



Standard Flexboy® bioprocessing bags



Description

Standard Flexboy® Bioprocessing bags are designed for the preparation, storage and transport of biopharmaceutical solutions, intermediates and final bulk products. They provide a single-use alternative to traditional glass, stainless steel and rigid plastic carboys in a large variety of applications.

Applications

The broad chemical compatibility of Flexboy® Bags assures the safe processing of a wide range of biopharmaceutical fluids in a variety of applications:

- Buffers and Media sterile filtration & storage
- Bulk Harvest
- Product pooling
- Fraction collection
- Sample collection
- Bulk intermediate hold
- Final Product transport

Cost reduction and risk reduction

Single-Use Systems used in biopharmaceutical manufacturing improve process safety as they reduce the risk of cross contamination from batch-to-batch and product-to-product. Cost and time consuming CIP & SIP operations are minimized. This results not only in significant cost savings within the entire manufacturing process, but also in the optimization of capacity utilization.

Flexibility

Standard Flexboy® bags are available as stand-alone bags and filter & bag assemblies incorporating a variety of filter and bag sizes allowing easy adaptation to process volume and media. Multiple configurations that also integrate thermoweldable TPE tubing are provided for flexible incorporation into your process. Thus, sterile connection and disconnection devices like the BioWelder® and the BioSealer® can be used to allow safe connections and disconnections from and to another process step.

Female luer fittings with a needle-free sampling port allow easy and convenient sampling, quick connects may be attached directly or adapted to a variety of connections and mini triclamps that are constantly used in industrial environment assure maximum flexibility.

Easy Implementation

Standard Flexboy® Bags are available in bag chamber volumes between 5 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 Flexboy® Trays and Racks facilitate an easy bag handling. Sartorius Stedim Biotech supports users already at the design & implementation phase of a new production facility with the most comprehensive support program that ensures successful design implementation of Single-Use Manufacturing.

Features	Benefits
Multiple manufacturing sites	High security of supply
100% integrity testing of bag and immediate connection	Process safety and integrity
All connections extensively qualified	Safe and robust
Full compliance with ISO11137	Highest sterility assurance level
Standard design	Most designs available from stock

Specifications

Bag Chamber	Multiple Film Construction, EVA Fluid Contact Layer
Tubing	EVA, TPE
Fittings	Female Luer Lock, MPC Male Coupling, Mini Triclamp, Needle free sampling port
Filters	Sartopore® 2 Gamma Filter Capsule
Number of Ports	3 (except for 5 mL: 1 Port)
Volumes	5 mL – 50 L
Sterilization	by Gamma Irradiation

Security of Supply

Sartorius Stedim Biotech has established multiple manufacturing sites with consistent industrial processes. The expertise of designing Single Use solutions based on collaborative supplier management and customer demand planning assures a state of the art and robust supply chain that can cope with strong market growth.

Validation

Flexboy® bags have been qualified applying the most complex and innovative test regimes. Biological, chemical and physical tests combined with extensive extractable testing provide users of Flexboy® with data representing the widest range of process fluids in a variety of processing conditions.

Full compliance with ISO11137 allows sterility assurance level validation of 10⁻⁶ for each Single Use System over its entire shelf life.

Quality Assurance

Sartorius Stedim Biotech Quality Systems for Single Use Products follow applicable ISO and FDA regulations for Medical Devices. Design, Manufacture and Sterilization processes are conducted under conditions that mirror biopharmaceutical operations and meet cGMP requirements.

Flexboy® bags are tested for compliance to:

- 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

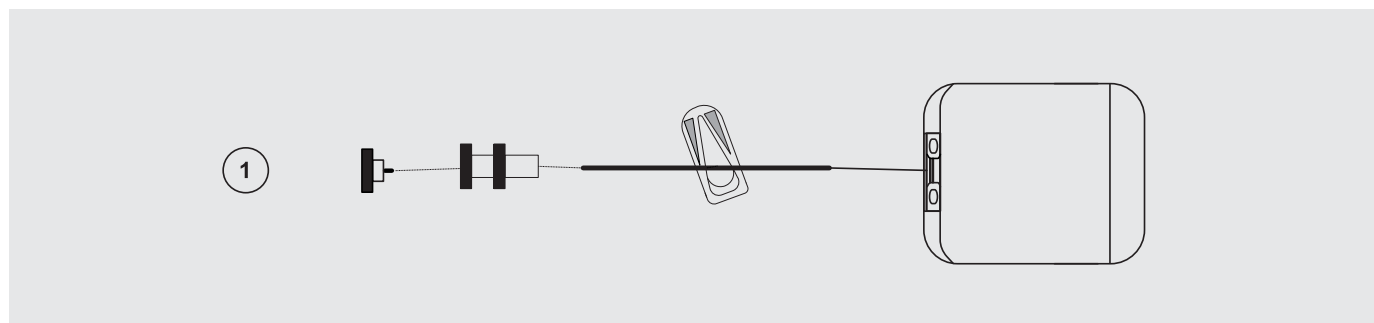
Rapid Supply

The majority of Standard Flexboy® storage systems are available from stock.

Ordering Information

1. Standard Flexboy® with EVA tubes

1.1. Standard Flexboy® with EVA tubes (5 mL with Luer® lock connection)



Part number	Description	Tubing	Bag Port 1	Bag Port 2	Bag Port 3	Qty/box
FFB115270	Flexboy® 5 mL	EVA	3/16" × 1/4" × 5 cm (2") Female LL + plug, slide clamp	NA	NA	100

Dimensions

5 mL – 3 L

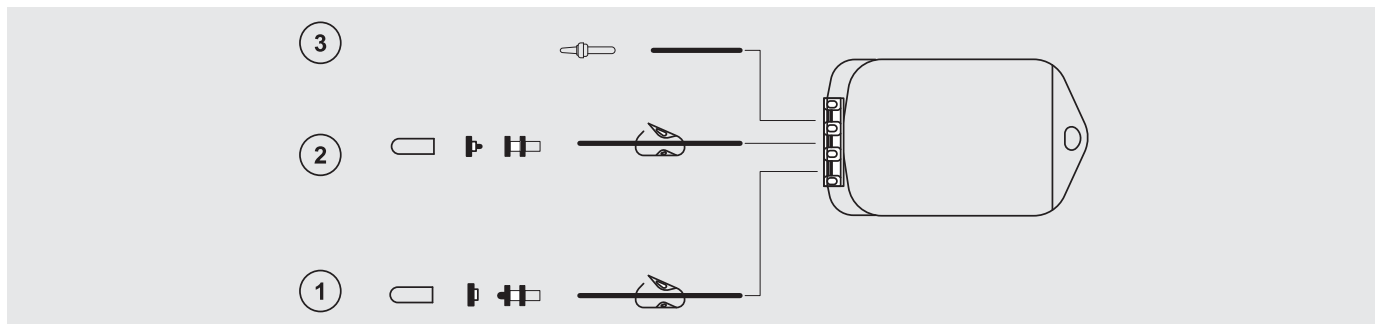
Volume	5 mL	50 mL	150 mL	250 mL	500 mL	1 L	3 L
Length (L) mm	70 (2.76")	134 (5.28")	205 (8.07")	230 (9.06")	241 (9.49")	299 (11.77")	381 (15.00")
Width (W) mm	59 (2.32")	95 (3.74")	85 (3.35")	94 (3.70")	130 (5.12")	155 (6.10")	223 (8.78")
Length inc. Tubing (T) mm	110 (4.33")	231 (9.09")	302 (11.89")	327 (12.88")	338 (13.31")	396 (15.59")	478 (18.82")
Film Surface Area cm ²	21 (3.3 in ²)	143 (22.2 in ²)	275 (42.6 in ²)	329 (51.0 in ²)	452 (70.0 in ²)	707 (109.6 in ²)	1346 (208.7 in ²)

5 L – 50 L

Volume	5 L	10 L	20 L	50 L
Length (L) mm	376 (14.80")	621 (24.45")	654 (25.75")	790 (31.10")
Width (W) mm	332 (13.07")	300 (11.81")	431 (16.97")	580 (22.83")
Length inc. Tubing (T) mm	473 (18.62")	718 (28.27")	749 (29.57")	887 (34.92")
Film Surface Area cm ²	1929 (299.0 in ²)	3528 (546.9 in ²)	4826 (748.0 in ²)	8106 (1256.4 in ²)

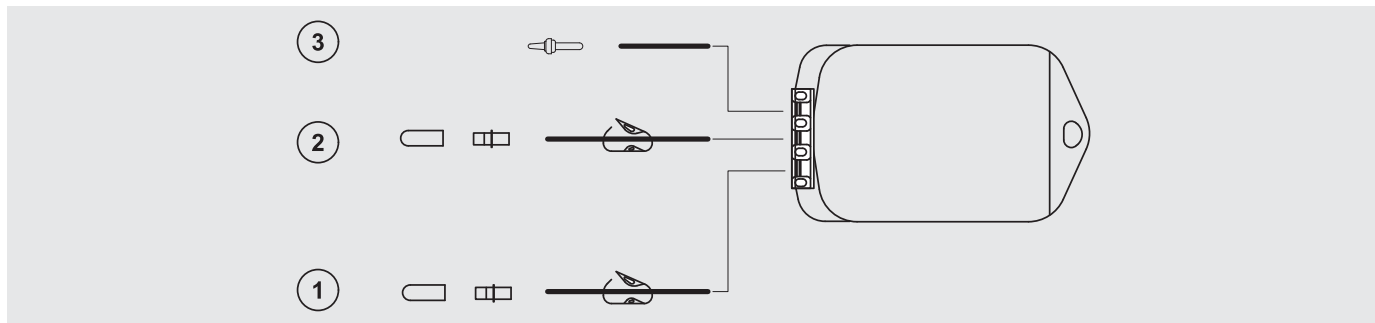
Ordering Information

1.2. Standard Flexboy® with EVA tubes (50mL to 3L with Luer lock connection)



Part number	Description	Tubing	Bag Port 1	Bag Port 2	Bag Port 3	Qty/box
FFB102603	Flexboy® 50 ml	EVA	1/4" × 5/16" × 10 cm (4") LL male + Cap, pinch clamp	1/4" × 5/16" × 10 cm (4") LL female + Cap, pinch clamp	3/16" × 1/4" × 5 cm (1,97 in.) + septum	20
FFB102643	Flexboy® 150 ml	EVA	1/4" × 5/16" × 10 cm (4") LL male + Cap, pinch clamp	1/4" × 5/16" × 10 cm (4") LL female + Cap, pinch clamp	3/16" × 1/4" × 5 cm (1,97 in.) + septum	20
FFB102670	Flexboy® 500 ml	EVA	1/4" × 5/16" × 10 cm (4") LL male + Cap, pinch clamp	1/4" × 5/16" × 10 cm (4") LL female + Cap, pinch clamp	3/16" × 1/4" × 5 cm (1,97 in.) + septum	20
FFB103547	Flexboy® 1000 ml	EVA	1/4" × 5/16" × 10 cm (4") LL male + Cap, pinch clamp	1/4" × 5/16" × 10 cm (4") LL female + Cap, pinch clamp	3/16" × 1/4" × 5 cm (1,97 in.) + septum	20
FFB102812	Flexboy® 3000 ml	EVA	1/4" × 5/16" × 10 cm (4") LL male + Cap, pinch clamp	1/4" × 5/16" × 10 cm (4") LL female + Cap, pinch clamp	3/16" × 1/4" × 5 cm (1,97 in.) + septum	20

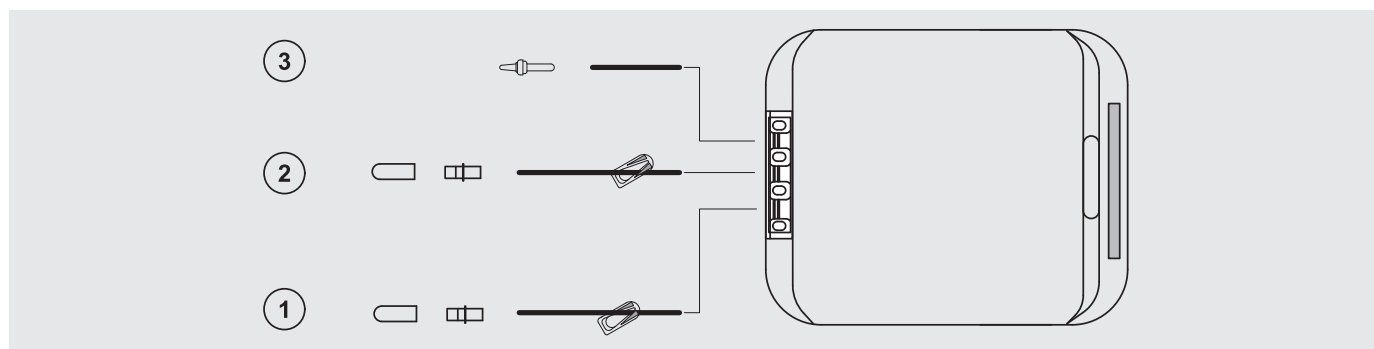
1.3. Standard Flexboy® with EVA tubes (50mL to 3L with MPC Connection)



Part Number	Description	Tubing	Bag Port 1	Bag Port 2	Bag Port 3	Qty/box
FFB102640	Flexboy® 50 ml	EVA	1/4" × 5/16" × 10 cm (4") MPC male + dust cap, pinch clamp	1/4" × 5/16" × 10 cm (4") MPC male + dust cap, pinch clamp	3/16" × 1/4" × 5 cm (1,97 in.) + septum	20
FFB102877	Flexboy® 150 ml	EVA	1/4" × 5/16" × 10 cm (4") MPC male + dust cap, pinch clamp	1/4" × 5/16" × 10 cm (4") MPC male + dust cap, pinch clamp	3/16" × 1/4" × 5 cm (1,97 in.) + septum	20
FFB103398	Flexboy® 500 ml	EVA	1/4" × 5/16" × 10 cm (4") MPC male + dust cap, pinch clamp	1/4" × 5/16" × 10 cm (4") MPC male + dust cap, pinch clamp	3/16" × 1/4" × 5 cm (1,97 in.) + septum	20
FFB102606	Flexboy® 1000 ml	EVA	1/4" × 5/16" × 10 cm (4") MPC male + dust cap, pinch clamp	1/4" × 5/16" × 10 cm (4") MPC male + dust cap, pinch clamp	3/16" × 1/4" × 5 cm (1,97 in.) + septum	20
FFB102704	Flexboy® 3000 ml	EVA	1/4" × 5/16" × 10 cm (4") MPC male + dust cap, pinch clamp	1/4" × 5/16" × 10 cm (4") MPC male + dust cap, pinch clamp	3/16" × 1/4" × 5 cm (1,97 in.) + septum	20

Ordering Information

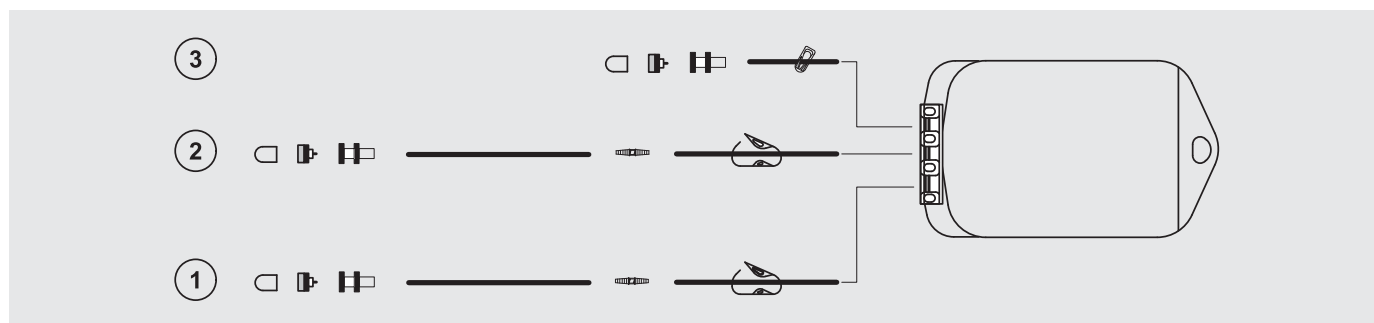
1.4. Standard Flexboy® with EVA tubes (5L to 50L with MPC Connection)



Part number	Description	Tubing	Bag Port 1	Bag Port 2	Bag Port 3	Qty/box
FFB102025	Flexboy® 5 liter	EVA	3/8" × 15/32" × 10 cm (4") MPC Male + dust cap, slide clamp	3/8" × 15/32" × 10 cm (4") MPC Male + dust cap, slide clamp	3/16" × 1/4" × 5 cm (1,97 in.) + septum	20
FFB101974	Flexboy® 10 liter	EVA	3/8" × 15/32" × 10 cm (4") MPC Male + dust cap, slide clamp	3/8" × 15/32" × 10 cm (4") MPC Male + dust cap, slide clamp	3/16" × 1/4" × 5 cm (1,97 in.) + septum	20
FFB101961	Flexboy® 20 liter	EVA	3/8" × 15/32" × 10 cm (4") MPC Male + dust cap, slide clamp	3/8" × 15/32" × 10 cm (4") MPC Male + dust cap, slide clamp	3/16" × 1/4" × 5 cm (1,97 in.) + septum	20
FFB102340	Flexboy® 50 liter	EVA	3/8" × 15/32" × 10 cm (4") MPC Male + dust cap, slide clamp	3/8" × 15/32" × 10 cm (4") MPC Male + dust cap, slide clamp	3/16" × 1/4" × 5 cm (1,97 in.) + septum	20

2. Standard Flexboy® with TPE tubes

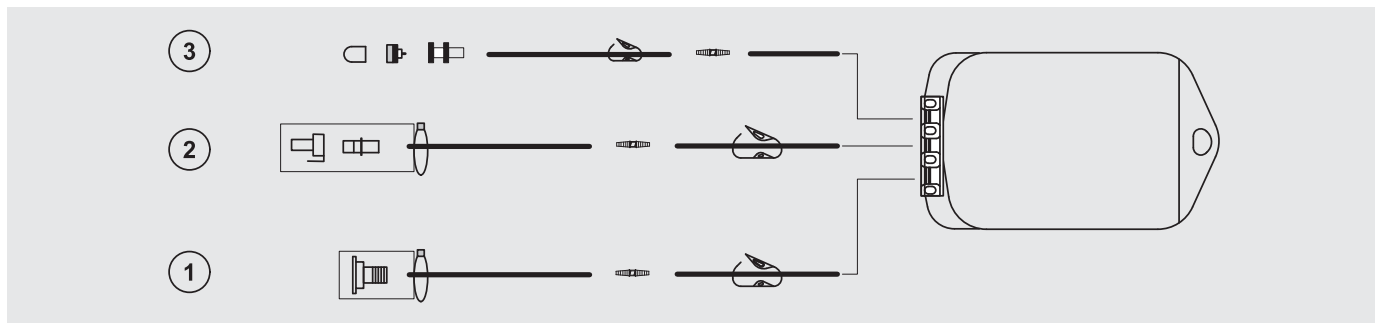
2.1. Standard Flexboy® with TPE tubes (150 mL)



Part number	Description	Tubing	Bag Port 1	Bag Port 2	Bag Port 3	Qty/box
FFB110898	Flexboy® 150 ml	EVA + Clear C-Flex 374	1/8" × 1/4" × 50 cm (20") LL female + needle free sampling port, dust cap, pinch clamp	1/8" × 1/4" × 50 cm (20") LL female + needle free sampling port, dust cap, pinch clamp	EVA port tube + slide clamp + LL female + needle free sampling port, dust cap	50

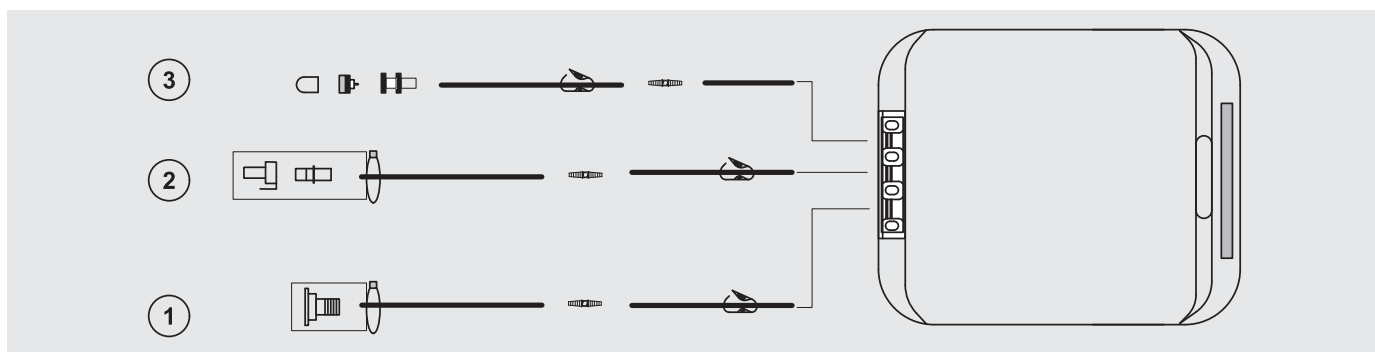
Ordering Information

2.2. Standard Flexboy® with TPE tubes (1L to 3L)



Part Number	Description	Tubing	Bag Port 1	Bag Port 2	Bag Port 3	Qty/box
FFB110900	Flexboy® 1000 ml	EVA + Clear C-Flex 374	1/4" × 7/16" × 50 cm (20") 3/4" Triclamp, pinch clamp	1/4" × 7/16" × 50 cm (20") MPC Male + sealing cap, pinch clamp	1/8" × 1/4" × 50 cm (20") LL female + needle free sampling port, pinch clamp	20
FFB110902	Flexboy® 3000 ml	EVA + Clear C-Flex 374	1/4" × 7/16" × 50 cm (20") 3/4" Triclamp, pinch clamp	1/4" × 7/16" × 50 cm (20") MPC Male + sealing cap, pinch clamp	1/8" × 1/4" × 50 cm (20") LL female + needle free sampling port, pinch clamp	20

2.3. Standard Flexboy® with TPE tubes (5L to 50L)

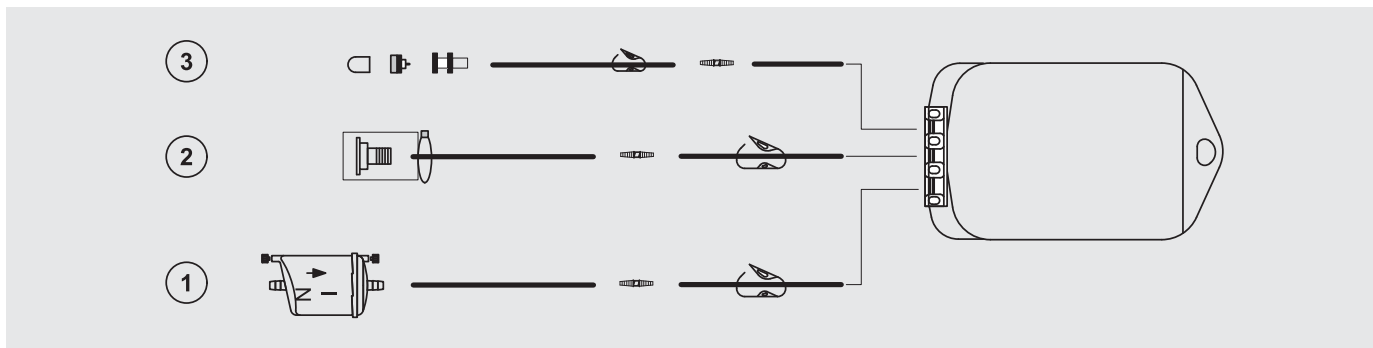


Part Number	Description	Tubing	Bag Port 1	Bag Port 2	Bag Port 3	Qty/box
FFB110904	Flexboy® 5 liter	EVA + Clear C-Flex 374	3/8" × 5/8" × 50 cm (20") 3/4" Triclamp, pinch clamp	3/8" × 5/8" × 50 cm (20") MPC Male + sealing cap, pinch clamp	1/8" × 1/4" × 50 cm (20") LL female + needle free sampling port, pinch clamp	20
FFB110905	Flexboy® 10 liter	EVA + Clear C-Flex 374	3/8" × 5/8" × 50 cm (20") 3/4" Triclamp, pinch clamp	3/8" × 5/8" × 50 cm (20") MPC Male + sealing cap, pinch clamp	1/8" × 1/4" × 50 cm (20") LL female + needle free sampling port, pinch clamp	20
FFB110906	Flexboy® 20 liter	EVA + Clear C-Flex 374	3/8" × 5/8" × 50 cm (20") 3/4" Triclamp, pinch clamp	3/8" × 5/8" × 50 cm (20") MPC Male + sealing cap, pinch clamp	1/8" × 1/4" × 50 cm (20") LL female + needle free sampling port, pinch clamp	10
FFB110907	Flexboy® 50 liter	EVA + Clear C-Flex 374	3/8" × 5/8" × 50 cm (20") 3/4" Triclamp, pinch clamp	3/8" × 5/8" × 50 cm (20") MPC Male + sealing cap, pinch clamp	1/8" × 1/4" × 50 cm (20") LL female + needle free sampling port, pinch clamp	10

Ordering Information

3. Standard Flexboy® with TPE tubes & Sartopore® 2 Gamma Capsules

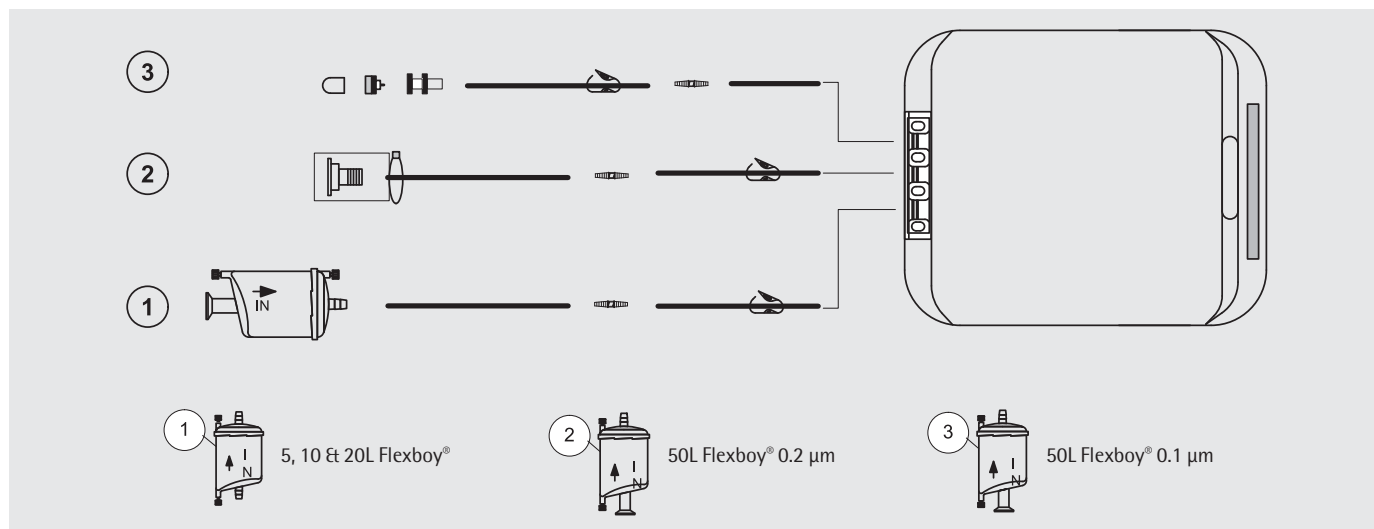
3.1. Standard Flexboy® with TPE tubes (1L to 3L)



Part number	Description	Tubing	Bag Port 1	Bag Port 2	Bag Port 3	Qty/box
FFB110908	Flexboy® 1000 ml	EVA + Clear C-Flex 374	1/4" × 7/16" × 50 cm (20") 5441307H4G-00, Sartopore 2, 0.2 µm, filter inlet: 1/4" stepped Hose Barb filter outlet: 1/4" stepped Hose Barb; 150 cm ² , pinch clamp	1/4" × 7/16" × 50 cm (20") 3/4" Triclamp, pinch clamp	1/8" × 1/4" × 50 cm (20") LL female + needle free sampling port, pinch clamp	20
FFB110909	Flexboy® 3000 ml	EVA + Clear C-Flex 374	1/4" × 7/16" × 50 cm (20") 5441307H4G-00, Sartopore 2, 0.2 µm, filter inlet: 1/4" stepped Hose Barb filter outlet: 1/4" stepped Hose Barb; 150 cm ² , pinch clamp	1/4" × 7/16" × 50 cm (20") 3/4" Triclamp, pinch clamp	1/8" × 1/4" × 50 cm (20") LL female + needle free sampling port, pinch clamp	20

Ordering Information

3.2. Standard Flexboy® with TPE tubes (5L to 50L)



Part number	Description	Tubing	Bag Port 1	Bag Port 2	Bag Port 3	Qty/box
FFB110910	Flexboy® 5 liter	EVA + Clear C-Flex 374	3/8" × 5/8" × 50 cm (20") 5441307H5G-00, Sartopore 2, 0.2 µm, filter inlet: 1/4" stepped Hose Barb filter outlet: 1/4" stepped Hose Barb; 300 cm ² , pinch clamp	3/8" × 5/8" × 50 cm (20") 3/4" Triclamp, pinch clamp	1/8" × 1/4" × 50 cm (20") LL female + needle free sampling port, pinch clamp	20
FFB110911	Flexboy® 10 liter	EVA + Clear C-Flex 374	3/8" × 5/8" × 50 cm (20") 5441307H5G-00, Sartopore 2, 0.2 µm, filter inlet: 1/4" stepped Hose Barb filter outlet: 1/4" stepped Hose Barb; 300 cm ² , pinch clamp	3/8" × 5/8" × 50 cm (20") 3/4" Triclamp, pinch clamp	1/8" × 1/4" × 50 cm (20") LL female + needle free sampling port, pinch clamp	20
FFB110912	Flexboy® 20 liter	EVA + Clear C-Flex 374	3/8" × 5/8" × 50 cm (20") 5441307H5G-00, Sartopore 2, 0.2 µm, filter inlet: 1/4" stepped Hose Barb filter outlet: 1/4" stepped Hose Barb; 300 cm ² , pinch clamp	3/8" × 5/8" × 50 cm (20") 3/4" Triclamp, pinch clamp	1/8" × 1/4" × 50 cm (20") LL female + needle free sampling port, pinch clamp	10
FFB110913	Flexboy® 50 liter	EVA + Clear C-Flex 374	1/2" × 3/4" × 50 cm (20") 5441307H7G-SM, Sartopore 2, 0.2 µm, filter inlet: 1.5" Sanitary flange filter outlet: 5/8" Hose Barb; 500 cm ² , pinch clamp	3/8" × 5/8" × 50 cm (20") 3/4" Triclamp, pinch clamp	1/8" × 1/4" × 50 cm (20") LL female + needle free sampling port, pinch clamp	10
FFB110915	Flexboy® 50 liter	EVA + Clear C-Flex 374	1/2" × 3/4" × 50 cm (20") 5441358K7G-SM, Sartopore 2, 0.1 µm, filter inlet: 1.5" Sanitary flange filter outlet: 5/8" Hose Barb; 500 cm ² , pinch clamp	3/8" × 5/8" × 50 cm (20") 3/4" Triclamp, pinch clamp	1/8" × 1/4" × 50 cm (20") LL female + needle free sampling port, pinch clamp	10

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