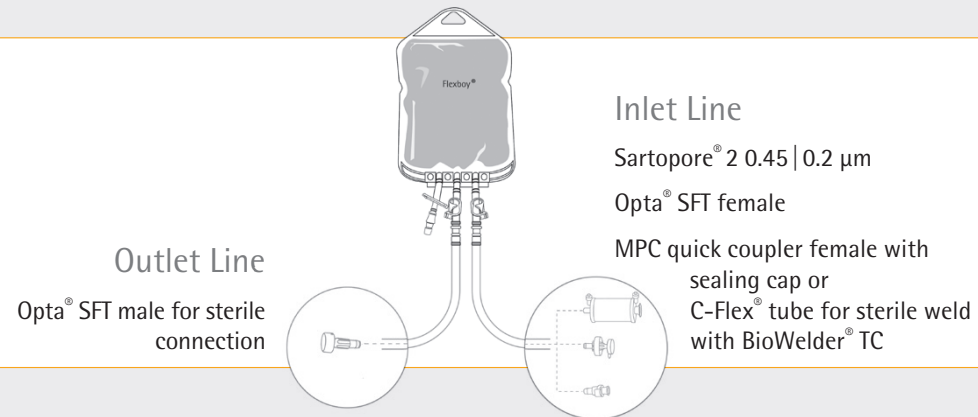
Sanitary or Aseptic Connection to Downstream Systems

Sterile Connection

Sterile Weld

Quick Coupler Connection

Tri-Clamp Connection



Sterile Connection to Downstream Systems

Bag volume	Part number	Units per box	Inlet ¹		Outlet ²	Sampling
			Filter or distal connector on filling line	Filter type and size	Distal connector on draining line	Sampling line
3 L	FFB128305	20	Sartopore® 2 0.45 0.2 µm	MidiCaps® size 4	1/4" Opta® SFT male	
	FFB128280	20	1/4" Opta® SFT female	NA		
	FFB128270	20	MPC female + sealing cap	NA		
5 L	FFB128306	20	Sartopore® 2 0.45 0.2 µm	MidiCaps® size 4	3/8" Opta® SFT male	3/16" ID EVA 50 mm (2") + 3/16" Luer Lock female + Clave connector
	FFB128281	20	3/8" Opta® SFT female	NA		
	FFB128271	20	MPC female + sealing cap	NA		
10 L	FFB128307	10	Sartopore® 2 0.45 0.2 µm	MidiCaps® size 7	3/8" Opta® SFT male	3/16" ID EVA 50 mm (2") + 3/16" Luer Lock female + Clave connector
	FFB128282	10	3/8" Opta® SFT female	NA		
	FFB128272	10	MPC female + sealing cap	NA		
20 L	FFB128308	10	Sartopore® 2 0.45 0.2 µm	MidiCaps® size 7	3/8" Opta® SFT male	3/16" ID EVA 50 mm (2") + 3/16" Luer Lock female + Clave connector
	FFB128283	10	3/8" Opta® SFT female	NA		
	FFB128273	10	MPC female + sealing cap	NA		
50 L	FFB128309	10	Sartopore® 2 0.45 0.2 µm	MidiCaps® size 7	3/8" Opta® SFT male	3/16" ID EVA 50 mm (2") + 3/16" Luer Lock female + Clave connector
	FFB128284	10	3/8" Opta® SFT female	NA		
	FFB128274	10	MPC female + sealing cap	NA		

¹ Inlet tubing line from end line to bag:

For 3 L Sartopore® 2 filters and Opta®
– 1/4" ID Silicone TuFlux® 300 mm (12") + 1/4" ID EVA 100 mm (4") + Clipster® in a separate pouch

For 5 L–50 L Sartopore® 2 filters and Opta®
– 3/8" ID Silicone TuFlux® 300 mm (12") + 3/8" ID EVA 100 mm (4") + Clipster® in a separate pouch

For 3 L MPC

– 1/4" ID Clear C-Flex® 500 mm (20") + 1/4" ID EVA 100 mm (4")

For 5 L–50 L MPC

– 3/8" ID Clear C-Flex® 500 mm (20") + 3/8" ID EVA 100 mm (4")

² Outlet tubing line from bag to end line:

For 3 L

– 1/4" ID EVA 100 mm (4") + 1/4" ID Silicone TuFlux® 300 mm (12")

For 5 L–50 L

– 3/8" ID EVA 100 mm (4") + 3/8" ID Silicone TuFlux® 300 mm (12")

17 Flexboy® 2D Pre-designed Solutions for Buffer Formulation

[Back to Table of Contents](#)

Buffer Formulation

Sterile Connection to Downstream Systems

Sterile Connection

Sterile Weld

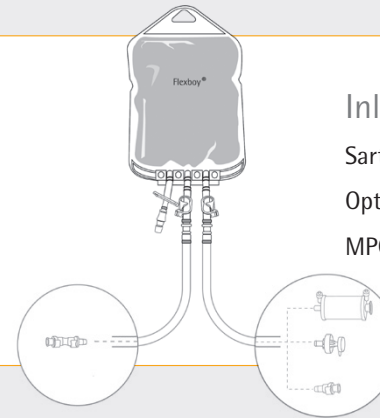
Sanitary or Aseptic Connection to Downstream Systems

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 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

Bag volume	Part number	Units per box	Inlet ¹		Outlet ²	Sampling
			Filter or distal connector on filling line	Filter type and size	Distal connector on draining line	Sampling line
3 L	FFB128300	20	Sartopore® 2 0.45 0.2 µm	MidiCaps® size 4	1/4" ID C-Flex® + 1/4" MPC male + sealing cap	
	FFB128275	20	1/4" Opta® SFT female	NA		
	FFB128265	20	MPC female + sealing cap	NA		
5 L	FFB128301	20	Sartopore® 2 0.45 0.2 µm	MidiCaps® size 4	3/8" ID C-Flex® + 3/8" MPC male + sealing cap	3/16" ID EVA 50 mm (2") + 3/16" Luer Lock female + Clave connector
	FFB128276	20	3/8" Opta® SFT female	NA		
	FFB128266	20	MPC female + sealing cap	NA		
10 L	FFB128302	10	Sartopore® 2 0.45 0.2 µm	MidiCaps® size 7	3/8" ID C-Flex® + 3/8" MPC male + sealing cap	3/16" ID EVA 50 mm (2") + 3/16" Luer Lock female + Clave connector
	FFB128277	10	3/8" Opta® SFT female	NA		
	FFB128267	10	MPC female + sealing cap	NA		
20 L	FFB128303	10	Sartopore® 2 0.45 0.2 µm	MidiCaps® size 7	3/8" ID C-Flex® + 3/8" MPC male + sealing cap	3/16" ID EVA 50 mm (2") + 3/16" Luer Lock female + Clave connector
	FFB128278	10	3/8" Opta® SFT female	NA		
	FFB128268	10	MPC female + sealing cap	NA		
50 L	FFB128304	10	Sartopore® 2 0.45 0.2 µm	MidiCaps® size 7	3/8" ID C-Flex® + 3/8" MPC male + sealing cap	3/16" ID EVA 50 mm (2") + 3/16" Luer Lock female + Clave connector
	FFB128279	10	3/8" Opta® SFT female	NA		
	FFB128269	10	MPC female + sealing cap	NA		

¹ Inlet tubing line from end line to bag:

For 3 L Sartopore® 2 filters and Opta®
– 1/4" ID Silicone TuFlux® 300 mm (12") + 1/4" ID EVA 100 mm (4") + Clipster® in a separate pouch

For 5 L–50 L Sartopore® 2 filters and Opta®
– 3/8" ID Silicone TuFlux® 300 mm (12") + 3/8" ID EVA 100 mm (4") + Clipster® in a separate pouch

For 3 L MPC

– 1/4" ID Clear C-Flex® 500 mm (20") + 1/4" ID EVA 100 mm (4")

For 5 L–50 L MPC

– 3/8" ID Clear C-Flex® 500 mm (20") + 3/8" ID EVA 100 mm (4")

² Outlet tubing line from bag to end line:

For 3 L

– 1/4" ID EVA 100 mm (4") + 1/4" ID C-Flex® 500 mm (20")

For 5 L–50 L

– 3/8" ID EVA 100 mm (4") + 3/8" ID C-Flex® 500 mm (20")

18 Flexboy® 2D Pre-designed Solutions for Buffer Formulation

[Back to Table of Contents](#)

Buffer Formulation

Sterile Connection to Downstream Systems

Sterile Connection

Sterile Weld

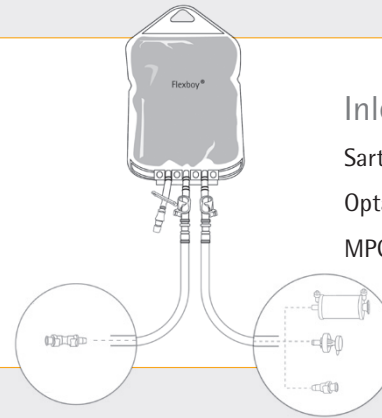
Sanitary or Aseptic Connection to Downstream Systems

Quick Coupler Connection

Tri-Clamp Connection

Outlet Line

MPC quick coupler male & female with cap 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

Quick Coupler Connection to Downstream Systems

Bag volume	Part number	Units per box	Inlet ¹		Outlet ²	Sampling
			Filter or distal connector on filling line	Filter type and size	Distal connector on draining line	Sampling line
3 L	FFB128300	20	Sartopore® 2 0.45 0.2 µm	MidiCaps® size 4	1/4" ID C-Flex® + 1/4" MPC male + sealing cap	3/16" ID EVA 50 mm (2") + 3/16" Luer Lock female + Clave connector
	FFB128275	20	1/4" Opta® SFT female	NA		
	FFB128265	20	MPC female + sealing cap	NA		
5 L	FFB128301	20	Sartopore® 2 0.45 0.2 µm	MidiCaps® size 4	3/8" ID C-Flex® + 3/8" MPC male + sealing cap	3/16" ID EVA 50 mm (2") + 3/16" Luer Lock female + Clave connector
	FFB128276	20	3/8" Opta® SFT female	NA		
	FFB128266	20	MPC female + sealing cap	NA		
10 L	FFB128302	10	Sartopore® 2 0.45 0.2 µm	MidiCaps® size 7	3/8" ID C-Flex® + 3/8" MPC male + sealing cap	3/16" ID EVA 50 mm (2") + 3/16" Luer Lock female + Clave connector
	FFB128277	10	3/8" Opta® SFT female	NA		
	FFB128267	10	MPC female + sealing cap	NA		
20 L	FFB128303	10	Sartopore® 2 0.45 0.2 µm	MidiCaps® size 7	3/8" ID C-Flex® + 3/8" MPC male + sealing cap	3/16" ID EVA 50 mm (2") + 3/16" Luer Lock female + Clave connector
	FFB128278	10	3/8" Opta® SFT female	NA		
	FFB128268	10	MPC female + sealing cap	NA		
50 L	FFB128304	10	Sartopore® 2 0.45 0.2 µm	MidiCaps® size 7	3/8" ID C-Flex® + 3/8" MPC male + sealing cap	3/16" ID EVA 50 mm (2") + 3/16" Luer Lock female + Clave connector
	FFB128279	10	3/8" Opta® SFT female	NA		
	FFB128269	10	MPC female + sealing cap	NA		

¹ Inlet tubing line from end line to bag:

For 3 L Sartopore® 2 filters and Opta®
– 1/4" ID Silicone TuFlux® 300 mm (12") + 1/4" ID EVA 100 mm (4") + Clipster® in a separate pouch

For 5 L – 50 L Sartopore® 2 filters and Opta®
– 3/8" ID Silicone TuFlux® 300 mm (12") + 3/8" ID EVA 100 mm (4") + Clipster® in a separate pouch

For 3 L MPC

– 1/4" ID Clear C-Flex® 500 mm (20") + 1/4" ID EVA 100 mm (4")

For 5 L – 50 L MPC

– 3/8" ID Clear C-Flex® 500 mm (20") + 3/8" ID EVA 100 mm (4")

² Outlet tubing line from bag to end line:

For 3 L

– 1/4" ID EVA 100 mm (4") + 1/4" ID C-Flex® 500 mm (20")

For 5 L – 50 L

– 3/8" ID EVA 100 mm (4") + 3/8" ID C-Flex® 500 mm (20")

19 Flexboy® 2D Pre-designed Solutions for Buffer Formulation

[Back to Table of Contents](#)

Buffer Formulation

Sterile Connection to Downstream Systems

Sterile Connection

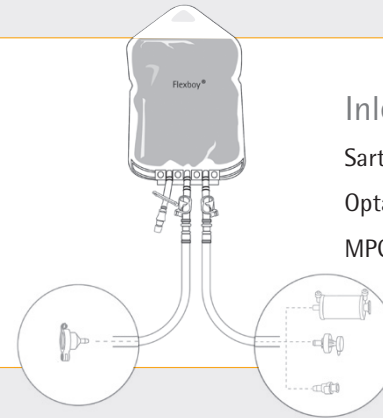
Sterile Weld

Sanitary or Aseptic Connection to Downstream Systems

Quick Coupler Connection

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 Connection to Downstream Systems

Bag volume	Part number	Units per box	Inlet ¹		Outlet ²	Sampling
			Filter or distal connector on filling line	Filter type and size	Distal connector on draining line	Sampling line
3 L	FFB128295	20	Sartopore® 2 0.45 0.2 µm	MidiCaps® size 4	1/4" Tri-Clamp sanitary flange with gasket, cap & union	
	FFB128290	20	1/4" Opta® SFT female	NA		
	FFB128285	20	MPC female + sealing cap	NA		
5 L	FFB128296	20	Sartopore® 2 0.45 0.2 µm	MidiCaps® size 4		
	FFB128291	20	3/8" Opta® SFT female	NA		
	FFB128286	20	MPC female + sealing cap	NA		
10 L	FFB128297	10	Sartopore® 2 0.45 0.2 µm	MidiCaps® size 7	3/8" Tri-Clamp sanitary flange with gasket, cap & union	3/16" ID EVA 50 mm (2") + 3/16" Luer Lock female + Clave connector
	FFB128292	10	3/8" Opta® SFT female	NA		
	FFB128287	10	MPC female + sealing cap	NA		
20 L	FFB128298	10	Sartopore® 2 0.45 0.2 µm	MidiCaps® size 7		
	FFB128293	10	3/8" Opta® SFT female	NA		
	FFB128288	10	MPC female + sealing cap	NA		
50 L	FFB128299	10	Sartopore® 2 0.45 0.2 µm	MidiCaps® size 7		
	FFB128294	10	3/8" Opta® SFT female	NA		
	FFB128289	10	MPC female + sealing cap	NA		

¹ Inlet tubing line from end line to bag:

For 3 L Sartopore® 2 filters and Opta®
– 1/4" ID Silicone TuFlux® 300 mm (12") + 1/4" ID EVA 100 mm (4") + Clipster® in a separate pouch

For 5 L – 50 L Sartopore® 2 filters and Opta®
– 3/8" ID Silicone TuFlux® 300 mm (12") + 3/8" ID EVA 100 mm (4") + Clipster® in a separate pouch

For 3 L MPC

– 1/4" ID Clear C-Flex® 500 mm (20") + 1/4" ID EVA 100 mm (4")

For 5 L – 50 L MPC

– 3/8" ID Clear C-Flex® 500 mm (20") + 3/8" ID EVA 100 mm (4")

² Outlet tubing line from bag to end line:

For 3 L

– 1/4" ID EVA 100 mm (4") + 1/4" ID Silicone TuFlux® 300 mm (12")

For 5 L – 50 L

– 3/8" ID EVA 100 mm (4") + 3/8" ID Silicone TuFlux® 300 mm (12")

Flexboy® 2D Pre-designed Solutions for Cell Harvest & Downstream Intermediates

[Back to Table of Contents](#)

Cell Harvest & Downstream Intermediates

Clarification and Sterilizing Filtration from Bioreactor

Cell Harvest or Downstream Intermediates Storage and Shipping

Harvest or Downstream Intermediates Transfer

Sterile Connection to Downstream Systems

Sterile Connection
Sterile Weld

Sanitary or Aseptic Connection to Downstream Systems

Quick Coupler Connection
Tri-Clamp Connection

Flexboy® 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.

Flexboy® 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 for sterile disconnection with Clipster® are available with Silicone TuFlux® tubing. Inlet and outlet lines are made of EVA + Silicone TuFlux® or EVA + C-Flex® tubings for welding and sealing.

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

Sampling

- Clave needlessly sampling port

Outlet Line

Connection and transfer by pumping or gravity

- Opta® SFT male for sterile connection
- C-Flex® with MPC plug for sterile weld to single-use system

- MPC 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

Clarification and sterile filtration from bioreactor or any downstream purification step

- 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

21 Flexboy® 2D Pre-designed Solutions for Cell Harvest & Downstream Intermediates

[Back to Table of Contents](#)

Cell Harvest & Downstream Intermediates

Sterile Connection to Downstream Systems

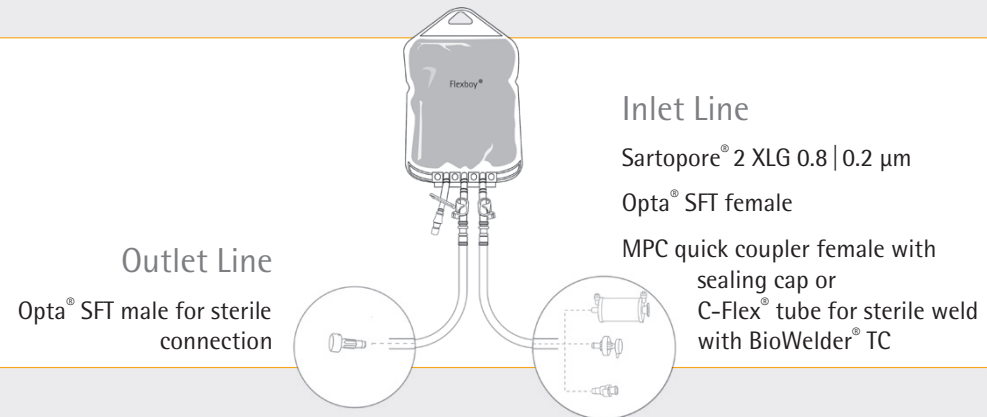
Sanitary or Aseptic Connection to Downstream Systems

Sterile Connection

Sterile Weld

Quick Coupler Connection

Tri-Clamp Connection



Sterile Connection to Downstream Systems

Bag volume	Part number	Units per box	Inlet ¹		Outlet ²	Sampling
			Filter or distal connector on filling line	Filter type and size	Distal connector on draining line	Sampling line
3 L	FFB128260	20	Sartopore® 2 XLG 0.8 0.2 µm	MidiCaps® size 4	1/4" Opta® SFT male	
	FFB128280	20	1/4" Opta® SFT female	NA		
	FFB128270	20	MPC female + sealing cap	NA		
5 L	FFB128261	20	Sartopore® 2 XLG 0.8 0.2 µm	MidiCaps® size 4	3/8" Opta® SFT male	3/16" ID EVA 50 mm (2") + 3/16" Luer Lock female + Clave connector
	FFB128281	20	3/8" Opta® SFT female	NA		
	FFB128271	20	MPC female + sealing cap	NA		
10 L	FFB128262	10	Sartopore® 2 XLG 0.8 0.2 µm	MidiCaps® size 7	3/8" Opta® SFT male	3/16" ID EVA 50 mm (2") + 3/16" Luer Lock female + Clave connector
	FFB128282	10	3/8" Opta® SFT female	NA		
	FFB128272	10	MPC female + sealing cap	NA		
20 L	FFB128263	10	Sartopore® 2 XLG 0.8 0.2 µm	MidiCaps® size 7	3/8" Opta® SFT male	3/16" ID EVA 50 mm (2") + 3/16" Luer Lock female + Clave connector
	FFB128283	10	3/8" Opta® SFT female	NA		
	FFB128273	10	MPC female + sealing cap	NA		
50 L	FFB128264	10	Sartopore® 2 XLG 0.8 0.2 µm	MidiCaps® size 7	3/8" Opta® SFT male	3/16" ID EVA 50 mm (2") + 3/16" Luer Lock female + Clave connector
	FFB128284	10	3/8" Opta® SFT female	NA		
	FFB128274	10	MPC female + sealing cap	NA		

¹ Inlet tubing line from end line to bag:

For 3 L Sartopore® 2 filters and Opta®
– 1/4" ID Silicone TuFlux® 300 mm (12") + 1/4" ID EVA 100 mm (4") + Clipster® in a separate pouch

For 5 L – 50 L Sartopore® 2 filters and Opta®
– 3/8" ID Silicone TuFlux® 300 mm (12") + 3/8" ID EVA 100 mm (4") + Clipster® in a separate pouch

For 3 L MPC
– 1/4" ID Clear C-Flex® 500 mm (20") + 1/4" ID EVA 100 mm (4")

For 5 L – 50 L MPC
– 3/8" ID Clear C-Flex® 500 mm (20") + 3/8" ID EVA 100 mm (4")

² Outlet tubing line from bag to end line:

For 3 L
– 1/4" ID EVA 100 mm (4") + 1/4" ID Silicone TuFlux® 300 mm (12")

For 5 L – 50 L
– 3/8" ID EVA 100 mm (4") + 3/8" ID Silicone TuFlux® 300 mm (12")

Flexboy® 2D Pre-designed Solutions for Cell Harvest & Downstream Intermediates

[Back to Table of Contents](#)

Cell Harvest & Downstream Intermediates

Sterile Connection to Downstream Systems

Sterile Connection

Sterile Weld

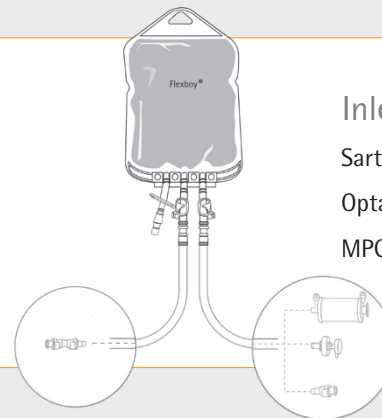
Sanitary or Aseptic Connection to Downstream Systems

Quick Coupler Connection

Tri-Clamp Connection

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

Bag volume	Part number	Units per box	Inlet ¹		Outlet ²	Sampling
			Filter or distal connector on filling line	Filter type and size	Distal connector on draining line	Sampling line
3 L	FFB128255	20	Sartopore® 2 XLG 0.8 0.2 µm	MidiCaps® size 4	1/4" ID C-Flex® + 1/4" MPC male + sealing cap	
	FFB128275	20	1/4" Opta® SFT female	NA		
	FFB128265	20	MPC female + sealing cap			
5 L	FFB128256	20	Sartopore® 2 XLG 0.8 0.2 µm	MidiCaps® size 4	3/8" ID C-Flex® + 3/8" MPC male + sealing cap	3/16" ID EVA 50 mm (2") + 3/16" Luer Lock female + Clave connector
	FFB128276	20	3/8" Opta® SFT female	NA		
	FFB128266	20	MPC female + sealing cap			
10 L	FFB128257	10	Sartopore® 2 XLG 0.8 0.2 µm	MidiCaps® size 7	3/8" ID C-Flex® + 3/8" MPC male + sealing cap	3/16" ID EVA 50 mm (2") + 3/16" Luer Lock female + Clave connector
	FFB128277	10	3/8" Opta® SFT female	NA		
	FFB128267	10	MPC female + sealing cap			
20 L	FFB128258	10	Sartopore® 2 XLG 0.8 0.2 µm	MidiCaps® size 7	3/8" ID C-Flex® + 3/8" MPC male + sealing cap	3/16" ID EVA 50 mm (2") + 3/16" Luer Lock female + Clave connector
	FFB128278	10	3/8" Opta® SFT female	NA		
	FFB128268	10	MPC female + sealing cap			
50 L	FFB128259	10	Sartopore® 2 XLG 0.8 0.2 µm	MidiCaps® size 7	3/8" ID C-Flex® + 3/8" MPC male + sealing cap	3/16" ID EVA 50 mm (2") + 3/16" Luer Lock female + Clave connector
	FFB128279	10	3/8" Opta® SFT female	NA		
	FFB128269	10	MPC female + sealing cap			

¹ Inlet tubing line from end line to bag:

For 3 L Sartopore® 2 filters and Opta®
– 1/4" ID Silicone TuFlux® 300 mm (12") + 1/4" ID EVA 100 mm (4")
+ Clipster® in a separate pouch

For 5 L–50 L Sartopore® 2 filters and Opta®
– 3/8" ID Silicone TuFlux® 300 mm (12") + 3/8" ID EVA 100 mm (4") +
Clipster® in a separate pouch

For 3 L MPC

– 1/4" ID Clear C-Flex® 500 mm (20") + 1/4" ID EVA 100 mm (4")

For 5 L–50 L MPC

– 3/8" ID Clear C-Flex® 500 mm (20") + 3/8" ID EVA 100 mm (4")

² Outlet tubing line from bag to end line:

For 3 L

– 1/4" ID EVA 100 mm (4") + 1/4" ID C-Flex® 500 mm (20")

For 5 L–50 L

– 3/8" ID EVA 100 mm (4") + 3/8" ID C-Flex® 500 mm (20")

Flexboy® 2D Pre-designed Solutions for Cell Harvest & Downstream Intermediates

[Back to Table of Contents](#)

Cell Harvest & Downstream Intermediates

Sterile Connection to Downstream Systems

Sterile Connection

Sterile Weld

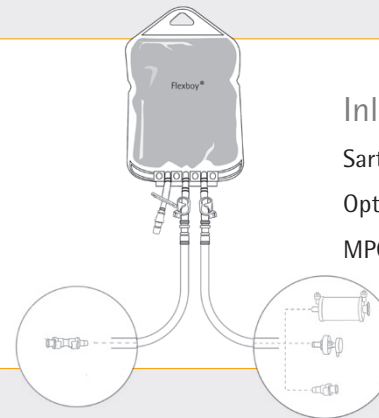
Sanitary or Aseptic Connection to Downstream Systems

Quick Coupler Connection

Tri-Clamp Connection

Outlet Line

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

Quick Coupler Connection to Downstream Systems

Bag volume	Part number	Units per box	Inlet ¹		Outlet ²	Sampling
			Filter or distal connector on filling line	Filter type and size	Distal connector on draining line	Sampling line
3 L	FFB128255	20	Sartopore® 2 XLG 0.8 0.2 µm	MidiCaps® size 4	1/4" ID C-Flex® + 1/4" MPC male + sealing cap	
	FFB128275	20	1/4" Opta® SFT female	NA		
	FFB128265	20	MPC female + sealing cap			
5 L	FFB128256	20	Sartopore® 2 XLG 0.8 0.2 µm	MidiCaps® size 4	3/8" ID C-Flex® + 3/8" MPC male + sealing cap	3/16" ID EVA 50 mm (2") + 3/16" Luer Lock female + Clave connector
	FFB128276	20	3/8" Opta® SFT female	NA		
	FFB128266	20	MPC female + sealing cap			
10 L	FFB128257	10	Sartopore® 2 XLG 0.8 0.2 µm	MidiCaps® size 7	3/8" ID C-Flex® + 3/8" MPC male + sealing cap	3/16" ID EVA 50 mm (2") + 3/16" Luer Lock female + Clave connector
	FFB128277	10	3/8" Opta® SFT female	NA		
	FFB128267	10	MPC female + sealing cap			
20 L	FFB128258	10	Sartopore® 2 XLG 0.8 0.2 µm	MidiCaps® size 7	3/8" ID C-Flex® + 3/8" MPC male + sealing cap	3/16" ID EVA 50 mm (2") + 3/16" Luer Lock female + Clave connector
	FFB128278	10	3/8" Opta® SFT female	NA		
	FFB128268	10	MPC female + sealing cap			
50 L	FFB128259	10	Sartopore® 2 XLG 0.8 0.2 µm	MidiCaps® size 7	3/8" ID C-Flex® + 3/8" MPC male + sealing cap	3/16" ID EVA 50 mm (2") + 3/16" Luer Lock female + Clave connector
	FFB128279	10	3/8" Opta® SFT female	NA		
	FFB128269	10	MPC female + sealing cap			

¹ Inlet tubing line from end line to bag:

For 3 L Sartopore® 2 filters and Opta®
 – 1/4" ID Silicone TuFlux® 300 mm (12") + 1/4" ID EVA 100 mm (4")
 + Clipster® in a separate pouch

For 5 L–50 L Sartopore® 2 filters and Opta®
 – 3/8" ID Silicone TuFlux® 300 mm (12") + 3/8" ID EVA 100 mm (4") +
 Clipster® in a separate pouch

For 3 L MPC

– 1/4" ID Clear C-Flex® 500 mm (20") + 1/4" ID EVA 100 mm (4")

For 5 L–50 L MPC

– 3/8" ID Clear C-Flex® 500 mm (20") + 3/8" ID EVA 100 mm (4")

² Outlet tubing line from bag to end line:

For 3 L

– 1/4" ID EVA 100 mm (4") + 1/4" ID C-Flex® 500 mm (20")

For 5 L–50 L

– 3/8" ID EVA 100 mm (4") + 3/8" ID C-Flex® 500 mm (20")

Flexboy® 2D Pre-designed Solutions for Cell Harvest & Downstream Intermediates

[Back to Table of Contents](#)

Cell Harvest & Downstream Intermediates

Sterile Connection to Downstream Systems

Sterile Connection

Sterile Weld

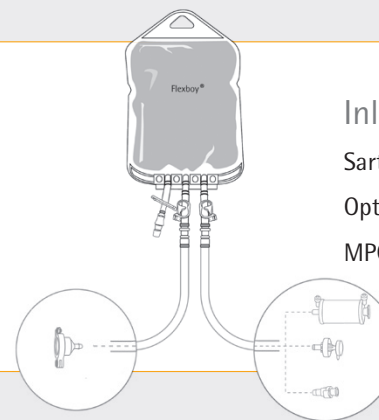
Sanitary or Aseptic Connection to Downstream Systems

Quick Coupler Connection

Tri-Clamp Connection

Outlet Line

Tri-Clamp flange for sanitary or aseptic 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

Tri-Clamp Connection to Downstream Systems

Bag volume	Part number	Units per box	Inlet ¹		Outlet ²	Sampling
			Filter or distal connector on filling line	Filter type and size	Distal connector on draining line	Sampling line
3 L	FFB128310	20	Sartopore® XLG 0.8 0.2 µm	MidiCaps® size 4	1/4" Tri-Clamp sanitary flange with gasket, cap & union	
	FFB128290	20	1/4" Opta® SFT female	NA		
	FFB128285	20	MPC female + sealing cap	NA		
5 L	FFB128311	20	Sartopore® XLG 0.8 0.2 µm	MidiCaps® size 4	3/8" Tri-Clamp sanitary flange with gasket, cap & union	3/16" ID EVA 50 mm (2") + 3/16" Luer Lock female + Clave connector
	FFB128291	20	3/8" Opta® SFT female	NA		
	FFB128286	20	MPC female + sealing cap	NA		
10 L	FFB128312	10	Sartopore® XLG 0.8 0.2 µm	MidiCaps® size 7	3/8" Tri-Clamp sanitary flange with gasket, cap & union	3/16" ID EVA 50 mm (2") + 3/16" Luer Lock female + Clave connector
	FFB128292	10	3/8" Opta® SFT female	NA		
	FFB128287	10	MPC female + sealing cap	NA		
20 L	FFB128313	10	Sartopore® XLG 0.8 0.2 µm	MidiCaps® size 7	3/8" Tri-Clamp sanitary flange with gasket, cap & union	3/16" ID EVA 50 mm (2") + 3/16" Luer Lock female + Clave connector
	FFB128293	10	3/8" Opta® SFT female	NA		
	FFB128288	10	MPC female + sealing cap	NA		
50 L	FFB128314	10	Sartopore® XLG 0.8 0.2 µm	MidiCaps® size 7	3/8" Tri-Clamp sanitary flange with gasket, cap & union	3/16" ID EVA 50 mm (2") + 3/16" Luer Lock female + Clave connector
	FFB128294	10	3/8" Opta® SFT female	NA		
	FFB128289	10	MPC female + sealing cap	NA		

¹ Inlet tubing line from end line to bag:

For 3 L Sartopore® 2 filters and Opta®
– 1/4" ID Silicone TuFlux® 300 mm (12") + 1/4" ID EVA 100 mm (4") + Clipster® in a separate pouch

For 5 L – 50 L Sartopore® 2 filters and Opta®
– 3/8" ID Silicone TuFlux® 300 mm (12") + 3/8" ID EVA 100 mm (4") + Clipster® in a separate pouch

For 3 L MPC

– 1/4" ID Clear C-Flex® 500 mm (20") + 1/4" ID EVA 100 mm (4")

For 5 L – 50 L MPC

– 3/8" ID Clear C-Flex® 500 mm (20") + 3/8" ID EVA 100 mm (4")

² Outlet tubing line from bag to end line:

For 3 L

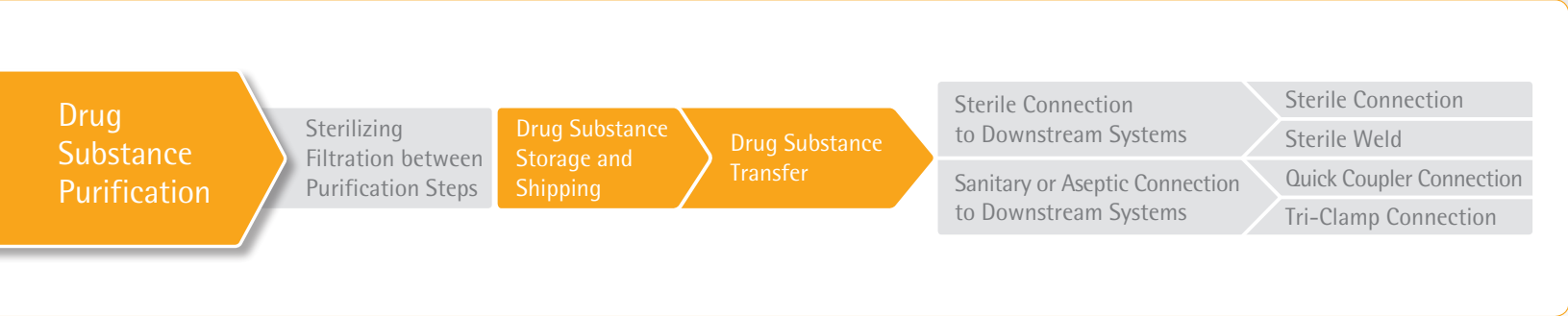
– 1/4" ID EVA 100 mm (4") + 1/4" ID Silicone TuFlux® 300 mm (12")

For 5 L – 50 L

– 3/8" ID EVA 100 mm (4") + 3/8" ID Silicone TuFlux® 300 mm (12")

25 Flexboy® 2D Pre-designed Solutions for Drug Substance Purification

[Back to Table of Contents](#)



Flexboy® 2D bags solutions for drug substance feature the Sartopore® Platinum 0.45 | 0.2 µm with exceptional throughput, flowrate and wetting performances for a cheaper and faster filtration process. The outstanding wetting properties of the modified membrane reduce by ten times the flushing volumes required prior to integrity testing and eliminate retesting due to insufficient wetting.

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

Sartopore® filters for sterile disconnection with Clipster® are available with Silicone TuFlux® tubing.

Inlet and outlet lines are made of EVA + Silicone TuFlux® or EVA + 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.

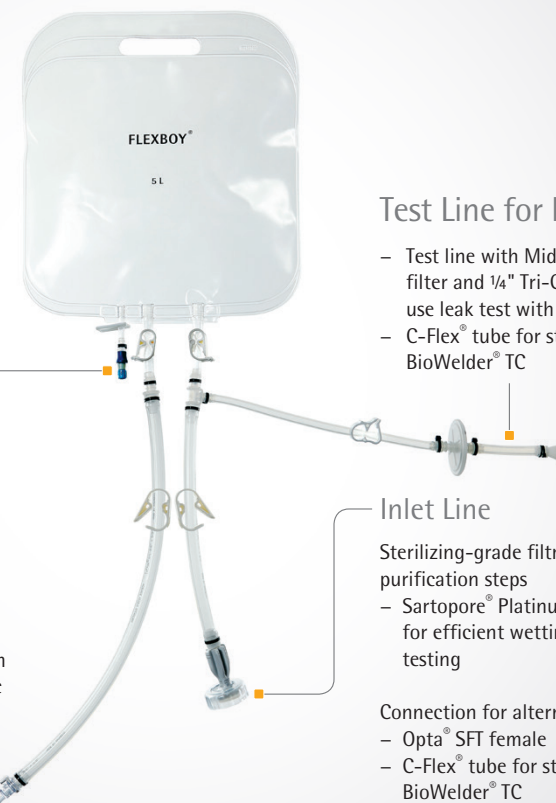
Flexboy® 2D Bags allow for sterile drug substance transfer to most common single-use and stainless steel downstream purification systems after the cross-flow step with a variety of sterile connections.

Outlet Line

- Connection and transfer by pumping or gravity
- Opta® SFT male for sterile connection
 - C-Flex® with MPC plug for sterile weld to single-use system

Sampling

- Clave needleless sampling port



Test Line for FlexAct® BT

- Test line with Midisart® BV 0.2 µm filter and ¼" Tri-Clamp for point of use leak test with FlexAct® BT
- C-Flex® tube for sterile weld with BioWelder® TC

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

Flexboy® 2D Pre-designed Solutions for Drug Substance Purification

[Back to Table of Contents](#)

Drug Substance Purification

Sterile Connection to Downstream Systems

Sanitary or Aseptic Connection to Downstream Systems

Sterile Connection

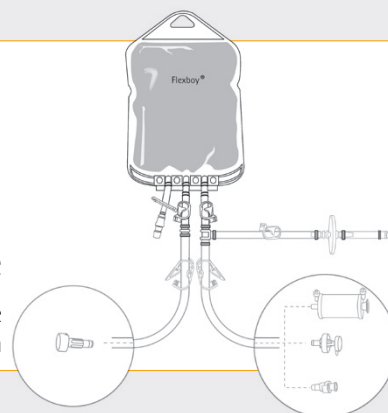
Sterile Weld

Quick Coupler Connection

Tri-Clamp Connection

Outlet Line

Opta® SFT male for sterile connection



Inlet Line

Test line with Midisart® BV
0.2 µm filter and 1/4" 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 Connection to Downstream Systems

Bag volume	Part number	Units per box	Inlet ¹		Outlet ²	Sampling
			Filter or distal connector on filling line	Filter type and size	Distal connector on draining line	Sampling line
3 L	FFB128355	16	Sartopore® Platinum 0.45 0.2 µm	MidiCaps® size 4	1/4" Opta® SFT male	
	FFB128340	16	1/4" Opta® SFT female	NA		
	FFB128325	16	MPC female + sealing cap			
5 L	FFB128356	16	Sartopore® Platinum 0.45 0.2 µm	MidiCaps® size 4		
	FFB128341	16	3/8" Opta® SFT female	NA		
	FFB128326	16	MPC female + sealing cap			
10 L	FFB128357	8	Sartopore® Platinum 0.45 0.2 µm	MidiCaps® size 7	3/8" Opta® SFT male	3/16" ID EVA 50 mm (2") + 3/16" Luer Lock female + Clave connector
	FFB128342	8	3/8" Opta® SFT female	NA		
	FFB128327	8	MPC female + sealing cap			
20 L	FFB128358	8	Sartopore® Platinum 0.45 0.2 µm	MidiCaps® size 7		
	FFB128343	8	3/8" Opta® SFT female	NA		
	FFB128328	8	MPC female + sealing cap			
50 L	FFB128359	8	Sartopore® Platinum 0.45 0.2 µm	MidiCaps® size 7		
	FFB128344	8	3/8" Opta® SFT female	NA		
	FFB128329	8	MPC female + sealing cap			

¹ Inlet tubing line from end line to bag:

For 3 L Sartopore® Platinum filters and Opta®
– 1/4" ID Silicone TuFlux® 300 mm (12") + 1/4" ID EVA 100 mm (4") + Clipster® in a separate pouch

For 5 L–50 L Sartopore® Platinum filters and Opta®
– 3/8" ID Silicone TuFlux® 300 mm (12") + 3/8" ID EVA 100 mm (4") + Clipster® in a separate pouch

For 3 L MPC

– 1/4" ID Clear C-Flex® 500 mm (20") + 1/4" ID EVA 100 mm (4")

For 5 L–50 L MPC

– 3/8" ID Clear C-Flex® 500 mm (20") + 3/8" ID EVA 100 mm (4")

Leak Test line

– 1/4" ID Clear C-Flex® 300 mm (12") + Midisart® BV 0.2 µm + 1/4" ID Silicone TuFlux® 100 mm (4") + 1/4" Tri-Clamp

² Outlet tubing line from bag to end line:

For 3 L

– 1/4" ID EVA 100 mm (4") + 1/4" ID Silicone TuFlux® 300 mm (12")

For 5 L–50 L

– 3/8" ID EVA 100 mm (4") + 3/8" ID Silicone TuFlux® 300 mm (12")
– (4") + 3/8" ID Silicone TuFlux® 300 mm (12")

27 Flexboy® 2D Pre-designed Solutions for Drug Substance Purification

[Back to Table of Contents](#)

Drug Substance Purification

Sterile Connection to Downstream Systems

Sterile Connection

Sterile Weld

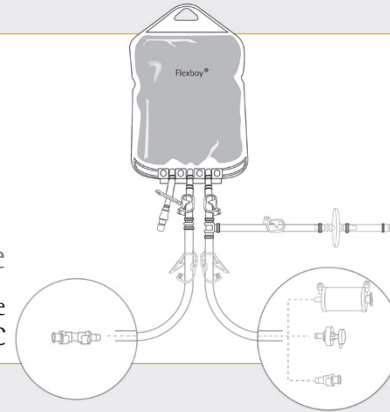
Sanitary or Aseptic Connection to Downstream Systems

Quick Coupler Connection

Tri-Clamp Connection

Outlet Line

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



Inlet Line

Test line with Midisart® BV
0.2 µm filter and 1/4" 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

Bag volume	Part number	Units per box	Inlet ¹		Outlet ²	Sampling
			Filter or distal connector on filling line	Filter type and size	Distal connector on draining line	Sampling line
3 L	FFB128350	16	Sartopore® Platinum 0.45 0.2 µm	MidiCaps® size 4	1/4" ID C-Flex® + 1/4" MPC male + sealing cap	3/16" ID EVA 50 mm (2") + 3/16" Luer Lock female + Clave connector
	FFB128335	16	1/4" Opta® SFT female	NA		
	FFB128320	16	MPC female + sealing cap	NA		
5 L	FFB128351	16	Sartopore® Platinum 0.45 0.2 µm	MidiCaps® size 4	3/8" ID C-Flex® + 3/8" MPC male + sealing cap	3/16" ID EVA 50 mm (2") + 3/16" Luer Lock female + Clave connector
	FFB128336	16	3/8" Opta® SFT female	NA		
	FFB128321	16	MPC female + sealing cap	NA		
10 L	FFB128352	8	Sartopore® Platinum 0.45 0.2 µm	MidiCaps® size 7	3/8" ID C-Flex® + 3/8" MPC male + sealing cap	3/16" ID EVA 50 mm (2") + 3/16" Luer Lock female + Clave connector
	FFB128337	8	3/8" Opta® SFT female	NA		
	FFB128322	8	MPC female + sealing cap	NA		
20 L	FFB128353	8	Sartopore® Platinum 0.45 0.2 µm	MidiCaps® size 7	3/8" ID C-Flex® + 3/8" MPC male + sealing cap	3/16" ID EVA 50 mm (2") + 3/16" Luer Lock female + Clave connector
	FFB128338	8	3/8" Opta® SFT female	NA		
	FFB128323	8	MPC female + sealing cap	NA		
50 L	FFB128354	8	Sartopore® Platinum 0.45 0.2 µm	MidiCaps® size 7	3/8" ID C-Flex® + 3/8" MPC male + sealing cap	3/16" ID EVA 50 mm (2") + 3/16" Luer Lock female + Clave connector
	FFB128339	8	3/8" Opta® SFT female	NA		
	FFB128324	8	MPC female + sealing cap	NA		

¹ Inlet tubing line from end line to bag:

For 3 L Sartopore® Platinum filters and Opta®
– 1/4" ID Silicone TuFlux® 300 mm (12") + 1/4" ID EVA 100 mm (4") + Clipster® in a separate pouch

For 5 L–50 L Sartopore® Platinum filters and Opta®
– 3/8" ID Silicone TuFlux® 300 mm (12") + 3/8" ID EVA 100 mm (4") + Clipster® in a separate pouch

For 3 L MPC
– 1/4" ID Clear C-Flex® 500 mm (20") + 1/4" ID EVA 100 mm (4")

For 5 L–50 L MPC
– 3/8" ID Clear C-Flex® 500 mm (20") + 3/8" ID EVA 100 mm (4")

Leak Test line

– 1/4" ID Clear C-Flex® 300 mm (12") + Midisart® BV 0.2 µm + 1/4" ID Silicone TuFlux® 100 mm (4") + 1/4" Tri-Clamp

² Outlet tubing line from bag to end line:

For 3 L
– 1/4" ID EVA 100 mm (4") + 1/4" ID Silicone TuFlux® 300 mm (12")

For 5 L–50 L
– 3/8" ID EVA 100 mm (4") + 3/8" ID Silicone TuFlux® 300 mm (12")

Flexboy® 2D Pre-designed Solutions for Drug Substance Purification

[Back to Table of Contents](#)

Drug Substance Purification

Sterile Connection to Downstream Systems

Sanitary or Aseptic Connection to Downstream Systems

Sterile Connection

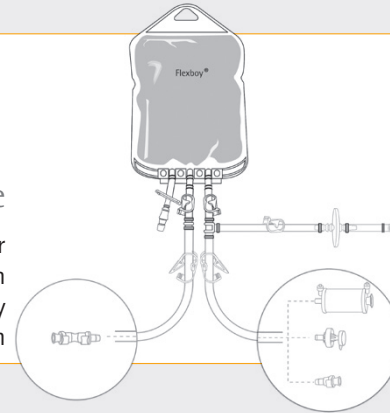
Sterile Weld

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® BV
0.2 µm filter and 1/4" 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

Quick Coupler Connection to Downstream Systems

Bag volume	Part number	Units per box	Inlet ¹		Outlet ²	Sampling
			Filter or distal connector on filling line	Filter type and size	Distal connector on draining line	Sampling line
3 L	FFB128350	16	Sartopore® Platinum 0.45 0.2 µm	MidiCaps® size 4	1/4" ID C-Flex® + 1/4" MPC male + sealing cap	3/16" ID EVA 50 mm (2") + 3/16" Luer Lock female + Clave connector
	FFB128335	16	1/4" Opta® SFT female	NA		
	FFB128320	16	MPC female + sealing cap	NA		
5 L	FFB128351	16	Sartopore® Platinum 0.45 0.2 µm	MidiCaps® size 4	3/8" ID C-Flex® + 3/8" MPC male + sealing cap	3/16" ID EVA 50 mm (2") + 3/16" Luer Lock female + Clave connector
	FFB128336	16	3/8" Opta® SFT female	NA		
	FFB128321	16	MPC female + sealing cap	NA		
10 L	FFB128352	8	Sartopore® Platinum 0.45 0.2 µm	MidiCaps® size 7	3/8" ID C-Flex® + 3/8" MPC male + sealing cap	3/16" ID EVA 50 mm (2") + 3/16" Luer Lock female + Clave connector
	FFB128337	8	3/8" Opta® SFT female	NA		
	FFB128322	8	MPC female + sealing cap	NA		
20 L	FFB128353	8	Sartopore® Platinum 0.45 0.2 µm	MidiCaps® size 7	3/8" ID C-Flex® + 3/8" MPC male + sealing cap	3/16" ID EVA 50 mm (2") + 3/16" Luer Lock female + Clave connector
	FFB128338	8	3/8" Opta® SFT female	NA		
	FFB128323	8	MPC female + sealing cap	NA		
50 L	FFB128354	8	Sartopore® Platinum 0.45 0.2 µm	MidiCaps® size 7	3/8" ID C-Flex® + 3/8" MPC male + sealing cap	3/16" ID EVA 50 mm (2") + 3/16" Luer Lock female + Clave connector
	FFB128339	8	3/8" Opta® SFT female	NA		
	FFB128324	8	MPC female + sealing cap	NA		

¹ Inlet tubing line from end line to bag:

For 3 L Sartopore® Platinum filters and Opta®
– 1/4" ID Silicone TuFlux® 300 mm (12") + 1/4" ID EVA 100 mm (4") + Clipster® in a separate pouch

For 5 L–50 L Sartopore® Platinum filters and Opta®
– 3/8" ID Silicone TuFlux® 300 mm (12") + 3/8" ID EVA 100 mm (4") + Clipster® in a separate pouch

For 3 L MPC

– 1/4" ID Clear C-Flex® 500 mm (20") + 1/4" ID EVA 100 mm (4")

For 5 L–50 L MPC

– 3/8" ID Clear C-Flex® 500 mm (20") + 3/8" ID EVA 100 mm (4")

Leak Test line

– 1/4" ID Clear C-Flex® 300 mm (12") + Midisart® BV 0.2 µm + 1/4" ID Silicone TuFlux® 100 mm (4") + 1/4" Tri-Clamp

² Outlet tubing line from bag to end line:

For 3 L

– 1/4" ID EVA 100 mm (4") + 1/4" ID Silicone TuFlux® 300 mm (12")

For 5 L–50 L

– 3/8" ID EVA 100 mm (4") + 3/8" ID Silicone TuFlux® 300 mm (12")

Flexboy® 2D Pre-designed Solutions for Drug Substance Purification

[Back to Table of Contents](#)

Drug Substance Purification

Sterile Connection to Downstream Systems

Sanitary or Aseptic Connection to Downstream Systems

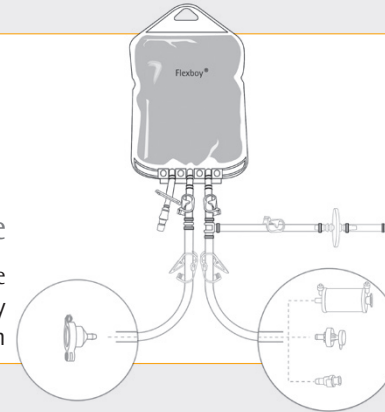
Sterile Connection

Sterile Weld

Quick Coupler Connection

Tri-Clamp Connection

Outlet Line
Tri-Clamp flange for sanitary or aseptic connection



Inlet Line

Test line with Midisart® BV
0.2 µm filter and 1/4" 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

Tri-Clamp Connection to Downstream Systems

Bag volume	Part number	Units per box	Inlet ¹		Outlet ²	Sampling
			Filter or distal connector on filling line	Filter type and size	Distal connector on draining line	Sampling line
3 L	FFB128345	16	Sartopore® Platinum 0.45 0.2 µm	MidiCaps® size 4	1/4" Tri-Clamp sanitary flange with gasket, cap & union	
	FFB128330	16	1/4" Opta® SFT female	NA		
	FFB128315	16	MPC female + sealing cap			
5 L	FFB128346	16	Sartopore® Platinum 0.45 0.2 µm	MidiCaps® size 4	3/8" Tri-Clamp sanitary flange with gasket, cap & union	3/16" ID EVA 50 mm (2") + 3/16" Luer Lock female + Clave connector
	FFB128331	16	3/8" Opta® SFT female	NA		
	FFB128316	16	MPC female + sealing cap			
10 L	FFB128347	8	Sartopore® Platinum 0.45 0.2 µm	MidiCaps® size 7	3/8" Tri-Clamp sanitary flange with gasket, cap & union	3/16" ID EVA 50 mm (2") + 3/16" Luer Lock female + Clave connector
	FFB128332	8	3/8" Opta® SFT female	NA		
	FFB128317	8	MPC female + sealing cap			
20 L	FFB128348	8	Sartopore® Platinum 0.45 0.2 µm	MidiCaps® size 7	3/8" Tri-Clamp sanitary flange with gasket, cap & union	3/16" ID EVA 50 mm (2") + 3/16" Luer Lock female + Clave connector
	FFB128333	8	3/8" Opta® SFT female	NA		
	FFB128318	8	MPC female + sealing cap			
50 L	FFB128349	8	Sartopore® Platinum 0.45 0.2 µm	MidiCaps® size 7	3/8" Tri-Clamp sanitary flange with gasket, cap & union	3/16" ID EVA 50 mm (2") + 3/16" Luer Lock female + Clave connector
	FFB128334	8	3/8" Opta® SFT female	NA		
	FFB128319	8	MPC female + sealing cap			

¹ Inlet tubing line from end line to bag:

For 3 L Sartopore® Platinum filters and Opta®
– 1/4" ID Silicone TuFlux® 300 mm (12") + 1/4" ID EVA 100 mm (4") + Clipster® in a separate pouch

For 5 L–50 L Sartopore® Platinum filters and Opta®
– 3/8" ID Silicone TuFlux® 300 mm (12") + 3/8" ID EVA 100 mm (4") + Clipster® in a separate pouch

For 3 L MPC

– 1/4" ID Clear C-Flex® 500 mm (20") + 1/4" ID EVA 100 mm (4")

For 5 L–50 L MPC

– 3/8" ID Clear C-Flex® 500 mm (20") + 3/8" ID EVA 100 mm (4")

Leak Test line

– 1/4" ID Clear C-Flex® 300 mm (12") + Midisart® BV 0.2 µm + 1/4" ID Silicone TuFlux® 100 mm (4") + 1/4" Tri-Clamp

² Outlet tubing line from bag to end line:

For 3 L

– 1/4" ID EVA 100 mm (4") + 1/4" ID Silicone TuFlux® 300 mm (12")

For 5 L–50 L

– 3/8" ID EVA 100 mm (4") + 3/8" ID Silicone TuFlux® 300 mm (12")

Flexboy® 2D Pre-designed Solutions for Drug Product Formulation

[Back to Table of Contents](#)

Drug Product Formulation

Sterilizing Filtration

Drug Product Storage

Drug Product Transfer

Sterile Connection to Final Filling

 Sterile Connection
Sterile Weld

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

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

Sartopore® filters for sterile disconnection with Clipster® are available with Silicone TuFlux® tubing.

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

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.

Flexboy® 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.

Sampling

- Clave needleless sampling port

Outlet Line

- Connection and transfer by pumping
- Opta® SFT male for sterile connection
- C-Flex® with press in plug for sterile welding to single-use system



Test Line for FlexAct® BT

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

Inlet Line

- Sterilizing-grade filtration from formulation mixer
- Sartopore® Platinum 0.45 | 0.2 µm for efficient wetting and integrity testing

- Connection for alternative filter line
- Opta® SFT female
- C-Flex® tube weld with BioWelder® TC

31 Flexboy® 2D Pre-designed Solutions for Drug Product Formulation

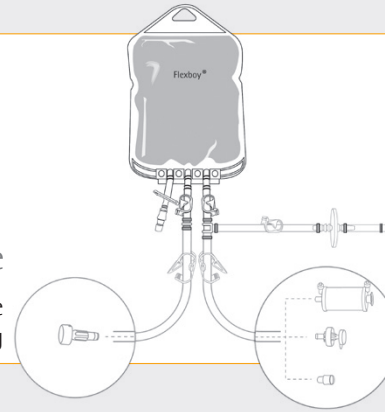
[Back to Table of Contents](#)

Drug Product Formulation

Sterile Connection to Final Filling

Sterile Connection
Sterile Weld

Outlet Line
Opta® SFT male for sterile connection to final filling



Inlet Line

Test line with Midisart® BV
0.2 µm filter and 1/4" Tri-Clamp

Sartopore® Platinum 0.45 | 0.2 µm

Opta® SFT female

C-Flex® with press-in-plug for
sterile weld with BioWelder® TC

Sterile Connection to Final Filling

Bag volume	Part number	Units per box	Inlet ¹		Outlet ²	Sampling
			Filter or distal connector on filling line	Filter type and size	Distal connector on outlet line	Sampling line
3 L	FFB128370	16	Sartopore® Platinum 0.45 0.2 µm	MidiCaps® size 4	1/4" Opta® SFT male	3/16" ID EVA 50 mm (2") + 3/16" Luer Lock female + Clave connector
	FFB128365	16	1/4" Opta® SFT female	NA		
5 L	FFB128371	16	Sartopore® Platinum 0.45 0.2 µm	MidiCaps® size 4	3/8" Opta® SFT male	
	FFB128366	16	3/8" Opta® SFT female	NA		
10 L	FFB128372	8	Sartopore® Platinum 0.45 0.2 µm	MidiCaps® size 7	3/8" Opta® SFT male	
	FFB128367	8	3/8" Opta® SFT female	NA		
20 L	FFB128373	8	Sartopore® Platinum 0.45 0.2 µm	MidiCaps® size 7	3/8" Opta® SFT male	
	FFB128368	8	3/8" Opta® SFT female	NA		
50 L	FFB128374	8	Sartopore® Platinum 0.45 0.2 µm	MidiCaps® size 7	3/8" Opta® SFT male	
	FFB128369	8	3/8" Opta® SFT female	NA		

¹ Inlet tubing line from end line to bag:

For 3 L Sartopore® Platinum filters and Opta®
– 1/4" ID Silicone TuFlux® 300 mm (12") + 1/4" ID EVA 100 mm (4") + Clipster® in a separate pouch

For 5 L – 50 L Sartopore® Platinum filters and Opta®
– 3/8" ID Silicone TuFlux® 300 mm (12") + 3/8" ID EVA 100 mm (4") + Clipster® in a separate pouch

Leak Test line

– 1/4" ID Clear C-Flex® 300 mm (12") + Midisart® BV 0.2 µm + 1/4" ID Silicone TuFlux® 100 mm (4") + 1/4" Tri-Clamp

² Outlet tubing line from bag to end line:

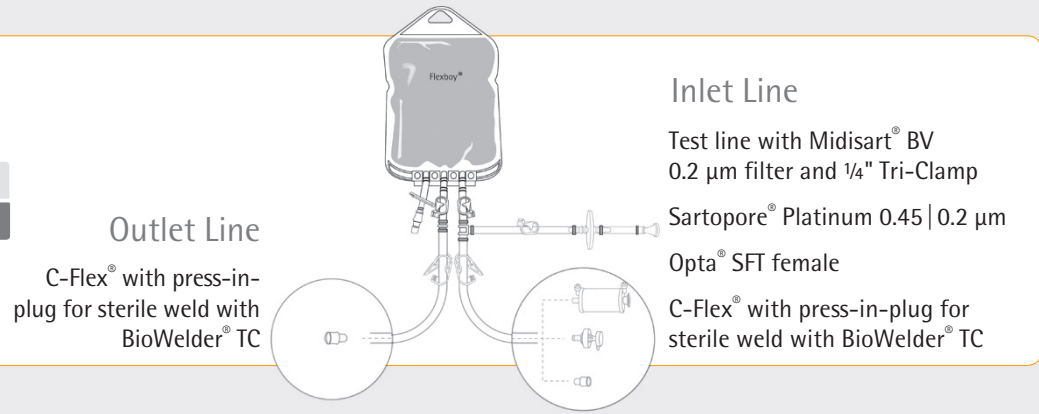
For 3 L
– 1/4" ID EVA 100 mm (4") + 1/4" ID Silicone TuFlux® 300 mm (12")

For 5 L – 50 L
– 3/8" ID EVA 100 mm (4") + 3/8" ID Silicone TuFlux® 300 mm (12")

32 Flexboy® 2D Pre-designed Solutions for Drug Product Formulation

[Back to Table of Contents](#)

Drug Product Formulation



Sterile Weld to Final Filling

Bag volume	Part number	Units per box	Inlet ¹		Outlet ²	Sampling
			Filter or distal connector on filling line	Filter type and size	Distal connector on outlet line	Sampling line
3 L	FFB128360	16	Press in plug	NA	1/4" Clear C-Flex® + Press-in-plug	3/16" ID EVA 50 mm (2") + 3/16" Luer Lock female + Clave connector
5 L	FFB128361	16	Press in plug	NA		
10 L	FFB128362	8	Press in plug	NA		
20 L	FFB128363	8	Press in plug	NA		
50 L	FFB128364	8	Press in plug	NA		

¹ Inlet tubing line from end line to bag:
 For 3 L
 - 1/4" ID Clear C-Flex® 500 mm (20") + 1/4" ID EVA 100 mm (4")
 For 5 L – 50 L
 - 3/8" ID Clear C-Flex® 500 mm (20") + 3/8" ID EVA 100 mm (4")
 Leak Test line
 - 1/4" ID Clear C-Flex® 300 mm (12") + Midisart® BV 0.2 µm + 1/4" ID Silicone TuFlux® 100 mm (4") + 1/4" Tri-Clamp

² Outlet tubing line from bag to end line:
 For 3 L
 - 1/4" ID EVA 100 mm (4") + 1/4" ID C-Flex® 500 mm (20")
 For 5 L – 50 L
 - 3/8" ID EVA 100 mm (4") + 3/8" ID C-Flex® 500 mm (20")

Other Bag Configurations for Storage and Sampling

Bag Volume	Part Number	Description	Units per box	Tubing	Inlet	Outlet	Sampling
5 mL	FFB115270	Flexboy® 5 mL	100	EVA	3/16" × 1/4" × 50 mm (2") LL Female + plug, side clamp	NA	NA
150 mL	FFB110898	Flexboy® 150 mL	50	EVA + Clear C-Flex®	1/8" × 1/4" × 500 mm (20") LL Female + needle free sampling port, dust cap, pinch clamp		EVA port tube LL Female + needle free sampling port, dust cap, slide clamp
50 mL	FFB102603	Flexboy® 50 mL	20	EVA	1/4" × 5/16" × 100 mm (4") LL Male + cap, pinch clamp	1/4" × 5/16" × 100 mm (4") LL Female + cap, pinch clamp	3/16" × 1/4" × 50 mm (4") Septum
150 mL	FFB102643	Flexboy® 150 mL					
500 mL	FFB102670	Flexboy® 500 mL					
1 L	FFB103547	Flexboy® 1 L					
3 L	FFB102812	Flexboy® 3 L					



34 FlexAct® BT (Bag Tester) Point of Use Leak Test for Flexboy® 2D Bags

[Back to Table of Contents](#)


Safe

- The restraining plates of FlexAct® BT maintain and protect the bag ensuring process and operator safety
- The test is performed through a Midisart® BV sterilizing vent filter to maintain the bag sterility therefore ensuring patient safety

Reliable

- The restraining plates reduce heat transfers, maintain a small inflation volume and allow a high test pressure for a best sensitivity of 30 µm
- The porous spacers between plates avoid any potential masking effect
- The 30 µm leak detection is validated using a large number of test samples and a differentiation of defective bags with 6 sigma confidence interval

Fast & Easy to Use

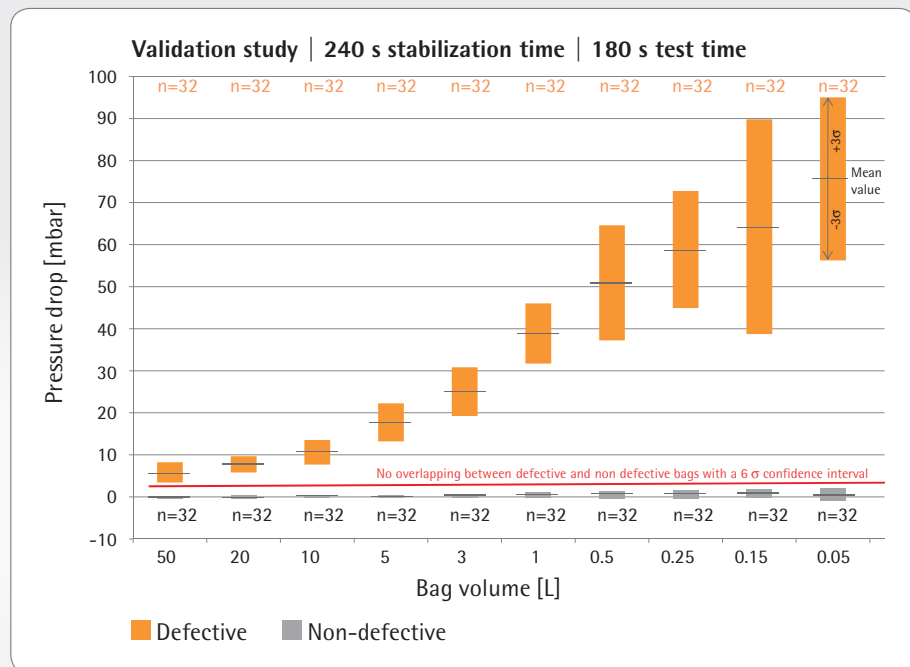
- The well-known ASTM F2095-01 standard pressure decay leak test at point of use and the well-established Sartocheck® technology make it easy to implement
- The restraining plates allow a small inflation volume thus reduce the total test time to less than 10 minutes
- The MultiUnit tester option increases test productivity by testing two 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

Watch FlexAct® BT Video:

<https://www.youtube.com/watch?v=enmMhorDjHQ>



Flexboy® 2D Tray and Rack Systems



Description

The Flexboy® Tray and Rack Systems are designed to facilitate handling of both individual and manifold Flexboy® Single-Use Bioprocessing Bags (5 L–20 L) within biopharmaceutical manufacturing processes.

Flexibility

The modular Tray and Rack System offers the possibility to expand the system according to process needs. Swivel wheels integrated in the rack allow individual or manifold Flexboy® bags to be easily moved around the facility. Additional rack systems focused on specific application demands are available upon request.

Safety

Smooth finish and integrated handles make the system both user friendly and safe. This allows reliable stacking of additional modules by maintaining highest safety levels.

Technology Integration Support

Sartorius Stedim Biotech supports users at the design & implementation phase of a new production facility with the most comprehensive support program that ensures successful design implementation and validation of Single-Use Manufacturing.

Quality Assurance

The Flexboy® 2D Tray and Rack Systems are designed, developed and manufactured in accordance with a ISO 9001 certified Quality Management System. They undergo extensive testing before shipping.

Available from Stock

Flexboy® 2D Tray and Rack Systems are available from stock.

Design, Application Development and Validation Services

Configure to Order (CTO) Options

All Flexboy® 2D 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
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