SARTORIUS

Configurable Flexsafe® 2D

Bags From 20 mL to 50 L

Product Information

Flexsafe® 2D Bags are designed for the preparation, storage and transport of biopharmaceutical solutions, intermediates and final bulk products.

Configurable Flexsafe® 2D Bags are designed from a database of pre-qualified components and proven functionalities using a web-based and interactive product configurator tool.

Description

The user friendly product configurator tool provides the flexibility needed for the application-based single-use configuration whilst improving design and quotation turnaround times, manufacturing lead times, security of supply and product reliability, safety and robustness.

They provide a single-use alternative to traditional glass, stainless steel and rigid plastic carboys in a large variety of applications. The broad chemical compatibility of Flexsafe® 2D Bags ensures the safe processing of a wide range of biopharmaceutical fluids in a variety of applications.

Applications

The multi-layer, PE and EVOH based S80 film provides a strong structure with low gas permeability and high chemical resistance, for the safe processing of a wide range of biopharmaceutical fluids in a variety of applications such as:
- Buffers and media sterile
- Filtration and storage
- Bulk harvest
- Product pooling
- Fraction collection
- Sample collection
- Bulk intermediate hold
- Final product handling

Flexibility

Configurable Flexsafe® 2D Bags are configured from pre-qualified components and proven functionalities including a variety of tubing, connectors, filter and sampling methods for a streamlined incorporation into your process. Multiple configurations are available with bag volumes from 20 mL to 50 L with TPE tubing, compatible with Biowelder® and Biosealer® for aseptic connection | disconnections, silicone Tuflux® tubing compatible with Clipster® Aseptic Disconnector and qualified for peristaltic pumping and TPE tubing for RF sealing with Vante™ Sealers. Sartopore® 2 Gamma Midicaps® are proposed with an optional flush bag. Needle free sampling port or sampling bag may be used for easy and convenient sampling. Quick couplers, triclamps, Luer® fittings, Steamthru™ valves and sterile-to-sterile connectors are provided for optimal connection compatibility flexibility in a production environment.

Easy Implementation

Configurable Flexsafe® 2D Bags are available in bag chamber volumes between 20 mL and 50 L. They are supplied, sterilized and ready to use. This allows an easy and convenient process implementation. A series of associated systems such as trays and racks facilitate an easy bag handling. Sartorius Stedim Biotech supports users already at the design and implementation phase of a new production facility, with the most comprehensive support program that ensures successful design implementation of Single-Use Manufacturing.

Features	Benefits
Pre-qualified component database and proven functionalities	Quality by design for improved product reliability
Standard components and manufacturing methods	Save on development and engineering costs
Instant design with a web-based product configurator	Shorten lead time for drawing and quotes
CTO dedicated supply chain and manufacturing capability	Shorten lead-time for products
Offer a large range of standardized configurable products	Reduce complexity and risks by standardization
Product configurator tool with preconfigured options and functionalities	Flexibility for optimal design tailored to the application needs
Most commonly used components and solutions in the market	Compatibility with end user process requirements

Robust Performance and Assurance of Supply

Flexsafe® 2D bags are designed for safe storage and shipping of biopharmaceutical solutions. Flexsafe® bags ensure consistent cell growth robustness and ease of use and are extensively validated for all process steps, from cell culture and downstream purification of drug substance to final formulation and filling of drug product. Characterization of resins and establishing supply contracts for the resins and the film ensure compliance, reliable assurance of supply and change control.

Validation

Flexsafe® 2D Bags have been qualified applying the most comprehensive and innovative test regimes. Biological, chemical and physical tests combined with extensive extractable testing provide users of configurable Flexsafe® 2D Bags with data representing the widest range of process fluids in a variety of processing conditions. Full compliance with ISO 11137 allows for a validated claim of sterility on all Sartorius Stedim Biotech single-use products with a sterility assurance level of 10^{-6} over the shelf life.

Quality Assurance

Sartorius Stedim Biotech Quality Systems for single-use products follow applicable ISO and FDA regulations. Design, manufacture and sterilization processes are conducted under conditions that mirror biopharmaceutical operations and meet cGMP requirements.

Flexsafe® 2D Bags are tested for compliance to:
- USP <85>: Bacterial endotoxins test
- USP <87>: Biological reactivity tests, in Vitro
- USP <88>: Biological reactivity tests, in Vivo
- USP <661>: Tests for plastic
- USP <788> and E.P. 2.9.19: Particulates
- ISO 11737: Bioburden
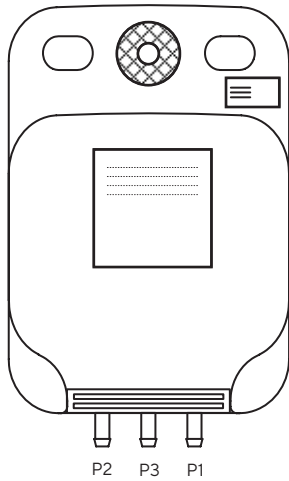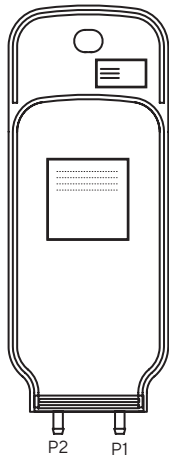- ISO 11137: Sterilization of medical devices

Supply Chain

Configurable Flexsafe® 2D Bags are available as configured to order products. Pre-configured products based on application knowledge allow savings on engineering time and production preparation, thus providing reduced lead-times compared to classical fully customized processes.

Configurable Transfer Line

Bag chamber	Multiple layer film, including EVOH gas barrier layer and TPE contact layer S80 film
Volumes	20 mL – 50 L
Tubing	Silicone Tuflux® or Silicone (Pt) compatible with Clipster® Aseptic Disconnector, TPE compatible with Biowelder® and Biosealer®
End connectors	Quick couplers Triclamp and mini-triclamp Luer® locks Steamthru™ valves for SIP connections Sterile-to-sterile connectors, including Opta® sterile connector
Filters	Sartopore® 2 0.2 µm Gamma Midicaps® size 4 Sartopore® 2 0.2 µm Gamma Midicaps® size 7 Sartopore® Platinum 0.2 µm Gamma Midicaps® size 7 Sartopore® Platinum 0.2 µm Gamma Midicaps® size 4 Sartopore® XLM 0.1 µm size 7 with optional flush bag for volume 1 L to 50 L
Sampling	Needleless sampling site Sampling with bag
Number of lines	2 lines for bags from 20 mL to 500 mL 3 lines for bags from 1 L to 50 L

Technical Data

Specifications

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

Number of Ports | Lines
- Three lines where P1 is assimilated to the filling line,
  P2 to the draining line or sampling line and
  P3 to the sampling line

Tubing Diameters
ID × OD = ¼" × ⁷⁄₁₆" for P1, P2, P3
¼" × ⅜" for P1, P2, P3
⅜" × ⅝" for P1, P2

Tubing Materials
Silicone tubing, Silicone Tuflux®, TPE tubing,
Silicone Tuflux® + TPE tubing, Silicone + TPE tubing

Tubing Lengths
150 mm, 300 mm, 500 mm, 1000 mm, 1500 mm,
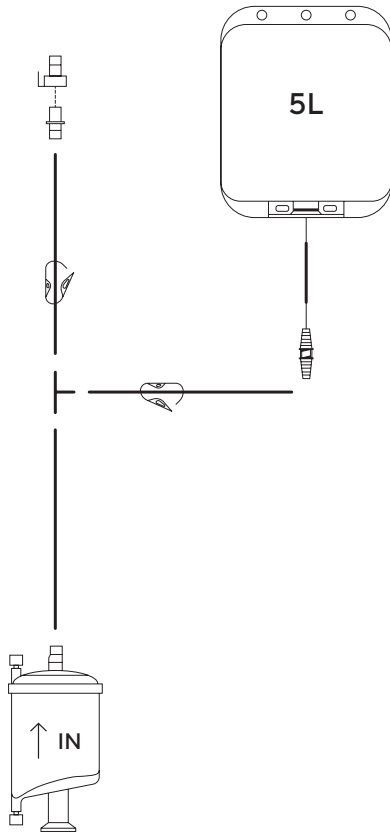2000 mm, no tubing

Type of Lines

Port	P1	P2	P3
Line	Line 1	Line 2	Line 3
Function	Fill	Drain | Sampling	Sampling
Normal Flow Rate with Filter	▪		
High Flow Rate with Filter	▪		
Normal Flow Rate	▪	▪	
High Flow Rate	▪ [1]	▪ [1]	
Sampling		▪	▪
Not Used		▪ [1]	▪ [2]

[1] For Flexsafe® 2D from 3 L to 50 L
[2] For Flexsafe® 2D from 20 mL to 500 mL

Functionalities
- Storage application

Line Type Normal Flow Rate With Filter and High Flow Rate With Filter: Port 1

Generic Description

5L

↑ IN

Specifications

Tubing Diameters
ID × OD = ¼" × ⁷⁄₁₆" (6.4 mm × 11.1 mm)
or ⅜" × ⅝" (9.5 mm × 15.8 mm)

Tubing Materials
- Silicone Tuflux® or Si(Pt)
  (filter removal with CPC Quick Coupler
  or no filter disconnection)
- TPE tubing (filter removal with tube sealing)

Tubing Lengths
- 150 mm
- No tubing

Type of Filters
- Sartopore® 2 0.2 μm Gamma Midicaps® size 4
- Sartopore® 2 0.2 μm Gamma Midicaps® size 7
- Sartopore® Platinum 0.2 μm Gamma Midicaps® size 4
- Sartopore® Platinum 0.2 μm Gamma Midicaps® size 7
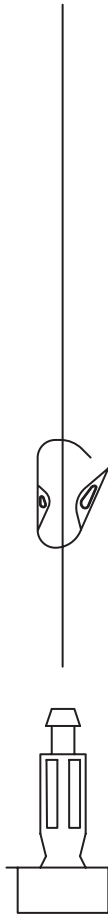- Sartopore® XLM 0.1 μm size 7

Options
- No flush bag for volume 20 mL to 1 L
- 1 L Flexboy® Flush Bag (only with normal flow rate)
- 5 L Flexboy® Flush Bag

Functionalities
- Filling through a sterilizing grade filter
- Optional filter flush bag only for volume > 1 L
- Optional filter disconnection with a Quick Coupler
  or with tube sealing (TPE)

Line Type Normal Flow Rate: Port 1 and 2 and High Flow Rate: Port 1 and 2

Generic Description

Functionalities
- Bag filling or bag drainage
- Transfer with a peristaltic pump or by gravity
- Tube to tube welding
- Tube sealing
- Aseptic connection
- Generic connection with a TriClamp or a Quick Coupler

Specifications

Tubing Diameters
ID × OD = ¼" × ⁷⁄₁₆" (6.4 mm × 11.1 mm)
or ¼" × ⅜" (9.5 mm × 15.8 mm)
or ⅜" × ⅝" (9.5 mm × 15.8 mm)

Tubing Materials
- Silicone Tuflux® or Si(Pt) for 10 hr maximum operation with a peristaltic pump
- TPE (thermoplastic tubing) for tube sealing and welding operations
- Silicone Tuflux® or Si(Pt) with a TPE extension for 10 hr maximum operation with a peristaltic pump and for tube sealing and welding applications
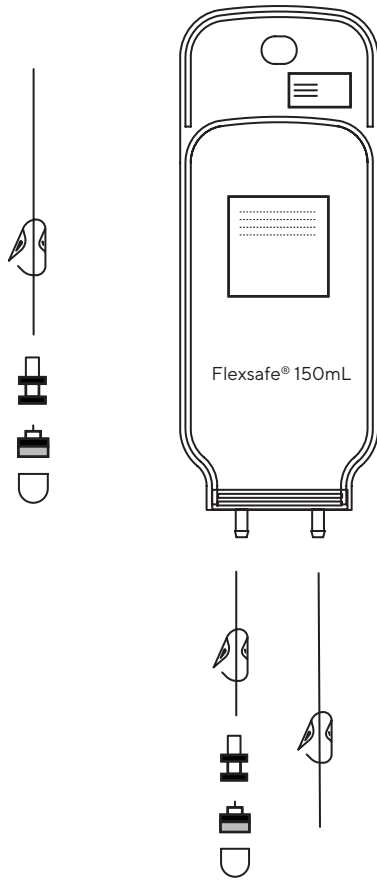
Tubing Lengths
- 150 mm (6") for Si(Pt) Tuflux® or Si(Pt)
- 300 mm (12") for Si(Pt) Tuflux® or Si(Pt)
- 500 mm (20") for Si(Pt) Tuflux®, Si(Pt) or TPE tubing
- 1,000 mm (39") total line length: 500 mm (20") Si(Pt) Tuflux® or Si(Pt) + 500 mm (20") TPE for Silicone with a TPE extension
- 1,500 mm (59") total line length: 1,000 mm (39") Si(Pt) Tuflux® or Si(Pt) + 500 mm (20") TPE for Silicone with a TPE extension
- 2,000 mm (79") total line length: 1,500 mm (59") Si(Pt) Tuflux® or Si(Pt) + 500 mm (20") TPE for Silicone with a TPE extension

Distal Connectors
- SSB Triclamp (1-½" or ¾" flange) with optional triclamp cap, plug, gasket and union
- Quick Coupler with plug – MPC (male or female)
- MPC PSU (male or female)
- OPTA® SFT – aseptic connection (male or female)
- STC I – CPC Steamthru™ connection (¾" × ¾" triclamp flanges)
- STC II - CPC Steamthru™ connection (¾" × ¾" triclamp flanges)
- KPC HT – male or female
- Luer® male or female with cap (only with normal flow rate)
- AseptiQuik® Genderless
- Lynx Valve ST ¼" or ⅜"

Line Type "Sampling" P2 - P3[1] Normal Flow Rate

Generic Description

Flexsafe® 150mL

Specifications

Tubing Diameters
ID × OD = ¼" × ⁷⁄₁₆" (6.4 mm × 11.1 mm)

Tubing Materials
- Silicone Tuflux® or Si(Pt) for needleless sampling port
- TPE (thermoplastic tubing) for welding and sealing operations (sampling bag disconnection)

Tubing Lengths
- 150 mm

Connector
- Clave

Sampling Bag
- Flexsafe® 2D bag 150 mL

Functionalities (Sampling)
- Clave connector
- Sampling bag

[1] P2 For volume 20 mL to 500 mL
    P3 for volume 1 L to 50 L

Line Type "Not Used" P2 – P3[2]

Functionality
- Not used
- Obstructed port

[2] P2 only for volumes > 1 L

Functionalities of the Flexsafe® 2D Bag From 20 mL to 50 L

	Normal Flow Rate with Filter or High Flow Rate with Filter	Normal Flow Rate	High Flow Rate	Sampling | Transfer
Function	Sterile Fill	Fill Drain Addition	Fill Drain Addition	Sampling
Port	P1	P1 – P2	P1 – P2	P2 – P3
Tube Dim.	¼" × ⁷⁄₁₆" (6.4 mm × 11.1 mm) ⅜" × ⅝" (9.5 mm × 15.8 mm)	¼" × ⁷⁄₁₆" (6.4 mm × 11.1 mm)	⅜" × ⅝" (9.5 mm × 15.8 mm)	¼" × ⁷⁄₁₆" (6.4 mm × 11.1 mm)
Tube Length mm	150 (6")	150 (6") 300 (12") 500 (20") 1,000 (39") 1,500 (59") 2,000 (79")	150 (6") 300 (12") 500 (20") 1,000 (39") 1,500 (59") 2,000 (79")	150 (6")
Tubing Materials	Si(Pt) Tuflux® Si(Pt) TPE	Si(Pt) Tuflux® Si(Pt) TPE Si(Pt) + TPE Si(Pt) Tuflux® + TPE	Si(Pt) Tuflux® Si(Pt) TPE Si(Pt) Tuflux® + TPE Si(Pt) + TPE	Si(Pt) Tuflux® Si(Pt) TPE
Standard Connectors		Luer® M-F SSB TC 1½" or ¾" w/wo cap, plug, gasket, union Quick Coupling MPC-M/F Quick Coupling PSU-M/F	Luer® M-F SSB TC 1½" or ¾" w/wo cap, plug, gasket, union Quick Coupling MPC-M/F Quick Coupling PSU-M/F	Clave
Aseptic Connectors		Opta® SFT-M/F AseptiQuik® Genderless	Opta® SFT-M/F AseptiQuik® Genderless STC I ¾" × ¾" STC II ¾" × ¾"	
Other Connectors		KPC HT-M/F Lynx ST ¼"	KPC HT-M/F Lynx ST ⅜"	
Filters	Sartopore® 2 0.2 µm Gamma Midicaps® size 4 Sartopore® 2 0.2 µm Gamma Midicaps® size 7 Sartopore® Platinum 0.2 µm Gamma Midicaps® size 7 Sartopore® Platinum 0.2 µm Gamma Midicaps® size 4 Sartopore® XLM 0.1 µm size 7			
Flush Bag	Flexboy® 1 or 5 L[1]			
Sampling Bags				Flexsafe® 2D Bag Bags 1 × 150 mL[2]

[1] Only for volume > 1 L
[2] Only for volume 1 L to 50 L