

Configurable Flexsafe® 3D Bioprocessing Bags

For Drum 50 L – 200 L



Product Information

Flexsafe® 3D bags are designed for processing, storing and transporting large-volume biopharmaceutical solutions in drum. They provide a single-use alternative to traditional stainless steel vessels in a large variety of applications.

Description

Configurable Flexsafe® 3D bags are designed from a database of pre-qualified components and proven functionalities using a web-based and interactive Product Configurator tool. The user friendly Product Configurator tool provides the flexibility needed for the application-based single-use configuration whilst improving design and quotation turn-around times, manufacturing lead times, security of supply, product reliability, quality and robustness.

Applications

The multi-layer, PE- and EVOH-based S80 film provides a strong structure with low gas permeability and high chemical resistance for the reliable processing of a wide range of biopharmaceutical fluids in a variety of applications such as:

- Buffers and media filtration and storage
- Bulk harvest
- Product pooling
- Fraction collection
- Sample collection
- Bulk intermediate filtration and hold
- Final product storage and transport

Flexibility

Configurable Flexsafe® 3D 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 thermoweldable TPE tubing, compatible with Biowelder® and Biosealer® for aseptic connection | disconnections, silicone Tuflux® tubing compatible with Clipster® Aseptic Disconnect and qualified for peristaltic pumping and EVA tubing for RF sealing with Vante™ Sealers. An extensive range of filters (Sartopore® 2, Sartopore® Platinum, Sartopore® 2 XLG, XLM and Sartoguard NF) are proposed with an optional flush bag. Needle-free sampling port or sampling bags may be used for easy and convenient sampling. Quick Couplers, tri-clamps, Steamthru™ valves and sterile-to-sterile connectors are provided for optimal connection flexibility in a production environment.

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 pre-configured 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

Cell Growth

The resins and additives used for the film of Flexsafe® bags are optimized to reduce extractables and 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.

Robustness

The combined thickness, strength and flexibility of Flexsafe® bags in drum offers a storage alternative with very small footprint.

Assurance of Supply and Quality

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

Consistent Extractable Profile

Specification and control of the resin and the film ensure well-characterized and consistent extractables. Extractable data is readily available for risk assessment, thus saving end users the time and money required for generating validation data. The validation established on extractables and |or leachable studies and toxicological analysis remains valid and reproducible from lot to lot.

Validation

Flexsafe® bags have been qualified applying the most comprehensive and innovative test regimes. Biological, chemical and physical tests combined with extensive extractable testing to provide users of configurable Flexsafe® 3D bags with data representing an exceptionally wide 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® 3D bags for drum are tested for compliance to:

- USP <85>: Bacterial endotoxins
- 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: Particulate
- ISO 11737: Bioburden
- ISO 11137: Sterilization of medical devices

Supply Chain

Configurable Flexsafe® 3D bags for drum 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 Flexafe® 3D for Drum

Bag chamber	Multiple layer film, including EVOH gas barrier layer and PE contact layer S80 film
Tubing	Silicone Tuflux® or Silicone (Pt) compatible with Clipster® Aseptic Disconnecter, TPE compatible with Biowelder® and Biosealer®
End connectors	Quick Couplers Triclamp and Mini-Triclamp Steamthru™ valves for SIP connections Sterile-to-sterile connectors, including Opta® sterile connector
Filters	Sartopore® 2 0.2µm gamma Midicaps® and T-Style Maxicaps® capsules Sartopore® Platinum 0.2 µm gamma Midicaps® and T-Style Maxicaps® capsules Sartopore® 2 XLG 0.8 0.2 µm gamma Midicaps® and T-Style Maxicaps® capsules Sartopore® 2 XLM 0.2 0.1 µm Midicaps® and T-Style Maxicaps® capsules Sartoguard NF Midicaps® and T-Style Maxicaps® capsules With optional flush bag
Sampling	Needleless sampling site Manifolded Flexboy® or Flexel® sampling bags TPE tubing for tube-to-tube welding
Volumes	50 L – 1,000 L
Number of ports	Four top ports One bottom port
Sterilization	By gamma irradiation

Technical Data

Generic Description

Functionalities

- Storage application
- Shipping application

Specifications

Volume

50 L, 100 L, 200 L

Number of Ports | Lines

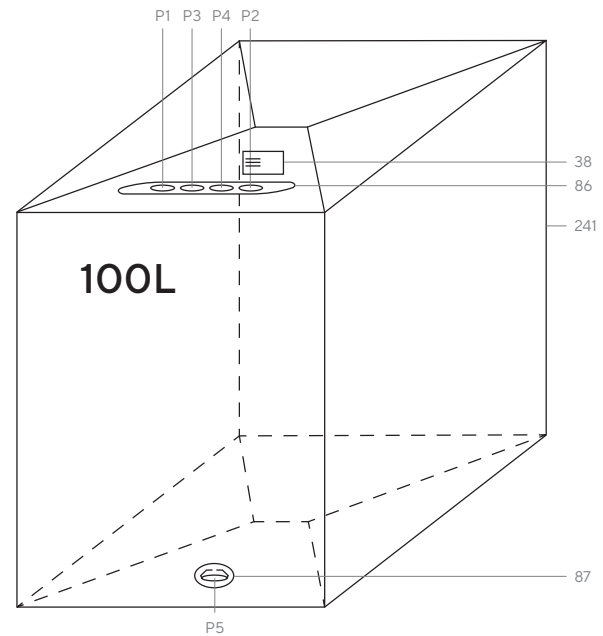
- Four top ports for all bag volumes
- One option bottom port (P5)

Type of Ports

- One top UPS4 port with one to four hose barb ($\frac{1}{4}$ ", $\frac{3}{8}$ ", $\frac{1}{2}$ ", $\frac{3}{4}$ ", plug)
- One bottom UPS1 with 1 hose barb ($\frac{1}{4}$ ", $\frac{3}{8}$ ", $\frac{1}{2}$ ", $\frac{3}{4}$ ", plug)

Type of Lines

Port	P1	P2	P3	P4	P5
Line	Line 1	Line 2	Line 3	Line 4	Line 5
Function	Fill	Addition	Addition	Sampling Addition	Drain
Normal flow rate with filter	■				
Normal flow rate	■	■	■	■	■
Small flow rate	■	■	■	■	■
High flow rate	■	■	■	■	■
Very small flow rate		■	■		
Sampling				■	
Transfer to filter					■
Not used	■	■	■	■	■

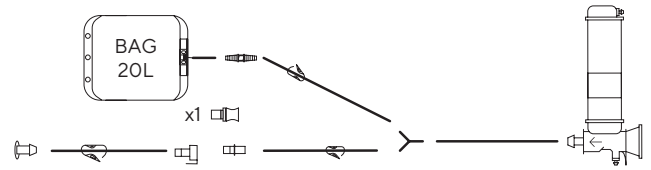


Line Type “Normal Flow Rate With Filter”

Generic Description

Functionalities

- Filling through large choice of filters
- Optional filter flush bag
- Filter disconnection with a MPX Quick Coupler (additional MPX plug provided in a PE pouch) or filter disconnection with tube sealing
- Filter removal with Clipster® aseptic disconnection system



Specifications

Flow Rate

Maximum flow rate with peristaltic pumping = 780 L/hr.

Flow rate varies with discharge pressure, suction, viscosity and product filterability.

Type of tubing	Tubing diameters	Tubing lengths	Function
Silicone Tuflux® or Silicone (Pt)	ID × OD = ½" × ¾" (12.70 mm × 19.05 mm)	800 mm (32") 1,500 mm (59") 3,000 mm (118") 5,000 mm (197")	Transfer with peristaltic pumping ≥1,000 mm length (10hr maximum)
TPE Tubing	ID × OD = ½" × ¾" (12.70 mm × 19.05 mm)	500 mm (19") 1,000 mm (39") 1,500 mm (59") 3,000 mm (118") 5,000 mm (197")	Transfer after tube-to-tube welding

Filter Range With Inlet TriClamp Flange 1-½"

Filter type	Size of filter
Sartopore® 2 0.2 µm gamma	Midicaps® sizes 7, 8, 9, 0 Maxicaps® T-Style sizes 1, 2, 3
Sartopore® Platinum 0.2 µm gamma	Midicaps® sizes 7, 8, 9, 0 Maxicaps® T-Style sizes 1, 2, 3
Sartopore® 2 XLG 0.8 0.2 µm gamma	Midicaps® sizes 7, 8, 9, 0 Maxicaps® T-Style sizes 1, 2, 3
Sartopore® 2 XLM 0.2 0.1 µm gamma	Midicaps® sizes 7, 8, 9, 0 Maxicaps® T-Style sizes 1, 2, 3
Sartoguard NF	Midicaps® sizes 8, 9, 0 Maxicaps® T-Style sizes 1, 2, 3

With optional flush bags: 5 L, 10 L and 20 L

Line Type “Normal Flow Rate”

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

Flow Rate

Maximum flow rate with a peristaltic pump = 780 L/hr.

Flow rate varies with discharge pressure, suction and viscosity.

Type of tubing	Tubing diameters	Tubing lengths	Disconnection	Function
Silicone Tuflux® or Silicone (Pt)	ID × OD = ½" × ¾" (12.70 mm × 19.05 mm)	300 mm (12") 500 mm (19") 1,000 mm (39") 1,500 mm (59") 3,000 mm (118") 5,000 mm (197")	Clipster® disconnection on Silicone (Pt) ≥ 1,000 mm length	Transfer with peristaltic pumping ≥ 1,000 mm length (10 hr maximum)
TPE tubing (not for bottom lines P5)	ID × OD = ½" × ¾" (12.70 mm × 19.05 mm)	500 mm (19") 1,000 mm (39") 1,500 mm (59") 3,000 mm (118")	Biosealer® or Biowelder® or Clipster® disconnection ≥ 1,000mm length	Transfer after tube-to-tube welding
Silicone Tuflux® or Silicone (Pt) with TPE tubing extension	ID × OD = ½" × ¾" (12.70 mm × 19.05 mm)	1,000 mm (39") silicone + 500 mm (19") TPE 2,500 mm (98") silicone + 500 mm (19") TPE 4,500 mm (177") silicone + 500 mm (19") TPE	Biosealer® or Biowelder® or Clipster® disconnection ≥ 1,000mm length	Transfer with peristaltic pumping ≥ 1,000 mm length (10 hr maximum) for silicone tubing

Distal Connectors

- Triclamp (1½" or ¾" flange) with or without a triclamp cap, gasket and union for silicone tubing only
- Quick Coupler with plug – MPX (male or female or double female)
- Opta® SFT – aseptic connection (male or female)
- STC and STC II – CPC Steamthru™ connection – (with 1½" and ¾" triclamp flanges or with ¾" × ¾" triclamp flanges)
- AseptiQuik® genderless HT
- Plug (for TPE only)
- KPC HT – male or female – Kleenpak™ sterile connectors

(Disclaimer: please refer to the third-party user manual and validation documentation)

Line Type “High Flow Rate”

Generic Description

Functionalities

- Bag filling or bag drainage
- Transfer with a peristaltic pump or by gravity
- Generic connection with a Triclamp or a Quick Coupler



Specifications

Flow Rate

Maximum flow rate with a peristaltic pump = 1,500 L/hr.
Flow rate varies with discharge pressure, suction and viscosity.

Tubing Diameters

ID × OD = $\frac{3}{4}$ " × $1\frac{1}{8}$ " (19.05 mm × 28.58 mm)

Tubing Materials

- Silicone Tuflux® or Si (Pt) for 10 hr maximum operation with a peristaltic pump

Tubing Lengths

- 300 mm (12")
- 1,000 mm (39")
- 1,500 mm (59")
- 3,000 mm (118")

Distal Connectors

- TriClamp ($1\frac{1}{2}$ " or $\frac{3}{4}$ " flange) with or without a triclamp cap, gasket and union
- Quick Coupler with plug – MPU (male or female)
- Opta® SFT – Aseptic connection (male or female)
- AseptiQuik® genderless HT

Accessory

- External pinch clamp

Line Type “Small Flow Rate”

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

Flow Rate

Maximum flow rate with a peristaltic pump = 420 L/hr.
Flow rate varies with discharge pressure, suction and viscosity.

Type of tubing	Tubing lengths	Disconnection	Function
Silicone Tuflux® or Silicone (Pt) ID × OD = 3/8" × 5/8" (9.53 mm × 15.88 mm)	300 mm (12") 500 mm (19") 1,000 mm (39") 1,500 mm (59") 3,000 mm (118") 5,000 mm (197")	Clipster® disconnection on Silicone Tuflux® or Silicone (Pt) ≥1,000 mm length	Transfer with peristaltic pumping ≥ 1,000 mm length (10 hr maximum)
TPE tubing ID × OD = 3/8" × 5/8" (9.53 mm × 15.88 mm)	500 mm (19") 1,000 mm (39") 1,500 mm (59") 3,000 mm (118")	Biosealer® or Biowelder® or Clipster® disconnection on Silicone Tuflux® or Silicone (Pt) ≥1,000 mm length	Transfer after tube-to-tube welding
Silicone Tuflux® or Silicone (Pt) with TPE tubing extension ID × OD = 3/8" × 5/8" (9.53 mm × 15.88 mm)	1,000 mm (39") silicone + 500 mm (19") TPE 2,500 mm (98") silicone + 500 mm (19") TPE 4,500 mm (177") Silicone + 500 mm (19") TPE	Biosealer® or Biowelder® or Clipster® disconnection on Silicone Tuflux® or Silicone (Pt) ≥1,000 mm length	Transfer after tube-to-tube welding

Distal Connectors

- TriClamp (1 1/2" or 3/4" flange) with or without a triclamp cap, gasket and union
- Quick Coupler with plug – MPC (male, female or double female)
- Opta® SFT – aseptic connection (male or female)
- STC and STC II – CPC Steamthru™ connection – (with 1 1/2" and 3/4" triclamp flanges or with 3/4" × 3/4" triclamp flanges)
- KPC HT – male or female – Kleenpak™ sterile connectors
- Lynx® Valve ST 1/2" – Lynx® ST connector
- AseptiQuik® genderless HT
- Plug (for TPE only)

(Disclaimer: please refer to the third-party user manual and validation documentation)

Line Type “Very Small Flow Rate”

Generic Description

Functionalities

- Solution addition
- Transfer with a peristaltic pump or by gravity
- Tube-to-tube welding
- Tube sealing
- Generic connection with a Quick Coupler



Specifications

Flow Rate

Maximum flow rate with peristaltic pumping 240 L/hr.
Flow rate varies with discharge pressure, suction and viscosity.

Tubing Diameters

ID × OD = ¼" × ⅞" (6.35 mm × 11.11 mm)

Silicone Tuflux[®] or Si (Pt) tubing

¼" × ⅜" (6.35 mm × 9.53 mm) TPE tubing

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

Tubing Lengths

- 1,500 mm (59")

Distal Connectors

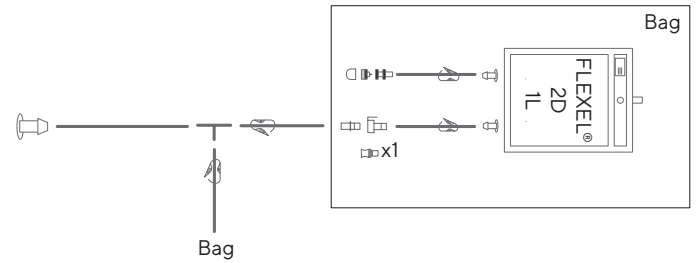
- Quick Coupler with plug – MPC, male (only silicone Tuflux[®] or Si (Pt))
- Plug (only TPE)

Line Type “Sampling Bags”

Generic Description

Functionalities

- On-line sampling
- Sample disconnections: tube-to-tube welding, tube sealing, Quick Coupler



Specifications

Flow Rate

Maximum flow rate with peristaltic pumping 240 L/hr.
Flow rate varies with discharge pressure, suction and viscosity.

Sampling bags

- 2 or 4 × 50 mL Flexboy®
- 2 or 4 × 150 mL Flexboy®
- 2 or 4 × 500 mL Flexboy®
- 2 × 1,000 mL Flexboy®
- 2 or 4 × 150 mL Flexel®
- 2 or 4 × 500 mL Flexel®
- 2 × 1,000 mL Flexel®

Tubing Diameter

ID × OD = ¼" × ⅞" (6.35 mm × 11.11 mm)

Silicone Tubing | Tubing Material

- Silicone Si (Pt) Tuflux® or Si (Pt)
- EVA section for sealing sampling bags

Flexboy® Sampling Bags

Distal connectors on sampling bags

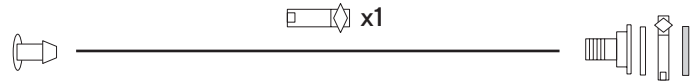
- Needleless connector
- Quick Coupler with plug – MPC male

Line Type “Transfer to Filter”

Generic Description

Functionalities

Drain and transfer with a peristaltic pump to a filter
(pressure rating of the line: 1.5 bar maximum)



Specifications

Flow Rate

Maximum flow rate with a peristaltic pump = 780 L/hr.
Flow rate varies with discharge pressure, suction, viscosity
and product filterability.

Tubing Diameter

ID × OD = 1/2" × 7/16" (12.7 mm × 22.2 mm)

Tubing Materials

Specifically formulated platinum-cured silicone tubing for
peristaltic pump applications, providing up to six times
the pump life of standard platinum-cured silicone tubing.

Tubing Lengths

- 1,500 mm (59")
- 3,000 mm (118")

Distal Connectors

- TriClamp (1 1/2" flange) with a triclamp cap,
gasket and union
- Opta® SFT – aseptic connection
(male or female)

Main Functionalities of the Flexsafe® Bag for Drums 50 L – 200 L

	Normal Flow Rate with Filter	Normal Flow Rate	High Flow Rate	Small Flow Rate	Very Small Flow Rate	Sampling	Transfer to Filter
Function	Sterile Fill	Fill drain Addition	Fill drain Addition	Fill drain Addition	Addition	Sampling	Drain to filter
Port	P1	P1 – P2 – P3 – P4 – P5	P1 – P2 – P3 – P4 – P5	P1 – P2 – P3 – P4 – P5	P2, P3	P4	P5
Tube dim.	½" – ¾"	½" – ¾"	¾" – 1 ⅛"	¾" – 5 ⅞"	¼" × 7 ⅛" or ¼" × 3 ⅞"	¼" × 7 ⅛"	½" – 7 ⅞"
Tube Length mm	500 (19") 1,000 (39") 1,500 (59") 3,000 (118") 5,000 (197")	300 (12") Silicone 500 (19") 1,000 (39") 1,500 (59") 3,000 (118") 5,000 (197")	300 (12") 1,000 (39") 1,500 (59") 3,000 (118")	300 (12") Silicone 500 (19") 1,000 (39") 1,500 (59") 3,000 (118") 5,000 (197")	1,500 (59")	100 (4")	1,500 (59") 3,000 (118")
Tubing materials	Si (Pt) Tuflux® Si (Pt) TPE	Si (Pt) Tuflux® Si (Pt) TPE (not for P5) Si (Pt) Tuflux® + TPE Si (Pt) + TPE	Si (Pt) Tuflux® Si (Pt)	Si (Pt) Tuflux® Si (Pt) TPE (not for P5) Si (Pt) Tuflux® + TPE Si (Pt) + TPE	Si (Pt) Tuflux® Si (Pt) TPE	Si (Pt) Tuflux® Si (Pt)	Si APT
Standard connectors		TC 1½ + cap TC ¾ + cap MPX - M/F/FF Plug on TPE	TC 1½ + cap TC ¾ + cap MPU - M/F	TC 1½ + cap TC ¾ + cap MPC - M/F/FF Plug on TPE	MPC - M/F/FF Plug	Clave	TC 1½ + cap
Aseptic connectors		Opta® SFT-M/F AseptiQuik® STC and STC II 1 ½, ¾ STC and STC II ¾, ¾	Opta® SFT-M/F AseptiQuik®	Opta® SFT-M/F AseptiQuik® STC and STC II 1 ½, ¾ STC and STC II ¾, ¾			Opta® SFT-M/F
Other Connectors		KPC HT - M/F		KPC HT - M/F Lynx® ST			
Sampling Bags						<ul style="list-style-type: none"> ▪ 2 or 4 × 50 mL Flexboy® ▪ 2 or 4 × 150 mL Flexboy® ▪ 2 or 4 × 500 mL Flexboy® ▪ 2 × 1,000 mL Flexboy® ▪ 2 or 4 × 150 mL Flexel® ▪ 2 or 4 × 500 mL Flexel® ▪ 2 × 1,000 mL Flexel® 	

Normal Flow Rate With Filter


Filters	Sartopore® 2 0.2 µm gamma Midicaps® sizes 7, 8, 9, 0 Maxicaps® T-Style sizes 1, 2, 3 Sartopore® Platinum 0.2 µm gamma Midicaps® sizes 7, 8, 9, 0 Maxicaps® T-Style sizes 1, 2, 3 Sartopore® 2 XLG 0.8 0.2 µm gamma Midicaps® sizes 7, 8, 9, 0 Maxicaps® T-Style sizes 1, 2, 3 Sartopore® 2 XLM 0.2 0.1µm gamma Midicaps® sizes 7, 8, 9, 0 Maxicaps® T-Style sizes 1, 2, 3 Sartoguard® NF Midicaps® sizes 8, 9, 0 Maxicaps® T-Style sizes 1, 2, 3
Flush bag	5 L, 10 L & 20 L

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Publication No.: S--2136-e | Order No.: 85037-551-96 | Status: 10 | 08 | 2021