# SARTORIUS

# Standard Scalable Flexel® 3D Bioprocessing Bags

## Description

Standard scalable Flexel® 3D bioprocessing bags are designed for processing and storage of small volume biopharmaceutical solutions. They provide a single-use alternative to traditional glass, stainless steel and rigid plastic carboys in a large variety of applications. With a volume range of 5 L to 50 L, the standard scalable Flexel® 3D bags are routinely used in bioresearch, process development and in small volume biomanufacturing. These bags are manufactured with very high quality standards for applications requiring remarkable levels of robustness, reliability and security.

Scaling-up operations to very large volumes (up to 3,000 L) is straightforward starting with scalable Flexel® 3D bags as they are manufactured with the same S40 film, same 3D bag technology and same port technology as the very large volume Flexel® 3D bags. Standard scalable Flexel® 3D bags are available with an extensive range of accessories (trays, racks, Palletank®, reusable handle, Biowelder®, Biosealer®) for a rapid and functional deployment of a complete single-use engineered liquid-handling and storage solutions in your process.

## 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. Costly and time-consuming CIP and 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

Standard scalable Flexel® 3D bioprocessing bags are constructed from S40, a multi-layer film that 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.

Typical applications requiring robust container storage include:
- Buffers and cell culture media filtration and storage
- Product harvest
- Product pooling
- Fraction collection
- Viral inactivation and filtration
- Bulk intermediate filtration and hold
- Final product storage

| Features | Benefits |
| --- | --- |
| Multiple manufacturing sites | High security of supply |
| All connections extensively qualified | Safe and robust |
| Full compliance with ISO 11137 | Highest sterility assurance level |
| Standard design | Most designs available from stock |
| Various bag size | High flexibility |
| Designed to fit standard tray and Palletank® | Space saving containment systems |
| Scalable S40 film | Process scalability with the same product contact materials from 5 L to 3,000 L |

## Flexibility

Standard scalable Flexel® 3D bags are available for a fast implementation in a customer process, using pre-defined bag configurations. The bag configurations may be readily customized to optimize the integration into a specific application and process, using pre-qualified and off the shelf OPUS components. Sartorius Stedim Biotech supports user design with a comprehensive support program that ensures successful design implementation of single-use manufacturing.

## Easy Implementation

Standard scalable Flexel® 3D bags are available with volume of 5 L, 10 L, 20 L and 50 L. They are supplied, sterilized and ready to use for easy and convenient process implementation. A 50 L configuration with thermoweldable TPE tubing is provided for flexible incorporation into your process. 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.

A series of associated systems such as reusable handles, plastic and stainless steel trays, racks and Palletanks®, facilitates bag handling, transportation and storage.

## 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, ensures a state-of-the-art product supported by a robust supply chain that can cope with strong market growth.

## Validation

Standard scalable Flexel® 3D 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 standard scalable Flexel® 3D bags with data representing a 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. Standard scalable 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 matters in injections
- USP<85> and E.P.2.6.14: Bacterial endotoxins
- ISO 11737: Bioburden
- ISO 11137: Sterilization of medical devices

## Supply Chain

The majority of standard scalable Flexel® 3D bag systems are available from stock.

# Specifications

## 1. Standard Scalable Flexel® 3D Bags

| | |
|---|---|
| Bag chamber | Multiple layer film construction, including EVOH gas barrier layer and a PE contact layer |
| Tubing | Silicone, TPE |
| Fittings | MPC and MPX male and female couplings, female luer lock, needle-less sampling port |
| Volumes | 5 L, 10 L, 20 L and 50 L |
| Number of ports | 3 ports (5 L, 10 L and 20 L)<br>3 top ports and 3 bottom ports (50 L) |
| Sterilization | By gamma irradiation |



## 2. Reusable Handle

| | |
|---|---|
| Description | Removable handle for Flexel® 3D 5-10-20 L |
| Material of construction | Silicone | PA coated steel |



## 3. Plastic Trays

| | |
|---|---|
| Material of construction | Polypropylene |
| Tray capacity | 5 L, 10 L and 20 L |
| Lids available for | 5 L, 10 L |
| Stackable | Yes |

| Dimensions | |
|---|---|
| 5 L | 400 × 300 × 175 mm – (15.8" × 11.8" × 6.9") |
| 10 L | 600 × 400 × 175 mm – (23.63" × 15.8" × 6.9") |
| 20 L | 1,000 × 400 × 214 mm – (39.4" × 11.8" × 8.4") |

| Weight of Tray | Bag and Lid (Bag Filled to Nominal Volume) | |
|---|---|
| 5 L | 6.2 Kg (13.7 lbs) |
| 10 L | 12.4 Kg (27.3 lbs) |
| 20 L | 24.1 Kg (53.0 lbs) |

## 4. Stainless Steel Trays

| | |
|---|---|
| Material | 304 L stainless steel |
| Surface finish | Bead blasted |
| Tray capacity | 5 L (for Flexel® 3D 5 L)<br>10 L (for Flexel® 3D 10 L and 20 L) |
| Lid available for | 5 L, 10 L |

| Dimensions | |
|---|---|
| 5 L | 475 × 330 × 117 mm – (18.7" × 12.9" × 4.6") |
| 10 L | 760 × 330 × 117 mm – (29.9" × 12.9" × 4.6") |

| Weight of Tray | Bag and Lid (Bag Filled to Nominal Volume) |
|---|---|
| 5 L | 8.6 Kg (18.9 lbs) |
| 10 L | 15.7 Kg (34.5 lbs) |
| 20 L in 10 L tray | 25.7 Kg (56.5 lbs) |

## 5. Rack System

(Please consult the Flexboy® Tray and Rack System Datasheet)

| | Base Module 1 | Additional Module 2 | Full System |
|---|---|---|---|
| Material | 304 L stainless steel | 304 L stainless steel | 304 L stainless steel |
| Surface finish | Bead blasted | Bead blasted | Bead blasted |
| Weight | 30.5 Kg (67.1 lbs) | 26 Kg (57.2 lbs) | 82.5 Kg (181.5 lbs) |
| Stainless steel tray compartments | 4 places for 5 or 10 L stainless steel trays – (2 places for 20 L stainless steel trays) | 8 places for 5 or 10 L stainless steel trays – (4 places for 20 L stainless steel trays) | 20 places for 5 or 10 L stainless steel trays – (10 Places for 20 L stainless steel trays) |
| Plastic tray compartments | 2 places for 20 L plastic trays or 2 places for 10 L plastic trays or 4 places for 5 L plastic trays | 4 places for 20 L plastic trays or 4 places for 10 L plastic trays or 8 places for 5 L plastic trays | 10 places for 20 L plastic trays or 10 places for 10 L plastic trays or 20 places for 5 L plastic trays |
| Peristaltic pumps compartment | Yes – Dimensions: 887 × 775 × 300 mm (34.9" × 30.5" × 11.8") | No | Yes – Dimensions: 887 × 775 × 300 mm (34.9" × 30.5" × 11.8") |
| Wheels | Four swivel wheels (Two with brakes) | – | Four swivel wheels (Two with brakes) |
| Additional features | Built in wheels (Non-autoclavable) | – | Full = 1 base + 2 additional modules |

## 6. Palletank® for Storage

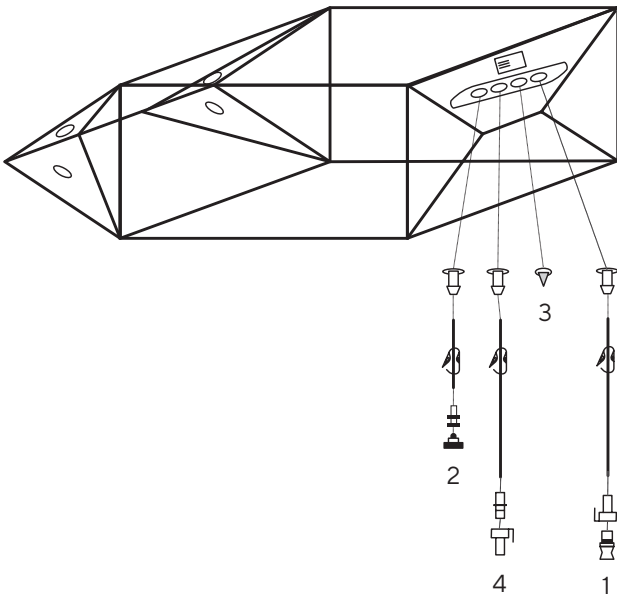| Description | Palletank® 50 L for storage stackable |
| --- | --- |
| Bag volume | 50 L |
| Construction material | 304 L stainless steel |
| Surface finishing | Bead blasted |
| Dimensions (approx.) | 490 × 490 × 750 mm (19.3" × 19.3" × 29.5") |
| Sliding gate | 1 |
| Stackability (static) | Yes (3) |
| Weight (approx.) | 24 kg (52.8 lb) |

### Accessories

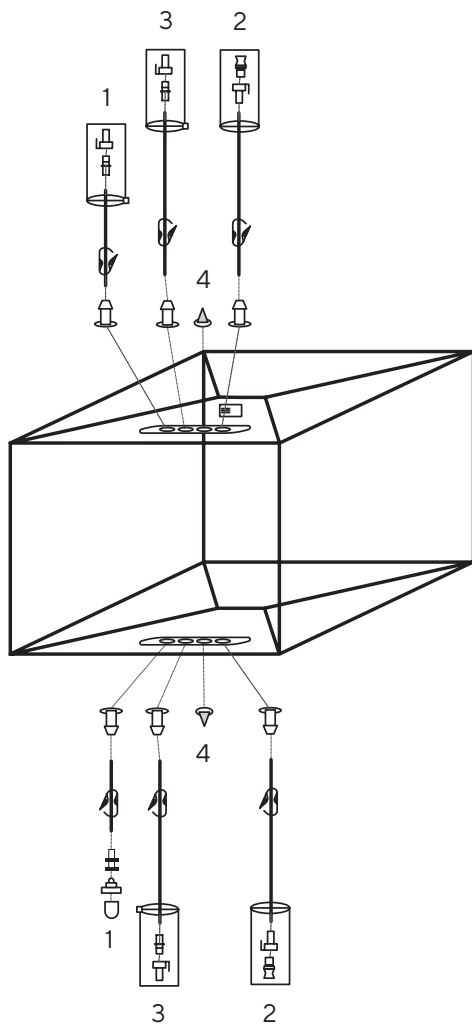| Description | Dolly for Palletank® 50 L for storage |
| --- | --- |
| Weight (approx.) | 7 kg (15.4 lb) |

# Ordering Information

## 1. Scalable Flexel® 3D Bioprocessing Bags



| Part Number | Description | Tubing | Bag Port 1 | Bag Port 2 | Bag Port 3 | Bag Port 4 | Qty/Box |
|---|---|---|---|---|---|---|---|
| FXB112850 | STD Flexel® 5 L | Silicone | ⅜" × ⅝" × 150 mm (6")<br>⅜" MPC female + plug | ¼" × ⅜" × 100 mm (4")<br>LL female + plug | Plug | ⅜" × ⅝" × 150 mm (6")<br>⅜" MPC male + cap | 12 |
| FXB112852 | STD Flexel® 10 L | Silicone | ⅜" × ⅝" × 150 mm (6")<br>⅜" MPC female + plug | ¼" × ⅜" × 100 mm (4")<br>LL female + plug | Plug | ⅜" × ⅝" × 150 mm (6")<br>⅜" MPC male + cap | 12 |
| FXB112853 | STD Flexel® 20 L | Silicone | ⅜" × ⅝" × 150 mm (6")<br>⅜" MPC female + plug | ¼" × ⅜" × 100 mm (4")<br>LL female + plug | Plug | ⅜" × ⅝" × 150 mm (6")<br>⅜" MPC male + cap | 12 |

| Part Number | Description | Tubing | Top Port 1 | Top Port 2 | Top Port 3 | Top Port 4 | Qty/Box |
|---|---|---|---|---|---|---|---|
| FXB113153 | STD Flexel® Cubical 50 L | Silicone and clear C-Flex®* 374 | ¼" × ⅜" × 10 cm (4") + male MPC + sealing cap | ½" × ¾" × 50 cm (20") + female MPX + sealing cap | ½" × ¾" × 50 cm (20") + male MPX + sealing cap | Plug | 4 |
| | | | **Bottom Port 1** | **Bottom Port 2** | **Bottom Port 3** | **Bottom Port 4** | |
| | | | ¼" × ⅜" × 10 cm (4") + LL female + needle-free sampling port | ½" × ¾" × 50 cm (20") + female MPX + sealing cap | ½" × ¾" × 50 cm (20") + male MPX + sealing cap | Plug | |

* C-Flex® is a registered trademark of Saint-Gobain Performance Plastics Corporation.

## 2. Reusable Handle

| Part Number | Description | Qty/Box |
|---|---|---|
| FXA113036 | Removable handle for Flexel® 3D 5–10–20 L | 3 |

## 3. Plastic Trays

| Part Number | Description | Qty/Box |
|---|---|---|
| FFA113141 | Plastic tray Flexel® \| Flexboy® 5 L + lid | 1 |
| FFA113142 | Plastic tray Flexel® \| Flexboy® 10 L - 20 L + lid | 1 |
| FFA113143 | Plastic tray Flexel® 20 L | 1 |

## 4. Stainless Steel Trays

| Part Number | Description | Qty/Box |
|---|---|---|
| FFA102705 | Flexboy® tray + lid 5 L | 1 |
| FFA102715 | Flexboy® tray + lid 10 L | 1 |

## 5. Rack System

| Part Number | Description | Qty/Box |
|---|---|---|
| FFA102707 | Flexboy® rack \| Base module 1 | 1 |
| FFA102714 | Flexboy® rack \| Module 2 | 1 |

## 6. Palletank® for Storage 50 L

| Part Number | Description | Qty/Box |
|---|---|---|
| FXC113946 | Std Palletank® storage 50 L (stackable) | 1 |
| FXA113988 | Std Palletank® accessory dolly 50 L (storage) | 1 |