Standard Flexel® 3D Bioprocessing Bags for Palletank® (For Europe, Asia and Latin America)

Description

Flexel® 3D standard bags are designed for processing, storing and transporting large-volume biopharmaceutical solutions in Sartorius Stedim Biotech's proven Palletank® containers. 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 and SIP operations are minimized. This results in significant cost savings within the entire manufacturing process, and 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 and storage
- Bulk harvest
- Product pooling
- Fraction collection
- Sample collection
- Bulk intermediate filtration and hold
- Final product storage and transport

Flexibility

Standard Flexel® 3D bags are available as standalone bags with silicone tubing, standalone bags with C-Flex® tubing, and filter and 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 to ensure maximum flexibility.

Fast Operation

The new defined range of standard Flexel® 3D bag systems incorporates 1,000 L standard bag solutions that enable the user to empty the bags quickly through ¾" ID tubing.

Features	Benefits
Multiple manufacturing sites	High security of supply
All connections extensively qualified	Reliable and robust
Full compliance with ISO 11137	Meets stringent sterility standards
Standard design	Most designs available from stock
Designed to fit Palletank®	Market leading space saving bag containment system
¾" ID bottom drain	Quick transfer of process fluid
Various bag and filter sizes	High flexibility

Standard Flexel® 3D for Palletank®

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, Needleless sampling port
Filters	Sartopore® 2 gamma filter capsule
Volumes	100 L – 1,000 L
Number of ports	Standard silicone: 100 L – 1,000 L: 3 (two top, one bottom)
	Standard TPE: 100 L – 1,000 L: 4 (three top, one bottom)
	Standard TPE and Sartopore® 2: 100 L – 1,000 L: 4 (three top, one bottom)
Sterilization	By gamma irradiation

Security of Supply

Sartorius 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 testings provide users of Flexel® 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 single-use products with a sterility assurance level of 10^{-6} over the shelf life.

Quality Assurance

Sartorius 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.

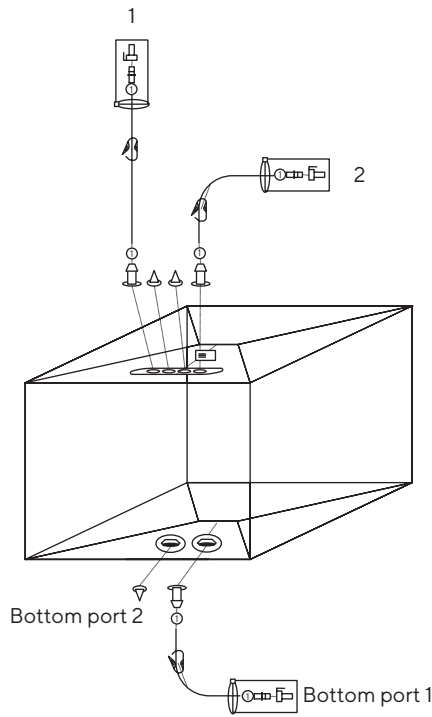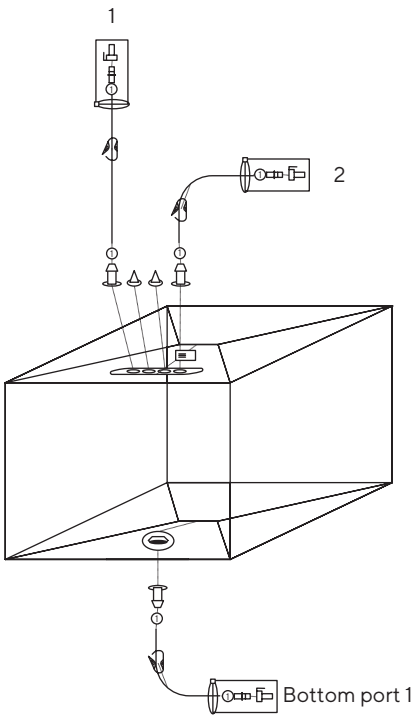Flexel® 3D bags for Palletank® are tested for compliance to:
▪ USP <87>: Biological reactivity tests, in Vitro
▪ USP <88>: Biological reactivity tests, in Vivo
▪ USP <661>: Tests for Plastic
▪ USP <788> and E.P. 2.9.19: Particulate
▪ ISO 11737: Bioburden
▪ ISO 11137: Sterilization of Medical Devices

Supply Chain

The majority of standard Flexel® 3D bags for Palletank® systems are available from stock.

Ordering Information

1. Standard Flexel® 3D bags with silicone tubes

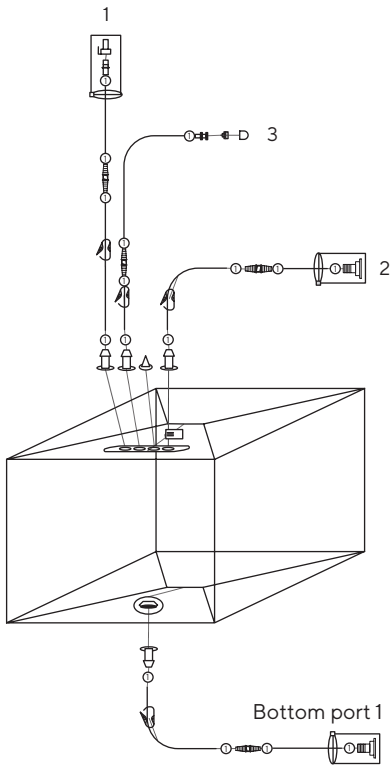Standard Flexel® 3D bags with silicone tubes
(100 L to 500 L)

Standard Flexel® 3D bags with silicone tubes
(1,000 L)

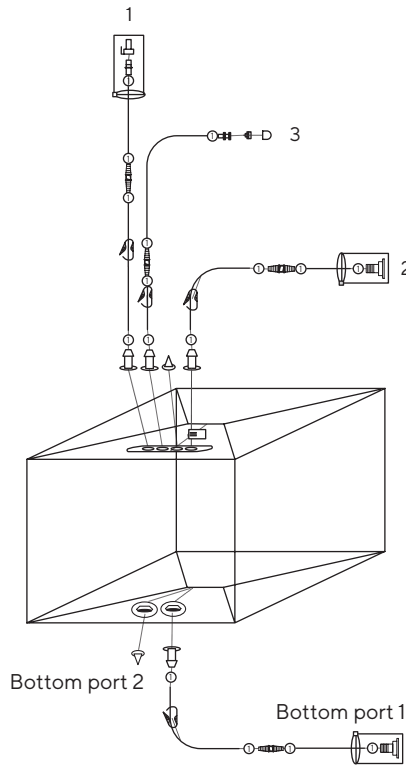| Part number	Description	Tubing	Top Port 1	Top Port 2	Bottom Port 1	Qty | Box
FXB103341	Flexel® 100 L for Palletank® ▪ Silicone	Silicone	½" × ¹¹⁄₁₆" × 0.5 m (20") ½" MPX male + sealing cap	½" × ¹¹⁄₁₆" × 0.5 m (20") ½" MPX male + sealing cap	½" × ¹¹⁄₁₆" × 0.5 m (20") ½" MPX male + sealing cap	5
FXB103364	Flexel® 200 L for Palletank® ▪ Silicone	Silicone	½" × ¹¹⁄₁₆" × 0.5 m (20") ½" MPX male + sealing cap	½" × ¹¹⁄₁₆" × 0.5 m (20") ½" MPX male + sealing cap	½" × ¹¹⁄₁₆" × 0.5 m (20") ½" MPX male + sealing cap	5
FXB103376	Flexel® 500 L for Palletank® ▪ Silicone	Silicone	½" × ¹¹⁄₁₆" × 0.5 m (20") ½" MPX male + sealing cap	½" × ¹¹⁄₁₆" × 0.5 m (20") ½" MPX male + sealing cap	½" × ¹¹⁄₁₆" × 0.5 m (20") ½" MPX male + sealing cap	5

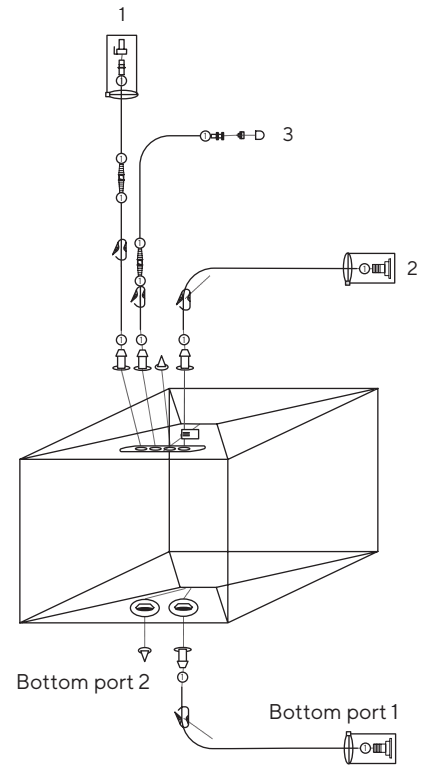| Part number	Description	Tubing	Top Port 1	Top Port 2	Bottom Port 1	Bottom Port 2	Qty | Box
FXB103426	Flexel® 1,000 L for Palletank® ▪ Silicone	Silicone	½" × ¹¹⁄₁₆" × 1.5 m (60") ½" MPX male + sealing cap	½" × ¹¹⁄₁₆" × 1.5 m (60") ½" MPX male + sealing cap	½" × ¹¹⁄₁₆" × 1 m (40") ½" MPX male + sealing cap	Plug	4

Ordering Information

2. Standard Flexel® 3D bags with TPE tubes

Standard Flexel® 3D bags with TPE tubes
(100 L to 500 L)

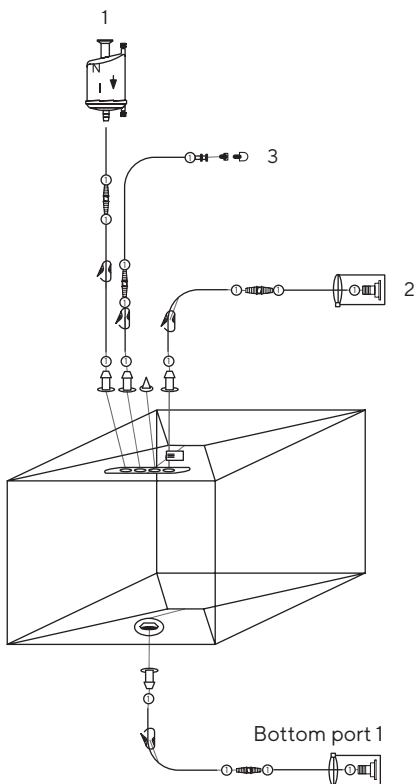Standard Flexel® 3D bags with TPE tubes
(1,000 L)

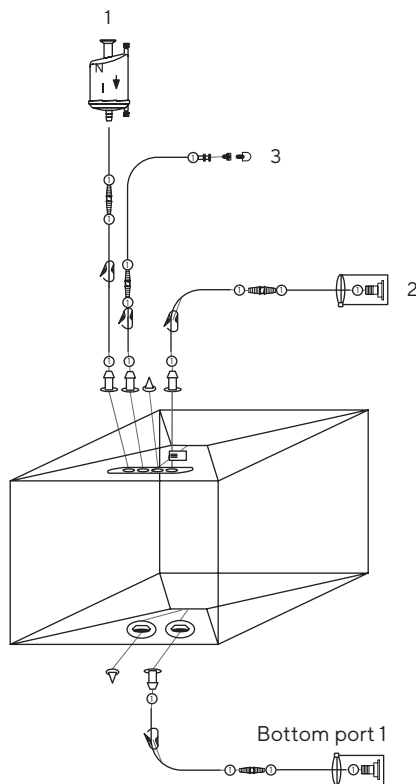Standard Flexel® 3D bags with TPE tubes
High flow rate (1,000 L)

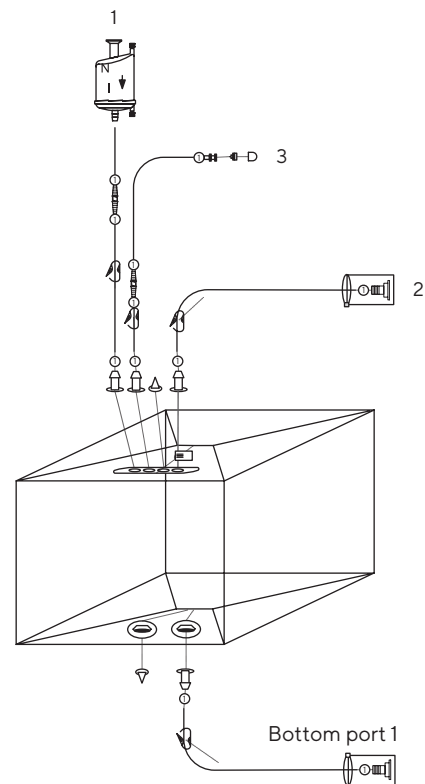| Part number	Description	Tubing	Top Port 1	Top Port 2	Top Port 3	Bottom Port 1	Qty | Box
FXB110925	Flexel® 100 L for Palletank® ▪ PTE	Silicone + clear C-Flex® 374	½" × ¾" × 1.5 m (60") ½" MPX male + sealing cap	½" × ¾" × 1.5 m (60") 1–½" Tri-Clamp	⅛" × ¼" × 1.1 m (40") LL female + needle-free sampling port	½" × ¾" × 1.5 m (60") 1–½" Tri-Clamp	4
FXB110927	Flexel® 200 L for Palletank® ▪ 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	½" × ¾" × 1.5 m (60") 1–½" Tri-Clamp	2
FXB110929	Flexel® 500 L for Palletank® ▪ 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	½" × ¾" × 1.5 m (60") 1–½" Tri-Clamp	2
FXB110930	Flexel® 1,000 L for Palletank® ▪ 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	½" × ¾" × 1.5 m (60") 1–½" Tri-Clamp	2
FXB111157	Flexel® 1,000 L for Palletank® ▪ High Flow ▪ TPE	Silicone + clear C-Flex® 374	½" × ¾" × 1.5 m (60") ½" MPX male + sealing cap	¾" × 1-⅛" × 1.5 m (60") Silicone 1–½" Tri-Clamp	⅛" × ¼" × 1.1 m (40") LL female + needle-free sampling port	¾" × 1-⅛" × 1.5 m (60") Silicone 1–½" Tri-Clamp	2

Ordering Information

3. Standard Flexel® 3D bags with TPE tubes and Sartopore® 2 gamma Midicaps®

Standard Flexel® 3D bags with TPE tubes and Sartopore® 2 gamma Midicaps® (100 L to 500 L)

Standard Flexel® 3D bags with TPE tubes and Sartopore® 2 gamma Maxicaps® (1,000 L)

Standard Flexel® 3D bags with TPE tubes and Sartopore® 2 gamma Midicaps® High flow rate (1,000 L)

Part number	Description	Tubing	Top Port 1	Top Port 2	Top Port 3	Bottom Port 1	Qty | Box
FXB110962	Flexel® 100 L for Palletank® ▪ TPE ▪ Sartopore® 2 gamma	Silicone + clear C-Flex® 374	½" × ¾" × 1.5 m (60") Sartopore® 2 gamma, Midicaps® size 8, 0.2 µm, filter inlet 1.5" sanitary flange 1,000 cm²	½" × ¾" × 1.5 m (60") 1–½" Tri-Clamp	⅛" × ¼" × 1.1 m (40") LL female + needle-free sampling port	½" × ¾" × 1.5 m (60") 1–½" Tri-Clamp	3
FXB110964	Flexel® 200 L for Palletank® ▪ TPE ▪ Sartopore® 2 gamma	Silicone + clear C-Flex® 374	½" × ¾" × 1.5 m (60") Sartopore® 2 gamma, Midicaps® size 9, 0.2 µm, filter inlet 1.5" sanitary flange 2,000 cm²	½" × ¾" × 1.5 m (60") 1–½" Tri-Clamp	⅛" × ¼" × 1.1 m (40") LL female + needle-free sampling port	½" × ¾" × 1.5 m (60") 1–½" Tri-Clamp	2
FXB110966	Flexel® 500 L for Palletank® ▪ TPE ▪ Sartopore® 2 gamma	Silicone + clear C-Flex® 374	½" × ¾" × 1.5 m (60") Sartopore® 2 gamma, Midicaps® size 0, 0.2 µm, filter inlet 1.5" sanitary flange 4,500 cm²	½" × ¾" × 1.5 m (60") 1–½" Tri-Clamp	⅛" × ¼" × 1.1 m (40") LL female + needle-free sampling port	½" × ¾" × 1.5 m (60") 1–½" Tri-Clamp	2

Standard Flexel® 3D bags with TPE tubes and Sartopore® 2 gamma Midicaps®, 0.1 µm (100 L to 500 L)

Part number	Description	Tubing	Top Port 1	Top Port 2	Top Port 3	Bottom Port 1	Qty | Box
FXB110975	Flexel® 100 L for Palletank® ▪ TPE ▪ Sartopore® 2 gamma	Silicone +clear C-Flex® 374	½" × ¾" × 1.5 m (60") Sartopore® 2 gamma, Midicaps® size 8, 0.1 µm, filter inlet 1.5" sanitary flange 1,000 cm²	½" × ¾" × 1.5 m (60") 1-½" Tri-Clamp	⅛" × ¼" × 1.1 m (40") LL female + needle-free sampling port	½" × ¾" × 1.5 m (60") 1-½" Tri-Clamp	3
FXB110976	Flexel® 200 L for Palletank® ▪ TPE ▪ Sartopore® 2 gamma	Silicone + clear C-Flex® 374	½" × ¾" × 1.5 m (60") Sartopore® 2 gamma, Midicaps® size 9, 0.1 µm, filter inlet 1.5" sanitary flange 2,000 cm²	½" × ¾" × 1.5 m (60") 1-½" Tri-Clamp	⅛" × ¼" × 1.1 m (40") LL female + needle-free sampling port	½" × ¾" × 1.5 m (60") 1-½" Tri-Clamp	2
FXB110977	Flexel® 500 L for Palletank® ▪ TPE ▪ Sartopore® 2 gamma	Silicone + clear C-Flex® 374	½" × ¾" × 1.5 m (60") Sartopore® 2 gamma, Midicaps® size 0, 0.1 µm, filter inlet 1.5" sanitary flange 4,500 cm²	½" × ¾" × 1.5 m (60") 1-½" Tri-Clamp	⅛" × ¼" × 1.1 m (40") LL female + needle-free sampling port	½" × ¾" × 1.5 m (60") 1-½" Tri-Clamp	2

Standard Flexel® 3D bags with TPE tubes and Sartopore® 2 gamma Maxicaps®, 0.2 and 0.1 µm (1,000 L)

Part number	Description	Tubing	Top Port 1	Top Port 2	Top Port 3	Bottom Port 1	Qty | Box
FXB110967	Flexel® 1,000 L for Palletank® ▪ TPE ▪ Sartopore® 2 gamma	Silicone + clear C-Flex® 374	½" × ¾" × 1.5 m (60") Sartopore® 2 gamma, Maxicaps® size 2, 0.2 µm, filter inlet 1.5" sanitary flange 1.2 m²	½" × ¾" × 1.5 m (60") 1-½" Tri-Clamp	⅛" × ¼" × 1.1 m (40") LL female + needle-free sampling port	½" × ¾" × 1.5 m (60") 1-½" Tri-Clamp	1
FXB110978	Flexel® 1,000 L for Palletank® ▪ TPE ▪ Sartopore® 2 gamma	Silicone + clear C-Flex® 374	½" × ¾" × 1.5 m (60") Sartopore® 2 gamma, Maxicaps® size 2, 0.1 µm, filter inlet 1.5" sanitary flange 1.2 m²	½" × ¾" × 1.5 m (60") 1-½" Tri-Clamp	⅛" × ¼" × 1.1 m (40") LL female + needle-free sampling port	½" × ¾" × 1.5 m (60") 1-½" Tri-Clamp	1

Standard Flexel® 3D bags with TPE tubes and Sartopore® 2 gamma Maxicaps® (1,000 L – High flow rate)

Part number	Description	Tubing	Top Port 1	Top Port 2	Top Port 3	Bottom Port 1	Qty | Box
FXB111153	Flexel® 1,000 L for Palletank® ▪ High flow ▪ TPE ▪ Sartopore® 2 gamma	Silicone + clear C-Flex® 374	½" × ¾" × 1.5 m (60") Sartopore® 2 gamma, Maxicaps® size 2, 0.2 µm, filter inlet 1.5" sanitary flange 1.2 m²	¾" × 1-⅛" × 1.5 m (60") Silicone 1-½" Tri-Clamp	⅛" × ¼" × 1.1 m (40") LL female + needle-free sampling port	¾" × 1-⅛" × 1.5 m (60") Silicone 1-½" Tri-Clamp	1
FXB111154	Flexel® 1,000 L for Palletank® ▪ High flow ▪ TPE ▪ Sartopore® 2 gamma	Silicone + clear C-Flex® 374	½" × ¾" × 1.5 m (60") Sartopore® 2 gamma, Maxicaps® size 2, 0.1 µm, filter inlet 1.5" sanitary flange 1.2 m²	¾" × 1" × 1.5 m (60") 1-½" Tri-Clamp	⅛" × ¼" × 1.1 m (40") LL female + needle-free sampling port	¾" × 1" × 1.5 m (60") 1-½" Silicone Tri-Clamp	1