

Flexsafe® 2D Advanced



Product Information

Flexsafe® 2D advanced bags are extensively qualified solutions for fluid handling throughout the production of cell and gene therapies (CGT). They are specifically designed for media transfer and harvest (via welding with polyvinyl chloride (PVC) and thermoplastic elastomer (TPE) and final filling, with a large design space and various components adapted to filling line designs (e.g., tubing, needles).

Flexsafe® film guarantees excellent biocompatibility and robustness. Combined with product compliance to the most stringent regulatory standards, it makes Flexsafe® 2D advanced bags the ideal solution for critical applications.

Features and Benefits

- Specifically designed to cover all CGT fluid handling production steps, from upstream to final filling
- Flexsafe® film supports excellent biocompatibility and robustness
- Qualified and flexible design space
- Supports regulatory compliance

Introduction

Relevant Applications

- Transfer
- Storage
- Final filling

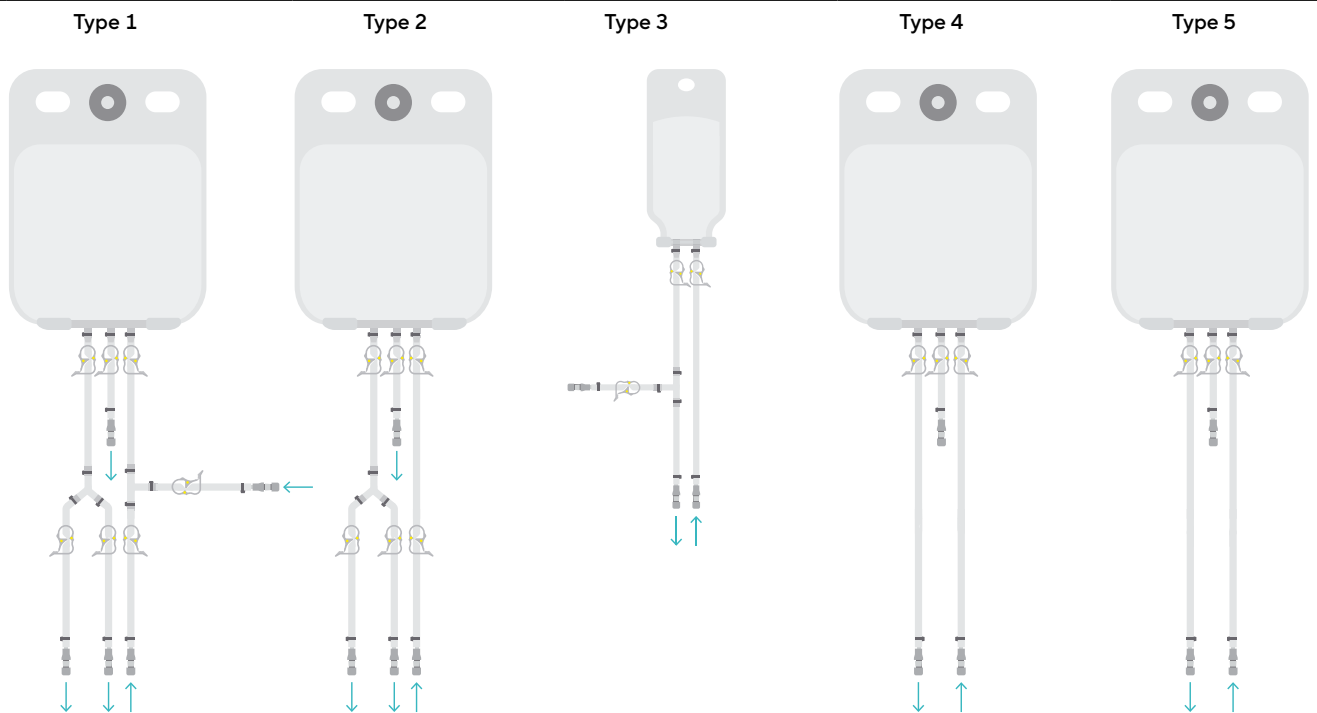
Relevant Process Steps

- Media transfer
- Media harvest
- Final filling
- Product harvest

Technical Specifications

Flexsafe® 2D Advanced PVC

Flexsafe® 2D advanced PVC are available as five different pre-designed solutions for transfer, harvest, and media handling applications:

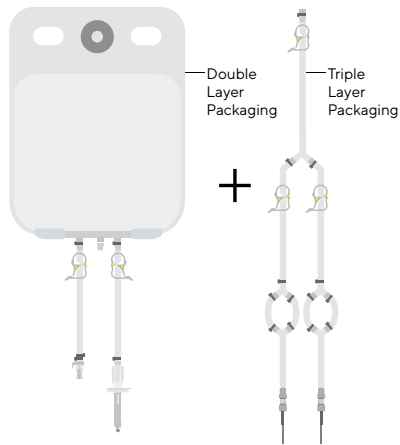


Volume	1, 3, 5, 10, 20 L	1, 3, 5, 10, 20 L	20, 50, 150, 250, 500 mL	1, 3, 5, 10, 20 L	1, 3, 5, 10, 20 L
Inlet	Tuflux TPE ¼" ID × ⅜" OD (500 mm) Addition line PVC DEHP-free ⅜" ID × ⅝" OD (300 mm)	Tuflux TPE ¼" ID × ⅜" OD (500 mm)	Tuflux TPE ⅛" ID × ¼" OD (500 mm) PVC ⅜" × ⅝" (300 mm)	Tuflux TPE ¼" ID × ⅜" OD (500 mm) PVC DEHP-free ⅜" × ⅝" (300 mm)	Tuflux TPE ¼" ID × ⅜" OD (500 mm) PVC DEHP-free ¼" × ⅜" (300 mm)
Outlet	Y line: Tuflux TPE ⅛" ID × ¼" ID (300 mm) PVC DEHP-free ⅜" ID × ⅝" OD (300 mm)	Y line: Tuflux TPE ⅛" ID × ¼" ID (300 mm) PVC DEHP-free ⅜" ID × ⅝" OD (300 mm)	Tuflux TPE ⅛" ID × ¼" OD (500 mm) Sampling line Tuflux TPE ⅛" ID × ¼" OD PVC DEHP-free ⅜" × ⅝" (300 mm)	Tuflux TPE ¼" ID × ⅜" OD (500 mm) PVC DEHP-free ¼" × ⅝" (300 mm)	Tuflux TPE ¼" ID × ⅜" OD (500 mm) PVC DEHP-free ¼" × ⅜" (300 mm)
Sampling	Tuflux TPE ¼" × ⅜" (150 mm)	Tuflux TPE ¼" × ⅜" (150 mm)	N/A	Tuflux TPE ¼" × ⅜" (150 mm)	Tuflux TPE ¼" × ⅜" (150 mm)

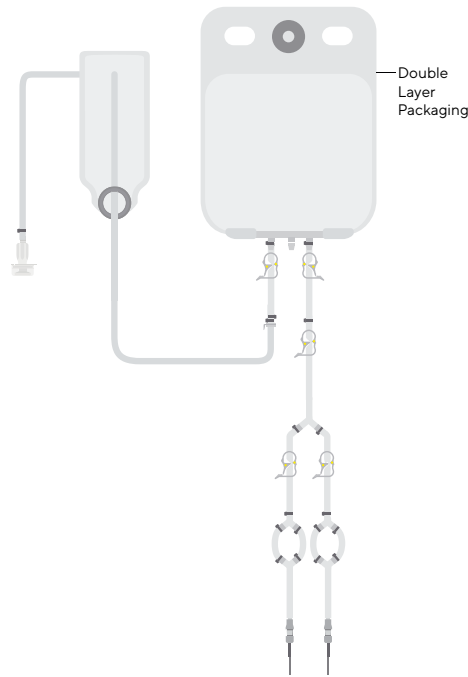
Flexsafe® 2D Advanced FF

Flexsafe® 2D advanced FF for final filling applications are available in three different fully customizable configurations via our Engineered-to-Order solutions. Bag volumes available: 1, 3, and 5 L. Different volumes are also available upon request. Filling sets can be configured with tubing material and needles suitable for most filling lines.

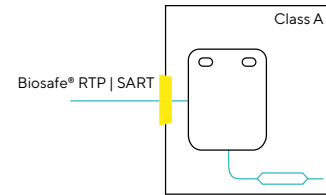
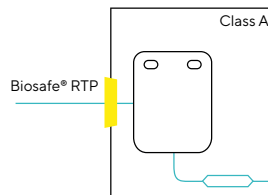
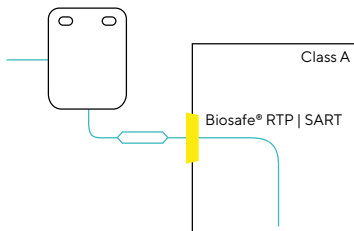
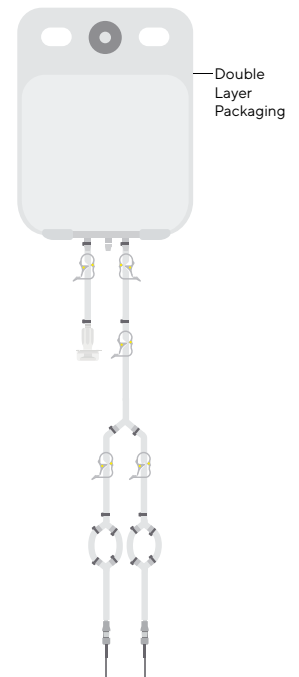
**Flexsafe® 2D Advanced
Filling Bag Outside Configuration
Grade A | Class 100**



**Flexsafe® 2D Advanced
Filling Bag Inside Configuration
Grade A | Class 100, Transfer via Biosafe®**



**Flexsafe® 2D Advanced
Filling Bag Inside Configuration
Grade A | Class 100, manual transfer**



Description

- Flexsafe® 2D bag outside | filling set inside of the Grade A | Class 100 filling space
- Bag outlet connected to filling set via Biosafe® 110 RAFT technology or SART Technology™
- Suitable for supplier integrity test and bag point-of-use integrity test
- Ideal for reduced machine footprint

- Flexsafe® 2D bag outside of Class A
- Filling set into Grade A | Class 100 filling space transfer via Biosafe® 110 RAFT technology
- Suitable for Supplier Integrity Testing
- Ideal for Isolators closed RABS

- Flexsafe® 2D bag triple-packed
- Positioned inside the isolator | RABS | clean room prior to decontamination
- Inlet connected via Biosafe® 110 RAFT technology or SART System®
- Suitable for supplier integrity testing

All Flexsafe® 2D advanced FF batches come with a Certificate of Release with the following lot release testing:

- Endotoxin testing according to USP <85>
- Bioburden testing according to ISO 11737
- Sub-visible particle testing according to USP <788>
- Visual Inspection and leak test on 100% of bags
- Gamma Irradiation Certificate
- Particle prevention program – Monitoring representative products for visible particles

Ordering Information

Product Name	Description	Volume	Order Number
Flexsafe® 2D advanced PVC	Type 1	1 L	FLS314256
Flexsafe® 2D advanced PVC	Type 1	3 L	FLS314257
Flexsafe® 2D advanced PVC	Type 1	5 L	FLS314258
Flexsafe® 2D advanced PVC	Type 1	10 L	FLS314259
Flexsafe® 2D advanced PVC	Type 1	20 L	FLS314260
Flexsafe® 2D advanced PVC	Type 2	1 L	FLS315549
Flexsafe® 2D advanced PVC	Type 2	3 L	FLS315550
Flexsafe® 2D advanced PVC	Type 2	5 L	FLS315551
Flexsafe® 2D advanced PVC	Type 2	10 L	FLS315552
Flexsafe® 2D advanced PVC	Type 2	20 L	FLS315553
Flexsafe® 2D advanced PVC	Type 3	20 mL	FLS314343
Flexsafe® 2D advanced PVC	Type 3	50 mL	FLS314344
Flexsafe® 2D advanced PVC	Type 3	150 mL	FLS314345
Flexsafe® 2D advanced PVC	Type 3	250 mL	FLS314347
Flexsafe® 2D advanced PVC	Type 3	500 mL	FLS314348
Flexsafe® 2D advanced PVC	Type 4	1 L	FLS314351
Flexsafe® 2D advanced PVC	Type 4	3 L	FLS314356
Flexsafe® 2D advanced PVC	Type 4	5 L	FLS314357
Flexsafe® 2D advanced PVC	Type 4	10 L	FLS314358
Flexsafe® 2D advanced PVC	Type 4	20 L	FLS314359
Flexsafe® 2D advanced PVC	Type 5	1 L	FLS314360
Flexsafe® 2D advanced PVC	Type 5	3 L	FLS314361
Flexsafe® 2D advanced PVC	Type 5	5 L	FLS314362
Flexsafe® 2D advanced PVC	Type 5	10 L	FLS314363
Flexsafe® 2D advanced PVC	Type 5	20 L	FLS314366



Shippers and Standalone Shells

Bag Volume [L]	Description	Units Per Box	Order Number
5	Standard shipper for 5 L shell with double PE overpouches per shipper	10 units shippers 20 units PE overpouches	FLA302721
10	Standard shipper for 10 L shell with double PE overpouches per shipper	10 units shippers 20 units PE overpouches	FLA300318
5	Standard shell 5 L 2D bag handling	5 top + 5 bottom	FLA302701
10	Standard shell 10 L 2D bag handling	5 top + 5 bottom	FLA300213
20	Standard shipper for 20 L shell with double PE overpouches per shipper	7 units shippers 15 units PE overpouches	FLA302723
20	Standard shell 20 L 2D bag handling	5 top + 5 bottom	FLA302706



Confidence® Validation Services: Extractables | Leachables Testing

Sartorius has provided validation services to the biopharmaceutical industry for more than 30 years. We have a deep understanding of the regulatory landscape, and we take a tailored and consultative approach with every customer. This makes us the perfect partner to address your validation-related challenges.

Confidence® Validation Services offers the necessary validation services to implement single-use systems or conventional equipment into your bioprocess. Our wide range of tests extends across all process components to provide a holistic solution.

Our extractables | leachables testing portfolio includes well-known solutions such as extractables tests and leachable screening. We also offer innovative solutions such as Extractables Assessments, facilitated by our proprietary software, the Extractables Simulator (ExSim).

As specified in USP <1663> and USP<1664>, we use state-of-the-art analytical methods, such as GC-MS, HPLC-UV, LC-MS, HS/GC-MS, NVR, FTIR, ICP-MS/OES, and IEC to detect and identify compounds released from polymer-based materials in even the most complex product formulations. We combine extractables, material, plastics, and toxicological data with intelligent algorithms to perform process-specific extractables scaling, even for assemblies consisting of multiple components.

Let our experts support you in identifying your validation needs and the appropriate testing scope.

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