



# Flexel® 3D Standard Bioprocessing Bags



## Description

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

## Applications

The multi-layer film construction of different materials 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 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.

## Easy Implementation

Flexel® 3D systems designed to fit into Palletank® containers are available in bag chamber volumes between 100 L and 1,000 L. For drums Flexel® 3D bags are available in sizes between 50 L and 1,000 L. All Flexel® 3D bags are equipped with silicone tubing and MPX quick connect couplings. They are supplied sterile and ready to use. Tankliners are not equipped with tubing and are supplied sterile or non sterile (bioburden controlled). This allows an easy and convenient process implementation.

Depending on space constraints and client handling requirements, Flexel® 3D bags are available with dimensions adapted to either the Palletank® container or cylindrical drums.\*

## Specifications

### Flexel® 3D for Palletank®

Bag Chamber	Multiple Film Construction, including EVOH gas barrier layer ULDPE Contact Layer
Tubing	Silicone
Outlet Fittings	MPX Couplings
Number of Ports	100 L–500 L: 3 (2 top, 1 bottom) 1,000 L: 4 (2 top, 2 bottom)
Volumes	100 L–1,000 L
Sterilization	by Gamma Irradiation

### Flexel® 3D for Drums

Bag Chamber	Multiple Film Construction, including EVOH gas barrier layer ULDPE Contact Layer
Tubing	Silicone
Outlet Fittings	MPX Couplings
Number of Ports	2 (2 top)
Volumes	50 L–1,000 L
Sterilization	by Gamma Irradiation

### Flexel® Tankliners

Film Material	Multiple Film Construction ULDPE Contact Layer (No gas barrier layer)
Tubing	None
Outlet Fittings	None
Number of Ports	None
Volumes	50 L–1,000 L
Sterilization	by Gamma Irradiation (non sterile, bioburden controlled liners are also available)

\* see datasheets for further details

### Technology Integration Support

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 and validation of Single-Use Manufacturing.

### 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

Flexel® 3D bags have been qualified applying the most stringent and innovative test regimes. Biological, chemical and physical tests combined with extensive extractable testing provide users of Flexel® 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<sup>-6</sup> for each Single-Use System over its entire 3 year 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.

### Available from Stock

Flexel® 3D standard bioprocessing systems are available up to 1,000 L volume from stock.

### Ordering Information

Order Code	Description	Pack Size (Pieces)
Flexel® 3D Bags for Pallettank®		
FXB103341	Flexel® 3D Bag 100 L, 2 Top Ports, 1 Bottom Drain, Silicone Tubing with ½" MPX Male Insert and Female Body	5
FXB103364	Flexel® 3D Bag 200 L, 2 Top Ports, 1 Bottom Drain, Silicone Tubing with ½" MPX Male Insert and Female Body	5
FXB103376	Flexel® 3D Bag 500 L, 2 Top Ports, 1 Bottom Drain, Silicone Tubing with ½" MPX Male Insert and Female Body	5
FXB103426	Flexel® 3D Bag 1,000 L, 2 Top Ports, 1 Bottom Drain, Silicone Tubing with ½" MPX Male Insert and Female Body	5
Flexel® 3D Bags for Cylindrical Drums		
FXB103162	Flexel® 3D Bag 50 L, 2 Top Ports, Silicone Tubing with ½" MPX Male Insert and Female Body	5
FXB102464	Flexel® 3D Bag 100 L, 2 Top Ports, Silicone Tubing with ½" MPX Male Insert and Female Body	5
FXB102465	Flexel® 3D Bag 200 L, 2 Top Ports, Silicone Tubing with ½" MPX Male Insert and Female Body	5
FXB103294	Flexel® 3D Bag 300 L, 2 Top Ports, Silicone Tubing with ½" MPX Male Insert and Female Body	5
FXB102167	Flexel® 3D Bag 560 L, 2 Top Ports, Silicone Tubing with ½" MPX Male Insert and Female Body	5
FXB102508	Flexel® 3D Bag 1,000 L, 2 Top Ports, Silicone Tubing with ½" MPX Male Insert and Female Body	5
Flexel® Tankliners		
Non Sterile		
FXB102120	Flexel® tank liner 50 L	20
FXB102116	Flexel® tank liner 100 L	20
FXB102117	Flexel® tank liner 200 L	20
FXB102119	Flexel® tank liner 300 L	20
FXB103406	Flexel® tank liner 370 L	20
FXB103357	Flexel® tank liner 560 L	20
FXB103143	Flexel® tank liner 1,000 L	20
Sterile		
FXB103126	Flexel® tank liner 50 L	40
FXB103087	Flexel® tank liner 100 L	20
FXB102965	Flexel® tank liner 200 L	20
FXB103132	Flexel® Tank Liner 300 L	20
FXB103318	Flexel® tank liner 370 L	20
FXB103368	Flexel® tank liner 560 L	20
FXB103144	Flexel® tank liner 1,000 L	20

Please note: Custom designs are available upon request.

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