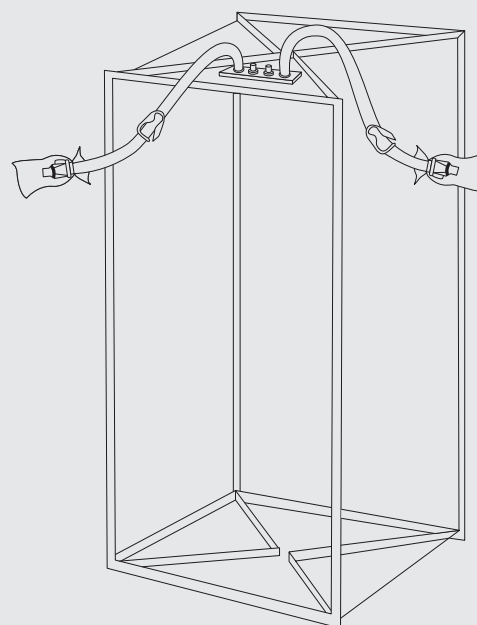


Standard Flexel[®] 3D Bioprocessing Bags for Drums

For Europe, Asia
and Latin America



Product Information

Flexel[®] 3D standard bags are designed for processing, storage and transport of large volume biopharmaceutical solutions in drums. They provide a single - use alternative to traditional stainless steel vessels in a large variety of applications.

Cost reduction and Risk reduction

Single-use Systems used in biopharmaceutical manufacturing improve process sterility as they reduce the risk of cross contamination from batch-to-batch and product-to-product. Costly 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.

Applications

The multi-layer film construction of different materials 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 & storage
- Bulk harvest
- Product pooling
- Fraction collection
- Sample collection
- Bulk intermediate filtration & hold
- Final product storage and transport

Flexibility

Standard Flexel® bags for drums are available as stand-alone bags with Silicone tubing, stand-alone bags with C-Flex tubing and Filter & Bag assemblies incorporating a variety of filter and bag sizes allowing easy adoption 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 aseptic connections and disconnections from and to another process step.

Female luer fittings with a needle free sampling port may be used for easy and convenient sampling, quick connects may be attached directly or adapted to a variety of connections and tri-clamps that are widely used in a production environment assure maximum flexibility.

Security of Supply

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

Validation

Flexel® 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 Flexel® with data representing an exceptionally wide range of process fluids in a variety of processing conditions.

Full compliance with ISO11137 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 for Medical Devices. Design, Manufacture and Sterilization processes are conducted under conditions that mirror biopharmaceutical operations and meet cGMP requirements.

Flexel® 3D 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

Supply Chain

The majority of Standard Flexel® 3D bags for drum systems are available from stock.

Features and Benefits

Multiple manufacturing sites	High security of supply
All connections extensively qualified	Reliable and robust
Full compliance with ISO11137	Meets stringent sterility standards
Standard design	Most designs available from stock
Various bag & filter sizes	High flexibility

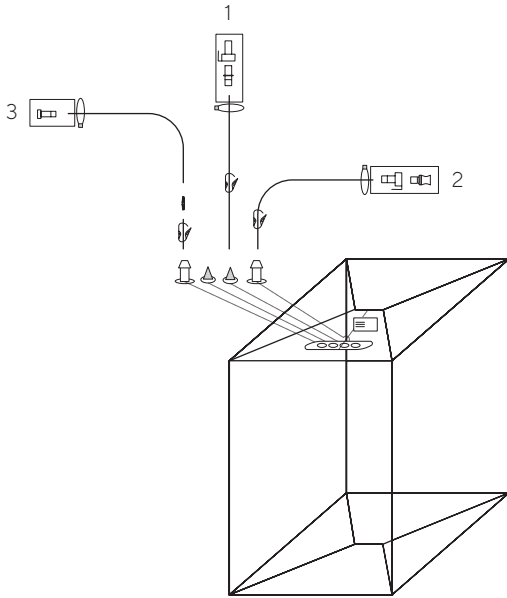
Technical Specifications

Standard Flexel® 3D for Drum

Bag chamber	Multiple layer film construction, including EVOH gas barrier layer, LLDPE Contact Layer
Tubing	Silicone, TPE
Fittings	MPX Couplings, Female Luer Lock, MPC Male Coupling, Triclamp, Needle free sampling port
Filters	Sartopore® 2 Gamma Capsule
Volumes	50 L – 1,000 L
Sterilization	by Gamma Irradiation

Ordering Information

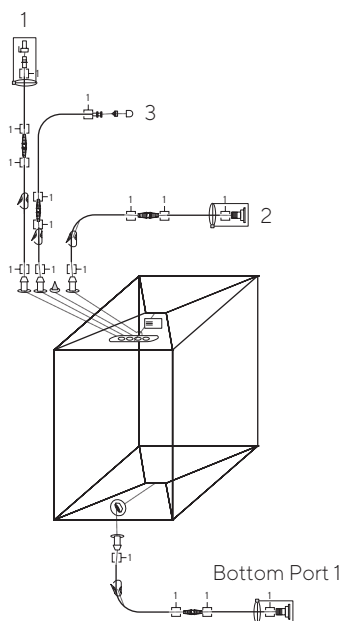
1. Standard Flexel® 3D bags for drum with silicone tubes



Part Number	Description	Tubing	Top Port 1	Top Port 2	Top Port 3	Top Port 4	Qty Box
FXB103162	Flexel® 50 L for Drum - Silicone	Silicone	½" × ⅛" × 0.5 m (20") ½" MPX male + sealing cap	½" × ⅛" × 0.5 m (20") ½" MPX male + sealing cap	Plug	Plug	5
FXB102464	Flexel® 100 L for Drum - Silicone	Silicone	½" × ⅛" × 0.5 m (20") ½" MPX male + sealing cap	½" × ⅛" × 0.5 m (20") ½" MPX male + sealing cap	Plug	Plug	5
FXB102465	Flexel® 200 L for Drum - Silicone	Silicone	½" × ⅛" × 0.5 m (20") ½" MPX male + sealing cap	½" × ⅛" × 0.5 m (20") ½" MPX male + sealing cap	Plug	Plug	5
FXB103294	Flexel® 300 L for Drum - Silicone	Silicone	½" × ⅛" × 0.5 m (20") ½" MPX male + sealing cap	½" × ⅛" × 0.5 m (20") ½" MPX male + sealing cap	Plug	Plug	5
FXB103367	Flexel® 370 L for Drum - Silicone	Silicone	½" × ⅛" × 0.5 m (20") ½" MPX male + sealing cap	½" × ⅛" × 0.5 m (20") ½" MPX male + sealing cap	Plug	Plug	5
FXB102167	Flexel® 560 L for Drum - Silicone	Silicone	½" × ⅛" × 0.5 m (20") ½" MPX male + sealing cap	½" × ⅛" × 0.5 m (20") ½" MPX male + sealing cap	Plug	Plug	5
FXB102508	Flexel® 1,000 L for Drum - Silicone	Silicone	½" × ⅛" × 0.5 m (20") ½" MPX male + sealing cap	½" × ⅛" × 0.5 m (20") ½" MPX male + sealing cap	Plug	Plug	5

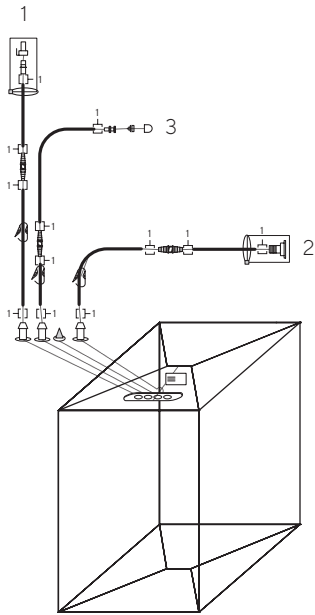
2. Standard Flexel® 3D bags for drum with silicone & TPE tubes

2.1. Standard Flexel® 3D bags for drum with silicone & TPE tubes with side bottom drain



Part Number	Description	Tubing	Top Port 1	Top Port 2	Top Port 3	Bottom Port 1	Qty Box
FXB110917	Flexel® 50 L for Drum - TPE	Silicone + Clear C - Flex® 374	½" × ¾" × 1.5 m (60") ½" MPX male + sealing cap	½" × ¾" × 1.5 m (60") 1-½" Tri - Clamp	⅝" × ¼" × 1.1 m (40") LL female + needle free sampling port	½" × ¾" × 1.5 m (60") 1-½" Tri - Clamp	5
FXB110919	Flexel® 100 L for Drum - TPE	Silicone + Clear C - Flex® 374	½" × ¾" × 1.5 m (60") ½" MPX male + sealing cap	½" × ¾" × 1.5 m (60") 1-½" Tri - Clamp	⅝" × ¼" × 1.1 m (40") LL female + needle free sampling port	½" × ¾" × 1.5 m (60") 1-½" Tri - Clamp	5
FXB110920	Flexel® 200 L for Drum - TPE	Silicone + Clear C - Flex® 374	½" × ¾" × 1.5 m (60") ½" MPX male + sealing cap	½" × ¾" × 1.5 m (60") 1-½" Tri - Clamp	⅝" × ¼" × 1.1 m (40") LL female + needle free sampling port	½" × ¾" × 1.5 m (60") 1-½" Tri - Clamp	5
FXB111626	Flexel® 300 L for Drum - TPE	Silicone + Clear C - Flex® 374	½" × ¾" × 1.5 m (60") ½" MPX male + sealing cap	½" × ¾" × 1.5 m (60") 1-½" Tri - Clamp	⅝" × ¼" × 1.1 m (40") LL female + needle free sampling port	½" × ¾" × 1.5 m (60") 1-½" Tri - Clamp	5
FXB111631	Flexel® 370 L for Drum - TPE	Silicone + Clear C - Flex® 374	½" × ¾" × 1.5 m (60") ½" MPX male + sealing cap	½" × ¾" × 1.5 m (60") 1-½" Tri - Clamp	⅝" × ¼" × 1.1 m (40") LL female + needle free sampling port	½" × ¾" × 1.5 m (60") 1-½" Tri - Clamp	5
FXB110921	Flexel® 560 L for Drum - TPE	Silicone + Clear C - Flex® 374	½" × ¾" × 1.5 m (60") ½" MPX male + sealing cap	½" × ¾" × 1.5 m (60") 1-½" Tri - Clamp	⅝" × ¼" × 1.1 m (40") LL female + needle free sampling port	½" × ¾" × 1.5 m (60") 1-½" Tri - Clamp	2

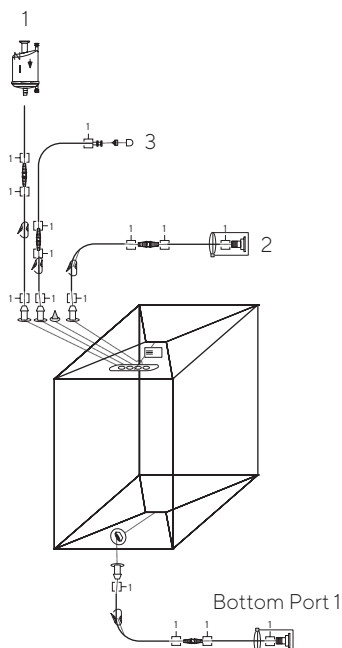
2.2. Standard Flexel® 3D bags for drum with silicone & TPE tubes



Part Number	Description	Tubing	Top Port 1	Top Port 2	Top Port 3	Bottom Port 1	Qty Box
FXB110922	Flexel® 50 L for Drum - TPE	Silicone + Clear C - Flex® 374	½" × ¾" × 1.5 m (60") ½" MPX male + sealing cap	½" × ¾" × 1.5 m (60") 1-½" Tri - Clamp	⅛" × ¼" × 1.1 m (40") LL female + needle free sampling port	No bottom drain	5
FXB110923	Flexel® 100 L for Drum - TPE	Silicone + Clear C - Flex® 374	½" × ¾" × 1.5 m (60") ½" MPX male + sealing cap	½" × ¾" × 1.5 m (60") 1-½" Tri - Clamp	⅛" × ¼" × 1.1 m (40") LL female + needle free sampling port	No bottom drain	5
FXB110924	Flexel® 200 L for Drum - TPE	Silicone + Clear C - Flex® 374	½" × ¾" × 1.5 m (60") ½" MPX male + sealing cap	½" × ¾" × 1.5 m (60") 1-½" Tri - Clamp	⅛" × ¼" × 1.1 m (40") LL female + needle free sampling port	No bottom drain	5

3. Standard Flexel® 3D bags for drum with silicone & TPE tubes & Sartopore® 2 Gamma MidiCaps

3.1. Standard Flexel® 3D bags for drum with silicone & TPE tubes with side bottom drain & Sartopore® 2 Gamma MidiCaps 0.2 µm (50 L to 370 L)

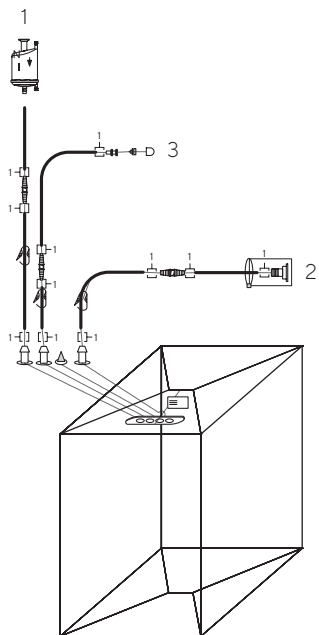


Part Number	Description	Tubing	Top Port 1	Top Port 2	Top Port 3	Bottom Port 1	Qty Box
FXB110954	Flexel® 50 L for Drum <ul style="list-style-type: none"> ▪ TPE ▪ Sartopore® 2 Gamma 	Silicone + Clear C - Flex® 374	1/2" x 3/4" x 1.5 m (60") Sartopore® 2 Gamma, 1-1/2" Tri - Clamp MidiCaps size 7, 0.2 µm; filter inlet 1.5" sanitary flange 500 cm ²	1/2" x 3/4" x 1.5 m (60")	1/8" x 1/4" x 1.1 m (40") LL female + needle free sampling port	1/2" x 3/4" x 1.5 m (60") 1-1/2" Tri - Clamp	5
FXB110958	Flexel® 100 L for Drum <ul style="list-style-type: none"> ▪ TPE ▪ Sartopore® 2 Gamma 	Silicone + Clear C - Flex® 374	1/2" x 3/4" x 1.5 m (60") Sartopore® 2 Gamma, 1-1/2" Tri - Clamp MidiCaps size 8, 0.2 µm; filter inlet 1.5" sanitary flange 1000 cm ²	1/2" x 3/4" x 1.5 m (60")	1/8" x 1/4" x 1.1 m (40") LL female + needle free sampling port	1/2" x 3/4" x 1.5 m (60") 1-1/2" Tri - Clamp	5
FXB110960	Flexel® 200 L for Drum <ul style="list-style-type: none"> ▪ TPE ▪ Sartopore® 2 Gamma 	Silicone + Clear C - Flex® 374	1/2" x 3/4" x 1.5 m (60") Sartopore® 2 Gamma 1-1/2" Tri - Clamp MidiCaps size 9, 0.2 µm; filter inlet 1.5" sanitary flange 2000 cm ²	1/2" x 3/4" x 1.5 m (60")	1/8" x 1/4" x 1.1 m (40") LL female + needle free sampling port	1/2" x 3/4" x 1.5 m (60") 1-1/2" Tri - Clamp	5
FXB111629	Flexel® 300 L for Drum <ul style="list-style-type: none"> ▪ TPE ▪ Sartopore® 2 Gamma 	Silicone + Clear C - Flex® 374	1/2" x 3/4" x 1.5 m (60") Sartopore® 2 Gamma 1-1/2" Tri - Clamp MidiCaps size 9, 0.2 µm; filter inlet 1.5" sanitary flange 2000 cm ²	1/2" x 3/4" x 1.5 m (60")	1/8" x 1/4" x 1.1 m (40") LL female + needle free sampling port	1/2" x 3/4" x 1.5 m (60") 1-1/2" Tri - Clamp	2
FXB111633	Flexel® 370 L for Drum <ul style="list-style-type: none"> ▪ TPE ▪ Sartopore® 2 Gamma 	Silicone + Clear C - Flex® 374	1/2" x 3/4" x 1.5 m (60") Sartopore® 2 Gamma 1-1/2" Tri - Clamp MidiCaps size 9, 0.2 µm; filter inlet 1.5" sanitary flange 2000 cm ²	1/2" x 3/4" x 1.5 m (60")	1/8" x 1/4" x 1.1 m (40") LL female + needle free sampling port	1/2" x 3/4" x 1.5 m (60") 1-1/2" Tri - Clamp	2

3.2. Standard Flexel® 3D bags for drum with silicone & TPE tubes with side bottom drain
& Sartopore® 2 Gamma MidiCaps 0.1 µm (50 L to 370 L)

Part Number	Description	Tubing	Top Port 1	Top Port 2	Top Port 3	Bottom Port 1	Qty Box
FXB110969	Flexel® 50 L for Drum ▪ TPE ▪ Sartopore® 2 Gamma	Silicone + Clear C - Flex® 374	½" × ¾" × 1.5 m (60") Sartopore® 2 Gamma, 1-½" Tri - Clamp MidiCaps size 7, 0.2 µm; filter inlet 1.5" sanitary flange 500 cm²	½" × ¾" × 1.5 m (60")	⅛" × ¼" × 1.1 m (40") LL female + needle free sampling port	½" × ¾" × 1.5 m (60") 1-½" Tri - Clamp	5
FXB110971	Flexel® 100 L for Drum ▪ TPE ▪ Sartopore® 2 Gamma	Silicone + Clear C - Flex® 374	½" × ¾" × 1.5 m (60") Sartopore® 2 Gamma, 1-½" Tri - Clamp MidiCaps size 8, 0.2 µm; filter inlet 1.5" sanitary flange 1000 cm²	½" × ¾" × 1.5 m (60")	⅛" × ¼" × 1.1 m (40") LL female + needle free sampling port	½" × ¾" × 1.5 m (60") 1-½" Tri - Clamp	5
FXB110973	Flexel® 200 L for Drum ▪ TPE ▪ Sartopore® 2 Gamma	Silicone + Clear C - Flex® 374	½" × ¾" × 1.5 m (60") Sartopore® 2 Gamma, 1-½" Tri - Clamp MidiCaps size 9, 0.2 µm; filter inlet 1.5" sanitary flange 2000 cm²	½" × ¾" × 1.5 m (60")	⅛" × ¼" × 1.1 m (40") LL female + needle free sampling port	½" × ¾" × 1.5 m (60") 1-½" Tri - Clamp	5
FXB111630	Flexel® 300 L for Drum ▪ TPE ▪ Sartopore® 2 Gamma	Silicone + Clear C - Flex® 374	½" × ¾" × 1.5 m (60") Sartopore® 2 Gamma, 1-½" Tri - Clamp MidiCaps size 9, 0.2 µm; filter inlet 1.5" sanitary flange 2000 cm²	½" × ¾" × 1.5 m (60")	⅛" × ¼" × 1.1 m (40") LL female + needle free sampling port	½" × ¾" × 1.5 m (60") 1-½" Tri - Clamp	2
FXB111634	Flexel® 370 L for Drum ▪ TPE ▪ Sartopore® 2 Gamma	Silicone + Clear C - Flex® 374	½" × ¾" × 1.5 m (60") Sartopore® 2 Gamma, 1-½" Tri - Clamp MidiCaps size 9, 0.2 µm; filter inlet 1.5" sanitary flange 2000 cm²	½" × ¾" × 1.5 m (60")	⅛" × ¼" × 1.1 m (40") LL female + needle free sampling port	½" × ¾" × 1.5 m (60") 1-½" Tri - Clamp	2

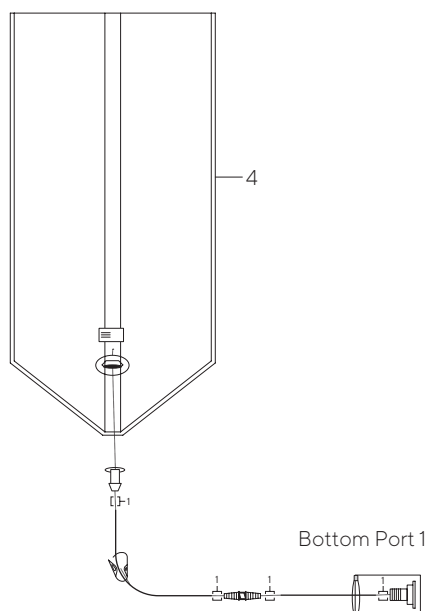
3.3. Standard Flexel® 3D bags for drum with silicone & TPE tubes & Sartopore® 2 Gamma MidiCaps 0.2 µm (50 L to 200 L)



Part Number	Description	Tubing	Top Port 1	Top Port 2	Top Port 3	Bottom Port 1	Qty Box
FXB110955	Flexel® 50 L for Drum <ul style="list-style-type: none"> ▪ TPE ▪ Sartopore® 2 Gamma 	Silicone + Clear C - Flex® 374	½" × ¾" × 1.5 m (60") Sartopore® 2 Gamma, 1-½" Tri - Clamp MidiCaps size 7, 0.2 µm; filter inlet 1.5" sanitary flange 500 cm²	½" × ¾" × 1.5 m (60")	⅝" × ¼" × 1.1 m (40") LL female + needle free sampling port	No bottom drain	5
FXB110959	Flexel® 100 L for Drum <ul style="list-style-type: none"> ▪ TPE ▪ Sartopore® 2 Gamma 	Silicone + Clear C - Flex® 374	½" × ¾" × 1.5 m (60") Sartopore® 2 Gamma, 1-½" Tri - Clamp MidiCaps size 8, 0.2 µm; filter inlet 1.5" sanitary flange 1000 cm²	½" × ¾" × 1.5 m (60")	⅝" × ¼" × 1.1 m (40") LL female + needle free sampling port	No bottom drain	5
FXB110961	Flexel® 200 L for Drum <ul style="list-style-type: none"> ▪ TPE ▪ Sartopore® 2 Gamma 	Silicone + Clear C - Flex® 374	½" × ¾" × 1.5 m (60") Sartopore® 2 Gamma 1-½" Tri - Clamp MidiCaps size 9, 0.2 µm; filter inlet 1.5" sanitary flange 2000 cm²	½" × ¾" × 1.5 m (60")	⅝" × ¼" × 1.1 m (40") LL female + needle free sampling port	No bottom drain	5
FXB110970	Flexel® 50 L for Drum <ul style="list-style-type: none"> ▪ TPE ▪ Sartopore® 2 Gamma 	Silicone + Clear C - Flex® 374	½" × ¾" × 1.5 m (60") Sartopore® 2 Gamma, 1-½" Tri - Clamp MidiCaps size 7, 0.1 µm; filter inlet 1.5" sanitary flange 500 cm²	½" × ¾" × 1.5 m (60")	⅝" × ¼" × 1.1 m (40") LL female + needle free sampling port	No bottom drain	5
FXB110972	Flexel® 100 L for Drum <ul style="list-style-type: none"> ▪ TPE ▪ Sartopore® 2 Gamma 	Silicone + Clear C - Flex® 374	½" × ¾" × 1.5 m (60") Sartopore® 2 Gamma, 1-½" Tri - Clamp MidiCaps size 8, 0.1 µm; filter inlet 1.5" sanitary flange 1000 cm²	½" × ¾" × 1.5 m (60")	⅝" × ¼" × 1.1 m (40") LL female + needle free sampling port	No bottom drain	5
FXB110974	Flexel® 200 L for Drum <ul style="list-style-type: none"> ▪ TPE ▪ Sartopore® 2 Gamma 	Silicone + Clear C - Flex® 374	½" × ¾" × 1.5 m (60") Sartopore® 2 Gamma 1-½" Tri - Clamp MidiCaps size 9, 0.1 µm; filter inlet 1.5" sanitary flange 2000 cm²	½" × ¾" × 1.5 m (60")	⅝" × ¼" × 1.1 m (40") LL female + needle free sampling port	No bottom drain	5

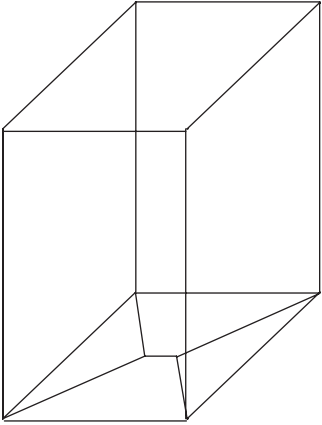
4. Standard Flexel® Tank Liners for drum

4.1. Standard Sterile Flexel® tank Liners for drum with side bottom drain



Part Number	Description	Tubing	Bottom Port 1	Qty Box
FXB110931	Flexel® 30 L liner - TPE	Silicone + Clear C - Flex® 374	½" x ¾" x 1.5 m (60") 1-½" Tri - Clamp	10
FXB110934	Flexel® 50 L liner - TPE	Silicone + Clear C - Flex® 374	½" x ¾" x 1.5 m (60") 1-½" Tri - Clamp	10
FXB110936	Flexel® 100 L liner - TPE	Silicone + Clear C - Flex® 374	½" x ¾" x 1.5 m (60") 1-½" Tri - Clamp	10
FXB110937	Flexel® 200 L liner - TPE	Silicone + Clear C - Flex® 374	½" x ¾" x 1.5 m (60") 1-½" Tri - Clamp	10
FXB111636	Flexel® 300 L liner - TPE	Silicone + Clear C - Flex® 374	½" x ¾" x 1.5 m (60") 1-½" Tri - Clamp	10
FXB111637	Flexel® 370 L liner - TPE	Silicone + Clear C - Flex® 374	½" x ¾" x 1.5 m (60") 1-½" Tri - Clamp	10
FXB110939	Flexel® 560 L liner - TPE	Silicone + Clear C - Flex® 374	½" x ¾" x 1.5 m (60") 1-½" Tri - Clamp	5
FXB110940	Flexel® 1,000 L liner - TPE	Silicone + Clear C - Flex® 374	½" x ¾" x 1.5 m (60") 1-½" Tri - Clamp	5

4.2. Standard Flexel® Tank Liners for drum




Part Number	Description	Sterility	Qty Box
FXB102120	Flexel® 50 L liner	Non sterile	20
FXB102116	Flexel® 100 L liner	Non sterile	20
FXB102117	Flexel® 200 L liner	Non sterile	20
FXB102119	Flexel® 300 L liner	Non sterile	20
FXB103406	Flexel® 370 L liner	Non sterile	20
FXB103357	Flexel® 560 L liner	Non sterile	20
FXB111118	Flexel® 30 L liner	Sterile	10
FXB103126	Flexel® 50 L liner	Sterile	20
FXB103087	Flexel® 100 L liner	Sterile	20
FXB102965	Flexel® 200 L liner	Sterile	10
FXB103132	Flexel® 300 L liner	Sterile	10
FXB103318	Flexel® 370 L liner	Sterile	15
FXB103368	Flexel® 560 L liner	Sterile	10

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