Sartorius MSC Manufacturing Solution

Data Sheet Collection

SARTORIUS

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Biostat STR®
Generation 3 and
Biobrain® Automation
Platform

Commercial Manufacturing

SARTORIUS

Engineered for Quality and Precision

The Biostat STR® Generation 3 single-use bioreactor system is now powered by Biobrain®, the new automation platform with data-driven software and a comprehensive suite of analytical tools. The system easily integrates into your existing process infrastructure and consistently delivers outstanding speed, quality, and productivity up to 2,000 L. The Biostat STR® system supports the intensification of your seed train process. Start working at lower volumes, skip one or two steps in your seed train while still generating an adequate number of cells.

- ✓ Optimize capital costs
- ✓ Reduce operating expenses
- ✓ Enhanced safety and optimized space
- ✓ Improve productivity and ease of use
- ✓ Increase facility throughput
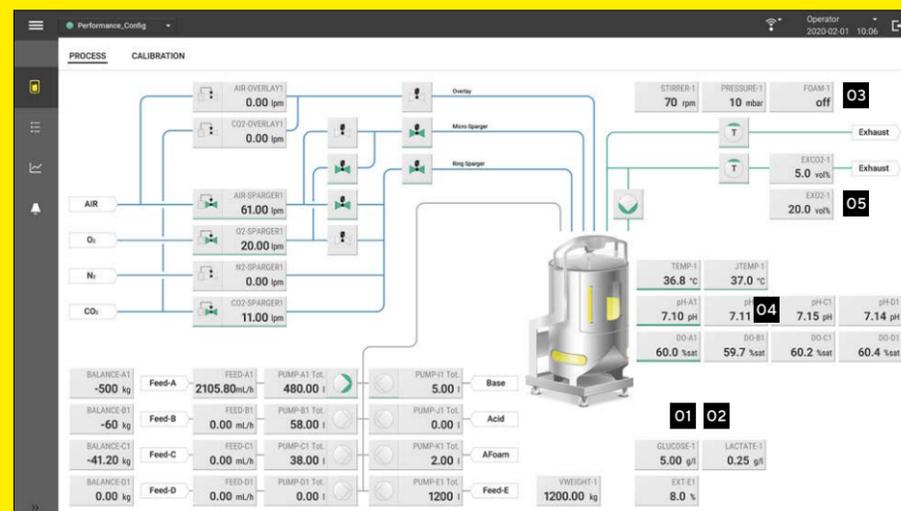
Maximize Quality and Consistency

Biostat STR® system simplifies technology transfer between production scales and ensures consistent quality without surprises and re-optimization.

The Flexsafe STR® bags with optimized resin formulation and minimized additive package lead to cell viability and higher cell densities. The complete control of the raw materials, the extrusion process and the bag assembly guarantee consistent lot-to-lot cell growth performance. The thickness, strength and flexibility of the polyethylene film enhances the mechanical robustness of Flexsafe® bags, making it ideal for all biopro-cessing applications.

The Sartorius scaling tool accurately predicts conditions required to scale your process by considering volumes, process parameters, and any constraints to identify those process parameters required to achieve your goals. Our technical support team can assist you with standard operating procedure (SOP) conversion from your existing scale or technology.

The BioPAT® toolbox helps you realize the full potential of intensified processing by improving output through automated feed and bleed, better process visibility, and by reducing risks associated with manual sampling and control.

01 BioPAT® ViaMass
In-line monitoring of viable biomass and automated cell bleed control

02 BioPAT® Trace
On-line monitoring of glucose and lactate and automated feed control

03 BioPAT® Foam
Monitoring of foam level with alarming and interlock functionalities

04 Electrochemical single-use pH sensors

05 BioPAT® Xgas
Oxygen-carbon dioxide sensor featuring automatic compensation of humidity and pressure

BioPAT® Spectro
Unlock the full potential of Raman spectroscopy

Flex Your Production

The Biostat STR® system with a working volume from 12.5 L to 2000 L and Biobrain® automation platform provides you the flexibility and power to adapt on-demand.

The fully configurable control tower can be used interchangeably with any bag holder size. The advanced user interface and improved connec-tivity make bioreactor operation more streamlined. Furthermore, the organizational racks for pumps and balances together with cable and tubing organizers plus flexible document tray fit in perfectly.

Each bioreactor has a fully scalable, stirred-tank design and offers high performance across a range of processes including high-cell density, micro carrier and perfusion. The Flexsafe STR® bags are designed with multiple sparger and impeller options on a magnetically coupled center-line shaft that deliver homogenous mixtures quickly, even at high volumes and low mixing speeds.

On top of that, Biostat STR® supports connection to Repligen's XCell™ ATF cell retention devices to increase the cell density and productivity and enables process intensification.

Attain Operational Excellence

The Biostat STR® system provides different control options to let you choose the best integration into your existing process infrastructure.

- Local management via control tower including Biobrain® automation platform with connection to data historians
- Full process management via distributed control systems e.g. Emerson, Siemens or Rockwell

Are you an Emerson DeltaV™ user?
Benefit from the native DeltaV™ solution.

Technical advantages:
- Complete mapping of your Biostat® system
- Full access to all process values and controller parameters
- Sartorius DeltaV™ library to manage sensors, actors and advanced analytics

The integration for native DeltaV™ comes with local support of an experienced project team which provides support from initial design to final installation.

⊕ **Find out more**
For more information, please visit www.sartorius.com/biostat-str

Biostat STR® Generation 3 Configurations

Our commerical manufacturing solutions have been predesigned into three configurations with flexible options and easy upgrades. Select the configuration that best fits your current needs and can conveniently adapt to any future requirements.

	Essential	Performance	Performance Plus
Perfusion ready		■	■
Process Analytical Technologies (PAT) Toolbox			
BioPAT® Foam	Optional	Optional	■
BioPAT® Trace		Optional	Optional
BioPAT® ViaMass		Optional	Optional
BioPAT® Xgas		Optional	Optional
BioPAT® Spectro		Optional	Optional
Electrochemical pH sensor	■	■	■
Peripherals			
No. of external pumps	2	4	4
Load cells	■	■	■
Mass flow controller	6	6	6
Flexsafe STR® bags	■	■	■
Sartocheck® bag tester	Optional	Optional	■
Integration Capabilities			
Recipe editing and execution	■	■	■
Local data storage	■	■	■
Native Emerson DeltaV™		■	■
Siemens SIMATIC PCS 7		■	■
Process design support and services		■	■

Sales and Service Contacts

For further contacts, visit www.sartorius.com

Germany
Sartorius Stedim Biotech GmbH
August-Spindler-Strasse 11
37079 Goettingen
Phone +49 551 308 0

China
Sartorius Stedim Biotech (Beijing) Co., Ltd.
No. 33 Yu'An Road
Konggang Industrial Zone B
Shunyi District
Beijing 101300
Phone +86 10 8042 6300

USA
Sartorius Corporation
565 Johnson Ave.
Bohemia, NY 11716
Phone +1 631 254 4249

Singapore
Sartorius Stedim Singapore Pte. Ltd.
10 Science Park Rd
The Alpha #02-13/14 Singapore
Science Park II
Singapore 117684
Phone +65 6872 3966

Biostat STR® Generation 3 Bioreactors and Flexsafe STR® Bags

Engineered for Ultimate Upstream Performance

Benefits

- Optimize capital costs
- Reduce operating expenses
- Enhanced safety and optimized space
- Improve productivity and ease of use
- Flexible configurations and simplified maintainance
- Increase speed to clinic

Product Information

Biostat STR® hardware, software, and consumables comprise a state-of-the-art single use biomanufacturing platform that delivers exceptional performance to meet your process development and commercial manufacturing needs. Biostat STR® bioreactors and Flexsafe STR® bags range in size from 50L to 2000L and are engineered to maximize the flexibility and scalability of your operations. This next generation of our Biostat STR® system is engineered for quality, precision and seamless scalability so that you can accelerate your success with a stable process that delivers a safe, reliable biologic medicine for patients around the world.

Technical Specifications

Bag Holder with TCU

	Biostat STR® 50	Biostat STR® 200	Biostat STR® 500	Biostat STR® 1000	Biostat STR® 2000
Material			AISI 304L stainless steel		
Dimensions W × D × H	815 × 1061 × 1951 mm 32 × 47.8 × 77 in.	815 × 1291 × 1977 mm 32 × 50.8 × 78 in.	1058 × 1614 × 2308 mm 41.7 × 63.5 × 91 in.	1250 × 1664 × 2689 mm 49.2 × 65.5 × 106 in.	3460 × 2676 × 3762 mm 136.2 × 105.4 × 148.1 in. (incl.platform)
Footprint	0.86 m² 9.26 ft²	1.05 m² 11.3 ft²	1.71 m² 18.41 ft²	2.08 m² 22.4 ft²	9.3 m² 100.1 ft² (incl.platform)
Weight	325 kg 716.5 lb	445 kg 981.1 lb	700 kg 1,543 lb	875 kg 1,929 lb	2,300 kg 5,070.6 lb (incl.platform)
Packaging dimensions	1450 × 1150 × 2200 mm 57.1 × 45.3 × 82.7 in.	1450 × 1150 × 2200 mm 57.1 × 45.3 × 82.7 in.	1800 × 1200 × 2400 mm 70.9 × 47.2 × 94.5 in.	1800 × 1500 × 2600 mm 70.9 × 59 × 102.4 in.	
Installed on skid	□	□	□	□	□
Double wall	□	□	□	□	□
Electro-polished	□	□	□	□	□
Single front door	□	□	□	□	□
Holder for gas filters	□	□	□	□	□
Viewing window	1	1	1	1	1
Lateral window for sensors and ports	2	2	2	2	2
Top drive motor	□	□	□	□	□

□ available   – not available   (□) optional, needs to be ordered separately

Biostat STR® 50   Biostat STR® 200   Biostat STR® 500   Biostat STR® 1000   Biostat STR® 2000

Control Tower

Specifications for all Biostat STR® models and sizes	
Material	AISI 304 stainless steel
Dimensions (W × D × H)	800 × 850 × 1820 mm | 31.5 × 33.5 × 71.7 in.
Footprint	0.68 m² | 7.32 ft²
Weight	240 kg | 529 lb
Packaging dimension	1000 × 1050 × 2100 mm | 39.4 × 41.3 × 82.7 in.
Single version	☐
Installed on skid	☐
Color touch screen	22″
Safety measurement and shut-off	☐
Different user level log in	(☐)
Audit Trail function	(☐)

Facility and Utility Requirements

	Biostat STR® 50	Biostat STR® 200	Biostat STR® 500	Biostat STR® 1000	Biostat STR® 2000
Power Supply Power | Frequency | Consumption					
208 VAC | 60 Hz | 23 A	☐	☐	☐	☐	☐
400 VAC | 50 Hz | 18 A	☐	☐	☐	☐	☐
Gas Supply	Gas specification according to ISO 8573-1: dry, free of oil and dust				
Compressed air (bar)	2	2	2	4	4
Gas pressure O_2, N_2, CO_2 (bar)	2	2	2	4	4
Water Supply					
Cooling water – supply pressure (bar)	1.5	1.5	1.5	1.5	2
Drain for water	25 lpm	25 lpm	25 lpm	25 lpm	40 lpm
Temperature	min. 8°C min. 46°F	min. 8°C min. 46°F	min. 8°C min. 46°F	min. 8°C min. 46°F	min. 8°C min. 46°F
Degree of hardness	max. 12 dH	max. 12 dH	max. 12 dH	max. 12 dH	max. 12 dH
Environmental Requirements					
Ambient temperature	5 – 40°C 41 – 104°F				
Relative humidity range	< 85%				

☐ available　　– not available　　(☐) optional, needs to be ordered separately

Process Control

	Biostat STR® 50	Biostat STR® 200	Biostat STR® 500	Biostat STR® 1000	Biostat STR® 2000
Agitation Module					
Max. stirrer speed*	240 rpm	150 rpm	110 rpm	90 rpm*	70 rpm
Temperature Control Unit					
Type	Heating | cooling	Heating | cooling	Heating | cooling	Heating | cooling	Heating | cooling
Heating kW | cooling HP					
Temperature control, double wall	8°C (46°F) above cooling water up to 40°C (104°F)	8°C (46°F) above cooling water up to 40°C (104°F)	8°C (46°F) above cooling water up to 40°C (104°F)	8°C (46°F) above cooling water up to 40°C (104°F)	8°C (46°F) above cooling water up to 40°C (104°F)
Over-temperature protection	□	□	□	□	□
Connection to pressure rated cooling water up to 6 bar	□	□	□	□	□
Aeration Module	4-gas mix (O_2, N_2, CO_2, air) with 3 outlets				
Mass Flow Controllers (MFC)					
▪ Number of MFCs	6	6	6	6	6
▪ Accuracy of MFC	± 1% full-scale	± 1% full-scale	± 1% full-scale	± 1% full-scale	± 1% full-scale
For sparger line	Ring sparger, micro- or combi-sparger (O_2, N_2, CO_2, air)				
▪ Flow rates (lpm)**	(0.025 – 5)	(0.1 – 20)	(0.25 – 50)	(0.5 – 100)	(1.0 – 200)
For overlay line	(CO_2, air)				
▪ Flow rates (lpm)**	(0.025 – 5)	(0.1 – 20)	(0.25 – 50)	(0.5 – 100)	(1.0 – 200)
Softkey to switch air | O_2 between ring and micro-sparger	□	□	□	□	□
Advanced DO controller	□	□	□	□	□
max. gassing rate	0.1 vvm for micro sparger				
max. total gassing rate	0.2 vvvm for all STR sizes				
Pump Module					
Max. 3 internal pumps installed					
WM314 speed-controlled	1	1	1	1	1
WM314 fixed speed	2	2	2	2	2
External Pumps					
Speed-controlled	(up to 5)	(up to 5)	(up to 5)	(up to 5)	(up to 5)

* Valid for 2 × 3-blade impellers. In case of 1 × 3-blade and 1 × 6-blade impellers, the maximum stirrer speed may be reduced depending on the filling level.
   At maximum filling level, the stirrer speed is limited to 70 rpm at 1,000 L scale.
** Alternative lower flow ranges are available upon request.

□ available   – not available   (□) optional, needs to be ordered separately

Process Control Continued

	Biostat STR® 50	Biostat STR® 200	Biostat STR® 500	Biostat STR® 1000	Biostat STR® 2000
Sensors & Measurement					
Temperature probe Pt 100	☐	☐	☐	☐	☐
■ Measurement range	0 – 150°C 32 – 302°F	0 – 150°C 32 – 302°F	0 – 150°C 32 – 302°F	0 – 150°C 32 – 302°F	0 – 150°C 32 – 302°F
pH, single-use	☐	☐	☐	☐	☐
■ Measurement range	6.0 – 8.0	6.0 – 8.0	6.0 – 8.0	6.0 – 8.0	6.0 – 8.0
■ Recalibration function	☐	☐	☐	☐	☐
pH, electro-chemical, multi-use and single-use	☐	☐	☐	☐	☐
■ Measurement range	4 – 10	4 – 10	4 – 10	4 – 10	4 – 10
DO, single-use	☐	☐	☐	☐	☐
■ Measurement range	0 – 110%	0 – 110%	0 – 110%	0 – 110%	0 – 110%
■ Recalibration function	☐	☐	☐	☐	☐
DO optical or polarographic, reusable	☐	☐	☐	☐	☐
■ Measurement range	0 – 100%	0 – 100%	0 – 100%	0 – 100%	0 – 100%
Load cells	☐	☐	☐	☐	☐
Balance substrate	(up to 4)	(up to 4)	(up to 4)	(up to 4)	(up to 4)
BioPAT® Viamass	☐	☐	☐	☐	☐
BioPAT® Trace (Glucose | Lactate sensor)	☐	☐	☐	☐	☐
■ Accuracy	0.1 g/L	0.1 g/L	0.1 g/L	0.1 g/L	0.1 g/L
Accessories					
Ladder | Platform	–	–	(☐)	(☐)	(☐)
Filter line IN	☐	☐	☐	☐	☐
Filter line OUT	☐	☐	☐	☐	☐
SU exhaust cooler	(☐)	(☐)	(☐)	(☐)	–
Holder for conventional probes	(☐)	(☐)	(☐)	(☐)	(☐)

☐ available   – not available   (☐) optional, needs to be ordered separately

Communication | Interface of Control Tower

	Biostat STR® 50	Biostat STR® 200	Biostat STR® 500	Biostat STR® 1000	Biostat STR® 2000
OPC UA	□	□	□	□	□
OPC DA (convertor)	(□)	(□)	(□)	(□)	(□)
RS232	up to 4	up to 4	4	4	5
Industrial Ethernet	□	□	□	□	□
Analog IN	4	4	4	4	4
Analog OUT	4	4	4	4	4
DeltaV™ connectivity	(□)	(□)	(□)	(□)	(□)
RemoteIO connectivity (on request)	(□)	(□)	(□)	(□)	(□)
native DetlaV™ solution (on request)	(□)	(□)	(□)	(□)	(□)

□ available   – not available   (□) optional, needs to be ordered separately

Flexsafe STR® Bags

Geometrical Data of Flexsafe STR® Bags

Flexsafe STR®	50 L	200 L	500 L	1,000 L	2,000 L
Total volume [L]	68	280	700	1,300	2,800
Max. working volume [L]	50	200	500	1,000	2,000
Min. working volume [L]	12.5	50	125	250	500
Turndown ratio	1 : 4	1 : 4	1 : 4	1 : 4	1 : 4
Bag diameter, d_1 [mm]	370	585	815	997	1,295
Bag height, h_1 [mm]	666	1,055	1,467	1,800	2,330
Ratio, h_1/d_1	1.8	1.8	1.8	1.8	1.8
Liquid height, h_2 [mm]	480	783	1,005	1,360	1,670
Ratio, h_2/d_1	1.3	1.34	1.23	1.36	1.29
Impeller diameter, d_2 [mm]	143	225	310	379	492
Ratio, d_2/d_1	0.38	0.38	0.38	0.38	0.38
Distance between impellers [mm]	186	300	403	493	640
Volume bottom impeller, fully immersed V_1 [L]	12.5	50	125	250	395
Volume top impeller does not touches surface V_2 [L]	23	95	247	450	953
Volume top impeller, fully immersed V_3 [L]*	31	125	327	597	1,266
Bag packaging dimensions W × D × H (mm | in.)	395 × 395 × 1170 | 15.5 × 15.5 × 46	395 × 595 × 1440 | 15.5 × 23.4 × 56.7	764 × 1153 × 1320 | 30.1 × 45.4 × 52	764 × 1153 × 1440 | 30.1 × 45.4 × 56.7	995 × 1195 × 1715 | 39.2 × 47 × 67.5

* Volume variied depending on the bag configuration (e.g. impeller and sparger configuration).

Example of Flexsafe STR® 200 L Basic Configuration

Pos.	Designation	Tubing Material	Tubing Termination	Remarks
A	Overlay aeration	Si(Pt)	Opta connector	Without spare port
B	Substrate line 1	Si - TPE	MPC quick coupling	
C	Substrate line 2	Si - TPE	MPC quick coupling	
D	Sparger aeration	Si(Pt)	Opta connector	Without spare port
E	Substrate 3 – 4	Si - TPE, C-Flex®*	MPC quick coupling	2 lines via Y, dip tube
F	Base addition	Si - TPE, C-Flex®*	Clave connector	
G	Antifoam addition	Si - TPE, C-Flex®*	Clave connector	
H	Gas out (exhaust)	ID, Si(Pt)	Opta connector	2 lines via Y
I	Temperature sensor	Si(Pt)	N/A	Reusable sensor (Pt100)
J | K	DO | pH Sensor	N/A	N/A	Optical sensor
L	Small-volume sampling	Si - TPE, Si(Pt)	Clave connector	
M	Bottom-drain harvest	Si - TPE, C-Flex®*	MPC quick coupling	

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

Ordering Information

Description	Order No.
Biostat STR® Bioreactor System	
System will be configured according to process requirements based on broad choice of configuration options. Please contact your sales representative.	
Flexsafe STR® Single-use Bioreactor Bag	
Standard Design	
Flexsafe STR® 50 L	FRS132668
Flexsafe STR® 200 L	FRS132670
Flexsafe STR® 500 L	FRS124057
Flexsafe STR® 1,000 L	FRS124058
Flexsafe STR® 2,000 L	FRS132367
Customer-specific designs: Please contact your sales representative.	
Bag Tester Fleece	
For 50 L STR®	DZ050L-S2SIT
For 200 L STR®	DZ200L-S2SIT
For 500 L STR®	DZ500L-S2SIT
For 1,000 L STR®	DZ001K-S2SIT
For 2,000 L STR®	DZ002K-S2SIT

Description	Order No.
Accessories	
Filter line IN 50 | 200 L	DS200L-SBFLI
Filter line OUT 50 | 200 L	DS200L-SBFLO
Filter line IN 500 |1,000 L	DS001K-SBFLI
Filter line OUT 500 |1,000 L	DS001K-SBFLO
Filter line IN 2,000 L	DS002K-SBFLI
Filter line OUT 2,000 L	DS002K-SBFLO
Lab Cart	1ZG—0032
Lifting device & adapter (STR® 2,000)	2ZG—0009
Biostat STR® Viamass Support 60mm	DZ------AD1
Biostat STR® Viamass Support 100mm	DZ------AD2
Autoclave tray for re-usable probes	1ZG—0034
Single-Use Exhaust Cooler	
SU exhaust cooler STR® 50 | 200	DS200L—EC
SU exhaust cooler STR® 500 |1,000	DS001K—EC

Flexsafe®

New PE Film.
New Benchmark.

Simplifying Progress

SARTORIUS

New Flexsafe®
Bag Family.

Sartorius Stedim Biotech introduced the first single-use bag for biopharmaceutical applications. Since then, demand for these bioprocessing bags has been rapidly increasing for use in critical applications. Their robustness, performance and compliance are crucial for ensuring process safety and economy.

We have developed a new polyethylene film and new bioprocessing bags to pave the way towards the single-use manufacturing facility of the future. Flexsafe® meets the most stringent customer needs for safe bioprocessing.
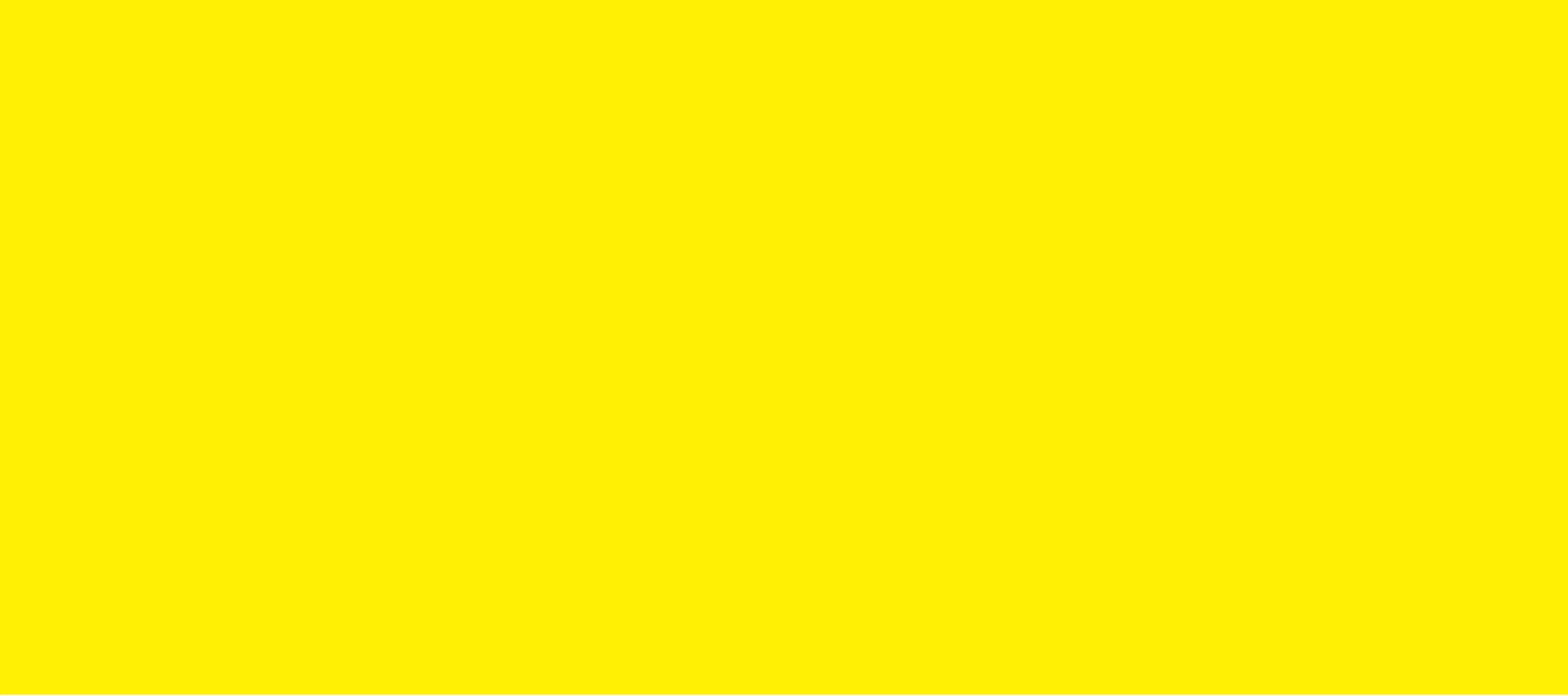
Cell Growth

The Challenge
Inconsistent and Poor Cell Growth

Our Solution
Optimized Resin and Additive Formulation plus Full
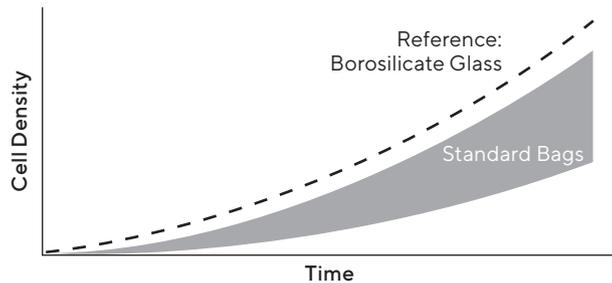
Several users have reported on poor or inconsistent cell growth in single-use bags.[1] Recent studies suggest that trace amounts of a degradation product derived from a commonly used antioxidant might impair cell growth. At the same time, such antioxidants are necessary to obtain robust and stable single-use bags.[2]

Flexsafe® bags are designed to excel due to:

Optimized antioxidant package	Excellent cell growth of the most sensitive cells
Use of pharmacopeialisted antioxidants only	Simplified toxicology assessment
Zero slipping agents	No risk of interference due to these agents
Mechanical anti-blocking	Reduces stickiness, facilitates extrusion and bag handling
Meaningful specifications and process control from polymer resin to finished bag	Reliable and reproducible growth performance, well-characterized extractables profile

Independent labs have confirmed that Flexsafe® bags are free of cytotoxic leachables. No bDtBPP is identified in WFI extracts of Flexsafe® bags.

1 Gammell P., et al. The impact of lot-to-lot variability of disposable cell culture bags on cell growth during the scale-up of a mammalian production cell line. Cell Culture Engineering XIII, April 2012.
  Eibl R., et al. Recommendation for leachable studies - Standardized cell culture test for the early identification of critical films for CHO cell lines in chemically defined culture media. DECHEMA Jan 2014.
2 Hammond M., et al. Identification of a Leachable Compound Detrimental to Cell Growth in Single-Use Bioprocess Containers. PDA J. Pharm. Sci. and Tech. 67 (2) 2013: 123-134.

Transparency ≠ Purity

The purity of a polymer film is characterized by its leachables and extractables profile, and is determined by the nature of the polymer, quantity and type of additives used to enable processing, and by the processing parameters themselves. There is no correlation between transparency of a film and its leachables and extractables profile.

Control of Manufacturing Processes	Your Results
	Excellent Growth and Lot-to-Lot Consistency

Film Polymers

∨

Additives

∨

Extrusion Process

∨

Assembly

∨

Gamma Irradiation

Cell Growth [% of Reference]: y-axis 0, 25, 50, 75, 100, 125

Legend:
- Reference
- Flexsafe® Batches
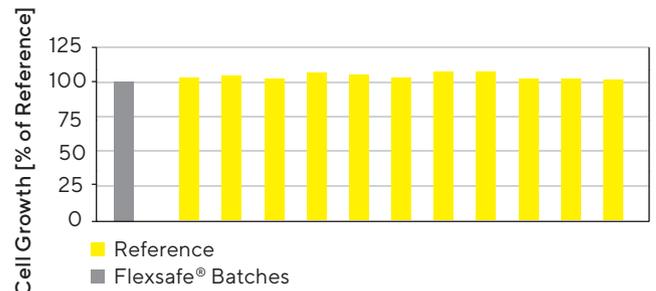
Flexsafe® bags ensure excellent and reproducible growth behavior of the most sensitive cell lines. This has been confirmed by biopharma companies worldwide using their specific cell lines.

Accelerated shelf life studies of dry bags confirm consistent cell growth from day one, as well as no aging effects after gamma irradiation. Further trials demonstrated that you can rely on Flexsafe® bags and store your serum-free or protein-free medium over extended periods.

In close collaboration with resin and film suppliers, our polymer scientists and biologists have developed a completely new polyethylene film, called S80.
A standardized cell growth assay has been used to optimize film formulation, define the operating ranges for extrusion, welding and gamma-irradiation processes and to establish specifications and process controls.

Excellent process understanding and robust control of the entire manufacturing process guarantee the consistent quality of Flexsafe® bags.

Assurance of Supply

Rely on a Sustainable Supply Chain and Robust Business Continuity Plans

Assurance of supply is a key success factor for long-term drug supply based on single-use technologies. This is why we set up a sustainable supply chain to give you real peace of mind.

Strong partnerships and long-term supply contracts with suppliers of polymers, additives and film suppliers enable us to achieve full traceability of raw materials, complete understanding of film formulation and robust control of the manufacturing process – from raw materials to sterile bags that are ready to use in your drug manufacturing process. Together with our partners, we have established the design space for film extrusion of our new Flexsafe® bags. Based on defined operating ranges and controls, we provide consistent and reproducible bag quality. Flexsafe® supports your drug development and manufacture – ranging from initial clinical trials to long-term supply many years after the launch of your drug products.

To meet the highest business continuity requirements, we have a robust contingency plan in place for uninterrupted film supply. It is based on redundant resin crackers, film extrusion lines and multiple manufacturing sites. In addition, we maintain safety stocks of resins and extruded film rolls.

We control the entire manufacture of critical components, such as filters and tubing. Moreover, we assemble and sterilize single-use bioprocessing bag solutions at our multiple manufacturing sites located across the globe.

Consistent Quality and Change Control
- Established resin specifications
- Design space for film extrusion
- Full traceability of resins and additives

Business Continuity
- Backup resin crackers
- Safety stocks of resin and film for up to 2 years supply
- Multiple bag manufacturing and sterilization sites

Global Supply Guarantee
Complete control over our manufacturing process from resin and film extrusion to final bag assembly

Long-Term Contracts with Suppliers
- 10-year contract with film manufacturer
- 2-year customer change notification period
- Last-time buy option for a minimum of 2 years' resin demand

Control of Critical Components
- Own bags, filters and connectors
- Strategic partnerships for tubing and sensors
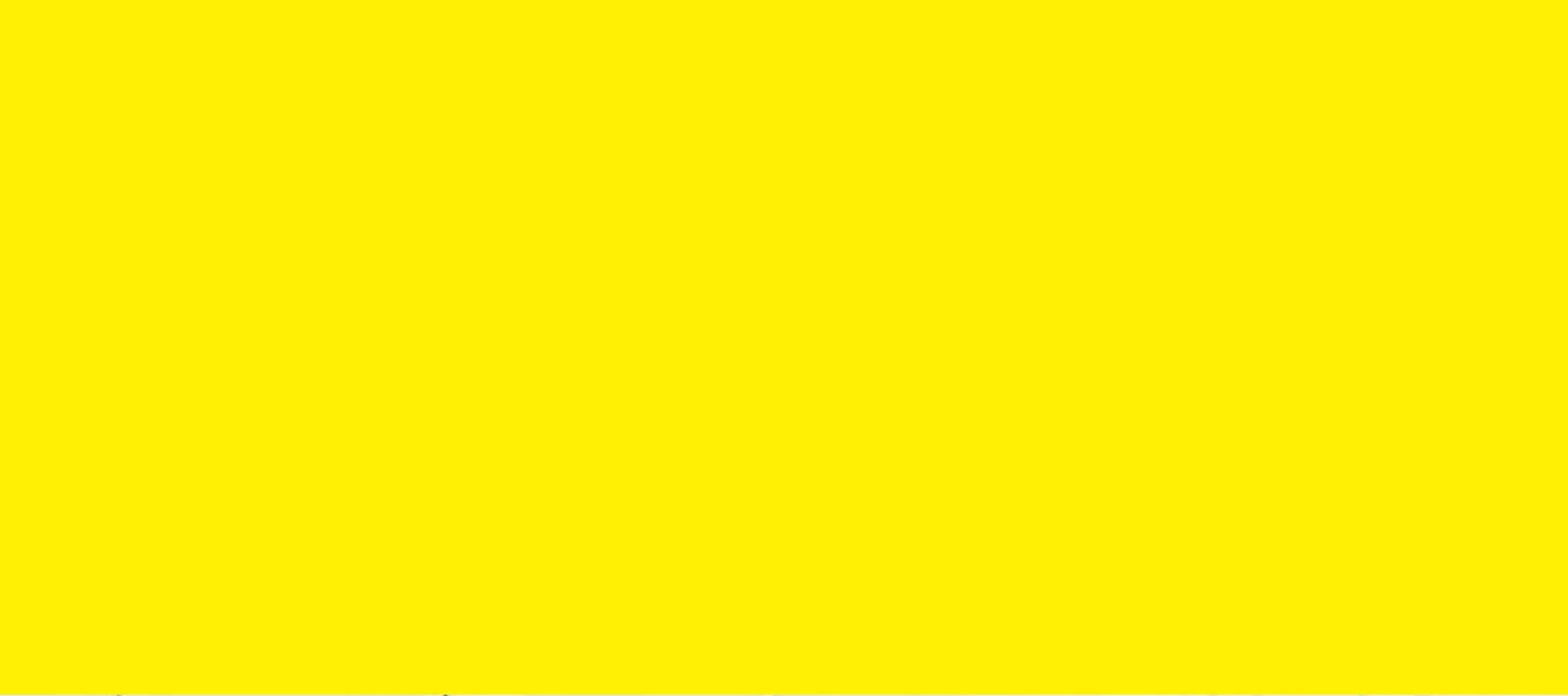
Material
Science

Strategic
Partner-
ship

Multiple
Production
Sites

Process
Under-
standing

Robustness

Safe and Convenient Single-Use Processing

Flexsafe® meets your requirements for outstanding robustness and ease of use throughout all steps of single-use processing – from cell cultivation to shipping of drug sustance.

Today, almost all unit operations in biologics development and production can be performed using single-use equipment. However, the requirements on mechanical and physical properties can vary considerably, depending on your application.

Rocking-motion cell cultivation or liquid shipping applications require a highly flexible bag resistant to material fatigue. A bag used for large-scale mixing or in a stirred tank bioreactor has to withstand the significant hydrostatic pressure generated by liquid volumes of 2,000 L to 3,000 L. Here, the strength of the film and its welds is critical. Apart from the robustness of a bag, it must be easy to install and use in routine manufacture of drugs.

Therefore, the development of our new Flexsafe® bags focused on combining strengths with flexibility to provide outstanding robustness and ease of use for your most demanding applications.

Superior Strength and Flexibility of Film and Welds

Bag A	
Bag B	
Bag C	
Flexsafe®	

Energy at Break
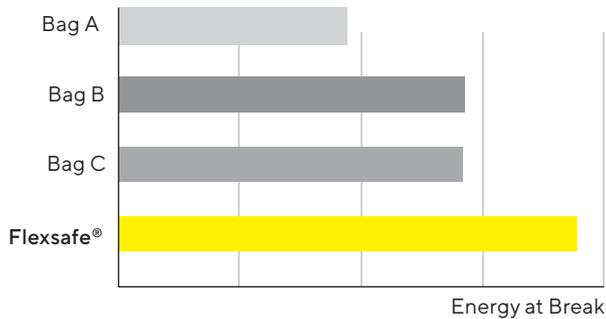
The thickness, strength and flexibility of the new S80 film enhance the mechanical robustness of Flexsafe®, making it ideal for all bioprocessing applications.

The strength of Flexsafe® significantly reduces the risk of accidental damage to the bag due to inappropriate handling.

Its flexibility enables convenient installation and selfdeployment of the bag in its container.

Excellent flexibility of each layer of our new polyethylene film and a total thickness of 400 µm provide extraordinary robustness.

Strength and flexibility of film material and welds qualified using multiple methods:

Standard flex durability of film	Highly resistant to fatigue and pinhole formation
Tensile strength	Strength of film and welds
Elongation and energy at break	Flexibility, ease of installation and use
In-house water burst test	Strength of bag
Extensive worst-case testing in actual use	Robustness of Flexsafe® in stirred tanks, in rocking motion bioreactors and under actual shipping conditions

Passed ASTM Shipping Test

Filled Flexsafe® shipping bags in Palletank® passed the most stringent shipping validation test according to ASTM D4169.

One for All

Get Peace of Mind With a Future-Proof Concept

Our range of scalable Flexsafe® bags enables you to implement single-use bioprocessing throughout all steps of drug manufacture, from process development to production – all using just one film.

Featuring high-performance polyethylene film, our new Flexsafe® bags will give you peace of mind based on their consistent performance, even in the most stringent bio processing applications like cell cultivation, long-term storage and shipping of drug products.

Biostat® RM | 1 L – 200 L

Biostat® STR | 50 L – 2,000 L

Flexact® | 50 L – 3,000 L

Octoplus FF®

Flexsafe®: All the Options Are Yours

Sartorius Flexsafe® bags are an integral part of our total solution offering for single-use manufacturing. Flexsafe® gives you all the options you need. For example, you can choose to use bioprocessing bags in a "stand-alone" configuration or set up a complete single-use factory.
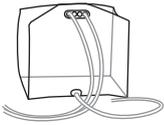
Single Bag
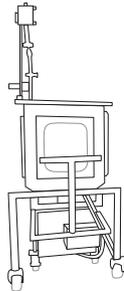
Application
Bag + Mixer
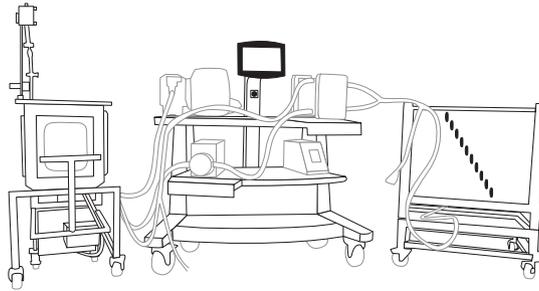
Unit Operation
Bag + Mixer + System[1]

[1] Example of Flexact® UD for ultra- and diafiltration: Mixing bag and mixer, vent filters, trolley with controller, pressure transmitters and pumps, crossflow cassettes, holder and recirculation bag, storage container and bag, complete tubing

Flexsafe® Range

Bag volumes from 20 mL to 3,000 L

Bags for all bioprocessing steps

A well-characterized, consistent extractables profile due to raw material and process controls
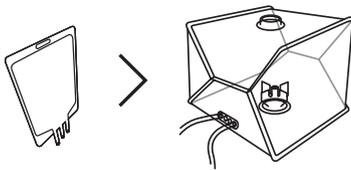
USP – DSP – F+F
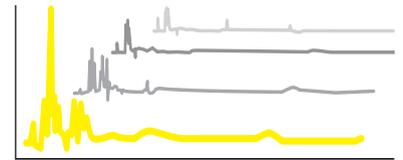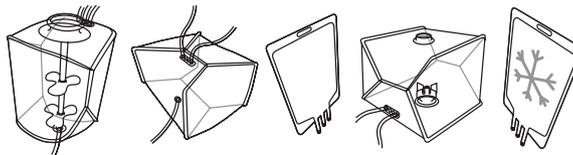
Facilitate single-use process implementation from process development to commercial manufacturing

- Reduce time and expense for process validation, extractables and leachables studies, toxicology assessment and stability studies
- Benefit from robustness, consistent quality and assurance of supply
- Ensure worry-free operations, quality and supply chain

- Facilitate leachables validation and toxicology assessment
- Obtain sustainable, reproducible and reliable process validation data

BI
Biological Industries
Culture of Excellence

NutriStem® MSC Culture System

A complete xeno-free, serum-free system for the growth and expansion of hMSCs
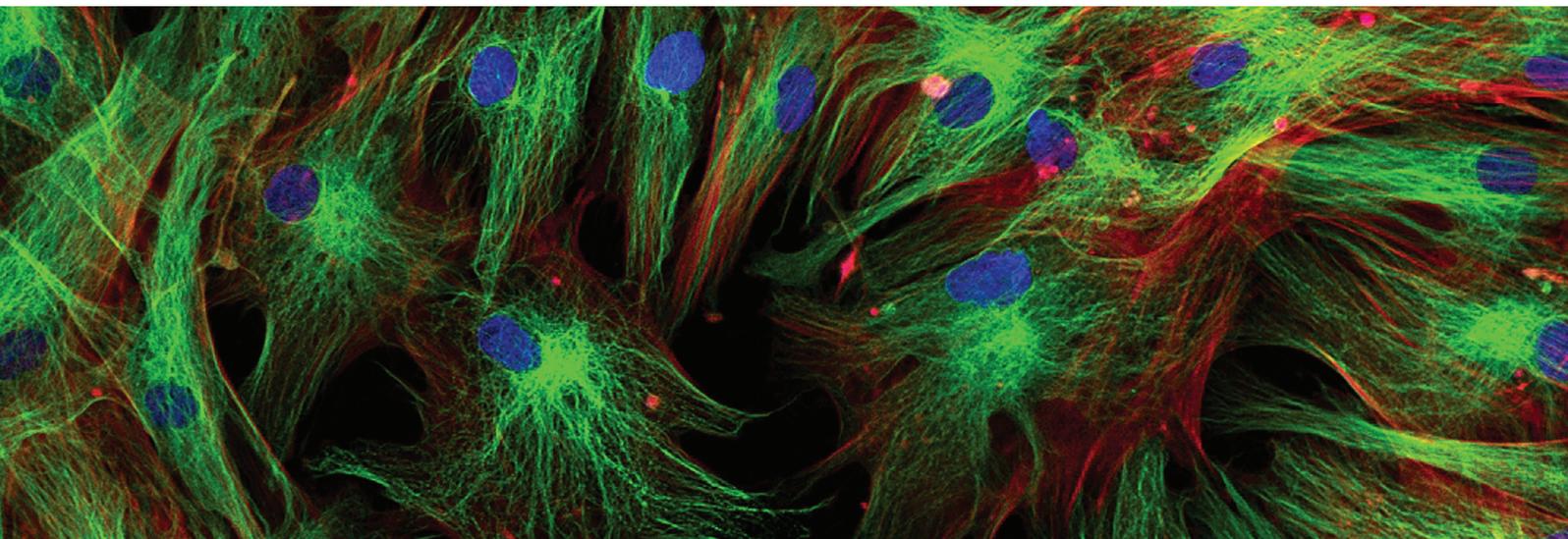
- **Defined, xeno-free, serum-free medium**

- **Superior proliferation of hMSCs**

- **Supports long-term growth and differentiation potential**

- **FDA Drug Master File**

Redefining stem cell excellence and advancing clinical applications

Defined, serum-free, xeno-free reagents are essential tools for all human mesenchymal stem cell (hMSC) research having potential clinical applications. The NutriStem® MSC Culture System includes defined reagents ideal for translational research use. hMSCs cultured in serum-free, xeno-free **NutriStem® MSC XF Medium** show superior proliferation and self-renewal potential in comparison to serum-containing media and other serum-free media. In addition, hMSCs maintain their proper fibroblast-like cell morphology, tri-lineage differentiation potential, and demonstrate normal hMSC marker profiles and karyotypic stability over long-term culture.

NutriStem® MSC XF Medium is designed for optimal growth and expansion of hMSCs derived from a variety of sources, including bone marrow (BM-hMSC), adipose tissue (AT-hMSC), Wharton's jelly (WJ-hMSC), placental tissue (PT-MSC), and umbilical cord matrix (UC-hMSC).
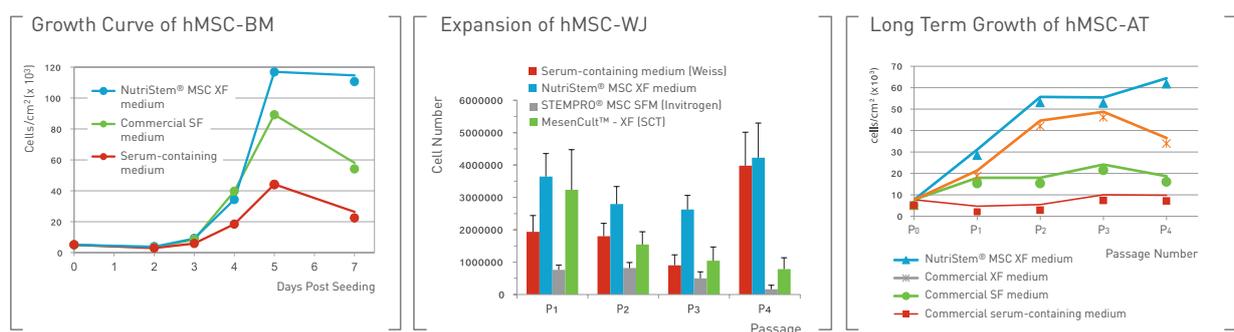
Figure 1: **NutriStem® MSC XF Medium** promotes superior proliferation and expansion of hMSCs over time as compared to other serum-free and serum-containing media.

MSC Attachment Solutions

- Xeno-free, purified human fibronectin/human fibrinogen
- Optimized for serum-free cultures
- For hMSC proliferation and differentiation
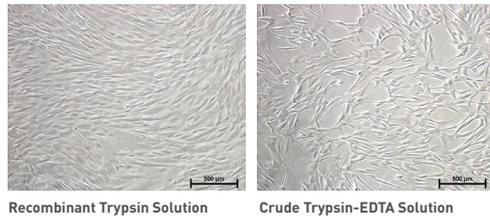
MSC Dissociation Solutions

- Ready-to-use, defined
- Recombinant trypsin solutions

NutriFreez™ D10 Cryopreservation Solution

- Chemically defined, animal component-free, protein-free
- Excellent cell attachment and viability

Recombinant Trypsin Solution   **Crude Trypsin-EDTA Solution**

Figure 2: MSC Dissociation Solutions. Recovery of BM-hMSC after dissociation with either Recombinant Trypsin Solution or Recombinant Trypsin-EDTA Solution and re-seeding on plates pre-coated with the MSC Attachment Solution and cultured in NutriStem® MSC XF Medium. Images were taken on Day 5 post-dissociation (100X).

1 hr   24 hrs   48 hrs

A

B

Figure 4: MSC Attachment Solutions. The use of MSC Attachment Solution greatly enhances BM-hMSC attachment and growth in culture. Cells in panel A images were cultured without MSC Attachment Solution. Cells in panel B were cultured with MSC Attachment Solution. Images were taken at the indicated time points post-seeding (200X).

1.5 hrs

24 hrs

72 hrs

96 hrs

Figure 3: NutriFreez™ D10 Cryopreservation Medium. Images show the recovery of BM-hMSC after thawing. Cells were frozen using NutriFreez™ D10 Cryopreservation Medium, thawed, and re-seeded in NutriStem® MSC Medium. Images were taken at the indicated time points post-thawing (200X).

Ordering Information

Cat. #	Product
05-200-1	MSC NutriStem® XF Basal Medium
05-201-1	MSC NutriStem® XF Supplement Mix
05-760-1	NutriCoat™ Attachment Solution
05-752-1	MSC Attachment Solution
05-713-1	NutriFreez™ D10 Cryopreservation Medium
03-078-1	Recombinant Trypsin Solution
03-079-1	Recombinant Trypsin-EDTA Solution
PLTGOLD100R	PLTGold® Human Platelet Lysate (Research-grade)
PLTGOLD100GMP	PLTGold® Human Platelet Lysate (Clinical-grade)
PLTGOLD100GMP-PI	PLTGold® Human Platelet Lysate (Pathogen Inactivated)
PLTMAX100R	PLTMax® Human Platelet Lysate (Research-grade)
PLTMAX100GMP	PLTMax® Human Platelet Lysate (Clinical-grade)

ALSO AVAILABLE

MSCgo™ Differentiation Media

A unique line of complete, serum-free, and xeno-free media for efficient and reproducible differentiation of hMSCs.

- MSCgo™ Osteogenic XF Medium
- MSCgo™ Rapid Osteogenic XF Medium
- MSCgo™ Chondrogenic XF Kit
- MSCgo™ Adipogenic XF Kit

How to Order

Biological Industries USA | T. 860.316.2702 F. 860.269.0596 | orders-usa@bioind.com

Biological Industries | T. 972.4.9960595 F. 972.4.9960631 | info@bioind.com

Culture of Excellence

CE   ISO 9001 2015   ISO 13485 2016   cGMP Manufacturing Facility

www.bioind.com

Expand Outside the Hood:
MYCAP® CCX Cell Expansion System

turning science into solutions

MYCAP® CCX Cell Expansion System – Reliable, Proven and Low-Risk

MYCAP® CCX brings reliable aseptic technique to cell culture expansion. This closed system featuring a revolutionary design ensures that media feed, inoculation, sampling and transfers are done aseptically, outside a biosafety cabinet.

MYCAP® Technology Platform

MYCAP® CCX is the next advance enabled by Sartorius' patented MYCAP® bottle closure system.

The MYCAP® CCX is assembled as follows: The tubing and the special gas exchange cartridge are inserted into pre-formed holes. Silicone elastomer is then dispensed into the cap to hermetically seal the installed components in place, creating the high-performance, plasticizer-free bottle closure.

Aseptic Fluid Transfer

Good aseptic technique is especially important upstream where preserving axenic, or monoculture, conditions is compulsory.

Tubing is integral in MYCAP® CCX, facilitating aseptic technique and eliminating the risk of contamination.

Your Benefits

- Feed media, inoculate flasks, collect samples and transfer out of flasks outside the laminar flow hood.
- Avoid contamination: Never open a flask. Never change a cap.
- Improve ergonomics and process efficiency by eliminating hood operations and liquid transfers by manual pipetting.

MYCAP® CCX Has It All
in One Revolutionary System

– Innovative gas exchange cartridge
  supports vigorous cell growth in an
  incubator
– QUICKSEAL® for trouble-free
  aseptic disconnection
– Perform passages using up to 3 L
  Erlenmeyer flasks
– Gamma-irradiated and single-use
– Based on the reliable and robust
  MYCAP® closure system
– Ready to use

MYCAP® CCX
Gas Exchange Cartridge

The MYCAP® CCX gas exchange cartridge
is a three-dimensional component
featuring two 0.2 μm hydrophobic filter
membranes.

The alignment of the cartridge in the
cap protects the membranes so they
are ideally positioned for abundant gas
exchange. Its stadium-like shape saves
space, leaving room for integral tubing
to allow all types of aseptic fluid transfer.
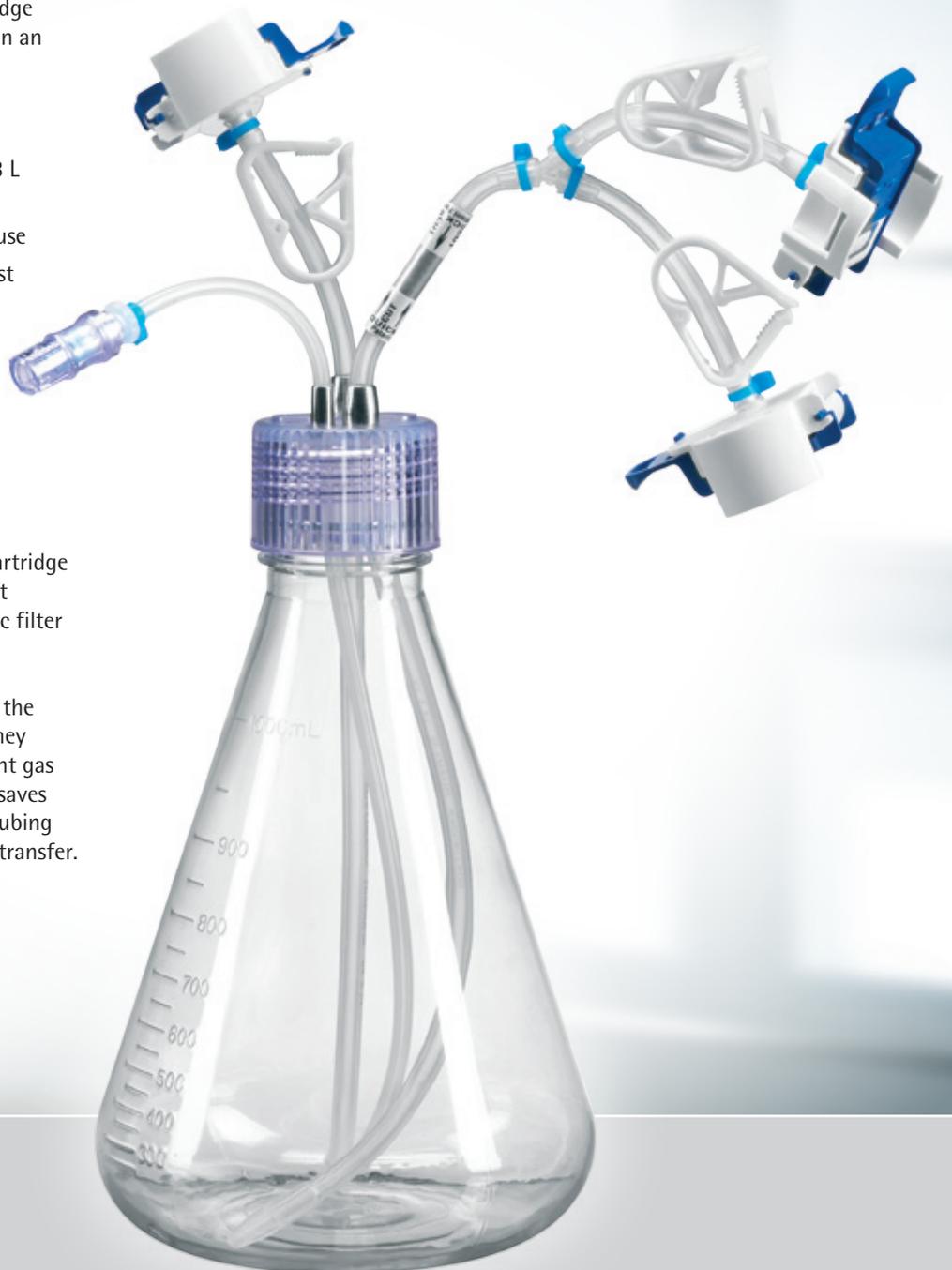
Cell Culture Expansion from Vial to Bioreactor

Fill your culture using MYCAP® CCX, without having to open a flask
or resort to using a biosafety cabinet.

Enjoy the freedom of working outside the biosafety cabinet (BSC):

– No BSC maintenance

– No decontamination of BSCs or materials

– Eliminate wasteful back-up passages

– Modernize your cell expansion process

MYCAP® CCX Process Diagram

Running a passage with MYCAP® CCX is simple and uses standard equipment:
No more fluid transfers by manual pipetting. The MYCAP® CCX product family features
smart and easy-to-use assemblies for each step of your cell expansion.

1 Pump Media into Flask

Aseptic Connections by:
– Aseptic Connector
– Tube Weld

150.00 g

Sartorius Balance for
Precise Monitoring
and Control of Volume

QUICKSEAL® for fast, easy and secure aseptic
disconnections after each fluid transfer
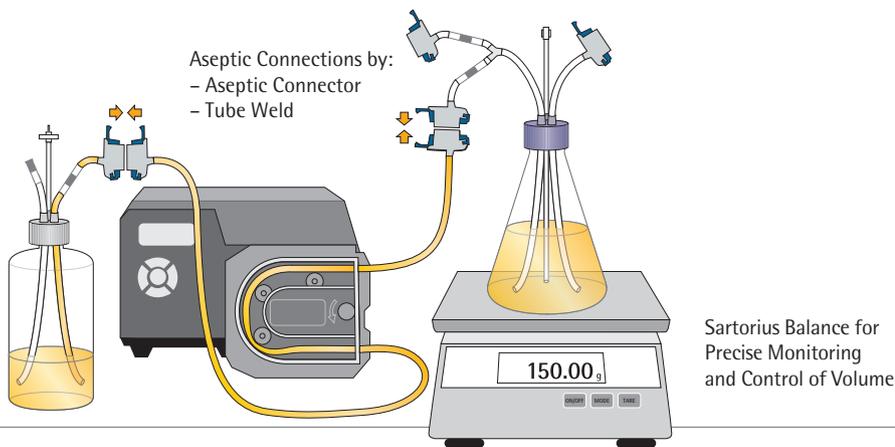
2 Inoculate Flask with Cell Culture

Aseptic Connections by:
– Aseptic Connector
– Tube Weld

150.00 g
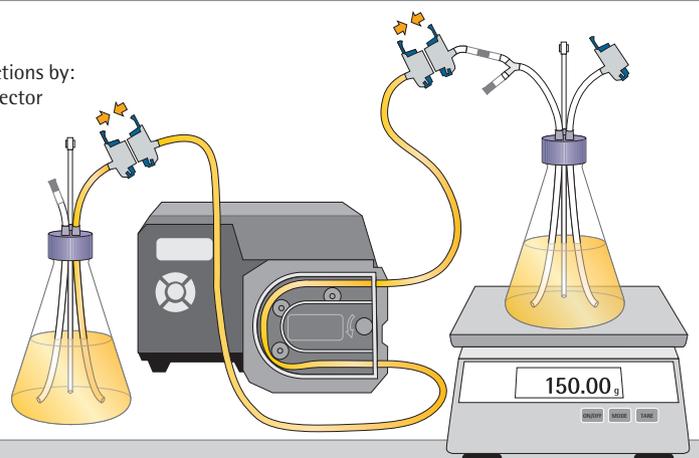
in the Open Space of Your Workbench

5 Transfer to Next Flask or Seed Reactor

Aseptic Connections by:
– Tube Weld

Aseptic Connections by:
– Aseptic Connector
– Tube Weld
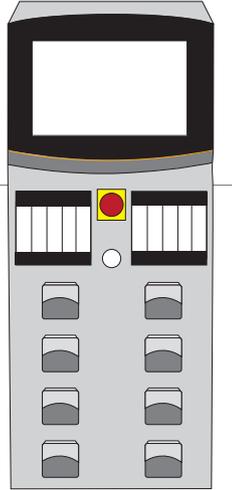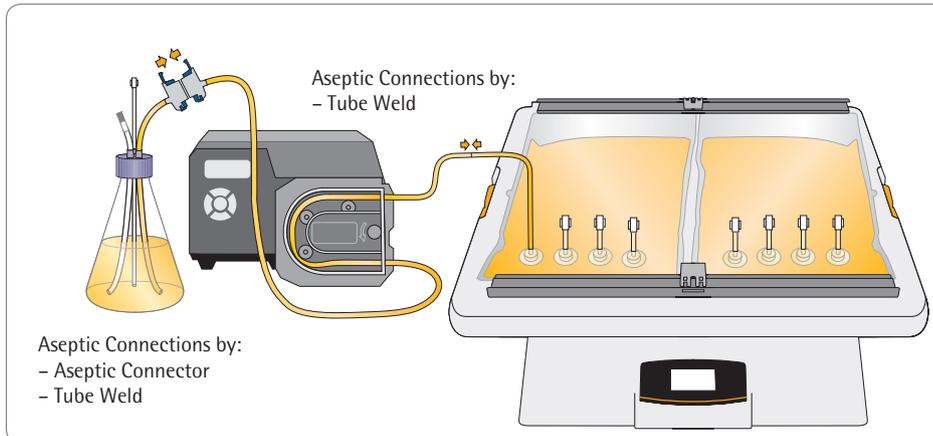
BIOSTAT® RM | BIOSTAT® A

4 Collect Samples for Cell Viability, Density, etc.

Sampling by
Syringe Connected
to BENCHMARK™
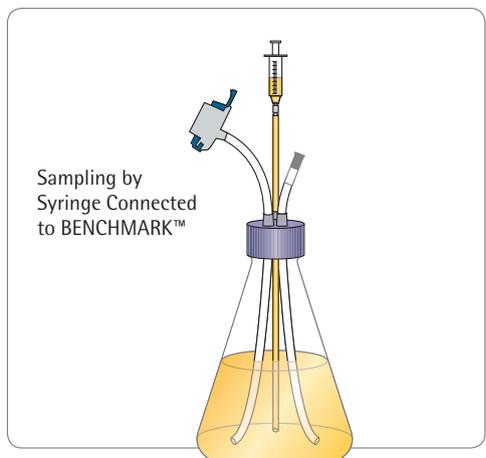
3 Grow Culture in Incubator
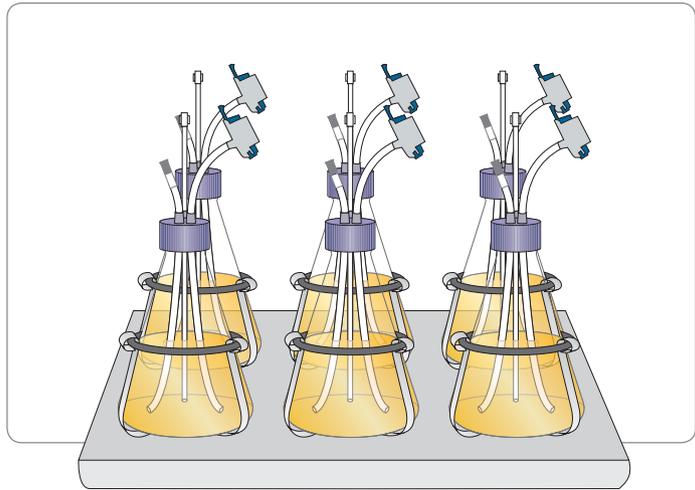
Watch MYCAP® CCX in Action here:

Proven Performance for Vibrant Cell Growth

Gas Exchange Comparison Between MYCAP® and Commercially Available Flask

Gas Exchange Comparison Between MYCAP® and Commercially Available Flask

- 5.0 CO_2 %
- 7.5 CO_2 %
- 10.0 CO_2 %
- 12.5 CO_2 %
- 2.5 CO_2 %
- 15.0 CO_2 %
- 12.0 CO_2 %

pH (y-axis): 6.8 – 7.6
Time (Hours) (x-axis): 1 – 15

Legend:
- Commercially Available 3 L
- Industry Avaliable 1 L
- MYCAP® CCX 1 L
- MYCAP® CCX 3 L
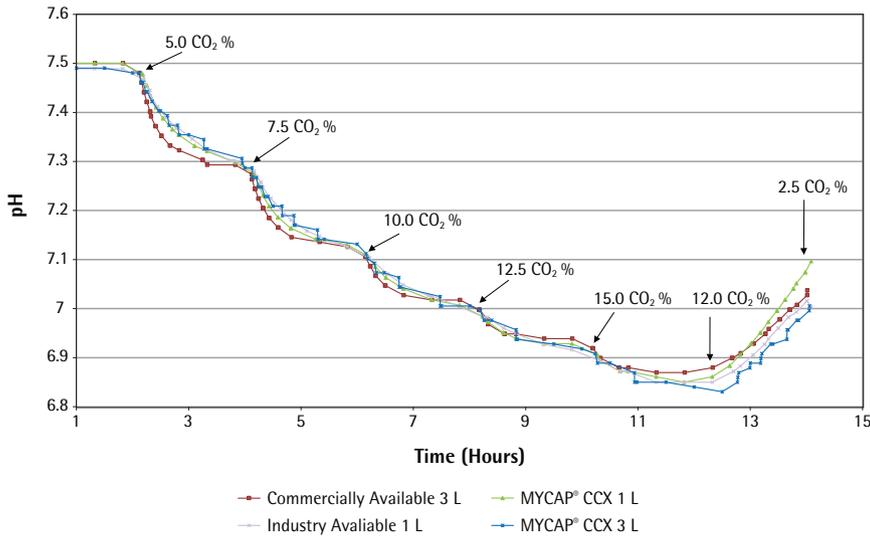
Exceptional Gas Exchange

Exchange of O_2 and CO_2 across a filter membrane is critical to cell growth. During cellular respiration, oxygen is consumed and carbon dioxide is produced. Cultures starved of O_2 will not expand; an overabundance of CO_2 increases acidity and harms cell viability.

Gas exchange in the incubator is passive. A large filtration area with unrestricted air flow is required for adequate gas exchange A study of the change in pH of a solution in response to a change of CO_2 in an incubator showed equivalent response between MYCAP® CCX and traditional Erlenmeyer flasks.

Culture Doubling Times between Traditional Flasks and MYCAP® CCX

Culture Doubling Time (hr) (y-axis): 0 – 30
x-axis: 500 mL Flask, 1000 mL Flask, 3000 mL Flask

Legend:
- Traditional Flask
- MYCAP® CCX Flask
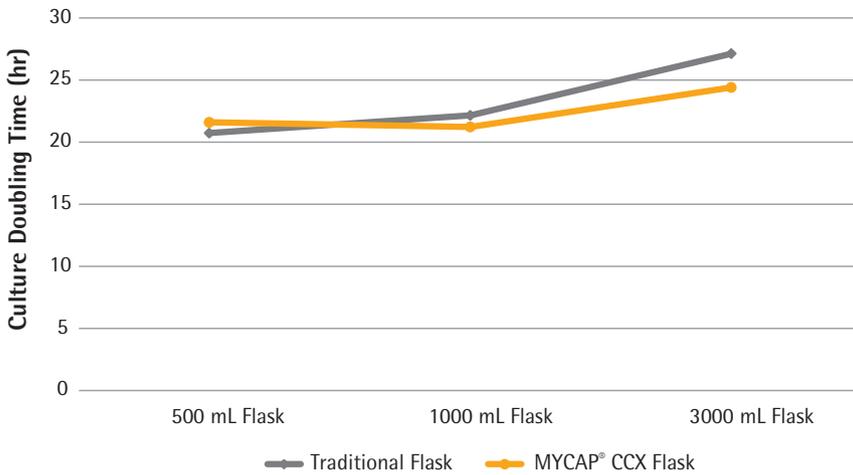
Proven Cell Growth

Cell expansion passage endpoints are typically measured by cell culture doublings. The MYCAP® CCX Cell Expansion System has been studied to confirm that it reaches critical endpoints, and the findings of these studies have been independently verified.

Sartorius compared experimental cell expansion passages from 500 mL through 3 L Erlenmeyer flasks with MYCAP® CCX and traditional vented caps. There were no discernible differences in cell culture doubling times between MYCAP® CCX and traditional flasks.

Simple Implementation

Thorough product validation and careful selection of materials make it simple to implement MYCAP® CCX in your expansion process. It has been validated for compliance with the following regulations and standards:

– USP Class VI biocompatibility

– USP 85 Bacterial Endotoxins Test

– USP 788 Particulate Matter in Injections

– ISO 11137-2 Sterilization of Health Care Products – sterility

– Extractables | Leachables Acc. to 21 CFR 177.2600 (Rubber Articles Intended for Repeated Use) and USP 381 (Elastomeric Closures)

– Container closure validation

Use our MYCAP® CCX Validation Template to guide you through efficient and thorough system implementation.

– Experimental design

– Data capture

– Analysis of results (charts, T-test)

Please contact your sales representative or email mycap@sartorius.com for further information
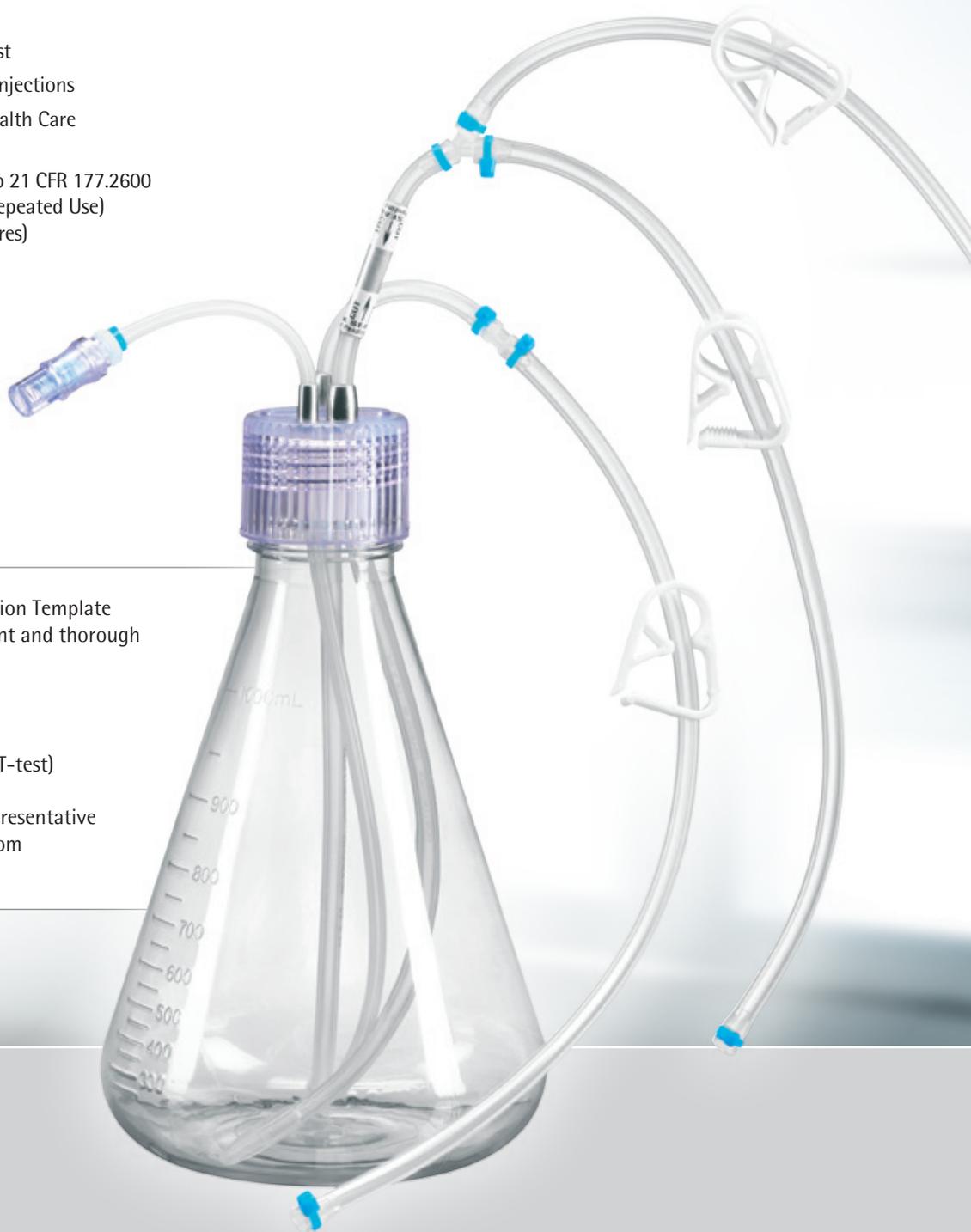
MYCAP® CCX Parts List

Growth and Transfer Systems

Transfer media and inoculum, collect samples and grow cells all in one system without opening a cap or ever using a biosafety cabinet.

Article Number	Description	Aseptic Connection Method
MCX050002040204A	MYCAP® CCX 500 mL Flask	Aseptiquik® S
MCX100002040204A	MYCAP® CCX 1000 mL Flask	Aseptiquik® S
MCX200002040204A	MYCAP® CCX 2000 mL Flask	Aseptiquik® S
MCX300002040204A	MYCAP® CCX 3000 mL Flask	Aseptiquik® S
MCX050002040204W	MYCAP® CCX 500 mL Flask	Tube Welding, ⅛ " ID × ¼ " OD C-Flex®
MCX100002040204W	MYCAP® CCX 1000 mL Flask	Tube Welding, ⅛ " ID × ¼ " OD C-Flex®
MCX200002040204W	MYCAP® CCX 2000 mL Flask	Tube Welding, ⅛ " ID × ¼ " OD C-Flex®
MCX300002040204W	MYCAP® CCX 3000 mL Flask	Tube Welding, ⅛ " ID × ¼ " OD C-Flex®

MYCAP® CCX Growth
and Transfer Cap

Transfer Caps

Install on smaller flasks to close the system and enable aseptic fluid transfer from the flasks.

Article Number	Description	Aseptic Connection Method
MCX01250204A	Transfer Cap for 125 mL Flask	Aseptiquik® S
MCX02500204A	Transfer Cap for 250 mL Flask	Aseptiquik® S
MCX01250204W	Transfer Cap for 125 mL Flask	Tube Welding, ⅛ " ID × ¼ " OD C-Flex®
MCX02500204W	Transfer Cap for 250 mL Flask	Tube Welding, ⅛ " ID × ¼ " OD C-Flex®

Transfer Assemblies

Connect media bottles to flasks, flasks to flasks and flasks to seed reactors to transfer fluids accurately and aseptically. Sized to fit in peristaltic pumps accepting size 16 tubing (1.6 mm⎮1/16 " wall)

Article Number	Description	Aseptic Connection Method
X020412W020418A	Transfer Assembly ⅛ " ID × ¼ " OD (Size 16)	Aseptiquik® S Tube Welding, ⅛ " ID × ¼ " OD C-Flex®
X020436AA	Transfer Assembly ⅛ " ID × ¼ " OD (Size 16)	Aseptiquik® S Aseptiquik® S
X040712W020418A	Transfer Assembly ⅛ " ID × ¼ " OD (Size 16)	Tube Welding, ¼ " ID × 7/16 " OD C- Flex® Aseptiquik® S
X020412W020412W	Transfer Assembly ⅛ " ID × ¼ " OD (Size 16)	Tube Welding, ⅛ " ID × ¼ " OD C-Flex® Tube Welding, ⅛ " ID × ¼ " OD C-Flex®
X020412W040712W	Transfer Assembly ⅛ " ID × ¼ " OD (Size 16)	Tube Welding, ⅛ " ID × ¼ " OD C-Flex® Tube Welding, ¼ " ID × 1/16 " OD C- Flex®
XY020403A	2-Way Splitter	Aseptiquik® S
XY020418W	2-Way Splitter	Tube Welding, ⅛ " ID × ¼ " OD C-Flex®
QSCUTTERSD	Small Diameter QUICKSEAL® Cutting Tool	
QSCAP04SILNT	QUICKSEAL® Protective Cap for ¼ " OD QUICKSEAL® Collar	

Transfer Caps

Transfer Assembly

C-Flex® is a trademark of St. Gobain Performance Plastics.
Aseptiquik® is a trademark of Colder Products.

Email **mycap@sartorius.com** to get in touch with a specialist
to create a list of MYCAP® CCX assemblies for your expansion process.

Configurable Flexsafe® 2D

Bags from 20 mL to 50 L

Product Information

Flexsafe® 2D Bags are designed for the preparation, storage and transport of biopharmaceutical solutions, intermediates and final bulk products.
Configurable Flexsafe® 2D Bags are designed from a database of pre-qualified components and proven functionalities using a web-based and interactive Product Configurator tool.
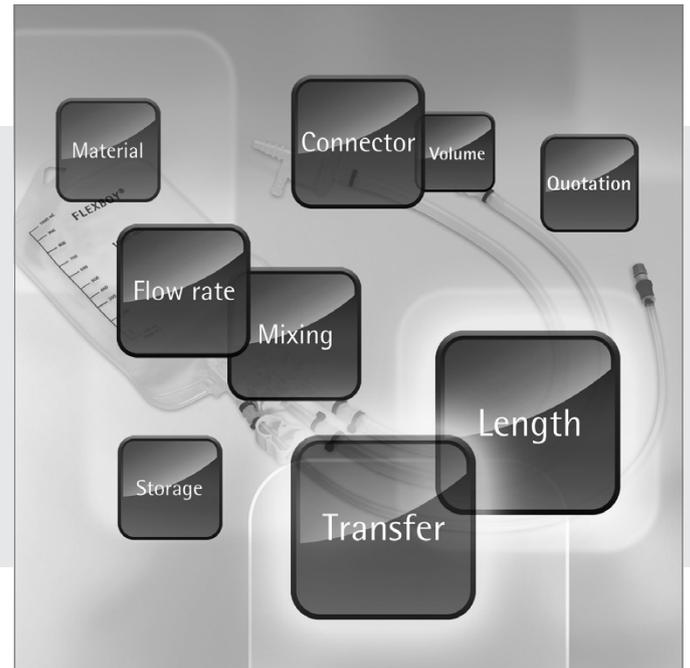
Description

The user friendly Product Configurator tool provides the flexibility needed for the application-based single-use configuration whilst improving design and quotation turnaround times, manufacturing lead times, security of supply and product reliability, safety and robustness.

They provide a single-use alternative to traditional glass, stainless steel and rigid plastic carboys in a large variety of applications. The broad chemical compatibility of Flexsafe® 2D Bags assures the safe processing of a wide range of biopharmaceutical fluids in a variety of applications.

Applications

The multi-layer, PE and EVOH based S80 film 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 sterile
– Filtration & storage
– Bulk Harvest
– Product pooling
– Fraction collection
– Sample collection
– Bulk intermediate hold
– Final Product handling

Flexibility

Configurable Flexsafe® 2D Bags are configured from pre-qualified components and proven functionalities including a variety of tubing, connectors, filter and sampling methods for a streamlined incorporation into your process. Multiple configurations are available with bag volumes from 20 mL to 50 L with TPE tubing, compatible with BioWelder® and BioSealer® for aseptic connection | disconnections, silicone TuFlux® tubing compatible with Clipster® Aseptic Disconnector and qualified for peristaltic pumping and TPE tubing for RF sealing with Vante™ Sealers. Sartopore® 2 Gamma MidiCaps® are proposed with an optional flush bag. Needle free sampling port or sampling bag may be used for easy and convenient sampling. Quick couplers, triclamps, Luer® fittings, Steam thru™ valves and Sterile-to-sterile connectors are provided for optimal connection compatibility flexibility in a production environment.

Easy Implementation

Configurable Flexsafe® 2D Bags are available in bag chamber volumes between 20 mL and 50 L. They are supplied sterilized and ready to use. This allows an easy and convenient process implementation. A series of associated systems such as Trays and Racks facilitate an easy bag handling. 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 of Single-Use Manufacturing.

Features	Benefits
Pre-qualified component database and proven functionalities	Quality by design for improved product reliability
Standard components & manufacturing methods	Save on development and engineering costs
Instant design with a web-based Product Configurator	Shorten lead time for drawing & quotes
CTO dedicated supply chain and manufacturing capability	Shorten lead-time for products
Offer a large range of standardized configurable products	Reduce complexity and risks by Standardization
Product Configurator tool with preconfigured options & functionalities	Flexibility for optimal design tailored to the application needs
Most commonly used components and solutions in the market	Compatibility with end user process requirements

Robust Performance and Assurance of Supply

Flexsafe® 2D bags are designed for safe storage and shipping of biopharmaceutical solutions. Flexsafe® bags ensure consistent cell growth robustness and ease of use and are extensively validated for all process steps, from cell culture and downstream purification of drug substance to final formulation and filling of drug product. Characterization of resins and establishing supply contracts for the resins and the film ensure compliance, reliable assurance of supply and change control.

Validation

Flexsafe® 2D 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 Configurable Flexsafe® 2D Bags with data representing the widest 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. Design, Manufacture and Sterilization processes are conducted under conditions that mirror biopharmaceutical operations and meet cGMP requirements.

Flexsafe® 2D Bags are tested for compliance to:

– USP <85>: Bacterial Endotoxins Test
– 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: Particulates
– ISO 11737: Bioburden
– ISO 11137: Sterilization of Medical Devices

Supply Chain

Configurable Flexsafe® 2D Bags are available as Configured to Order products. Pre-configured products based on application knowledge allow savings on engineering time and production preparation, thus providing reduced lead-times compared to classical fully customized processes.

Configurable Transfer line

Bag Chamber	Multiple layer film, including EVOH gas barrier layer and TPE contact layer S80 film
Volumes	20 mL – 50 L
Tubing	Silicone TuFlux® or Silicone (Pt) compatible with Clipster® Aseptic Disconnector, TPE compatible with BioWelder® and BioSealer®
End Connectors	Quick Couplers Triclamp and Mini-Triclamp Luer® Locks Steam thru™ valves for SIP connections Sterile-to-sterile connectors, including Opta® sterile connector
Filters	Sartopore® 2 0.2 µm Gamma MidiCaps® size 4 Sartopore® 2 0.2 µm Gamma MidiCaps® size 7 Sartopore® Platinum 0.2 µm Gamma MidiCaps® size 7 Sartopore® Platinum 0.2 µm Gamma MidiCaps® size 4 Sartopore XLM 0.1 µm size 7 with optional flush bag for volume 1 L to 50 L
Sampling	Needleless sampling site Sampling with bag
Number of Lines	2 lines for bags from 20 mL to 500 mL 3 lines for bags from 1 L to 50 L

Technical Data

Functionalities
– Storage application

Specifications

Volume
20 mL, 50 mL, 150 mL, 250 mL, 500 mL,
1 L, 3 L, 5 L, 10 L, 20 L, 50 L

Number of Ports │ Lines
– 3 lines where P1 is assimilated to the filling line,
 P2 to the draining line or sampling line and
 P3 to the sampling line

Tubing Diameters
$ID \times OD = \frac{1}{4}" \times \frac{7}{16}"$ for P1, P2, P3
$\frac{1}{4}" \times \frac{3}{8}"$ for P1, P2, P3
$\frac{3}{8}" \times \frac{5}{8}"$ for P1, P2

Tubing Materials
Silicone Tubing, Silicone TuFlux®, TPE Tubing, Silicone TuFlux® +
TPE Tubing, Silicone + TPE tubing

Tubing Lengths
150 mm, 300 mm, 500 mm, 1000 mm, 1500 mm, 2000 mm,
no tubing

Type of Lines

Port	P1	P2	P3
Line	Line 1	Line 2	Line 3
Function	Fill	Drain │ Sampling	Sampling
Normal Flow Rate with Filter	●		
High Flow Rate with Filter	●		
Normal Flow Rate	●	●	
High Flow Rate	● [1]	● [1]	
Sampling		●	●
Not Used		● [1]	● [2]

[1] For Flexsafe® 2D from 3 L to 50 L
[2] For Flexsafe® 2D from 20 mL to 500 mL

Line Type Normal Flow Rate with Filter and High Flow Rate with filter: port 1

Generic Description
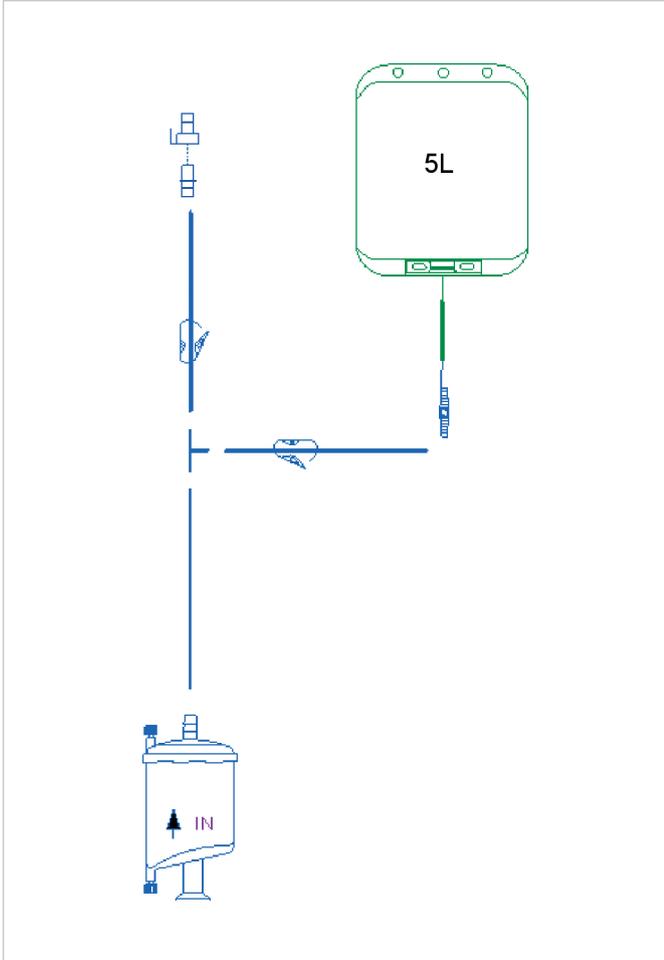
Specifications

Tubing Diameters
ID × OD = ¼" × ⁷⁄₁₆" (6.4 mm × 11.1 mm)
$\qquad$ or ³⁄₈" × ⁵⁄₈" (9.5 mm × 15.8 mm)

Tubing Materials
– Silicone TuFlux® or Si(Pt)
  (filter removal with CPC Quick Coupler
  or no filter disconnection)
– TPE tubing (filter removal with tube sealing)

Tubing Lengths
– 150 mm
– No Tubing

Type of filters
– Sartopore® 2 0.2 µm Gamma MidiCaps® size 4
– Sartopore® 2 0.2 µm Gamma MidiCaps® size 7
– Sartopore® Platinum 0.2 µm Gamma MidiCaps® size 4
– Sartopore® Platinum 0.2 µm Gamma MidiCaps® size 7
– Sartopore® XLM 0.1 µm size 7

Option
– No flush bag for volume 20 mL to 1 L
– 1 L Flexboy® Flush Bag (only with Normal Flow Rate)
– 5 L Flexboy® Flush Bag

Functionalities
– Filling through a sterilizing grade filter
– Optional filter flush bag only for volume > 1 L
– Optional filter disconnection with a Quick Coupler
  or with tube sealing (TPE)

Line Type Normal Flow Rate: port 1 & 2 and High Flow Rate: port 1 & 2

Generic Description
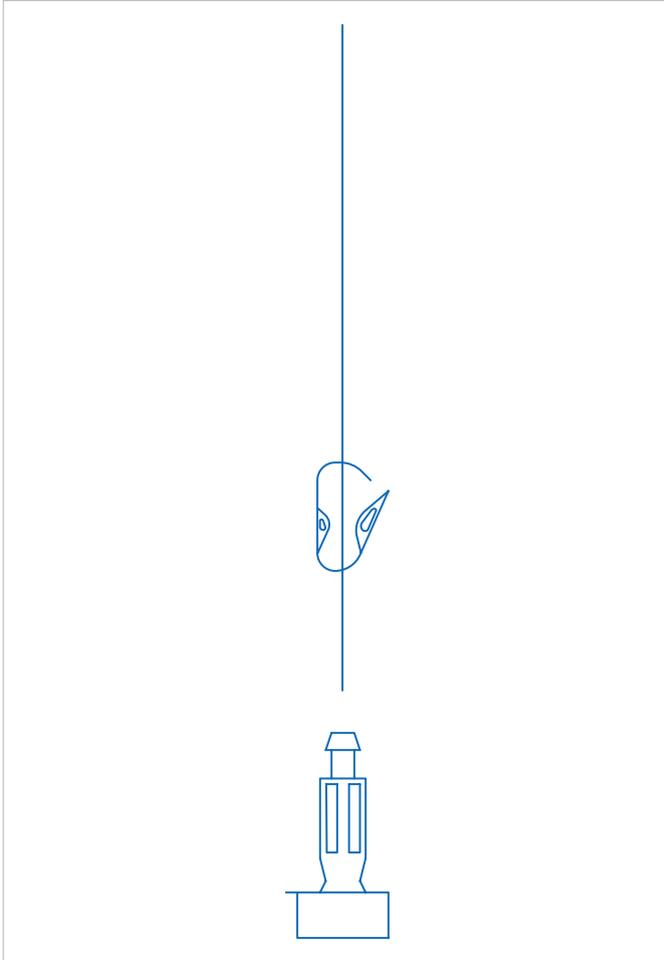
Functionalities
– Bag filling or bag drainage
– Transfer with a peristaltic pump or by gravity
– Tube to tube welding
– Tube sealing
– Aseptic connection
– Generic connection with a TriClamp or a Quick Coupler

Specifications

Tubing Diameters
ID × OD = ¼" × ⁷⁄₁₆" (6.4 mm × 11.1 mm)
       or ¼" × ³⁄₈" (9.5 mm × 15.8 mm)
       or ³⁄₈" × ⁵⁄₈" (9.5 mm × 15.8 mm)

Tubing Materials
– Silicone TuFlux® or Si(Pt) for 10 hr maximum operation with a
  peristaltic pump
– TPE (thermoplastic tubing) for tube sealing and welding
  operations
– Silicone TuFlux® or Si(Pt) with a TPE extension for 10 hr
  maximum operation with a peristaltic pump and for tube
  sealing and welding applications

Tubing Lengths
– 150 mm (6″) for Si(Pt) TuFlux® or Si(Pt)
– 300 mm (12") for Si(Pt) TuFlux® or Si(Pt)
– 500 mm (20″) for Si(Pt) TuFlux®, Si(Pt) or TPE tubing
– 1,000 mm (39″) total line length: 500 mm (20″) Si(Pt) TuFlux® or
  Si(Pt) + 500 mm (20″) TPE for Silicone with a TPE extension
– 1,500 mm (59") total line length: 1,000 mm (39″) Si(Pt) TuFlux®
  or Si(Pt) + 500 mm (20″) TPE for Silicone with a TPE extension
– 2,000 mm (79″) total line length: 1,500 mm (59″) Si(Pt) TuFlux®
  or Si(Pt) + 500 mm (20″) TPE for Silicone with a TPE extension

Distal Connectors
– SSB TriClamp (1–½" or ¾" flange) with optional triclamp cap,
  plug, gasket and union
– Quick Coupler with plug – MPC (Male or Female)
– MPC PSU (Male or Female)
– OPTA® SFT – aseptic connection (Male or Female)
– STC I – CPC Steamthru™ connection (¾" × ¾" triclamp flanges)
– STC II - CPC Steamthru™ connection (¾" × ¾" triclamp flanges)
– KPC HT – Male or Female
– Luer Male or Female with cap (only with Normal Flow Rate)
– Aseptiquick genderless
– Lynx Valve ST ¼" or ³⁄₈"

Line Type "Sampling" P2 – P3[1] Normal Flow Rate

Generic Description
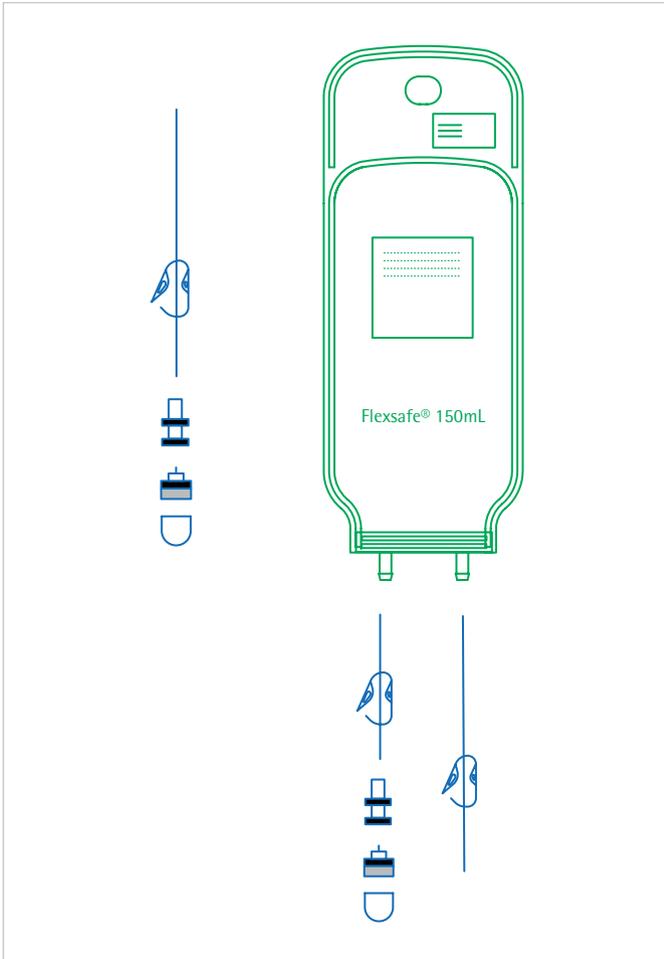
Specifications

Tubing Diameters
$ID \times OD = \frac{1}{4}" \times \frac{7}{16}"$ (6.4 mm $\times$ 11.1 mm)

Tubing Materials
– Silicone TuFlux® or Si(Pt) for needleless sampling port
– TPE (thermoplastic tubing) for welding and sealing operations
  (sampling bag disconnection)

Tubing Lengths
– 150 mm

Connector
– Clave

Sampling Bag
– Flexsafe® 2D bag 150 mL

Functionalities (Sampling)
– Clave Connector
– Sampling Bag

[1] P2 For volume 20 mL to 500 mL
   P3 for volume 1 L to 50 L

Line Type "Not Used" P2 – P3[2]

Functionality
– Not Used
– Obstructed port

[2] P2 only for volumes > 1 L

Functionalities of the Flexsafe® 2D Bag from 20 mL to 50 L

|	Normal Flow Rate with filter or High Flow Rate with filter	Normal Flow Rate	High Flow Rate	Sampling | Transfer
Function	Sterile Fill	Fill Drain Addition	Fill Drain Addition	Sampling
Port	P1	P1 – P2	P1 – P2	P2 – P3
Tube Dim.	$\frac{1}{4}$" × $\frac{7}{16}$" (6.4 mm × 11.1 mm) $\frac{3}{8}$" × $\frac{5}{8}$" (9.5 mm × 15.8 mm)	$\frac{1}{4}$" × $\frac{7}{16}$" (6.4 mm × 11.1 mm)	$\frac{3}{8}$" × $\frac{5}{8}$" (9.5 mm × 15.8 mm)	$\frac{1}{4}$" × $\frac{7}{16}$" (6.4 mm × 11.1 mm)
Tube Length mm	150 (6")	150 (6") 300 (12") 500 (20") 1,000 (39") 1,500 (59") 2,000 (79")	150 (6") 300 (12") 500 (20") 1,000 (39") 1,500 (59") 2,000 (79")	150 (6")
Tubing Materials	Si(Pt) TuFlux® Si(Pt) TPE	Si(Pt) TuFlux® Si(Pt) TPE Si(Pt) + TPE Si(Pt) TuFlux® + TPE	Si(Pt) TuFlux® Si(Pt) TPE Si(Pt) TuFlux® + TPE Si(Pt) + TPE	Si(Pt) TuFlux® Si(Pt) TPE
Standard Connectors		Luer M-F SSB TC 1½" or ¾" w/wo cap, plug, gasket, union Quick Coupling MPC-M/F Quick coupling PSU-M/F	Luer M-F SSB TC 1½" or ¾" w/wo cap, plug, gasket, union Quick Coupling MPC-M/F Quick Coupling PSU-M/F	Clave
Aseptic Connectors		Opta® SFT-M/F AseptiQuik® Genderless	Opta® SFT-M/F AseptiQuik® Genderless STC I ¾" × ¾" STC II ¾" × ¾"	
Other Connectors		KPC HT-M/F Lynx ST ¼"	KPC HT-M/F Lynx ST ³⁄₈"	
Filters	Sartopore® 2 0.2 µm Gamma MidiCaps® size 4 Sartopore® 2 0.2 µm Gamma MidiCaps® size 7 Sartopore® Platinum 0.2 µm Gamma MidiCaps® size 7 Sartopore® Platinum 0.2 µm Gamma MidiCaps® size 4 Sartopore® XLM 0.1 µm size 7			
Flush Bag	Flexboy® 1 or 5 L[1]			
Sampling Bags				Flexsafe® 2D Bag Bags 1 × 150 mL[2]

[1] Only for volume > 1 L
[2] Only for volume 1 L to 50 L

Sales and Service Contacts

For further contacts, visit www.sartorius-stedim.com

Europe

Germany
Sartorius Stedim Biotech GmbH
August-Spindler-Strasse 11
37079 Goettingen

Phone +49.551.308.0

Sartorius Stedim Systems GmbH
Robert-Bosch-Strasse 5 – 7
34302 Guxhagen

Phone +49.5665.407.0

France
Sartorius Stedim FMT S.A.S.
ZI des Paluds
Avenue de Jouques – CS 91051
13781 Aubagne Cedex

Phone +33.442.845600

Sartorius Stedim France SAS
ZI des Paluds
Avenue de Jouques – CS 71058
13781 Aubagne Cedex

Phone +33.442.845600

Austria
Sartorius Stedim Austria GmbH
Modecenterstrasse 22
1030 Vienna

Phone +43.1.7965763.18

Belgium
Sartorius Stedim Belgium N.V.
Rue Colonel Bourg 105
1030 Bruxelles

Phone +32.2.756.06.80

Hungary
Sartorius Stedim Hungária Kft.
Kagyló u. 5
2092 Budakeszi

Phone +36.23.457.227

Italy
Sartorius Stedim Italy S.r.l.
Via dell'Antella, 76/A
50012 Antella-Bagno a Ripoli (FI)

Phone +39.055.63.40.41

Netherlands
Sartorius Stedim Netherlands B.V.

Phone +31.30.60.25.080

filtratie.nederland@sartorius-stedim.com

Poland
Sartorius Stedim Poland Sp. z o.o.
ul. Wrzesinska 70
62-025 Kostrzyn

Phone +48.61.647.38.40

Russian Federation
LLC "Sartorius Stedim RUS"
Vasilyevsky Island
5th line 70, Lit. A
199178 St. Petersburg

Phone +7.812.327.53.27

Spain
Sartorius Stedim Spain, S.A.U.
Avda. de la Industria, 32
Edificio PAYMA
28108 Alcobendas (Madrid)

Phone +34.913.586.098

Switzerland
Sartorius Stedim Switzerland AG
Ringstrasse 24 a
8317 Tagelswangen

Phone +41.52.354.36.36

U.K.
Sartorius Stedim UK Ltd.
Longmead Business Centre
Blenheim Road, Epsom
Surrey KT19 9 QQ

Phone +44.1372.737159

Ukraine
LLC "Sartorius Stedim RUS"
Post Box 440 "B"
01001 Kiev, Ukraine

Phone +380.44.411.4918

Americas

USA
Sartorius Stedim North America Inc.
5 Orville Drive, Suite 200
Bohemia, NY 11716

Toll-Free +1.800.368.7178

Argentina
Sartorius Argentina S.A.
Int. A. Ávalos 4251
B1605ECS Munro
Buenos Aires

Phone +54.11.4721.0505

Brazil
Sartorius do Brasil Ltda
Avenida Senador Vergueiro 2962
São Bernardo do Campo
CEP 09600-000 - SP- Brasil

Phone +55.11.4362.8900

Mexico
Sartorius de México, S.A. de C.V.
Libramiento Norte de Tepotzotlan s/n,
Colonia Barrio Tlacateco,
Municipio de Tepotzotlan,
Estado de México,
C.P. 54605

Phone +52.55.5562.1102

leadsmex@sartorius.com

Peru
Sartorius Peru S.A.C.
Avenue Alberto del Campo 411
Floor 12 – The Office
15076 – San Isidro, Lima

Phone +51.1.441 0158

Asia | Pacific

Australia
Sartorius Stedim Australia Pty. Ltd.
Unit 5, 7–11 Rodeo Drive
Dandenong South Vic 3175

Phone +61.3.8762.1800

China
Sartorius Stedim (Shanghai)
Trading Co., Ltd.
3rd Floor, North Wing, Tower 1
No. 4560 Jinke Road
Zhangjiang Hi-Tech Park
Pudong District
Shanghai 201210, P.R. China

Phone +86.21.6878.2300

Sartorius Stedim (Shanghai)
Trading Co., Ltd.
Beijing Branch Office
No. 33 Yu'an Road
Airport Industrial Park Zone B
Shunyi District, Beijing 101300

Phone +86.10.8042.6501

Sartorius Stedim (Shanghai)
Trading Co., Ltd.
Guangzhou Branch Office
Room 1105
Xing Guang Ying Jing Building
No. 119, Shui Yin Road
Yue Xiu District, Guangzhou 510075

Phone +86.20.3836.4193

India
Sartorius Stedim India Pvt. Ltd.
#69/2-69/3, NH 48, Jakkasandra
Nelamangala Tq
562 123 Bangalore, India

Phone +91.80.4350.5250

Japan
Sartorius Stedim Japan K.K.
4th Fl., Daiwa Shinagawa North Bldg.
8-11, Kita-Shinagawa 1-chome
Shinagawa-ku, Tokyo, 140-0001 Japan

Phone +81.3.4331.4300

Malaysia
Sartorius Stedim Malaysia Sdn. Bhd.
Lot L3-E-3B, Enterprise 4
Technology Park Malaysia
Bukit Jalil
57000 Kuala Lumpur, Malaysia

Phone +60.3.8996.0622

Singapore
Sartorius Stedim Singapore Pte. Ltd.
10 Science Park Rd
The Alpha #02-13/14
Singapore Science Park II
Singapore 117684

Phone +65.6872.3966

South Korea
Sartorius Korea Biotech Co., Ltd.
8th Floor, Solid Space B/D,
PanGyoYeok-Ro 220, BunDang-Gu
SeongNam-Si, GyeongGi-Do, 463-400

Phone +82.31.622.5700

www.sartorius–stedim.com

Microcarrier Products

Simplifying adherent, cell-based research and manufacturing
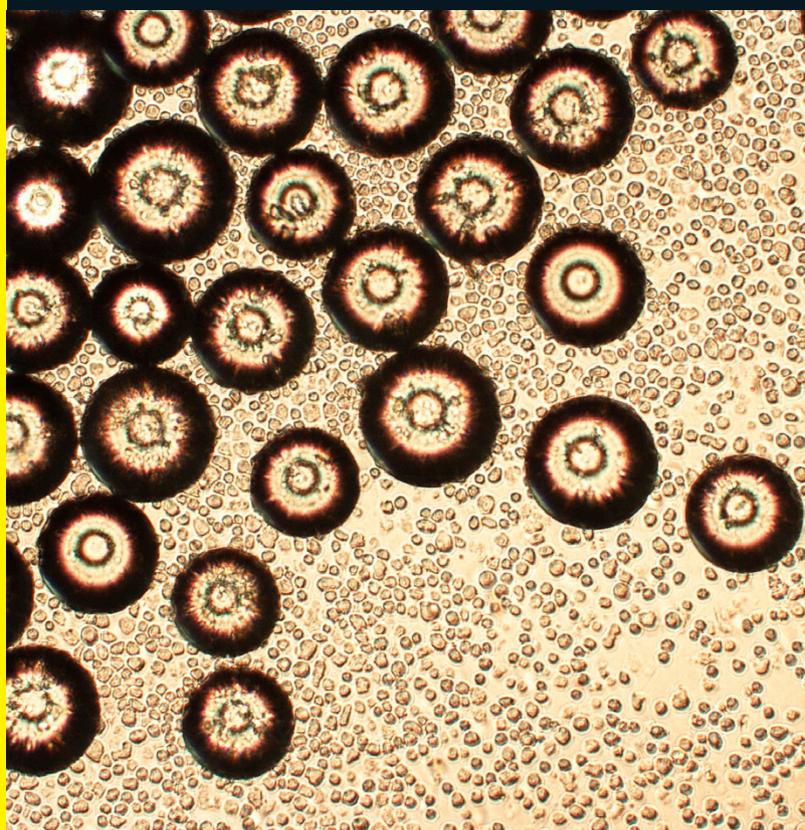
Product Information

Since its inception in 1984, SoloHill® has developed an extensive range of commercially available microcarrier products. By successfully combining cutting-edge research with high-quality manufacturing, SoloHill® not only offers excellent products but also provides valuable technical expertise to ensure optimal results. Our talented scientists are available to assist with product selection, process optimization, and technology transfer to end-user laboratories.

Microcarriers are tiny spheres that normally range from 90 to 300 microns in diameter. The relative density of microcarriers is close to water, which facilitates easy suspension in a cell culture medium. Their core material, surface chemistry, and coating promote attachment and growth of anchorage-dependent cells and influences the production of biologics in cell culture processes. A fundamental benefit of microcarriers is that they provide a large effective surface area with a relatively small footprint, allowing large-scale manufacturing of biologics for lower capital investment.
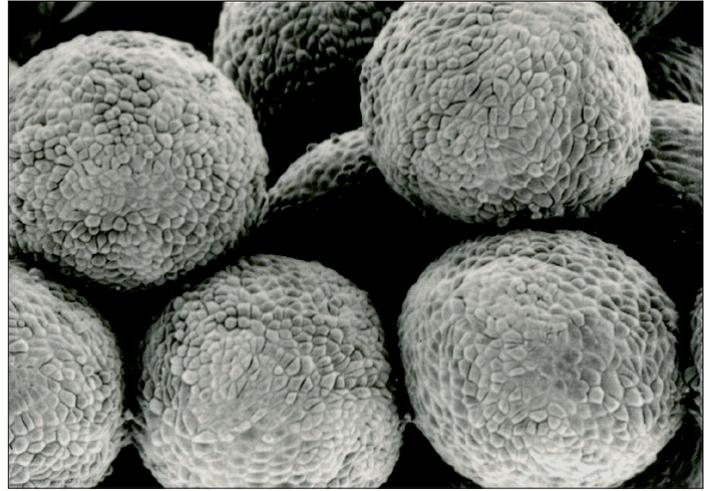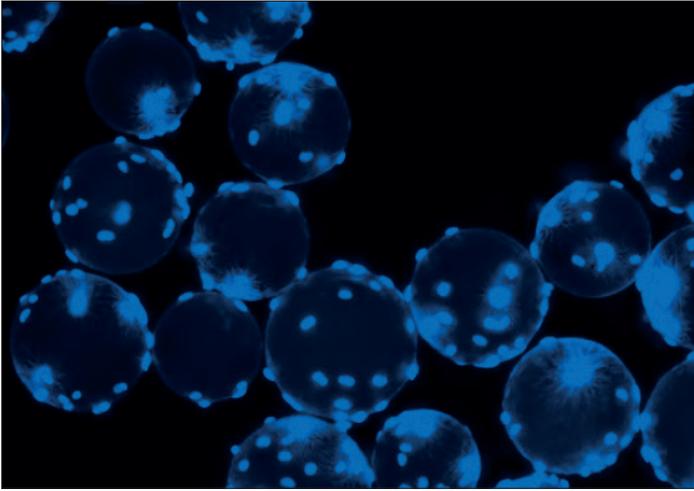
Human mesenchymal stromal/stem cells (hMSCs) growing on SoloHill® Microcarriers

Scanning electron micrograph of Vero cells on SoloHill® Microcarriers

Benefits

Sartorius SoloHill® Microcarrier technology has many advantages for the large-scale production of high-quality, anchorage-dependent cells.

- **Proven Track Record:** Used by the animal and human health industry for over 30 years.
- **Streamlined Solution:** Simply sterilize and use: hydration and pre-swelling steps are not required.
- **Ready-to-Use:** Sterile format with sterility assurance level (SAL) 10^{-6} eliminates sterilization validation and shortens manufacturing process.

SoloHill® Microcarriers

Operational Efficiency — Manufactured from the same core material as 2D plastic culture ware, minimum adaptation required.

Broad Selection — Optimized size, surface chemistry, and relative density to support easy suspension and allow superior cell attachment and growth of diverse cell types.

Ready to Use — Sterile format (SAL =10^{-6}) offers convenient and easy way to transfer sterile microcarrier in a bioreactor bag.

Rigid Core — Withstands mechanical harvest methods, promotes easy and rapid cell disassociation and separation from cell suspension, and simplifies seed-train scale-up applications.

Applications

Microcarrier technology provides an efficient, cost-effective tool to scale up various adherent, cell-based biopharmaceutical applications such as advanced cell and gene therapy, vaccines, and biologics production. Historically, microcarrier and stirred-tank bioreactor technologies have been used successfully by the biopharmaceutical industry, and this platform is accepted by regulatory agencies for both animal and human health product manufacturing.

A wide range of commercially available, traditional stainless steel, and single-use stirred-tank bioreactors are used to scale processes up to 3000 m² surface area or greater using microcarrier technology. Additionally, microcarrier-based scale-up performed in controlled bioreactor systems facilitates automated closed system operations, thereby diminishing contamination risks and providing a regulated manufacturing environment for consistent product manufacturing.

Product Specification

SoloHill's diverse microcarrier products are manufactured and handled under ISO 9001 standards. All microcarrier types are offered in standard non-sterile and sterile (gamma-irradiated), ready-to-use formats that facilitate ease of use. Specific cell types have different requirements for attachment, growth, and biologic production, hence the optimal microcarrier should be selected experimentally.

Microcarriers are offered in a convenient starter kit format to accelerate this initial screening and evaluation. Selecting the optimal microcarrier type is key to a successful culture. Sartorius offers a variety of microcarrier types in multiple size formats ranging from 10 grams to 1000 grams, allowing user flexibility during the selection and optimization of manufacturing processes.

Microcarrier Types and Their Properties

Microcarrier type, core material, and surface chemistry	Relative density range	Size (microns)	Surface area (cm²/g)	Surface charge	Protein-coated	Number of MC per gram
Plastic Cross-linked polystyrene	1.022 – 1.030	125 – 212	360	No	No	4.6×10^5
	1.022 – 1.030	90 – 150	480	No	No	1.0×10^6
Plastic Plus Cross-linked polystyrene, cationic-charged	1.022 – 1.030	125 – 212	360	Yes	No	4.6×10^5
Star-Plus Cross-linked modified polystyrene, cationic-charged	1.022 – 1.030	125 – 212	360	Yes	No	4.6×10^5
Hillex II® Modified polystyrene, cationic-charged	1.090 – 1.150	160 – 200	515	Yes	No	5.5×10^5
Collagen Cross-linked polystyrene coated with Type 1 porcine collagen (gelatin)	1.022 – 1.030	125 – 212	360	No	Yes	4.6×10^5
	1.034 – 1.046	125 – 212	360	No	Yes	4.6×10^5
	1.022 – 1.030	90 – 150	480	No	Yes	1.0×10^6
Fact III Cross-linked polystyrene coated with Type 1 porcine collagen (gelatin), cationic-charged	1.022 – 1.030	125 – 212	360	Yes	Yes	4.6×10^5

Ordering Information

Microcarrier type	Part number	Weight (gram)	Ready to use (Sterile)
Plastic Cross-linked polystyrene	P-221-020	10	No
	P-221-050	100	No
	P-221-070	500	No
	P-221-080	1000	No
	PIR-221-020	10	Yes
	AMDS05PS100	100	Yes
Plastic Plus Cross-linked polystyrene, cationic-charged	PP-221-020	10	No
	PP-221-050	100	No
	PP-221-070	500	No
	PP-221-080	1000	No
	PPIR-221-020	10	Yes
	AMDS05PPS100	100	Yes
Star-Plus Cross-linked modified polystyrene, cationic-charged	SP-221-020	10	No
	SP-221-050	100	No
	SP-221-070	500	No
	SP-221-080	1000	No
	SPIR-221-020	10	Yes
	AMDS05SPS100	100	Yes
Hillex II® Modified polystyrene, cationic-charged	H-170-020	10	No
	H-170-050	100	No
	H-170-070	500	No
	H-170-080	1000	No
	HIR-170-020	10	Yes
	AMDS05HS100	100	Yes
Collagen-coated Cross-linked polystyrene coated with Type 1 porcine collagen (gelatin)	C-221-020	10	No
	C-221-050	100	No
	C-221-070	500	No
	C-221-080	1000	No
	CIR-221-020	10	Yes
	AMDS05CS100	100	Yes
FACT III Cross-linked polystyrene coated with Type 1 porcine collagen (gelatin), cationic-charged	F-221-020	10	No
	F-221-050	100	No
	F-221-070	500	No
	F-221-080	1000	No
	FIR-221-020	10	Yes
	AMDS05FS100	100	Yes
Microcarrier Starter Kit (Plastic, Plastic Plus, Star-Plus, Hillex® II, Collagen-coated, Fact III)	SK102-1521B	10g of each	No

Custom size options are available upon request, contact at microcarriers@sartorius.com.

Germany
Sartorius Stedim Biotech GmbH
August-Spindler-Straße 11
37079 Göttingen
Phone +49 551 308 0

🌐 For further contacts, visit
www.sartorius.com

USA
Sartorius Stedim North America Inc.
565 Johnson Avenue
Bohemia, NY 11716
Toll-Free +1 800 368 7178

SARTORIUS

Ksep® Systems

Advanced, Scalable, Single-Use Automated Centrifugation Systems

Introduction

Sartorius Ksep® systems provide robust, single-use bioprocessing solutions in the areas of recombinant therapeutics, cell therapy, vaccine manufacturing, and blood processing. As per your process requirements, our fully-automated systems are optimized to recover supernatant or solids (cells | particles) in a continuous manner.

Ksep® systems solve the problems of traditional centrifugation and filtration based technologies by handling very high cell densities while providing high recoveries and product quality.

Description

Patented Ksep® systems technology is the only current technology that provides significant advantages for users that want to either harvest cells as product or discard cells as by-product during manufacturing.

Through the balance of centrifugal and fluid flow forces, the Ksep® retains particles such as cells or microcarriers, as a concentrated fluidized bed under a continuous flow of media or buffer. These are the only bowl centrifuges that do not stop rotating while discharging. The system can be operated under sterile conditions and all consumables are delivered pre-sterilized.

Benefits

Smart Bioprocessing

- Integrates and | or reduces processing steps and time
- Improves recoveries of both solids and liquids
- Provides option to selectively remove small particulate impurities, e.g. plastic generated, cell debris, extracellular viruses
- Built-in scalability (4–6 fold) for development and manufacturing using the same system
- Automated with option to run in complete manual mode
- No hardware change for different applications
- Handles low to high cell density cultures (>150 million cells/mL) equally well

Advanced Cell Handling

- Imparts low shear on cells and keeps the cells intact
- Maintains a healthy environment to sustain cell viability
- Complete supernatant product recovery from slurry without dilution
- Reduces intracellular protein contamination for harvest applications by keeping the cells intact

Ensures cGMP Manufacturing

- Closed system with single-use class VI product contact surfaces
- Simple, robust, and scalable
- One software for all systems
- Clog-free and continuous operation

Ksep® Centrifuge Function Principle

Centrifugal force
Fluidized Cell Bed
Chamber
rotation axis
Fluid flow force
Cell culture Inlet
Spent Media Outlet
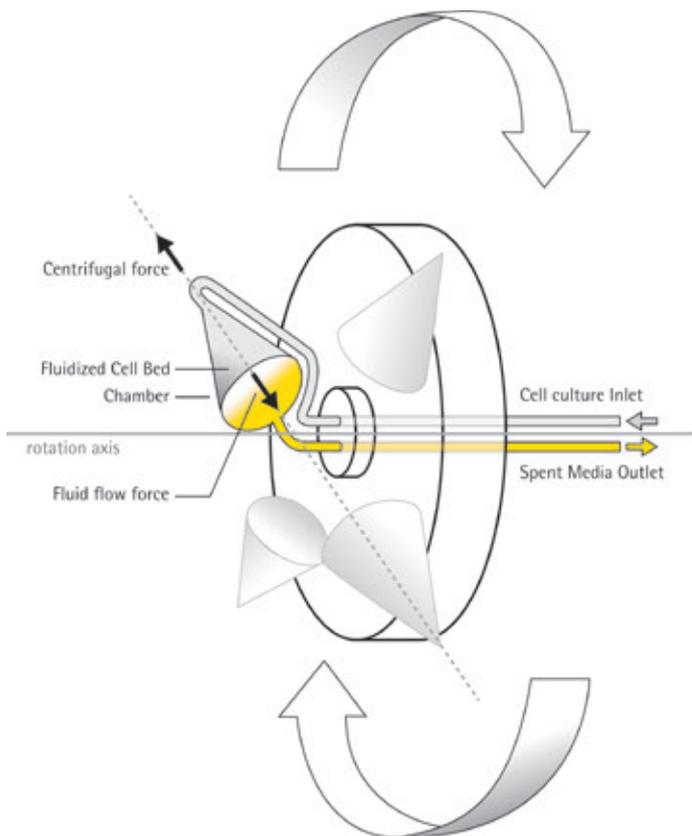
Applications

- Harvest | Clarification
- Cell Therapy
- Vaccine Manufacturing
- Blood Processing

Concentrate-Wash-Harvest

Ksep® systems concentrate cells with high recovery while maintaining high viability. Additionally, Ksep® systems can remove cell debris, light particulate impurities, all while significantly reducing any aggregation of cells. Ksep® systems do not contain any rotary seals (providing completely closed system) or filters (for reduced issues from clogging). These features are critical for cell therapy manufacturing. Once captured and concentrated, the cells can efficiently be washed, manipulated, and harvested. Ksep® is a breakthrough for applications requiring maintenance of cellular integrity during processing. This automated sequence is currently being used for cell therapy manufacturing, perfusion, cell banking, and vaccine manufacturing processes. This is the only perfusion technology where the bleeding of cells does not cause loss of recovery.

Harvest Clarification

Ksep® systems are the first single-use centrifugation systems that are completely closed. These systems are fully-automated and designed to recover >97% of product by efficient product displacement from slurry. This process is independent of cell density. In addition, low-shear process ensures reduced downstream contamination (due to cellular debris or proteolytic enzymes) and high product quality.

Additional Applications

We are continually working with clients and have developed a wide range of additional applications including microcarrier separation and coating, blood separation, infection, and transfection.

Technical Specifications

	Ksep®400	Ksep®6000S
Functional		
Max g-force	1,000 g	2,000 g
Max Flow Rate	114 L/hr	720 L/hr
Volume	400 mL (4 × 100 mL)	6000 mL (6 × 1,000 mL)
Cell Capacity per Cycle (CHO)	Up to 80 Billion	Up to 1200 Billion
Processing Volumes	0.1 – 500 L	10 – 2,000 L
Physical		
Height	140 cm	179 cm
Length	107.5 cm	225 cm
Width	72 cm	106 cm
Weight	350 kg	2141 kg

	Ksep®400	Ksep®6000S
Process Connections		
All	⅜″ × ¼″ C-Flex®	⅝″ × ⅜″ C-Flex®

Utility Requirements		
Voltage	208–240 V 1 Ph	208–240 V 3 Ph (US) | 400 V 3 Ph (EU)
Current	20 A	60 A
Process Air	Not required	90 psi – ½″ NPT
Connection	NEMA L6–20	Customer supplied
Chilled Water (Optional)	½″ NPT	¾″ NPT

PLTGold® Product Insert

About PLTGold®

PLTGold® is a non-xenogeneic, animal serum-free product derived from human platelets. PLTGold® is used as a manufacturing component in the generation of adult stems cells. A Drug Master File for PLTGold® is registered with the FDA and is cross-referenceable. Contact us for more information on the DMF.

Product	Catalog Number	Size
PLTGold® Research Grade	PLTGold27R	27mL
	PLTGold100R	100mL
	PLTGold500R	500mL
PLTGold® Clinical Grade (GMP)	PLTGold27GMP	27mL
	PLTGold100GMP	100mL
	PLTGold500GMP	500mL

Safety Information

All PLTGold® donors have been tested for infectious diseases; however, universal precautions for handling and disposal of biological products should be used when working with PLTGold®.

Using PLTGold®

- Thaw at 37°C or 4°C.
- It is not recommended to expose PLTGold® to repeated temperature changes that could affect the integrity of its components. For that reason, we recommend thawing the product and preparing aliquots as soon as it is received.
- Aliquots can be stored at -20°C or colder. Storage at 4°C is recommended for periods no longer than 2 weeks.
- Complete media can be prepared, aliquoted and stored at -80ºC for up to 9 months. Do not store complete media at 4ºC for longer than 2 weeks.
- Filtration of PLTGold® or complete media containing PLTGold® is NOT recommended.

Culture Conditions Using PLTGold®

- Cell seeding should be performed following the general guidelines for the specific cell type. For Mesenchymal Stem Cells (MSCs), cells are typically plated at approximately $2x10^3 - 5x10^3$ cells per cm^2.
- For MSCs, PLTGold® can be used at 5% vol/vol in a typical cell culture medium such as DMEM or α-MEM. If the basic media doesn't contain Glutamine, a source of L-Glutamine will need to be added to the media at a final concentration of 2mM. For other types of cells, the concentration of PLTGold® will need to be titrated according to the application (a titration from 2% vol/vol to 10% vol/vol is recommended to establish the percentage of PLTGold® needed for the cell type to use).
- Do not allow primary MSC confluence to exceed 70-80%.

Origin

- PLTGold® was developed to eliminate the need for heparin in hPL. It is an unfractionated product derived from our original hPL, PLTMax® that does not contain or require the addition of heparin. PLTGold® remains clot free and with similar performance to PLTMax®.

References

- Crespo-Diaz R, Behfar A, Butler GW, et al. **Platelet lysate consisting of a natural repair proteome supports human mesenchymal stem cell proliferation and chromosomal stability.** *Cell Transplant.* 2011;20(6):797-811.

- Burnouf T, Strunk D, Koh MB, et al. **Human platelet lysate: Replacing fetal bovine serum as a gold standard for human cell propagation?** *Biomaterials.* 2016 Jan;76:371-87.

- Alonso-Camino V, Clarke B, Nielsen J, et al. **In vitro expansion of mesenchymal stem cells using media supplemented with unfractionated heparin-free platelet lysate.** Poster presented at: ISCT Annual Meeting. London, UK. 2017 May.

- Bulur P, Wiltshire T, Dudakovic A, et al. **Impact of media supplementation on the secretion of IFN-γ induced indoleamine 2-3 deoxygenase and resultant immune suppression by mesenchymal stromal cells.** Poster presented at: ISCT Annual Meeting. Montreal, Canada. 2018 May.

- Alonso-Camino V, Mirsch W. **In vitro expansion of human primary endothelial cells for clinical use using EndoGo™ XF Medium supplemented with PLTGold® human platelet lysate.** Poster presented at: ISCT Annual Meeting. Montreal, Canada. 2018 May.

Biosealer® TC

For Robust and Consistent Sealing

Applications

The Biosealer® TC is used to disconnect thermoplastic tubing (TPE) such as Tuflux® TPE, C-Flex® 374, AdvantaFlex®, SaniPure™ BDF™ and Pharmed® BPT, on disposable assemblies used in biopharmaceutical manufacturing processes. Individual components of assemblies can be disconnected in a non-sterile environment while maintaining sterility of the product.

Product Information

The Biosealer® TC is a fully automated device for disconnecting thermoplastic tubing in a sterile sealing operation. This proven technology allows for sterile disconnection of tubing from ¼" up to 1" outer diameter.

Feature	Benefit
Sealing of dry or liquid filled tubing from ¼" to 1" OD without the need for accessories	One device to seal all tubing sizes under different process conditions
Larger sealing area with cutting guide	Increased sealing robustness and safer disconnection
Fully automated portable device without accessory required	Repeatable and easy to use
Standard programs for TPE tubings	Ready to use for Tuflux® TPE (except ½" × ¾", ¾" × 1"), C-Flex® 374, AdvantaFlex®, SaniPure™ BDF™ (except ¾" × 1") and PharMed® BPT
New design	Ergonomic Operator friendly Easy to use

C-Flex®, Sani-Pure™ and PharMed® are registered trademarks of Saint-Gobain Performance Plastics Corporation.

Simple Operating Principle

The inserted dry or liquid filled tubing is compressed between two heating elements. The heat and the compression force generate a homogeneous sealing of the tubing section. The resulting sealing can be cut through the embedded guideline using scissors.

Flexibility

The Biosealer® TC device is capable of sealing TPE tubing, either gamma-irradiated or autoclaved, from ¼" up to 1" OD. Sealing parameters for all tubing dimensions and materials are pre-installed on the system and simple to select. Disconnections can be performed on dry, wet or liquid filled tubing. Due to its weight and small dimensions the unit is portable and can be easily used in a variety of locations.

Ease of Use

A LCD touch screen guides the user through the operator menu which is aligned with Biowelder® TC. Each step of the sealing process can be easily followed and monitored by the information provided on the display. The Biosealer® TC is equipped with an SD Card slot to allow loading and printing of the sealing cycle data via a computer. A kit is available as accessory for purchase to allow user to verify the temperature of the device.

Process Time

Depending on the tubing size and TPE material the sealing process time is between 2 to 4 minutes.

Summary table of validated tubing materials and sizes which can be sealed on Biosealer® TC.
These parameter sets have been validated at room temperature.

TPE tubing material	Sealing parameter name installed on Biosealer® TC	Sterilization methods of tubing covered by the parameters	Tubing sizes qualified per sealing parameter					
			8" × ¼"	¼" × ⅜"	¼" × ⁷⁄₁₆"	⅜" × ⅝"	½" × ¾"	¾" × 1"
TuFlux® TPE	TuFlux TPE	A or G	☐ (yellow)	☐ (orange)	☐ (red)	☐ (white)		
C-Flex® 374	C-Flex 374	A or G	☐	☐	☐	☐	☐	☐
AdvantaFlex®	AdvantaFlex	A or G	☐	☐	☐	☐	☐	☐
SaniPure™ BDF™	SaniPure	A or G	☐	☐	☐	☐	☐	
Pharmed® BPT	Pharmed	A or G	☐	☐	☐	☐	☐	☐
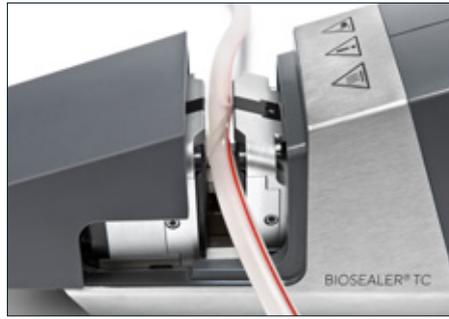
Robust Disconnection

The thermal seals produced by the Biosealer® TC ensure an extraordinary level of stability and guarantees sterile disconnections. The sealing parameters have been qualified by stringent and innovative test regimes. Biological, physical and extractables qualification tests were performed and the results are compiled into a validation guide.

Service

The Installation Qualification and Operational Qualification is recommended and should only be performed by Sartorius Service.

Other services are available for Biosealer® TC upon request such as device installation, temperature calibration, preventive maintenance and several levels of maintenance contracts.

Ordering Information

Order Code	Description	Unit / box
16391-000	Biosealer® TC	1
16391-010	Extension cable 3 m	1
16391-011	Temperature validation kit	1

Service

Order Code	Description
S873SINST	Installation, Biosealer® TC
S873SIQOQ	IQOQ, Biosealer® TC

Service and maintenance contract of different levels are available for the Biosealer® TC.

Technical Data

Type designation	Biosealer® TC
Input voltage	24 VDC
Supply current	6.25 A
In and out connections	Device plug, XLR max. 24 VDC Ethernet jack type RJ45
Operating temperature	+5°C to 40°C
Place of use	Indoor
Pollution degree	2
Humidity	80% up to 31°C, linearly diminishing to 50% relative humidity at 40°C not condensing
Altitude	Up to 2000 m
Degree of protection	IP20
Weight	Approx. 3 kg
Dimension (L×W×H)	391 mm × 115 mm × 147 mm
Power Supply	
Input Voltage	100 VDC – 240 VDC
Input frequency (power supply)	47 Hz – 63 Hz
Input current	2.5 A
Power cord	According to local regulations Min. 3 × AWG18 or 3 × 0.75 mm² Min. local mains supply voltage

Sealing paremeters validation

The parameter sets have been validated at room temperature (about 22°C) with WFI solution.

It is customer responsibilty to validate the usage of the Biosealer® TC in the process conditions.

Germany
Sartorius Stedim Biotech GmbH
August-Spindler-Strasse 11
37079 Goettingen
Phone +49 551 308 0

🌐 For further contacts, visit
www.sartorius.com

USA
Sartorius Stedim North America Inc.
565 Johnson Avenue
Bohemia, NY 11716
Toll-Free +1 800 368 7178

BioWelder® Total Containment

Fully automated device for welding dry and liquid filled tubing

Product Information

The BioWelder® TC is a fully automated device for connecting thermoplastic tubing in a sterile welding operation. This innovative technology allows for the sterile connection of tubing from ¼" up to 1" outer diameter.

Applications

The BioWelder® TC is used to connect thermoplastic tubing such as TuFlux® TPE, C-Flex® 374*, AdvantaFlex®, SaniPure™* BDF™ and PharMed®* BPT used on disposable bags or bag assemblies within all biopharmaceutical manufacturing processes. BioWelder® TC can weld either dry or liquid-filled tubing in non classified and classified environment while maintaining product sterility.

TuFlux® TPE welding parameters only allow for the cowelding of this tubing material to C-Flex® 374 and to AdvantaFlex®. This unique feature allows one to weld together these 2 different tubing materials to TuFlux® TPE and is supported by a complete validation study."

Feature	Benefit
Dry or liquid filled tubing from ¼" to 1" OD	Process flexibility & multiple additions via the same tubing line
Fully automated device	Repeatable and easy to use
Standard programs	Ready to use for TuFlux® TPE, C-Flex® 374*, AdvantaFlex®, SaniPure™* (except ⅝" × ⅞" and ¾" × 1" sizes) and PharMed®* (except ⅛" × ¼" size) tubing
New design (device & color coded tube holders)	Ergonomic Operator friendly Easy to use
Extensively qualified	Safe and robust connections
Welding time	Fast connections

* C-Flex®, SaniPure™ and PharMed® are registered trademarks of Saint-Gobain Performance Plastics Corporation.

Simple Operating Principle

The holders, the blade and the tubes are inserted into the BioWelder® TC. The welding process is fully automated and is started via the LCD touch screen. The blade is first heated up for depyrogenation then cooled down to the welding temperature. An infrared sensor monitors and controls the blade temperature throughout the welding process. When the blade reaches the welding temperature, the blade cuts the tubes and the new fluid path is welded together.

Flexibility

The interchangeable and color coded tube holders are available in a variety of sizes between ⅛" ID × ¼" OD and ¾" ID × 1" OD, which allow a quick and easy adaptation to the process needs. The BioWelder® TC identifies each holder size when installed, which minimizes operator error. The standard BioWelder® TC unit is programmed with parameter sets for TuFlux® TPE, C-Flex® 374*, AdvantaFlex®, PharMed®* BPT and SaniPure™* BDF™.

Ease Of Use

A LCD touch screen guides the user through the operator menu. Each process step can easily be followed and monitored by the information provided on the display. The BioWelder® TC is equipped with an SD Card slot to allow loading and printing of the welding cycle data via a computer.

Fast Process Times

The average welding cycle times are between 1 min 30 and 2 min 30 which provides time savings along the process chain.

Ultra Safe Connection

The thermal weld produced by the BioWelder® TC have an extraordinary level of stability and guarantee a sterile connection. The thermal weld has been qualified by applying the most stringent and innovative test regimes. Biological, physical and extractable tests were combined to provide users with data representing a variety of process conditions. Methodologies and equipment are detailed in the validation guide.

Service

All units are individually tested before released to ensure maximum reliability. The Installation Qualification and Operational Qualification is recommended and should only be performed by Sartorius Stedim Biotech Service upon customer request. Calibration and maintenance contrat services are available for BioWelder® TC.

Summary table of validated TPE tubing materials and sizes which can be welded on BioWelder® TC

TPE tubing material	Welding parameter name installed on BioWelder® TC	Validated welding capabilities	Sterilization methods of tubing covered by the parameters	Tubing sizes and holders qualified per welding parameters						
				⅛" × ¼"	¼" × ⅜"	¼" × ⁷⁄₁₆"	⅜" × ⅝"	½" × ¾"	⅝" × ⅞"	¾" × 1"
TuFlux® TPE	TuFlux® TPE	TuFlux® TPE to TuFlux® TPE	G–G; A-A, G-A	×	×	×	×	×		×
TuFlux® TPE	TuFlux® TPE	TuFlux® TPE to C-Flex® 374	G–G; A-A, G-A	×	×	×	×	×		×
TuFlux® TPE	TuFlux® TPE	TuFlux® TPE to AdvantaFlex®	G–G; A-A, G-A	×	×	×	×	×		×
C-Flex® 374	C-Flex® 374	C-Flex® 374 to C-Flex® 374	G–G; A-A, G-A	×	×	×	×	×	×	×
AdvantaFlex®	AdvantaFlex®	AdvantaFlex® to AdvantaFlex®	G–G; A-A, G-A	×	×	×	×	×	×	×
Pharmed® BPT	Pharmed®	Pharmed® BPT to Pharmed® BPT	G–G; A-A, G-A		×	×	×	×	×	×
Sanipure® BDF	Sanipure®	Sanipure® BDF to Sanipure® BDF	G–G; A-A, G-A	×	×	×	×	×		

Note: G = gamma irradiated, A = autoclaved

Technical Specification

Type designation	BioWelder® TC, BWTC
Power connection	100 VAC – 240 VAC
Input frequency	50 | 60 Hz
Power input	300 VA
In and out connections	Device plug C14 max. 250VAC Ethernet jack type RJ45
Power connection of fuse	2 × 3.15 A T (Type FST)
Battery	CR2032
Operating temperature	+5℃ – +40℃ *
Place of use	Indoor (Laboratory)
Transient overvoltage	Overvoltage category II
Pollution degree	2
Altitude	up to 2000 m
Humidity	– 80% up to 31℃, linearly diminishing to 50% – relative humidity at 40℃, not condensing
Degree of protection	IP20
Weight	16.4 kg
External size (L × W × H)	555 mm × 261 mm × 269 mm

Power cord	According to local regulations – minimum 3 × AWG18 or 3 × 0.75 mm^2 – minimum local mains supply voltage
Tube holder size (ID × OD; color)	⅛" × ¼"; yellow ¼" × ⅜"; orange ¼" × ⁷⁄₁₆"; red ⅜" × ⅝"; white ½" × ¾"; grey ⅝" × ⅞"; green ¾" × 1"; blue
Welding Cycle	1 min 30 – 2 min 30 (depending on tube diameters and material)
Standard settings for	TuFlux® TPE, C-Flex® 374*, AdvantaFlex®, PharMed®* BPT, SaniPure™* BDF™
Minimum tubing length	450 mm
Max operating pressure validated	1 bar

* The device is programmed with standard parameter sets for welding TuFlux® TPE, C-Flex® 374, AdvantaFlex®, PharMed® BPT and SaniPure™ BDF™. These parameter sets have been validated at room temperature.

Ordering Information

Order Code	Description	Unit/box
16389	BioWelder® Total Containment	1
16389-009	BioWelder® TC Tube Holder ⅛" ID × ¼" OD	2
16389-010	BioWelder® TC Tube Holder ¼" ID × ⅜" OD	2
16389-011	BioWelder® TC Tube Holder ¼" ID × ⁷⁄₁₆" OD	2
16389-001	BioWelder® TC Tube Holder ⅜" ID × ⅝" OD	2
16389-002	BioWelder® TC Tube Holder ½" ID × ¾" OD	2
16389-003	BioWelder® TC Tube Holder ⅝" ID × ⅞" OD	2
16389-004	BioWelder® TC Tube Holder ¾" ID × 1" OD	2
16389-012	BioWelder® TC Disposable Blades in box (50)	1
16389-013	BioWelder® TC Blade Remover Tool	1
16389-006	Calibration Kit	1
16389-007	SD card	1
16389-008	Carrying case for BioWelder® TC Tube Holder (Max 6 sets)	1

Flexsafe® Pro Mixer Pre-designed Solutions
The Fast, Flexible and Intelligent Single-Use Mixer
for All Mixing Steps in cGMP Bioprocessing

turning science into solutions

Table of Contents

* for temperature sensor insertion

Digital Selection Map

Media Formulation
- pH sensor & Thermowell*
- Thermowell*
- No sensor

Buffer Formulation
- pH sensor & Thermowell* & Conductivity sensor
- Conductivity sensor & Thermowell*
- pH sensor & Thermowell*
- Thermowell*
- No sensor

Downstream Intermediates
- pH sensor & Thermowell*
- Thermowell*

Drug Substance Purification
- pH sensor & Thermowell*
- Thermowell*

Drug Product Formulation
- pH sensor & Thermowell*
- No sensor & with sterile connections and disconnections
- No sensor & with aseptic connections and disconnections under ISO laminar air flow

A Fast, Flexible and Intelligent Solution From 50 L up to 3,000 L

Building on 20 years of experience in designing single-use fluid management solutions, we have established Pre-designed Solutions (PDS) for all process steps where either powerful or low shear mixing performances are required.

The Flexsafe® Pro Mixer is a unique, single-use mixer that can accommodate a wide range of mixing steps in both upstream and downstream processes.

Flexsafe® Pro Mixer consists of three main components:

- Flexsafe® Pro Mixer Bag
- Palletank for Mixing
- Pro Mixer drive unit

Flexsafe® Pro Mixer technology combines speed and efficiency to deliver high performance mixing during powder dissolution and a levitating impeller to preserve the drug during low shear blending applications:

- Its strong vertical vortex combined with a baffle effect and cubical tank design enables instant downward movement and the efficient dissolution of floating powders such as media.

- Its high torque facilitates the efficient mixing of high concentration or viscous powders such as buffers.

- Its levitating impeller eliminates the shear effects that can impact product quality and prevents the generation of aggregates and particles that can reduce filtration performance.

- Low shear mixing combined with a high torque allows the homogenization, viral inactivation and formulation of sensitive drug substances and products

Drug Product Formulation, Fill and Finish

Downstream Intermediates to Drug Substances

Buffer Formulation
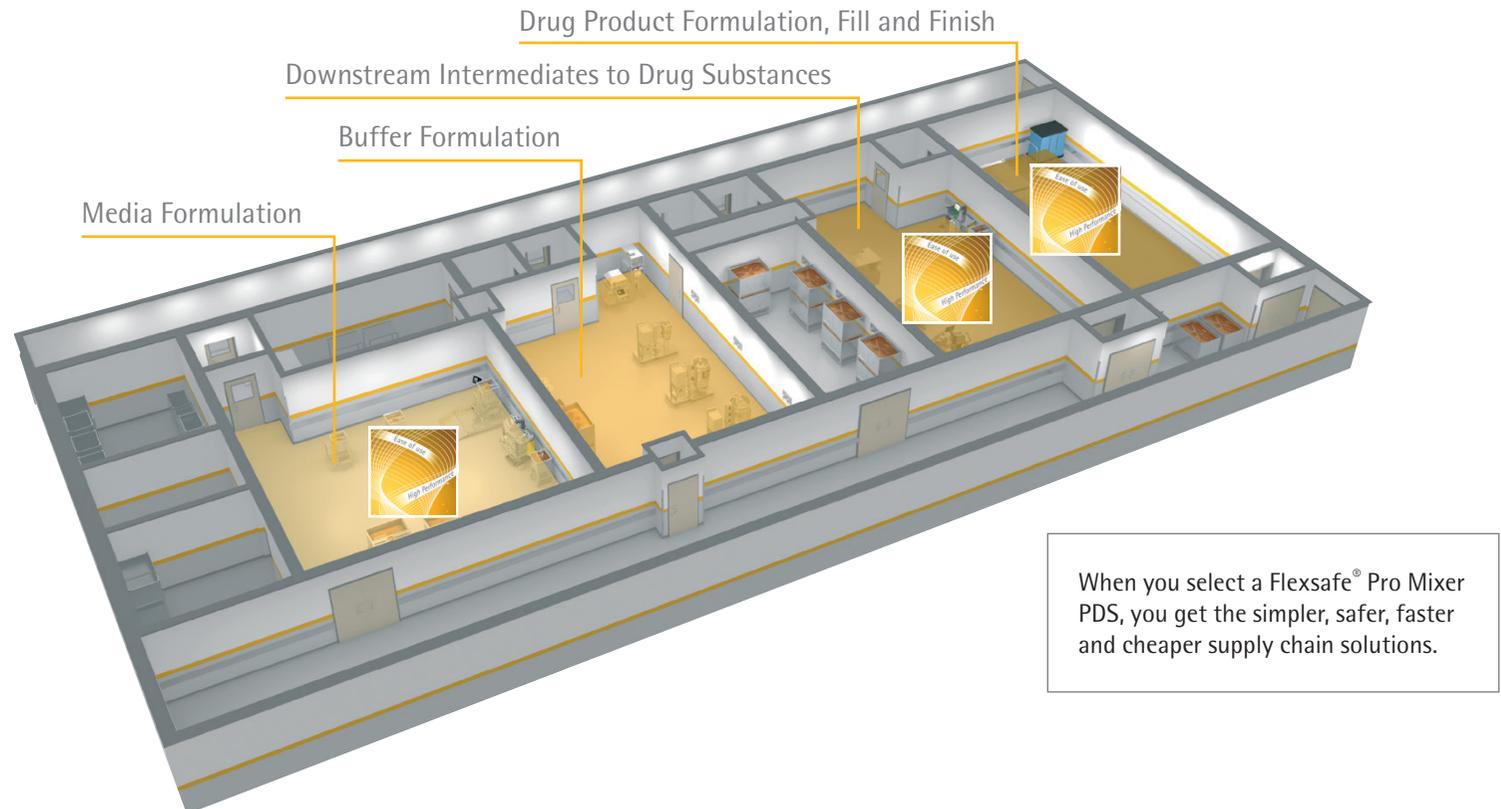
Media Formulation

When you select a Flexsafe® Pro Mixer PDS, you get the simpler, safer, faster and cheaper supply chain solutions.

A Fast, Flexible and Intelligent Solution from 50 L up to 3,000 L
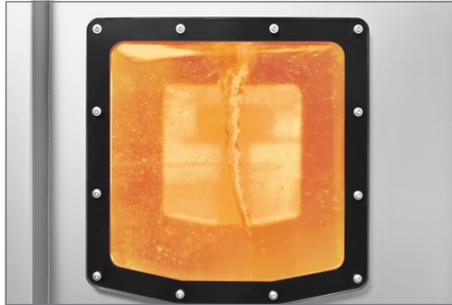
Media Formulation

Pre-designed Solutions for media formulation

Buffer Formulation

Pre-designed Solutions for buffer formulation

Downstream Intermediates

Pre-designed Solutions for downstream intermediates

Drug Substance Purification

Pre-designed Solutions for drug substance purification

Drug Product Formulation

Pre-designed Solutions for drug product formulation

Assurance of Supply for All Fluid-contact Components

Component Quality and Change Control

Fluid-contact components used for Flexsafe® Pro Mixer PDS are secured by long term contracts and quality agreements to offer the best assurance of supply.

Our supply contracts and quality agreements ensure at least a 24-month change notification on fluid-contact components thus providing robust change control and business continuity.

Fluid-contact components are also available off-the-shelf to offer the best delivery ability.

Material Qualification

Flexsafe® Pro Mixer PDS components are evaluated for conformity against the EP and USP standards after reviewing technical documentation and certificates of quality available from our suppliers.

Additional internal qualification tests are performed to establish extractable profiles, post gamma sterilization shelf life and consistent functional properties.

Criteria for Component Selection	Reference
Biological safety (USP Class VI)	USP<87> & USP<88>
TSE–BSE questionnaire	Compliance with EMA/410/01 and E.P 5.2.8
Endotoxin	USP<85> or EP 2.6.14
Bioburden	ISO 11737
Sub visible particles	USP<788> or EP 2.9.19
Others	Bisphenol A free, REACH compliance

Our core expertise in plastics and polymers enables the selection of the cleanest and most inert materials to minimize chemical interactions with biopharmaceutical fluids, and leacheable substances.

Design Qualification

Component designs are selected to maximize tubing engagement tensile strength and tightness. Test samples are visually inspected for absence of defect and tested for leak, burst pressure, traction and compression.

Using a Flexsafe® Pro Mixer Pre-designed Solution in all your process steps provide you with the best quality, change control, business continuity and delivery performances.

Flexsafe® Pro Mixer PDS

Components	Biocompatibility USP <87> or USP<88> Class VI	TSE–BSE EMA/410/01 & REACH
Flexsafe® Pro Mixer bags	Yes	Yes
Impeller and cup	Yes	Yes
Top ports	Yes	Yes
TuFlux® tubes	Yes	Yes
Opta® sterile connectors	Yes	Yes
Fittings	Yes	Yes
Connectors	Yes	Yes
Sensors (condutivity, pH, thermowell)	Yes	Yes
Drain valve	Yes	Yes

Validation and Quality Assurance

Flexsafe® Pro Mixer PDS are qualified against extensive biological, chemical, physical, extractable and functional testing.

Sartorius Stedim Biotech Quality Systems for single-use products follow applicable ISO 9001 standard. Design, manufacture, quality control and sterilization of PDS are conducted under conditions that mirror biopharmaceutical operations and meet cGMP like requirements to ensure they are supplied clean, pure, non-pyrogenic fluid path and sterile.

PDS are validated and routinely controlled to provide consistent performance for:

Robustness
- Internal standardized methods for connection tests and functional qualification in real process conditions
- ASTM D882, ASTM D3787, F392 for tensile properties, resistance to puncture and flex durability

Gas Transmission (Film)
- ASTM F3985, ISO 15106-3, ASTM F2476: Oxygen, Water Vapor Transmission Rate and Carbon Dioxide.

Biocompatibility and Chemical Compatibility
- USP<87>: Biological reactivity tests, in Vitro
- USP<88>: Biological reactivity tests, in Vivo
- USP<661> and EP 3.1.5: Containers, physico-chemical tests – Plastics
- ASTM D543-06: resistance of plastic to chemical reagents

Purity, Extractable and Leachable
- Extractable data
- TSE/BSE: EP 5.2.8

Cleanliness, Particles and Sterilization
- USP<788> and EP 2.9.19: Particulate Matter in Injections Endotoxin
- Visible particles: Representative product has been analyzed for particles with sizes ≥ 100 μm according to internally developed and validated method. Results are monitored.
- USP<85> and E.P. 2.6.14: Bacterial endotoxins Sterility
- ISO 11737 Sterilization of medical devices – Microbiological methods: Bioburden
- ISO 11137 Sterilization by irradiation of Medical Devices: Sterilization of Medical Devices
- ISO 14644: Cleanroom environmental controls
- Gamma radiation dose mapping

PDS for media, buffer, harvest & downstream intermediates and drug substance process steps are released on the basis of a weekly quality control for bioburden, sub-visible particulates and endotoxin performed on representative samples.

Media, Buffer, Downstream Intermediates & Drug substance	Drug Product[1]
Weekly testing of bioburden, sub-visible particles and endotoxin on representative sample	Lot release testing of bioburden, sub-visible particles and endotoxin on actual product sample

[1] None of the PDS for Drug Product are yet released on the basis of a lot release testing

Certificate of Release

Statement	Monitoring*	100% Batch testing	Particles prevention program
USP Class VI USP<87>: Biological reactivity tests, in Vitro USP<88>: Biological reactivity tests, in Vivo	**Bioburden** ISO 11737	**Gamma radiation** Dose	**Visible Particles monitoring**
	Endotoxin USP<85> and E.P. 2.6.14	**Visual inspection** Film, bag, seal and packaging	
Physico-chemical testing USP<661> and EP 3.1.5	**Sub-visible Particulates** USP<788> and EP 2.9.19 **Sterility** ISO 11137	**Technical Drawing conformity** Batch record review	
TSE/BSE EMA/410/01 rev 3 and EP 5.2.8			

* performed weekly on representative samples

The Fast, Flexible and Intelligent Solution for All Mixing Steps in cGMP Bioprocessing

Flexible and Ergonomic Design

Front door and cubical shape for an easy bag installation

Front access to sensors and tubing for easy manipulation

8 inches top opening for easy powder addition

Intelligent Mixing
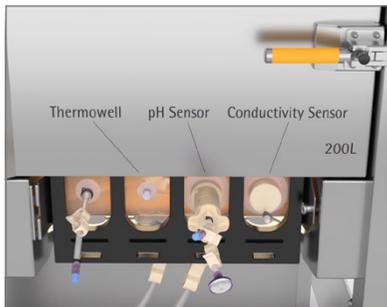
From left to right: sampling line, thermowell, pH sensor, conductivity sensor

Weight control (Picture of one load cell)

Heat exchange jacket and temperature control

Pro Mixer Drive unit touchscreen

The Flexible and Ergonomic Design of the Flexsafe® Pro Mixer 50 – 3,000 L Offers Ease of Use:

The Flexsafe® Pro Mixer Bag (50 –1,000 L) contains a central magnetic impeller assembly. Its unique sided K-weld design simplifies installation and facilitates the unfolding and folding of the bag during filling and draining operations. The 8" diameter top port allows easy and contained powder transfer into the mixing bag during buffer and media applications.

The Flexsafe® Pro Mixer Bag (1,500 to 3,000 L) contains an off-center magnetic impeller assembly and a 4" top port for powder transfer. Its bottom and top K-welds, combined with the Palletank lifting system, facilitates bag installation as well as filling and emptying operations.

The positioning of the tubing lines and sensors allow for easy installation and direct access during filling, sampling and draining.

The Flexsafe® Pro Mixer bag and Palletank are designed for easy product handling and quick-started processing just a few minutes after installation.

The drive unit touchscreen guides users from bag installation to the end of the mixing run with simple-to-follow instructions for each stage of the process.

Intelligent Mixing for Your cGMP Biomanufacturing

The Flexsafe® Pro Mixer provides the high levels of control that are essential for cGMP biomanufacturing:

- Inline control and monitoring of pH, conductivity and temperature are performed with a preassembled single-use pH probe, conductivity sensor and thermowell.
- Inline sensors meet PAT and cGMP requirements, eliminate the risk of contamination associated with reusable probes and reduce operator time.
- Palletank for Intelligent Mixers are available with weighing functions and heat exchange jackets for integrated volume and temperature control.
- The Pro Mixer drive unit features automated control, monitors the impeller speed, offers mixing recipes and includes password management.

One Unique Mixing Solution for All Mixing Steps in cGMP Bioprocessing

Top lines
- pH adjustment lines with CPC Quick coupler or Opta® SFT female

or when using drain valves on the bottom lines:
- top addition lines with CPC Quick coupler or Opta® SFT female
- and | or sampling line with clave needleless sampling port

Single-Use Sensors for in line measurement
- pH sensor with 2 calibration points
- Pre-calibrated conductivity sensor
- Thermowell for temperature measurement

Bottom Port
- Drain valve
- UPS 4 ports

Large 8'' diameter Top Port
- Opened Top Port for powder transfer
- Closed Top Port for sterile or low bioburden application

Mixing Technology
Flexsafe® Pro Mixer is unique single-use mixer for both upstream and downstream processes

Bottom Lines
- Filling line with Tri-Clamp connector or Opta® SFT female
- Draining line with Tri-Clamp connector or Opta® SFT male
- Addition lines with CPC Quick coupler or Opta® SFT female
- Sampling line using clave needleless sampling port

Inlet and Outlet Connectors

- Tri-Clamp 1½" sanitary flange are used for either sanitary connection or aseptic connection under ISO5 laminar air flow to stainless steel systems
- CPC quick couplers are used for either sanitary connection or aseptic connection under ISO5 laminar air flow to single-use systems
- Opta® SFT Female enables sterile connections to other single-use systems
- Clave needleless sampling port enables sterile sampling

Tubes

- TuFlux® Silicone tubing enables safe and fast pumping
- TuFlux® TPE tubing allows for sterile weld connection with BioWelder® TC and sterile seal disconnection with BioSealer®

Sensors

Single-use pH sensor:
- Electrochemical pH electrode with integrated Pt-1000
- Pre-installed and pre-sterilized single-use pH sensor
- Large measurement range pH2 – pH11, 4 – 50°C
- High accuracy after 2 points calibration: pH2 – pH11: ±0.8
- Retractable probe: 3 activations (insertion-removal-insertion) validated with maintained sterility

Single-use conductivity sensor:
- Pre-installed and pre-sterilized single-use conductivity sensor
- Pre-calibrated single-use conductivity sensor and ready to use
- Large measurement range 100μS/cm up to 200 mS/cm
- Accuracy:
  <100 mS/cm: 2%
  100 – 200 mS/cm: 5%

Thermowell:
- 3.2 mm ID for reusable temperature sensor insertion

Media Formulation

Media Formulation

| pH sensor & Thermowell |
| Thermowell |
| No sensor |

Flexsafe® Pro Mixer technology combines speed and efficiency to deliver high performance mixing during powder dissolution such as media powder.

An optimized media formulation process involves filling the mixer with water for injection (WFI) up to 60% to 80% of the final volume. WFI can be heated up with the heat exchange jacket to accelerate the dissolution. The mixing drive unit is started and the media powder or a concentrated liquid media is added during mixing.

Once the dissolution is complete, WFI is added to adjust to the final volume. Volume adjustment can be automatically performed using weighing control.

Temperature and pH can be monitored and adjusted in-line. Process samples are taken off-line for other QC tests.

When the formulation is complete, the media is filtered for sterilization and mycoplasma removal and stored before further transfer to the bioreactor.

Flexsafe® Pro Mixer PDS for media are available in:
- Intelligent version using single-use and integrated sensors for in-line pH and temperature monitoring and adjustment required for your cGMP biomanufacture.
- Without sensor using either reusable sensors via the 8" top opening for in-line controls or sampling in single-use bags for off-line controls.

Filling and draining lines are available with TuFlux® Silicone tubing and Tri-Clamp 1½" sanitary flange. Samples can be taken via an additional TuFlux® Silicone line equipped with a clave needleless sampling port.

The following options are also available:
- Lines for other liquid additions with TuFlux® Silicone tubing and quick coupler connector.
- Drain valves to prevent powder accumulation in bottom tubing lines.

Media Formulation

Media Formulation

| pH sensor & Thermowell |
| Thermowell |
| No sensor |

Example of a 200 L mixing bag equipped with pH sensor & Thermowell

Intelligent Flexsafe® Pro Mixer Bag with pH Sensor & Thermowell

Bag Volume	Part Number	Units per Box	Drain Valves	Top Port	Inlet	Outlet	Sampling	Addition 1	Addition 2	pH Adjustment
50 L	FMS500004	1	Yes	Opened 8" Top Port with gasket, cap & union	½" ID TuFlux® Silicone 1,5 m (60") + ½" Tri-Clamp 1½" sanitary flange with gasket, cap & union	½" ID TuFlux® Silicone 1,5 m (60") + ½" Tri-Clamp 1½" sanitary flange with gasket, cap & union	¼" ID TuFlux® Silicone 0.1 m (4") + Clave needleless sampling port	When drain valves: 1 top line: ⅜" ID TuFlux® Silicone 0.15 m (6") + MPC Female + sealing cap When no drain valve: 1 bottom line: ⅜" ID TuFlux® Silicone 1.5 m (60") + MPC Female + sealing cap	NA	2 top lines: ¼" ID TuFlux® Silicone 0.1 m (4") + MPC female + sealing cap
	FMS500042	1	No							
100 L	FMS500005	1	Yes							
	FMS500043	1	No							

Media Formulation

Media Formulation	pH sensor & Thermowell
	Thermowell
	No sensor

Example of a 200 L mixing bag equipped with pH sensor & Thermowell

Intelligent Flexsafe® Pro Mixer Bag with pH Sensor & Thermowell

Bag Volume	Part Number	Units per Box	Drain Valves	Top Port	Inlet	Outlet	Sampling	Addition 1	Addition 2	pH Adjustment
200 L	FMS500018	2	Yes	Opened 8" Top Port with gasket, cap & union	½" ID TuFlux® Silicone 1,5 m (60") + ½" Tri-Clamp 1½" sanitary flange with gasket, cap & union	½" ID TuFlux® Silicone 1,5 m (60") + ½" Tri-Clamp 1½" sanitary flange with gasket, cap & union	¼" ID TuFlux® Silicone 0.1 m (4") + Clave needleless sampling port	When drain valves: 1 bottom line: ½" ID TuFlux® Silicone 1.5 m (60") + MPC Female + sealing cap When no drain valve: 1 bottom line: ⅜" ID TuFlux® Silicone 1.5 m (60") + MPC Female + sealing cap	When drain valves: 1 bottom line: ½" ID TuFlux® Silicone 1.5 m (60") + MPC Female + sealing cap When no drain valve: 1 bottom line: ⅜" ID TuFlux® Silicone 1.5 m (60") + MPC Female + sealing cap	2 top lines: ¼" ID TuFlux® Silicone 0.1 m (4") + MPC female + sealing cap
	FMS500038	2	No							
400 L	FMS500019	2	Yes							
	FMS500039	2	No							
650 L	FMS500020	1	Yes							
	FMS500040	1	No							
1,000 L	FMS500021	1	Yes							
	FMS500041	1	No							
1,500 L	FMS500022	1	No							
2,000 L	FMS500023	1	No							
2,500 L	FMS500024	1	No							
3,000 L	FMS500025	1	No							

Media Formulation

Media Formulation

pH sensor & Thermowell
Thermowell
No sensor

Example of a 200 L mixing bag equipped with Thermowell

Intelligent Flexsafe® Pro Mixer Bag with Thermowell

Bag Volume	Part Number	Units per Box	Drain Valves	Top Port	Inlet	Outlet	Sampling	Addition 1	Addition 2	pH Adjustment
50 L	FMS500044	1	Yes	Opened 8" Top Port with gasket, cap & union	½" ID TuFlux® Silicone 1,5 m (60") + ½" Tri-Clamp 1½" sanitary flange with gasket, cap & union	½" ID TuFlux® Silicone 1,5 m (60") + ½" Tri-Clamp 1½" sanitary flange with gasket, cap & union	¼" ID TuFlux® Silicone 0.1 m (4") + Clave needleless sampling port	When drain valves: Top line: ³⁄₈'' ID TuFlux® Silicone 0.15 m (6") + MPC Female + sealing cap When no drain valve: Bottom line: ³⁄₈'' ID TuFlux® Silicone 1.5 m (60") + MPC Female + sealing cap	When drain valves: Top line: ³⁄₈'' ID TuFlux® Silicone 0.15 m (6") + MPC Female + sealing cap When no drain valve: Bottom line: ³⁄₈'' ID TuFlux® Silicone 1.5 m (60") + MPC Female + sealing cap	2 top lines: ¼" ID TuFlux® Silicone 0.1 m (4") + MPC female + sealing cap
	FMS500045	1	No							
100 L	FMS500046	1	Yes							
	FMS500047	1	No							

Flexsafe® Pro Mixer Pre-designed Solutions for

Media Formulation

Media Formulation	pH sensor & Thermowell
	Thermowell
	No sensor

Example of a 200 L mixing bag equipped with Thermowell

Intelligent Flexsafe® Pro Mixer Bag with Thermowell

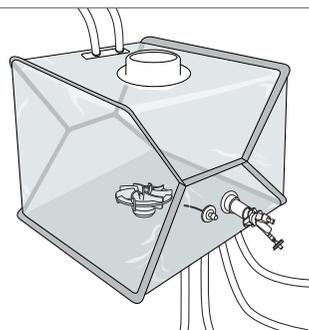| Bag Volume	Part Number	Units per Box	Drain Valves	Top Port	Inlet	Outlet	Sampling	Addition 1	Addition 2	pH Adjustment
200 L	FMS500048	2	Yes	Opened 8" Top Port with gasket, cap & union	½" ID TuFlux® Silicone 1,5 m (60") + ½" Tri-Clamp 1½" sanitary flange with gasket, cap & union	½" ID TuFlux® Silicone 1,5 m (60") + ½" Tri-Clamp 1½" sanitary flange with gasket, cap & union	¼" ID TuFlux® Silicone 0.1 m (4") + Clave needleless sampling port	When drain valves: Bottom line: ½" ID TuFlux® Silicone 1.5 m (60") + MPC Female + sealing cap When no drain valve: Bottom line: ⅜" ID TuFlux® Silicone 1.5 m (60") + MPC Female + sealing cap	When drain valves: Bottom line: ½" ID TuFlux® Silicone 1.5 m (60") + MPC Female + sealing cap When no drain valve: Bottom line: 3/8" ID TuFlux® Silicone 1.5 m (60") + MPC Female + sealing cap	2 top lines: ¼" ID TuFlux® Silicone 0.1 m (4") + MPC female + sealing cap
	FMS500049	2	No							
400 L	FMS500050	2	Yes							
	FMS500051	2	No							
650 L	FMS500052	1	Yes							
	FMS500053	1	No							
1,000 L	FMS500054	1	Yes							
	FMS500055	1	No							
1,500 L	FMS500056	1	No	Opened 4" Top Port with gasket, cap & union	1" ID TuFlux® Silicone 3 m (119") + 1" Tri-Clamp 1½" sanitary flange with gasket, cap & union	1" ID TuFlux® Silicone 3 m (119") + 1" Tri-Clamp 1½" sanitary flange with gasket, cap & union	¼" ID TuFlux® Silicone 0.1 m (4") + Clave needleless sampling port	¾" ID TuFlux® Silicone 1,5 m (60") + ¾" Tri-Clamp 1½" sanitary flange with gasket, cap & union	¾" ID TuFlux® Silicone 1,5 m (60") + ¾" Tri-Clamp 1½" sanitary flange with gasket, cap & union	
2,000 L	FMS500057	1	No							
2,500 L	FMS500058	1	No							
3,000 L	FMS500059	1	No							

Media Formulation

| pH sensor & Thermowell |
| Thermowell |
| No sensor |

Media Formulation

Example of a 200 L mixing bag without single-use sensor

Flexsafe® Pro Mixer Without Single-use Sensor

Bag Volume	Part Number	Units per Box	Drain Valves	Top Port	Inlet	Outlet	Sampling	Addition 1	Addition 2	pH Adjustment
50 L	FMS500060	1	Yes	Opened 8" Top Port with gasket, cap & union	½" ID TuFlux® Silicone 1,5 m (60") + ½" Tri-Clamp 1½" sanitary flange with gasket, cap & union	½" ID TuFlux® Silicone 1,5 m (60") + ½" Tri-Clamp 1½" sanitary flange with gasket, cap & union	¼" ID TuFlux® Silicone 0.1 m (4") + Clave needleless sampling port	NA	NA	NA
	FMS500061	1	No							
100 L	FMS500062	1	Yes							
	FMS500063	1	No							
200 L	FMS500064	2	Yes							
	FMS500065	2	No							
400 L	FMS500066	2	Yes							
	FMS500067	2	No							
650 L	FMS500068	1	Yes							
	FMS500069	1	No							
1,000 L	FMS500070	1	Yes							
	FMS500071	1	No							
1,500 L	FMS500072	1	No	Opened 4" Top Port with gasket, cap & union	1" ID TuFlux® Silicone 3 m (119") + 1" Tri-Clamp 1½" sanitary flange with gasket, cap & union	1" ID TuFlux® Silicone 3 m (119") + 1" Tri-Clamp 1½" sanitary flange with gasket, cap & union	¼" ID TuFlux® Silicone 0.1 m (4") + Clave needleless sampling port			
2,000 L	FMS500073	1	No							
2,500 L	FMS500074	1	No							
3,000 L	FMS500075	1	No							

Buffer Formulation

pH sensor, conductivity sensor & Thermowell

Conductivity sensor & Thermowell

Buffer Formulation

pH sensor & Thermowell

Thermowell

No sensor
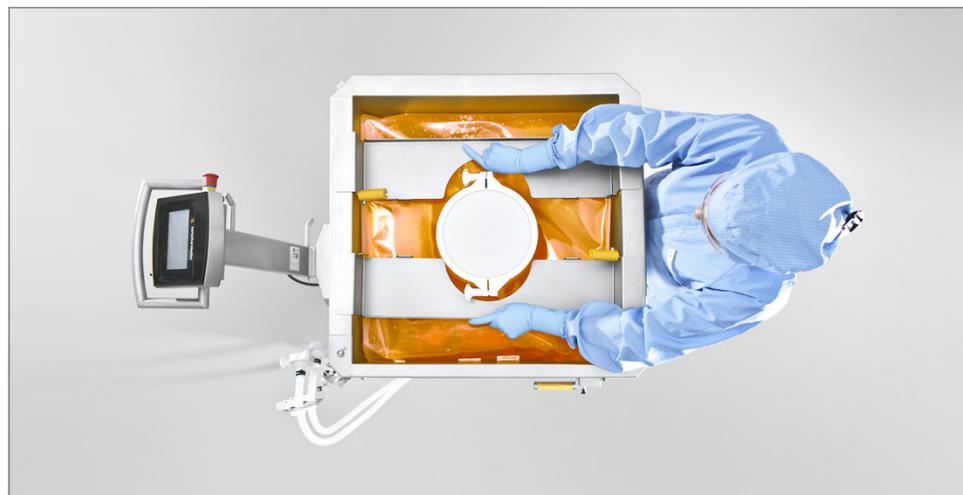
Flexsafe® Pro Mixer technology combines speed and efficiency to deliver high performance mixing during powder dissolution such as buffer powder.

An optimized buffer formulation process involves filling the mixer with water for injection (WFI) up to 60% to 80% of the final volume. WFI can be heated up with the heat exchange jacket to accelerate the dissolution. The mixing drive unit is started and the buffer powder or a concentrated liquid buffer is added during mixing.

Once the dissolution is complete, WFI is added to adjust to the final volume. Volume adjustment can be automatically performed using weighing control.

Temperature, conductivity, and pH can be monitored and adjusted in-line. Process samples are taken off-line for other QC tests.

When the formulation is complete, the buffer is sterile filtered and stored before further use for drug substance purification or final drug product formulation.

Flexsafe® Pro Mixer PDS for buffer are available in:
• Intelligent version using single-use and integrated sensors for in-line pH, conductivity and temperature monitoring and adjustment required for your cGMP biomanufacture.
• Without sensor using either reusable sensors via the 8" top opening for in-line controls or sampling in single-use bags for off-line controls.

Filling and draining lines are available with TuFlux® Silicone tubing and Tri-Clamp 1½" sanitary flange. Samples can be taken via TuFlux® Silicone line equiped with a clave needleless sampling port.

The following options are also available:
• Lines for liquid additions with TuFlux® Silicone tubing and quick coupler connector.
• Drain valves to prevent powder accumulation in bottom mounted tubing.

Buffer Formulation

| pH sensor, conductivity sensor & Thermowell |
| Conductivity sensor & Thermowell |
| pH sensor & Thermowell |
| Thermowell |
| No sensor |

Buffer Formulation

Example of a 200 L mixing bag equipped with pH sensor, conductivity sensor & Thermowell

Intelligent Flexsafe® Pro Mixer Bag with pH Sensor, Conductivity sensor & Thermowell

Bag Volume	Part Number	Units per Box	Drain Valves	Top Port	Inlet	Outlet	Sampling	Addition 1	Addition 2	pH Adjustment
50 L	FMS500014	1	Yes	Opened 8" Top Port with gasket, cap & union	½" ID TuFlux® Silicone 1,5 m (60") + ½" Tri-Clamp 1½" sanitary flange with gasket, cap & union	½" ID TuFlux® Silicone 1,5 m (60") + ½" Tri-Clamp 1½" sanitary flange with gasket, cap & union	¼" ID TuFlux® Silicone 0.1 m (4") + Clave needleless sampling port	When drain valves: NA When no drain valve: 1 top line: ⅜" ID TuFlux® Silicone 0.15 m (6") + MPC Female + sealing cap	When drain valves: NA When no drain valve: 1 top line: ⅜" ID TuFlux® Silicone 0.15 m (6") + MPC Female + sealing cap	2 top lines: ¼" ID TuFlux® Silicone 0.1 m (4") + MPC female + sealing cap
	FMS500015	1	No							
100 L	FMS500017	1	Yes							
	FMS500016	1	No							

Buffer Formulation

| pH sensor, conductivity sensor & Thermowell |
| Conductivity sensor & Thermowell |
| pH sensor & Thermowell |
| Thermowell |
| No sensor |

Buffer Formulation

Example of a 200 L mixing bag equipped with pH sensor, conductivity sensor & Thermowell

Intelligent Flexsafe® Pro Mixer Bag with pH Sensor, Conductivity sensor & Thermowell

Bag Volume	Part Number	Units per Box	Drain Valves	Top Port	Inlet	Outlet	Sampling	Addition 1	Addition 2	pH Adjustment
200 L	FMS500006	2	Yes	Opened 8" Top Port with gasket, cap & union	½" ID TuFlux® Silicone 1,5 m (60") + ½" Tri-Clamp 1½" sanitary flange with gasket, cap & union	½" ID TuFlux® Silicone 1,5 m (60") + ½" Tri-Clamp 1½" sanitary flange with gasket, cap & union	¼" ID TuFlux® Silicone 0.1 m (4") + Clave needleless sampling port	When drain valves: 1 bottom line: ½" ID TuFlux® Silicone 1.5 m (60") + MPC Female + sealing cap When no drain valve: 1 bottom line: ⅜'' ID TuFlux® Silicone 1.5 m (60") + MPC Female + sealing cap	When drain valves: 1 bottom line: ½" ID TuFlux® Silicone 1.5 m (60") + MPC Female + sealing cap When no drain valve: 1 bottom line: ⅜'' ID TuFlux® Silicone 1.5 m (60") + MPC Female + sealing cap	2 top lines: ¼" ID TuFlux® Silicone 0.1 m (4") + MPC female + sealing cap
	FMS500007	2	No							
400 L	FMS500008	2	Yes							
	FMS500009	2	No							
650 L	FMS500010	1	Yes							
	FMS500011	1	No							
1,000 L	FMS500012	1	Yes							
	FMS500013	1	No							
1,500 L	FMS500000	1	No	Opened 4" Top Port with gasket, cap & union	1" ID TuFlux® Silicone 3 m (119") +1" Tri-Clamp 1½" sanitary flange with gasket, cap & union	1" ID TuFlux® Silicone 3 m (119") +1" Tri-Clamp 1½" sanitary flange with gasket, cap & union	¼" ID TuFlux® Silicone 0.1 m (4") + Clave needleless sampling port	¾" ID TuFlux® Silicone 1,5 m (60") + ¾" Tri-Clamp 1½" sanitary flange with gasket, cap & union	¾" ID TuFlux® Silicone 1,5 m (60") + ¾" Tri-Clamp 1½"sanitary flange with gasket, cap & union	
2,000 L	FMS500001	1	No							
2,500 L	FMS500002	1	No							
3,000 L	FMS500003	1	No							

18   Flexsafe® Pro Mixer Pre-designed Solutions for

Buffer Formulation

Buffer Formulation	pH sensor, conductivity sensor & Thermowell
	Conductivity sensor & Thermowell
	pH sensor & Thermowell
	Thermowell
	No sensor

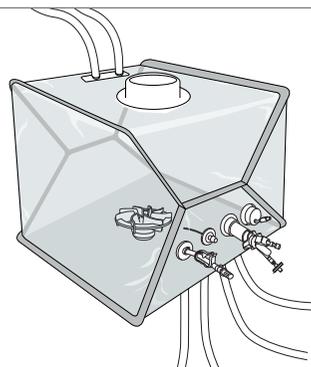Example of a 200 L mixing bag equipped with conductivity sensor & Thermowell

Intelligent Flexsafe® Pro Mixer with Conductivity sensor & Thermowell

Bag Volume	Part Number	Units per Box	Drain Valves	Top Port	Inlet	Outlet	Sampling	Addition 1	Addition 2	pH Adjustment
50 L	FMS500112	1	Yes	Opened 8" Top Port with gasket, cap & union	½" ID TuFlux® Silicone 1,5 m (60") + ½" Tri-Clamp 1½" sanitary flange with gasket, cap & union	½" ID TuFlux® Silicone 1,5 m (60") + ½" Tri-Clamp 1½" sanitary flange with gasket, cap & union	¼" ID TuFlux® Silicone 0.1 m (4") + Clave needleless sampling port	When drain valves: 1 top line: ³⁄₈" ID TuFlux® Silicone 0.15 m (6") + MPC Female + sealing cap When no drain valve: 1 bottom line: ³⁄₈" ID TuFlux® Silicone 1.5 m (60") + MPC Female + sealing cap	NA	NA
	FMS500138	1	No							
100 L	FMS500113	1	Yes							
	FMS500139	1	No							

Buffer Formulation

| pH sensor, conductivity sensor & Thermowell |
| Conductivity sensor & Thermowell |
| pH sensor & Thermowell |
| Thermowell |
| No sensor |

Buffer Formulation

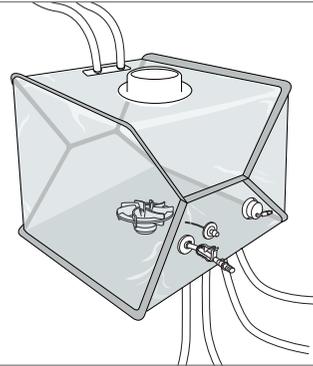Example of a 200 L mixing bag equipped with conductivity sensor & Thermowell

Intelligent Flexsafe® Pro Mixer with Conductivity sensor & Thermowell

Bag Volume	Part Number	Units per Box	Drain Valves	Top Port	Inlet	Outlet	Sampling	Addition 1	Addition 2	pH Adjustment
200 L	FMS500026	2	Yes	Opened 8" Top Port with gasket, cap & union	½" ID TuFlux® Silicone 1,5 m (60") + ½" Tri-Clamp 1½" sanitary flange with gasket, cap & union	½" ID TuFlux® Silicone 1,5 m (60") + ½" Tri-Clamp 1½" sanitary flange with gasket, cap & union	¼" ID TuFlux® Silicone 0.1 m (4") + Clave needleless sampling port	When drain valves: 1 bottom line: ½" ID TuFlux® Silicone 1.5 m (60") + MPC Female + sealing cap When no drain valve: 1 bottom line: ⅜'' ID TuFlux® Silicone 1.5 m (60") + MPC Female + sealing cap	When drain valves: 1 bottom line: ½" ID TuFlux® Silicone 1.5 m (60") + MPC Female + sealing cap When no drain valve: 1 bottom line: ⅜'' ID TuFlux® Silicone 1.5 m (60") + MPC Female + sealing cap	NA
	FMS500027	2	No							
400 L	FMS500028	2	Yes							
	FMS500029	2	No							
650 L	FMS500030	1	Yes							
	FMS500031	1	No							
1,000 L	FMS500032	1	Yes							
	FMS500033	1	No							
1,500 L	FMS500034	1	No	Opened 4" Top Port with gasket, cap & union	1" ID TuFlux® Silicone 3 m (119") +1" Tri-Clamp 1½" sanitary flange with gasket, cap & union	1" ID TuFlux® Silicone 3 m (119") +1" Tri-Clamp 1½" sanitary flange with gasket, cap & union	¼" ID TuFlux® Silicone 0.1 m (4") + Clave needleless sampling port	¾" ID TuFlux® Silicone 1,5 m (60") + ¾" Tri-Clamp 1½" sanitary flange with gasket, cap & union	¾" ID TuFlux® Silicone 1,5 m (60") + ¾" Tri-Clamp 1½"sanitary flange with gasket, cap & union	
2,000 L	FMS500035	1	No							
2,500 L	FMS300036	1	No							
3,000 L	FMS300037	1	No							

20   Flexsafe® Pro Mixer Pre-designed Solutions for

Buffer Formulation

pH sensor, conductivity sensor & Thermowell

Conductivity sensor & Thermowell

pH sensor & Thermowell

Thermowell

No sensor

Buffer Formulation

Example of a 200 L mixing bag equipped with pH sensor & Thermowell

Intelligent Flexsafe® Pro Mixer with pH Sensor & Thermowell

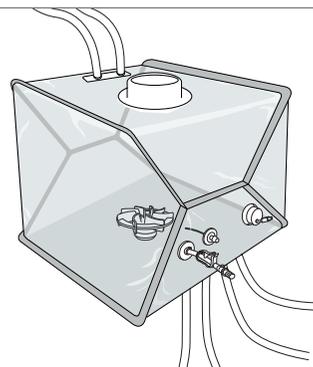| Bag Volume	Part Number	Units per Box	Drain Valves	Top Port	Inlet	Outlet	Sampling	Addition 1	Addition 2	pH Adjustment
50 L	FMS500004	1	Yes	Opened 8" Top Port with gasket, cap & union	½" ID TuFlux® Silicone 1,5 m (60") + ½" Tri-Clamp 1½" sanitary flange with gasket, cap & union	½" ID TuFlux® Silicone 1,5 m (60") + ½" Tri-Clamp 1½" sanitary flange with gasket, cap & union	¼" ID TuFlux® Silicone 0.1 m (4") + Clave needleless sampling port	When drain valves: 1 top line: ³⁄₈" ID TuFlux® Silicone 0.15 m (6") + MPC Female + sealing cap	NA	2 top lines: ¼" ID TuFlux® Silicone 0.1 m (4") + MPC female + sealing cap
	FMS500042	1	No							
100 L	FMS500005	1	Yes					When no drain valve: 1 bottom line: ³⁄₈" ID TuFlux® Silicone 1.5 m (60") + MPC Female + sealing cap		
	FMS500043	1	No							

Buffer Formulation

pH sensor, conductivity sensor & Thermowell	
Conductivity sensor & Thermowell	Example of a 200 L mixing bag equipped with pH sensor & Thermowell
pH sensor & Thermowell	
Thermowell	
No sensor	

Buffer Formulation

Intelligent Flexsafe® Pro Mixer with pH Sensor & Thermowell

Bag Volume	Part Number	Units per Box	Drain Valves	Top Port	Inlet	Outlet	Sampling	Addition 1	Addition 2	pH Adjustment
200 L	FMS500018	2	Yes	Opened 8" Top Port with gasket, cap & union	½" ID TuFlux® Silicone 1,5 m (60") + ½" Tri-Clamp 1½" sanitary flange with gasket, cap & union	½" ID TuFlux® Silicone 1,5 m (60") + ½" Tri-Clamp 1½" sanitary flange with gasket, cap & union	¼" ID TuFlux® Silicone 0.1 m (4") + Clave needleless sampling port	When drain valves: 1 bottom line: ½" ID TuFlux® Silicone 1.5 m (60") + MPC Female + sealing cap When no drain valve: 1 bottom line: ⅜'' ID TuFlux® Silicone 1.5 m (60") + MPC Female + sealing cap	When drain valves: 1 bottom line: ½" ID TuFlux® Silicone 1.5 m (60") + MPC Female + sealing cap When no drain valve: 1 bottom line: ⅜'' ID TuFlux® Silicone 1.5 m (60") + MPC Female + sealing cap	2 top lines: ¼" ID TuFlux® Silicone 0.1 m (4") + MPC female + sealing cap
	FMS500038	2	No							
400 L	FMS500019	2	Yes							
	FMS500039	2	No							
650 L	FMS500020	1	Yes							
	FMS500040	1	No							
1,000 L	FMS500021	1	Yes							
	FMS500041	1	No							
1,500 L	FMS500022	1	No	Opened 4" Top Port with gasket, cap & union	1" ID TuFlux® Silicone 3 m (119") +1" Tri-Clamp 1½" sanitary flange with gasket, cap & union	1" ID TuFlux® Silicone 3 m (119") +1" Tri-Clamp 1½" sanitary flange with gasket, cap & union	¼" ID TuFlux® Silicone 0.1 m (4") + Clave needleless sampling port	¾" ID TuFlux® Silicone 1,5 m (60") + ¾" Tri-Clamp 1½" sanitary flange with gasket, cap & union	¾" ID TuFlux® Silicone 1,5 m (60") + ¾" Tri-Clamp 1½"sanitary flange with gasket, cap & union	
2,000 L	FMS500023	1	No							
2,500 L	FMS500024	1	No							
3,000 L	FMS500025	1	No							

Buffer Formulation

pH sensor, conductivity sensor & Thermowell

Conductivity sensor & Thermowell

Buffer Formulation

pH sensor & Thermowell

Thermowell

No sensor

Example of a 200 L mixing bag equipped with Thermowell

Intelligent Flexsafe® Pro Mixer with Thermowell

Bag Volume	Part Number	Units per Box	Drain Valves	Top Port	Inlet	Outlet	Sampling	Addition 1	Addition 2	pH Adjustment
50 L	FMS500044	1	Yes	Opened 8" Top Port with gasket, cap & union	½" ID TuFlux® Silicone 1,5 m (60") + ½" Tri-Clamp 1½" sanitary flange with gasket, cap & union	½" ID TuFlux® Silicone 1,5 m (60") + ½" Tri-Clamp 1½" sanitary flange with gasket, cap & union	¼" ID TuFlux® Silicone 0.1 m (4") + Clave needleless sampling port	When drain valves: Top line: ⅜" ID TuFlux® Silicone 0.15 m (6") + MPC Female + sealing cap When no drain valve: Bottom line: ⅜" ID TuFlux® Silicone 1.5 m (60") + MPC Female + sealing cap	When drain valves: Top line: ⅜" ID TuFlux® Silicone 0.15 m (6") + MPC Female + sealing cap When no drain valve: Bottom line: ⅜" ID TuFlux® Silicone 1.5 m (60") + MPC Female + sealing cap	2 top lines: ¼" ID TuFlux® Silicone 0.1 m (4") + MPC female + sealing cap
	FMS500045	1	No							
100 L	FMS500046	1	Yes							
	FMS500047	1	No							

Buffer Formulation

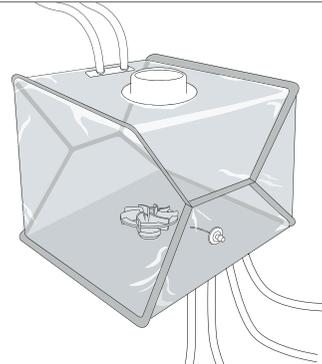|	
Buffer Formulation	pH sensor, conductivity sensor & Thermowell
	Conductivity sensor & Thermowell
	pH sensor & Thermowell
	Thermowell
	No sensor

Example of a 200 L mixing bag equipped with Thermowell

Intelligent Flexsafe® Pro Mixer with Thermowell

Bag Volume	Part Number	Units per Box	Drain Valves	Top Port	Inlet	Outlet	Sampling	Addition 1	Addition 2	pH Adjustment
200 L	FMS500048	2	Yes	Opened 8" Top Port with gasket, cap & union	½" ID TuFlux® Silicone 1,5 m (60") + ½" Tri-Clamp 1½" sanitary flange with gasket, cap & union	½" ID TuFlux® Silicone 1,5 m (60") + ½" Tri-Clamp 1½" sanitary flange with gasket, cap & union	¼" ID TuFlux® Silicone 0.1 m (4") + Clave needleless sampling port	When drain valves: Bottom line: ½" ID TuFlux® Silicone 1.5 m (60") + MPC Female + sealing cap	When drain valves: Bottom line: ½" ID TuFlux® Silicone 1.5 m (60") + MPC Female + sealing cap	2 top lines: ¼" ID TuFlux® Silicone 0.1 m (4") + MPC female + sealing cap
	FMS500049	2	No							
400 L	FMS500050	2	Yes							
	FMS500051	2	No					When no drain valve: Bottom line: ⅜" ID TuFlux® Silicone 1.5 m (60") + MPC Female + sealing cap	When no drain valve: Bottom line: 3/8" ID TuFlux® Silicone 1.5 m (60") + MPC Female + sealing cap	
650 L	FMS500052	1	Yes							
	FMS500053	1	No							
1,000 L	FMS500054	1	Yes							
	FMS500055	1	No							
1,500 L	FMS500056	1	No	Opened 4" Top Port with gasket, cap & union	1" ID TuFlux® Silicone 3 m (119") + 1" Tri-Clamp 1½" sanitary flange with gasket, cap & union	1" ID TuFlux® Silicone 3 m (119") + 1" Tri-Clamp 1½" sanitary flange with gasket, cap & union	¼" ID TuFlux® Silicone 0.1 m (4") + Clave needleless sampling port	¾" ID TuFlux® Silicone 1,5 m (60") + ¾" Tri-Clamp 1½" sanitary flange with gasket, cap & union	¾" ID TuFlux® Silicone 1,5 m (60") + ¾" Tri-Clamp 1½" sanitary flange with gasket, cap & union	
2,000 L	FMS500057	1	No							
2,500 L	FMS500058	1	No							
3,000 L	FMS500059	1	No							

Buffer Formulation

| pH sensor, conductivity sensor & Thermowell |
| Conductivity sensor & Thermowell |
| **Buffer Formulation** |
| pH sensor & Thermowell |
| Thermowell |
| No sensor |

Example of a 200 L mixing bag without single-use sensor

Flexsafe® Pro Mixer Without Single-use Sensor

Bag Volume	Part Number	Units per Box	Drain Valves	Top Port	Inlet	Outlet	Sampling	Addition 1	Addition 2	pH Adjustment
50 L	FMS500060	1	Yes	Opened 8" Top Port with gasket, cap & union	½" ID TuFlux® Silicone 1,5 m (60") + ½" Tri-Clamp 1½" sanitary flange with gasket, cap & union	½" ID TuFlux® Silicone 1,5 m (60") + ½" Tri-Clamp 1½" sanitary flange with gasket, cap & union	¼" ID TuFlux® Silicone 0.1 m (4") + Clave needleless sampling port	NA	NA	NA
	FMS500061	1	No							
100 L	FMS500062	1	Yes							
	FMS500063	1	No							
200 L	FMS500064	2	Yes							
	FMS500065	2	No							
400 L	FMS500066	2	Yes							
	FMS500067	2	No							
650 L	FMS500068	1	Yes							
	FMS500069	1	No							
1,000 L	FMS500070	1	Yes							
	FMS500071	1	No							
1,500 L	FMS500072	1	No	Opened 4" Top Port with gasket, cap & union	1" ID TuFlux® Silicone 3 m (119") + 1" Tri-Clamp 1½" sanitary flange with gasket, cap & union	1" ID TuFlux® Silicone 3 m (119") + 1" Tri-Clamp 1½" sanitary flange with gasket, cap & union	¼" ID TuFlux® Silicone 0.1 m (4") + Clave needleless sampling port			
2,000 L	FMS500073	1	No							
2,500 L	FMS500074	1	No							
3,000 L	FMS500075	1	No							

Downstream Intermediates

Downstream Intermediates

pH sensor & Thermowell
Thermowell

Flexsafe® Pro Mixer technology allows low shear mixing to preserve the drug during viral inactivation. PDS are designed with single-use sensors for safe and reliable use along the process steps.

Low pH viral inactivation of downstream process intermediates consists of 3 steps:

The pH of the downstream intermediate is first reduced and maintained at low pH for a validated period of time, usually at pH 3–4 for an hour, until the virus is totally inactivated. The low pH inactivation is followed by a neutralisation step where the pH is increased, usually up to pH 7–8 and a final filtration.

All three steps require mixing for inactivation, neutralization and homogenization.

To ensure that the entire content of the first mixer is inactivated, including droplets on the mixer wall or dead volume inside tubing, some processes are operated using 3 single-use mixing bags:
- 1 for low pH viral inactivation
- 1 for neutralisation
- 1 for homogenization of the filtered drug substance.

Some processes are operated with two single-use mixing bags by combining the 2 mixing steps, low pH inactivation and neutralisation, into the same single-use mixing bag.

PDS for Low pH virus inactivation and neutralisation are designed with:
- Fully closed 8″ diameter top port for a safe mixing.
- Integrated single-use pH sensor and thermowell for in-line monitoring and control of the inactivation process.
- Top lines with TuFlux® Silicone tubing and quick coupler connector for pH adjustment.
- Bottom lines with TuFlux® Silicone tubing and Tri-Clamp 1½″ sanitary flange for filling and draining.
- Bottom lines with TuFlux® Silicone tubing and clave needleless port for sterile sampling.

The following options are also available:
- Lines for other liquid additions with TuFlux® Silicone tubing and quick coupler connector.
- Drain valves to avoid hold up volumes into the tubes.

PDS for post filtration are designed with:
- Integrated thermowell for temperature monitoring and control.
- A combined TuFlux® Silicone + TuFlux® TPE tubing ended by an Opta® SFT female to allow sterile connection and disconnection of the adequate filter line.
- A combined TuFlux® Silicone + TuFlux® TPE tubing ended by a Tri-Clamp 1 ½″ sanitary flange for draining.
- Bottom line with TuFlux® Silicone tubing and clave needleless port for sterile sampling.
- Bottom line with TuFlux® Silicone tubing and quick coupler connector for liquid additions.

Downstream Intermediates

| Downstream Intermediates | pH sensor & Thermowell |
| | Thermowell |

Example of a 200 L mixing bag equipped with pH sensor & Thermowell

Flexsafe® Pro Mixer with pH Sensor and Thermowell for Low pH Viral Inactivation and Neutralisation

Bag Volume	Part Number	Units per Box	Drain Valves	Top Port	Inlet	Outlet	Sampling	Addition 1	Addition 2	pH Adjustment
50 L	FMS500076	1	Yes	Closed 8" Top Port	½" ID TuFlux® Silicone 1,5 m (60") + ½" Tri-Clamp 1½" sanitary flange with gasket, cap & union	½" ID TuFlux® Silicone 1,5 m (60") + ½" Tri-Clamp 1½" sanitary flange with gasket, cap & union	¼" ID TuFlux® Silicone 0.1 m (4") + Clave needleless sampling port	When drain valves: 1 top line: ³⁄₈" ID TuFlux® Silicone 0.15 m (6") + MPC Female + sealing cap

When no drain valve: 1 bottom line: ³⁄₈" ID TuFlux® Silicone 1.5 m (60") + MPC Female + sealing cap | NA | 2 top lines: ¼" ID TuFlux® Silicone 0.1 m (4") + MPC female + sealing cap |
	FMS500077	1	No							
100 L	FMS500078	1	Yes							
	FMS500079	1	No							

Downstream Intermediates

Downstream Intermediates

pH sensor & Thermowell
Thermowell

Example of a 200 L mixing bag equipped with pH sensor & Thermowell

Flexsafe® Pro Mixer with pH Sensor and Thermowell for Low pH Viral Inactivation and Neutralisation

Bag Volume	Part Number	Units per Box	Drain Valves	Top Port	Inlet	Outlet	Sampling	Addition 1	Addition 2	pH Adjustment
200 L	FMS500080	2	Yes	Closed 8" Top Port	½" ID TuFlux® Silicone 1,5 m (60") + ½" Tri-Clamp 1½" sanitary flange with gasket, cap & union	½" ID TuFlux® Silicone 1,5 m (60") + ½" Tri-Clamp 1½" sanitary flange with gasket, cap & union	¼" ID TuFlux® Silicone 0.1 m (4") + Clave needleless sampling port	When drain valves: 1 bottom line: ½" ID TuFlux® Silicone 1.5 m (60") + MPC Female + sealing cap When no drain valve: 1 bottom line: ⅜" ID TuFlux® Silicone 1.5 m (60") + MPC Female + sealing cap	When drain valves: 1 bottom line: ½" ID TuFlux® Silicone 1.5 m (60") + MPC Female + sealing cap When no drain valve: 1 bottom line: ⅜''' ID TuFlux® Silicone 1.5 m (60") + MPC Female + sealing cap	2 top lines: ¼" ID TuFlux® Silicone 0.1 m (4") + MPC female + sealing cap
	FMS500081	2	No							
400 L	FMS500082	2	Yes							
	FMS500083	2	No							
650 L	FMS500084	1	Yes							
	FMS500085	1	No							
1,000 L	FMS500086	1	Yes							
	FMS500087	1	No							

Downstream Intermediates

Downstream Intermediates
pH sensor & Thermowell
Thermowell
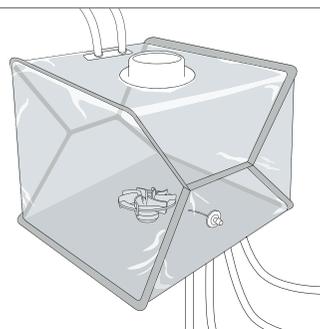
Example of a 200 L mixing bag equipped with Thermowell

Flexsafe® Pro Mixer with Thermowell for Post Filtration

Bag Volume	Part Number	Units per Box	Drain Valves	Top Port	Inlet	Outlet	Sampling	Addition 1	Addition 2	pH Adjustment
50 L	FMS300095	1	No	Closed 8" Top Port	½" ID TuFlux® Silicone 1 m (40") + ½" ID TuFlux® TPE 0.5 m (20") + ½" Opta® SFT female	½" ID TuFlux® Silicone 1 m (40") + ½" ID TuFlux® TPE 0.5 m (20") + ½" Tri-Clamp 1½" sanitary flange with gasket, cap & union	¼" ID TuFlux® Silicone 0.1 m (4") + Clave needleless sampling port	³∕₈" ID TuFlux® Silicone 1.5 m (60") + MPC Female + sealing cap	³∕₈" ID TuFlux® Silicone 1.5 m (60") + MPC Female + sealing cap	NA
100 L	FMS300097	1	No							
200 L	FMS300099	2	No							
400 L	FMS300095	2	No							
650 L	FMS300097	1	No							
1,000 L	FMS300099	1	No							

Drug Substance Purification

Drug Substance Purification

| pH sensor & Thermowell |
| Thermowell |

Flexsafe® Pro Mixer features a levitating impeller to preserve the drug substance during low shear blending applications. PDS are designed with single-use sensors for safe and reliable use along the process steps.

Process samples are taken off-line for other QC tests such as product quality attributes and bioburden prior to sterile filtration.

The Opta® SFT connector or the BioWelder® TC are used for respectively sterile connection or sterile weld.

Tri-Clamp or quick coupler connectors are used for aseptic connections under ISO laminar air flow.

Sterile disconnection is done using the BioSealer® TC.

PDS for mixing during drug substance purification are designed for
• Aseptic filling and draining operations under ISO laminar air flow:
  bottom lines with TuFlux® Silicone tubing and Tri-Clamp 1 ½" sanitary flange.
• Integrated single-use pH sensor and | or thermowell for in-line monitoring and control.
• Top lines with TuFlux® Silicone tubing and quick coupler connector for pH adjustment.
• Bottom line with TuFlux® Silicone tubing and clave needleless port for sampling.
• Bottom lines with TuFlux® Silicone tubing and quick coupler connector for liquid additions.
• Fully closed 8" diameter top port for a safe mixing.

Drug Substance Purification

Drug Substance Purification

pH sensor & Thermowell
Thermowell

Example of a 200 L mixing bag equipped with pH sensor & Thermowell

Flexsafe® Pro Mixer with pH Sensor and Thermowell

Bag Volume	Part Number	Units per Box	Drain Valves	Top Port	Inlet	Outlet	Sampling	Addition 1	Addition 2	pH Adjustment
50 L	FMS300095	1	No	Closed 8" Top Port	½" ID TuFlux® Silicone 1,5 m (60") + ½" Tri-Clamp 1½" sanitary flange with gasket, cap & union	½" ID TuFlux® Silicone 1,5 m (60") + ½" Tri-Clamp 1½" sanitary flange with gasket, cap & union	¼" ID TuFlux® Silicone 0.1 m (4") + Clave needleless sampling port	³/₈" ID TuFlux® Silicone 1.5 m (60") + MPC Female + sealing cap	³/₈" ID TuFlux® Silicone 1.5 m (60") + MPC Female + sealing cap	2 top lines: ¼" ID TuFlux® Silicone 0.1 m (4") + MPC female + sealing cap
100 L	FMS300097	1	No							
200 L	FMS300099	2	No							
400 L	FMS300095	2	No							
650 L	FMS300097	1	No							
1,000 L	FMS300099	1	No							

Drug Substance Purification

Drug Substance Purification

| pH sensor & Thermowell |
| Thermowell |

Example of a 200 L mixing bag equipped with Thermowell

Flexsafe® Pro Mixer with Thermowell

Bag Volume	Part Number	Units per Box	Drain Valves	Top Port	Inlet	Outlet	Sampling	Addition 1	Addition 2	pH Adjustment
50 L	FMS500088	1	No	Closed 8" Top Port	½" ID TuFlux® Silicone 1,5 m (60") + ½" Tri-Clamp 1½" sanitary flange with gasket, cap & union	½" ID TuFlux® Silicone 1,5 m (60") + ½" Tri-Clamp 1½" sanitary flange with gasket, cap & union	¼" ID TuFlux® Silicone 0.1 m (4") + Clave needleless sampling port	⅜" ID TuFlux® Silicone 1.5 m (60") + MPC Female + sealing cap	⅜" ID TuFlux® Silicone 1.5 m (60") + MPC Female + sealing cap	2 top lines: ¼" ID TuFlux® Silicone 0.1 m (4") + MPC female + sealing cap
100 L	FMS500089	1	No							
200 L	FMS500090	2	No							
400 L	FMS500091	2	No							
650 L	FMS500092	1	No							
1,000 L	FMS500093	1	No							

Drug Product Formulation

Drug Product Formulation

pH sensor & Thermowell
No sensor & with sterile connections and disconnections
No sensor & with aseptic connections and disconnections under ISO laminar air flow

Flexsafe® Pro Mixer features a levitating impeller to preserve the drug product during final formulation. PDS are designed with single-use sensors for safe and reliable use along the process steps.

The drug product formulation involves a mixing step where the product is formulated before final filtration, fill and finish in its final container.

During this step, the drug substance is mixed with other buffers and excipients to obtain the final drug product concentration and composition.

pH is monitored and | or adjusted in-line and samples are taken off-line for other QC tests such as product quality attributes and bioburden prior to sterile filtration.

Flexsafe® Pro Mixer PDS for final formulation are available in:
• With single-use and integrated sensors for in-line pH and temperature monitoring and adjustment required for your cGMP biomanufacture.
• Without single-use sensors where sterile samples are taken for off-line controls.

PDS are designed for either sterile or aseptic connections and disconnections.

The Opta® SFT connector or the BioWelder® TC are used for respectively sterile connection or sterile weld.

Tri-Clamp or quick coupler connectors are used for aseptic connections under ISO laminar air flow.

Sterile disconnection is done using the BioSealer® TC.

Intelligent PDS for final formulation are designed with:
• Bottom lines with a combined TuFlux® Silicone + TuFlux® TPE tubing ended by an Opta® SFT connector to allow pumping and sterile weld and | or seal
• Integrated single-use pH sensor and thermowell for in-line monitoring and control
• Top lines with TuFlux® Silicone tubing and Opta® SFT connector for sterile pH adjustment
• Bottom line with TuFlux® Silicone tubing and clave needleless port for sterile sampling
• Bottom or top line with TuFlux® Silicone tubing and Opta® SFT connector for sterile liquid additions
• Fully closed 8" diameter top port for sterile mixing

Flexsafe® Pro Mixer PDS without sensor for final formulation are designed for:
• Aseptic operations under ISO laminar air flow:

– filling and draining lines with TuFlux® Silicone tubing and Tri-Clamp 1½" sanitary flange
– additions and pH adjustment lines with TuFlux® Silicone tubing and quick coupler connector
– sampling line with TuFlux® tubing and clave needleless port
• For sterile operations:
– filling and draining lines with a combined TuFlux® Silicone and TuFlux® TPE tubing ended by an Opta® SFT connector
– pH adjustement top lines with TuFlux® Silicone tubing ended by Opta® SFT connector
– sampling line with a clave needleless port
– liquid addition lines with TuFlux® Silicone tubing ended by Opta® SFT connector
• Fully closed 8" diameter top port for sterile mixing.

Options with drain valves to avoid hold up volumes into the tubes are also available.

Drug Product Formulation

Drug Product Formulation

| pH sensor & Thermowell |
| No sensor & with sterile connections and disconnections |
| No sensor & with aseptic connections and disconnections under ISO laminar air flow |

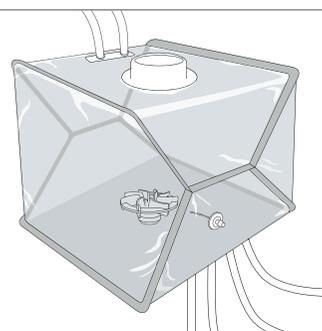Example of a 200 L mixing bag equipped with pH sensor & Thermowell

Flexsafe® Pro Mixer with pH Sensor and Thermowell

Bag Volume	Part Number	Units per Box	Drain Valves	Top Port	Inlet	Outlet	Sampling	Addition 1	Addition 2	pH Adjustment
50 L	FMS500114	1	Yes	Closed 8" Top Port	½" TuFlux® Silicone 1 m (40") + ½" ID TuFlux® TPE 0.5 m (20") + ½" Opta® SFT female	½" ID TuFlux® Silicone 1 m (40") + ½" ID TuFlux® TPE 0.5 m (20") + ½" Opta® SFT male	¼" ID TuFlux® Silicone 0.1 m (4") + Clave needleless sampling port	When drain valves: 1 top line: ⅜" ID TuFlux® Silicone 0.15 m (6") + ⅜" Opta® SFT female When no drain valve: 1 bottom line: ⅜" ID TuFlux® Silicone 1.5 m (60") + ⅜" Opta® SFT female	NA	2 top lines: ¼" ID TuFlux® Silicone 0.1 m (4") + MPC female + sealing cap
	FMS500115	1	No							
100 L	FMS500116	1	Yes							
	FMS500117	1	No							

Drug Product Formulation

Drug Product Formulation

| pH sensor & Thermowell |
| No sensor & with sterile connections and disconnections |
| No sensor & with aseptic connections and disconnections under ISO laminar air flow |

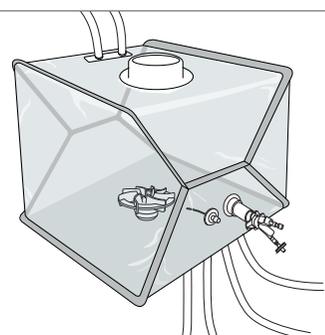Example of a 200 L mixing bag equipped with pH sensor & Thermowell

Flexsafe® Pro Mixer with pH Sensor and Thermowell

Bag Volume	Part Number	Units per Box	Drain Valves	Top Port	Inlet	Outlet	Sampling	Addition 1	Addition 2	pH Adjustment
200 L	FMS500118	2	Yes	Closed 8" Top Port	½" TuFlux® Silicone 1 m (40") + ½" ID TuFlux® TPE 0.5 m (20") + ½" Opta® SFT female	½" ID TuFlux® Silicone 1 m (40") + ½" ID TuFlux® TPE 0.5 m (20") + ½" Opta® SFT male	¼" ID TuFlux® Silicone 0.1 m (4") + Clave needleless sampling port	When drain valves: 1 bottom line: ½" ID TuFlux® Silicone 1.5 m (60") + ½" Opta® SFT female When no drain valve: 1 bottom line: ⅜" ID TuFlux® Silicone 1.5 m (60") + ⅜" Opta® SFT female	When drain valves: 1 bottom line: ½" ID TuFlux® Silicone 1.5 m (60") + ½" Opta® SFT female When no drain valve: 1 bottom line: ⅜" ID TuFlux® Silicone 1.5 m (60") + ⅜" Opta® SFT female	2 top lines: ¼" ID TuFlux® Silicone 0.1 m (4") + MPC female + sealing cap
	FMS500119	2	No							
400 L	FMS500120	2	Yes							
	FMS500121	2	No							
650 L	FMS500122	1	Yes							
	FMS500123	1	No							
1,000 L	FMS500124	1	Yes							
	FMS500125	1	No							

Media	Buffer	Downstream Intermediates	Drug Substance	Drug Product	Back to Table of Contents

35 Flexsafe® Pro Mixer Pre-designed Solutions for

Drug Product Formulation

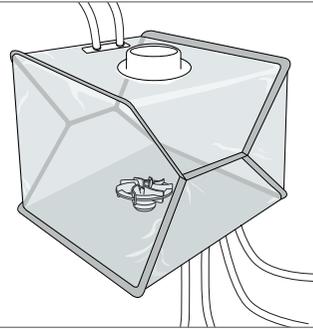| Drug Product Formulation | pH sensor & Thermowell |
| | No sensor & with sterile connections and disconnections |
| | No sensor & with aseptic connections and disconnections under ISO laminar air flow |

Example of a 200 L mixing bag without single-use sensor and with sterile connections and disconnections

Flexsafe® Pro Mixer Without Single-use Sensor and With Sterile Connections and Disconnections

Bag Volume	Part Number	Units per Box	Drain Valves	Top Port	Inlet	Outlet	Sampling	Addition 1	Addition 2	pH Adjustment
50 L	FMS500126	1	Yes	Closed 8" Top Port	½" TuFlux® Silicone 1 m (40") + ½" ID TuFlux® TPE 0.5 m (20") + ½" Opta® SFT female	½" ID TuFlux® Silicone 1 m (40") + ½" ID TuFlux® TPE 0.5 m (20") + ½" Opta® SFT male	¼" ID TuFlux® Silicone 0.1 m (4") + Clave needleless sampling port	When drain valves: 1 top line: ³⁄₈" ID TuFlux® Silicone 0.15 m (6") + ³⁄₈" Opta® SFT female When no drain valve: 1 bottom line: ³⁄₈" ID TuFlux® Silicone 1.5 m (60") + ³⁄₈" Opta® SFT female	When drain valves: 1 top line: ³⁄₈" ID TuFlux® Silicone 0.15 m (6") + ³⁄₈" Opta® SFT female When no drain valve: 1 bottom line: ³⁄₈" ID TuFlux® Silicone 1.5 m (60") + ³⁄₈" Opta® SFT female	NA
	FMS500127	1	No							
100 L	FMS500128	1	Yes							
	FMS500129	1	No							

Drug Product Formulation

Drug Product Formulation	pH sensor & Thermowell
	No sensor & with sterile connections and disconnections
	No sensor & with aseptic connections and disconnections under ISO laminar air flow

Example of a 200 L mixing bag without single-use sensor and with sterile connections and disconnections

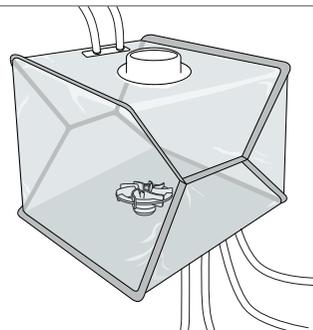## Flexsafe® Pro Mixer Without Single-use Sensor and With Sterile Connections and Disconnections

Bag Volume	Part Number	Units per Box	Drain Valves	Top Port	Inlet	Outlet	Sampling	Addition 1	Addition 2	pH Adjustment
200 L	FMS500130	2	Yes	Closed 8" Top Port	½" TuFlux® Silicone 1 m (40") + ½" ID TuFlux® TPE 0.5 m (20") + ½" Opta® SFT female	½" ID TuFlux® Silicone 1 m (40") + ½" ID TuFlux® TPE 0.5 m (20") + ½" Opta® SFT male	¼" ID TuFlux® Silicone 0.1 m (4") + Clave needleless sampling port	When drain valves: 1 bottom line: ½" ID TuFlux® Silicone 1.5 m (60") + ½" Opta® SFT female When no drain valve: 1 bottom line: ⅜" ID TuFlux® Silicone 1.5 m (60") + ⅜" Opta® SFT female	When drain valves: 1 bottom line: ½" ID TuFlux® Silicone 1.5 m (60") + ½" Opta® SFT female When no drain valve: 1 bottom line: ⅜" ID TuFlux® Silicone 1.5 m (60") + ⅜" Opta® SFT female	NA
	FMS500131	2	No							
400 L	FMS500132	2	Yes							
	FMS500133	2	No							
650 L	FMS500134	1	Yes							
	FMS500135	1	No							
1,000 L	FMS500136	1	Yes							
	FMS500137	1	No							

Flexsafe® Pro Mixer Pre-designed Solutions for

Drug Product Formulation

Drug Product Formulation

| pH sensor & Thermowell |
| No sensor & with sterile connections and disconnections |
| No sensor & with aseptic connections and disconnections under ISO laminar air flow |

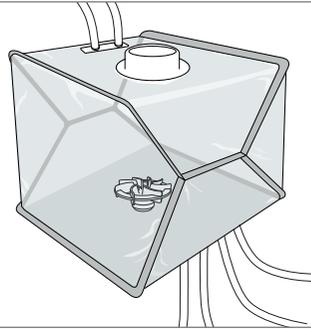Example of a 200 L mixing bag without single-use sensor and with aseptic connections and disconnections under ISO laminar air flow

Flexsafe® Pro Mixer Without Single-use Sensor and With Aseptic Connections and Disconnections under ISO Laminar Air Flow

Bag Volume	Part Number	Units per Box	Drain Valves	Top Port	Inlet	Outlet	Sampling	Addition 1	Addition 2	pH Adjustment
50 L	FMS500100	1	Yes	Closed 8" Top Port	½" ID TuFlux® Silicone 1,5 m (60") + ½" Tri-Clamp 1½" sanitary flange with gasket, cap & union	½" ID TuFlux® Silicone 1,5 m (60") + ½" Tri-Clamp 1½" sanitary flange with gasket, cap & union	¼" ID TuFlux® Silicone 0.1 m (4") + Clave needleless sampling port	When drain valves: 1 top line: ⅜" ID TuFlux® Silicone 0.15 m (6") + MPC Female + sealing cap \n\n When no drain valve: 1 bottom line: ⅜" ID TuFlux® Silicone 1.5 m (60") + MPC Female + sealing cap	When drain valves: 1 top line: ⅜" ID TuFlux® Silicone 0.15 m (6") + MPC Female + sealing cap \n\n When no drain valve: 1 bottom line: ⅜" ID TuFlux® Silicone 1.5 m (60") + MPC Female + sealing cap	NA
	FMS500101	1	No							
100 L	FMS500102	1	Yes							
	FMS500103	1	No							

Drug Product Formulation

Drug Product Formulation

| pH sensor & Thermowell |
| No sensor & with sterile connections and disconnections |
| No sensor & with aseptic connections and disconnections under ISO laminar air flow |

Example of a 200 L mixing bag without single-use sensor and with aseptic connections and disconnections under ISO laminar air flow

Flexsafe® Pro Mixer Without Single-use Sensor and With Aseptic Connections and Disconnections under ISO Laminar Air Flow
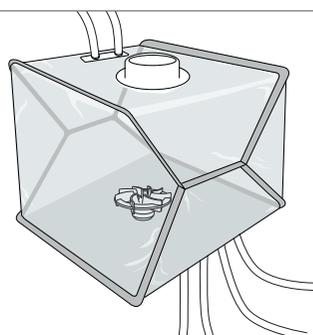
Bag Volume	Part Number	Units per Box	Drain Valves	Top Port	Inlet	Outlet	Sampling	Addition 1	Addition 2	pH Adjustment
200 L	FMS500104	2	Yes	Closed 8" Top Port	½" ID TuFlux® Silicone 1,5 m (60") + ½" Tri-Clamp 1½" sanitary flange with gasket, cap & union	½" ID TuFlux® Silicone 1,5 m (60") + ½" Tri-Clamp 1½" sanitary flange with gasket, cap & union	¼" ID TuFlux® Silicone 0.1 m (4") + Clave needleless sampling port	When drain valves: 1 bottom line: ½" ID TuFlux® Silicone 1.5 m (60") + MPC Female + sealing cap When no drain valve: 1 bottom line: ⅜" ID TuFlux® Silicone 1.5 m (60") + MPC Female + sealing cap	When drain valves: 1 bottom line: ½" ID TuFlux® Silicone 1.5 m (60") + MPC Female + sealing cap When no drain valve: 1 bottom line: ⅜" ID TuFlux® Silicone 1.5 m (60") + MPC Female + sealing cap	NA
	FMS500105	2	No							
400 L	FMS500106	2	Yes							
	FMS500107	2	No							
650 L	FMS500108	1	Yes							
	FMS500109	1	No							
1,000 L	FMS500110	1	Yes							
	FMS500111	1	No							

Palletank for Mixing

Palletank for Mixing	
Single-Walled	
With Weighing	
Jacketed	
Jacketed with Weighing	

| Description	Volumes	Technical Specification
Volumes		50 L | 100 L | 200 L | 400 L | 650 L | 1,500 L | 2,000 L | 2,500 L | 3,000 L
Main construction materials	50 L to 3,000 L	Stainless Steel 304L
	50 L to 1,000 L	Windows made of PC and EPDM sealing
Surface finish	50 L to 3,000 L	Acid cleaned, stainless steel bead blasted and passivated
Door	50 L to 400 L	Front hinged door and PC windows
	650 L and 1,000 L	Front hinged doors and PC windows
	1,500 L to 3,000 L	Front and lateral hinged doors
Bag tubing gate	50 L to 3,000 L	Front bottom port for bag lines | sensor access
Port	50 L to 3,000 L	Railed port for drive unit coupling
Mobility	50 L to 1,000 L	Mounted on stainless cart with four clean room wheels and push handles
	1,500 L to 3,000 L	Mounted on stainless cart with four clean room fixed feet
Minimum door height	1,500 L to 3,000 L	1,550 mm
Minimum ceiling height	1,500 L	3,000 mm
	2,000 L	3,500 mm
	2,500 L	4,000 mm
	3,000 L	4,500 mm
Operating temperature	50 L to 3,000 L	0°C to 50°C

Palletank for Mixing

Palletank for Mixing	Single-Walled
	With Weighing
	Jacketed
	Jacketed with Weighing
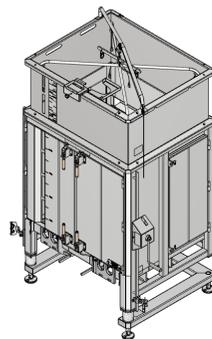
Palletank for Mixing

Dimensions and Weight European Version (Metric Units)

Part Number	Volume	Dimensions (approx.) W×D×H	Weight
FXC301951	50 L	785 × 705 × 989 mm	78 kg
FXC301952	100 L	785 × 705 × 1,094 mm	86 kg
FXC301953	200 L	785 × 705 × 1,194 mm	105 kg
FXC301954	400 L	1,031 × 873 × 1,344 mm	142 kg
FXC301955	650 L	1,181 × 1,008 × 1,454 mm	175 kg
FXC301956	1,000 L	1,296 × 1,157 × 1,654 mm	256 kg
FXC301958	1,500 L	1,733 × 1,076 × 2,444 mm	465 kg
FXC301959	2,000 L	1,733 × 1,076 × 2,944 mm	528 kg
FXC301960	2,500 L	1,733 × 1,076 × 3,445 mm	592 kg
FXC301961	3,000 L	1,733 × 1,076 × 3,945 mm	656 kg

Dimensions and Weight North American Version (Imperial Units)

| Part Number	Volume	Dimensions (approx.) W×D×H	Weight
FXC301973	50 L	785 × 705 × 989 mm	78 kg
FXC301974	100 L	785 × 705 × 1,094 mm	86 kg
FXC301975	200 L	785 × 705 × 1,194 mm	105 kg
FXC301976	400 L	1,031 × 873 × 1,344 mm	142 kg
FXC301977	650 L	1,181 × 1,008 × 1,454 mm	175 kg
FXC301978	1,000 L	1,296 × 1,157 × 1,654 mm	256 kg
FXC301980	1,500 L	1,733 × 1,076 × 2,444 mm	465 kg
FXC301981	2,000 L	1,733 × 1,076 × 2,944 mm	528 kg
FXC301982	2,500 L	1,733 × 1,076 × 3,445 mm	592 kg
FXC301983	3,000 L	1,733 × 1,076 × 3,945 mm	656 kg

Palletank for Mixing

Palletank for Mixing	Single-Walled
	With Weighing
	Jacketed
	Jacketed with Weighing
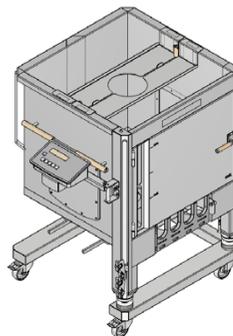
Palletank for Mixing with Weighing

Palletank for Mixing with Weighing

Description	Technical Specification
Scale Indicator	Minebea Combics 1
Material of construction	Stainless Steel 304
Keyboard	6 keys
Display	14 segments
20 mm weight readout	650 L
Interface	RS232
IP protection rate	IP69K
Operating temperature range	-10°C to 40°C
Integrated load cells	Weighing module Minebea Novego
Material of construction	304 and 4418 (sensor)
IP protection rate	IP68 + IP69
Overload	High overload protection
Vibration resistance	Resistance against oscillations (IEC 68-2-6 Fc); 20g, 100h, 10 to 150 Hz
Design	In accordance with European Hygienic Engineering and Design Group (EHEDG) guidelines
Lift-off	Lift-off protector and anti-wobbling mechanism

Weighing Characteristics

| Volumes	Maximum net capacity	Resolution	Accuracy
50 L	60 kg	20 g	60 g
100 L	110 kg	20 g	60 g
200 L	220 kg	20 g	60 g
400 L	450 kg	50 g	150 g
650 L	750 kg	50 g	150 g
1,000 L	1,100 kg	100 g	300 g
1,500 L	1,750 kg	100 g	300 g
2,000 L	2,200 kg	200 g	600 g
2,500 L	2,750 kg	200 g	600 g
3,000 L	3,300 kg	200 g	600 g

Palletank for Mixing

Palletank for Mixing
Single-Walled
With Weighing
Jacketed
Jacketed with Weighing
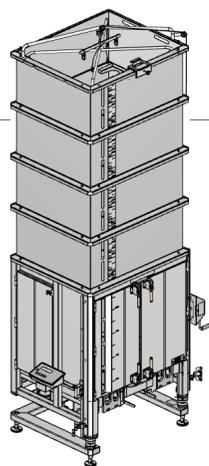
Palletank for Mixing

Dimensions and Weight European Version (Metric Units)

Part Number	Volume	Dimensions (approx.) W × D × H	Weight
FXC301962	50 L	878 × 705 × 1,018 mm	81 kg
FXC301963	100 L	921 × 705 × 1,115 mm	90 kg
FXC301964	200 L	981 × 705 × 1,194 mm	108 kg
FXC301965	400 L	1,159 × 873 × 1,344 mm	145 kg
FXC301966	650 L	1,311 × 1,008 × 1,454 mm	178 kg
FXC301967	1,000 L	1,426 × 1,157 × 1,654 mm	259 kg
FXC301968	1,500 L	1,860 × 1,076 × 2,444 mm	469 kg
FXC301969	2,000 L	1,860 × 1,076 × 2,944 mm	533 kg
FXC301970	2,500 L	1,860 × 1,076 × 3,445 mm	596 kg
FXC301971	3,000 L	1,860 × 1,076 × 3,945 mm	660 kg

Dimensions and Weight North American Version (Imperial Units)

| Part Number	Volume	Dimensions (approx.) W × D × H	Weight
FXC301984	50 L	878 × 705 × 1,018 mm	81 kg
FXC301985	100 L	921 × 705 × 1,115 mm	90 kg
FXC301986	200 L	981 × 705 × 1,194 mm	108 kg
FXC301987	400 L	1,159 × 873 × 1,344 mm	145 kg
FXC301988	650 L	1,311 × 1,008 × 1,454 mm	178 kg
FXC301989	1,000 L	1,426 × 1,157 × 1,654 mm	259 kg
FXC301990	1,500 L	1,860 × 1,076 × 2,444 mm	469 kg
FXC301991	2,000 L	1,860 × 1,076 × 2,944 mm	533 kg
FXC301992	2,500 L	1,860 × 1,076 × 3,445 mm	596 kg
FXC301993	3,000 L	1,860 × 1,076 × 3,945 mm	660 kg

Palletank for Mixing

Single-Walled

With Weighing

Jacketed
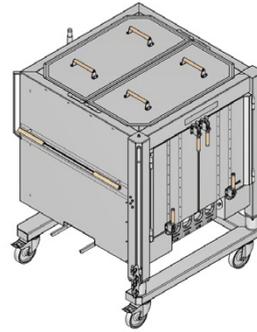
Jacketed with Weighing

Palletank for Mixing
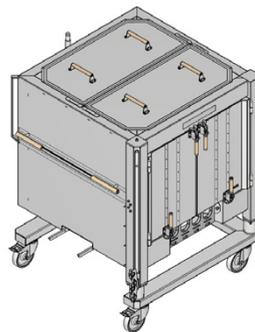
Palletank for Mixing
Jacketed

Palletank Jacketed

Description		Technical Specification	
		Version: PED (for Europe, Asia and NEMA)	Version: ASME (for North America)
Volumes		50 L │ 100 L │ 200 L │ 400 L │ 650 L │ 1,500 L │ 2,000 L │ 2,500 L │ 3,000 L	
Main construction materials	50 L to 3,000 L	Stainless Steel 304L, Perlit Balls (insulation)	Stainless Steel 304L, Foam Glass and Ceramic Fiber (insulation)
Surface finish	50 L to 3,000 L	Acid cleaned, stainless steel bead blasted and passivated	
Door	50 L │ 100 L	No door	
	200 L │ 400 L	Front insulated hinged door	
	650 L to 3,000 L	Front insulated hinged doors	
Bag tubing gate	50 L to 3,000 L	Hinged PTFE bottom door	Hinged UHMW bottom door
Port	50 L to 3,000 L	Railed port for drive unit coupling	
Mobility	50 L to 1,000 L	Mounted on stainless cart with four clean room wheels and push handles	
	1,500 L to 3,000 L	Mounted on stainless cart with four clean room fixed feet	
Minimum door height	1,500 L to 3,000 L	2,070 mm	
Minimum ceiling height	1,500 L	3,000 mm	
	2,000 L	3,500 mm	
	2,500 L	4,000 mm	
	3,000 L	4,500 mm	

Palletank for Mixing

Palletank for Mixing	Single-Walled
	With Weighing
	Jacketed
	Jacketed with Weighing

Palletank for Mixing
Jacketed

Palletank Jacketed

| Description		Technical Specification	
		Version: PED (for Europe, Asia and NEMA)	**Version: ASME (for North America)**
Operating temperature	50 L to 3,000 L	0°C to 50°C	
Working pressure	50 L to 3,000 L	–1 to 6 bars	10 bars
Test pressure	50 L to 3,000 L	9 bars	13 bars
Compliance	50 L to 3,000 L	PED	Heat exchanger ASME certified From heat exchanger: designed and build under ASME code
Insulated	50 L to 3,000 L	On all sides, the bottom and the lids	
Jacketed	50 L and 100 L	4 sides and bottom	
	200 L to 1,000 L	3 sides and bottom	
	1,500 L to 3,000 L	3 sides and bottom for 1,500 L base, module and top insulated only	
Inlet|outlet of heat transfer fluid	50 L to 3,000 L	Manual ¾ ball valve and ¾ Tri-Clamp	Male NPT connection

Palletank for Mixing

| Single-Walled |
| With Weighing |
| Jacketed |
| Jacketed with Weighing |

Palletank for Mixing
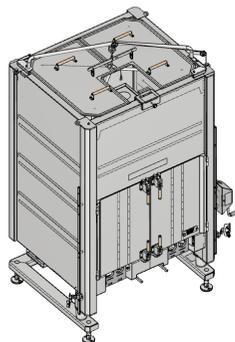
Palletank for Mixing Jacketed

Dimensions and Weight PED Version (for Europe, Asia and NEMA)

Part Number	Volume	Dimensions (approx.) W × D × H	Weight
FXC301930	50 L	847 × 817 × 1,045 mm	118 kg
FXC301931	100 L	878 × 817 × 1,150 mm	178 kg
FXC301932	200 L	949 × 969 × 1,250 mm	238 kg
FXC301933	400 L	1,158 × 1,186 × 1,399 mm	347 kg
FXC301934	650 L	1,242 × 1,319 × 1,509 mm	456 kg
FXC301935	1,000 L	1,376 × 1,435 × 1,710 mm	592 kg
FXC301936	1,500 L	1,822 × 1,135 × 2,530 mm	791 kg
FXC301937	2,000 L	1,822 × 1,135 × 3,050 mm	933 kg
FXC301938	2,500 L	1,822 × 1,135 × 3,570 mm	1,076 kg
FXC301939	3,000 L	1,822 × 1,135 × 4,090 mm	1,218 kg

Dimensions and Weight ASME Version (North America)

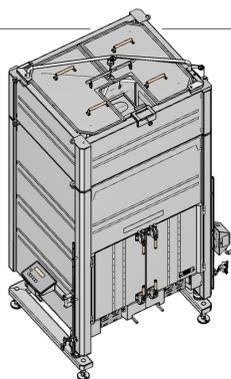| Part Number	Volume	Dimensions (approx.) W × D × H	Weight
FXC301994	50 L	847 × 817 × 1,045 mm	118 kg
FXC301995	100 L	878 × 817 × 1,150 mm	178 kg
FXC301996	200 L	949 × 969 × 1,250 mm	238 kg
FXC301997	400 L	1,158 × 1,186 × 1,399 mm	347 kg
FXC301998	650 L	1,242 × 1,319 × 1,509 mm	456 kg
FXC301999	1,000 L	1,376 × 1,435 × 1,710 mm	592 kg
FXC302000	1,500 L	1,822 × 1,135 × 2,530 mm	791 kg
FXC302001	2,000 L	1,822 × 1,135 × 3,050 mm	933 kg
FXC302002	2,500 L	1,822 × 1,135 × 3,570 mm	1,076 kg
FXC302003	3,000 L	1,822 × 1,135 × 4,090 mm	1,218 kg

Palletank for Mixing

Palletank for Mixing
Single-Walled
With Weighing
Jacketed
Jacketed with Weighing

Palletank for Mixing
Jacketed with Weighing

Dimensions and Weight PED Version (for Europe, Asia and NEMA)

Part Number	Volume	Dimensions (approx.) W × D × H	Weight
FXC301940	50 L	970 × 817 × 1,058 mm	121 kg
FXC301941	100 L	1,013 × 817 × 1,150 mm	181 kg
FXC301942	200 L	1,112 × 969 × 1,250 mm	241 kg
FXC301943	400 L	1,287 × 1,186 × 1,399 mm	350 kg
FXC301944	650 L	1,412 × 1,319 × 1,509 mm	459 kg
FXC301945	1,000 L	1,511 × 1,435 × 1,710 mm	595 kg
FXC301946	1,500 L	1,949 × 1,135 × 2,530 mm	794 kg
FXC301947	2,000 L	1,949 × 1,135 × 3,050 mm	936 kg
FXC301948	2,500 L	1,949 × 1,135 × 3,570 mm	1,079 kg
FXC301949	3,000 L	1,949 × 1,135 × 4,090 mm	1,221 kg

Dimensions and Weight ASME Version (North America)

Part Number	Volume	Dimensions (approx.) W × D × H	Weight
FXC302004	50 L	970 × 817 × 1,058 mm	121 kg
FXC302005	100 L	1,013 × 817 × 1,150 mm	181 kg
FXC302006	200 L	1,112 × 969 × 1,250 mm	241 kg
FXC302007	400 L	1,287 × 1,186 × 1,399 mm	350 kg
FXC302008	650 L	1,412 × 1,319 × 1,509 mm	459 kg
FXC302009	1,000 L	1,511 × 1,435 × 1,710 mm	595 kg
FXC302010	1,500 L	1,949 × 1,135 × 2,530 mm	794 kg
FXC302011	2,000 L	1,949 × 1,135 × 3,050 mm	936 kg
FXC302012	2,500 L	1,949 × 1,135 × 3,570 mm	1,079 kg
FXC302013	3,000 L	1,949 × 1,135 × 4,090 mm	1,221 kg

Pro Mixer Drive Unit

Description	Unit	Value
Dimensions (width × length × height)	mm	439 × 1,242 × 1,006
Weight	kg	100
Materials		Device surfaces: 316L │ 1.2 Ra
		Display: Foil coated with polyester foil
		Castors: Polyamide
Mobility		Mounted on stainless cart with four clean room wheels and push handle
Initial set-up time		Not applicable
Speed of the impeller	rpm	20 – 750
Working Temperature	°C	+2 – +30
Relative humidity, maximum (at temperatures of up to 31 °C)	%	80
Protection class according to IEC 60529		IP 23
Voltage	VAC	100 – 240 ±10 %
Frequency	Hz	50 – 60
Performance (Current consumption), maximum	W	1200
Length of the power supply cable	m	10
Acoustic pressure level, max.	dB (A)	60
Operating Modes		Local operation (Manual, Recipe) │ Remote Operation
Remote Operation	V	10 Input signals from remote control
	mA	0 – 20 Output signals of the device in remote operation
Remote Operation		Functions available: • Motor – start, stop • Speed – adjustment, indication • Alarm – indication • Mode of control (remote│local) – indication
Type of connection cable for remote operation		Shielded 8-pin plug, M12, A coded, screw assembly with M16 thread, 8 × 0.25 mm^2
Recipe storage		25 Number of recipes, max.
		10 Number of phases in the recipe, max.
Compliance		CE │ UL

Item	Quantity	Part Number
Flexsafe® Pro Mixer Drive Unit	1	FMD300001
Power supply cable - EU	1	FMA303410
Power supply cable – US	1	FMA303411
Power supply cable – China	1	FMA303412
Power supply cable – Australia	1	FMA303413
Power supply cable – Great Britain	1	FMA303415
Connection cable for remote operation, length 3 m	1	FMA303416

Accessories

| Powder Transfer System |
| Tubing Holder |
| Filter Holder |
| pH Reader Holder and pH Bag Holder |

Powder Bag Holders

Description	Powder Bag Holder 50 L to 200 L	Powder Bag Holder 400 L to 1,000 L	Powder Bag Holder 1,500 L to 3,000 L
Part Number	FXA304216	FXA304217	FXA304218
Construction material	Stainless Steel 304 and Nylon		
Surface finish	Bead Blasted		
Dimensions	660 × 1,360 mm	960 × 1,360 mm	860 × 1,360 mm
Weight	14 kg	16 kg	14 kg
Height above Palletank	1349 mm	1349 mm	1349 mm
Filling weight, maximum	30 kg	30 kg	30 kg
Ambient Conditions	+2℃ – +30℃	+2℃ – +30℃	+2℃ – +30℃

Accessories

Powder Transfer Bags

Description	Technical Specifications
Bag Chamber	Multiple layer film construction, (mLLDPE | MDPE-LDPE | mLLDPE)
Fittings	4-inch triclamp
Accessory	Pinch clamp
Volumes	15 L and 30 L
Number of Port	1 port
Irradiation	25–45 kGy

Triclamp Reducer

Description	Technical Specifications
Triclamp Reducer	8-inch to 4-inch triclamp reducer with a 4-inch triclamp plug, 4-inch triclamp gasket and 4-inch triclamp union
Material of Construction	Reducer: polyethylene Plug: polyethylene Gasket: platinum cured silicone 4-inch triclamp union: glass reinforced polyamide
Sterility	Non sterile

Cap | Gasket | Union

Description	Technical Specifications
Cap | Gasket | Union	4-inch triclamp plug, 4-inch triclamp gasket, 4-inch triclamp union
Material of Construction	Plug: polyethylene Gasket: platinum cured silicone 4-inch triclamp union: glass reinforced polyamide
Sterility	Non sterile

Part Number	Description	Bag Port 1	Qty. | Box
FMA300221	STD Powder Bag 15 L (PWD Port) with pinch clamp	4-inch triclamp	5
FMA300222	STD Powder Bag 30 L (PWD Port)with pinch clamp	4-inch triclamp	5
FMA114007	8-inch to 4-inch triclamp reducer	NA	1
FMA114179	Component Plug|Gasket|Union for TC4"	NA	5

Accessories

| Powder Transfer System |
| Tubing Holder |
| Filter Holder |
| pH Reader Holder and pH Bag Holder |

Tubing Holder

Description	Part Number	Type	Outer Tube Diameter	Material	Surface Finish	Dimensions	Weight
Tubing Holder Single ⅝"	FXC301562	Single	⅝"	Stainless Steel 304 and TPE	Bead Blasted	139 × 68 mm	423 g
Tubing Holder Twin ⅝"	FXC301563	Twin	⅝"			150 × 113 mm	465 g
Tubing Holder Triple ⅝"	FXC301564	Triple	⅝"			150 × 158 mm	506 g
Tubing Holder Quattro ⅝"	FXC301565	Quattro	⅝"			150 × 205 mm	546 g
Tubing Holder Single ¾"	FXC301566	Single	¾"			139 × 77 mm	427 g
Tubing Holder Twin ¾"	FXC301567	Twin	¾"			150 × 132 mm	474 g
Tubing Holder Triple ¾"	FXC301568	Triple	¾"			150 × 188 mm	518 g
Tubing Holder Quattro ¾"	FXC301569	Quattro	¾"			150 × 243 mm	559 g
Tubing Holder Single 1"	FXC301570	Single	1"			139 × 86 mm	434 g
Tubing Holder Twin 1"	FXC301571	Twin	1"			160 × 151 mm	510 g
Tubing Holder Triple 1"	FXC301572	Triple	1"			160 × 216 mm	571 g
Tubing Holder Quattro 1"	FXC301573	Quattro	1"			160 × 281 mm	626 g
Tubing Holder Single 1 ⅛"	FXC301574	Single	1 ⅛"			146 × 86 mm	445 g
Tubing Holder Twin 1 ⅛"	FXC301575	Twin	1 ⅛"			160 × 151 mm	510 g
Tubing Holder Triple 1 ⅛"	FXC301576	Triple	1 ⅛"			160 × 216 mm	570 g
Tubing Holder Quattro 1 ⅛"	FXC301577	Quattro	1 ⅛"			160 × 281 mm	627 g

Accessories

Accessories	Powder Transfer System
	Tubing Holder
	Filter Holder
	pH Reader Holder and pH Bag Holder

Tubing Holder

Description	Part Number	Type	Outer Tube Diameter	Material	Surface Finish	Dimensions	Weight
Tubing Holder Single 1 $^3/_8$"	FXC301578	Single	1 $^3/_8$"	Stainless Steel 304 and TPE	Bead Blasted	156 × 89 mm	454 g
Tubing Holder Twin 1 $^3/_8$"	FXC301579	Twin	1 $^3/_8$"			171 × 157 mm	527 g
Tubing Holder Triple 1 $^3/_8$"	FXC301580	Triple	1 $^3/_8$"			171 × 225 mm	595 g
Tubing Holder Quattro 1 $^3/_8$"	FXC301581	Quattro	1 $^3/_8$"			171 × 293 mm	657 g

Accessories

Accessories

| Powder Transfer System |
| Tubing Holder |
| Filter Holder |
| pH Reader Holder and pH Bag Holder |

Filter Holder

Description	Part number	Type	Filter diameter	Material	Surface finish	Dimensions	Weight
Filter Holder Short 55 mm	FXC301582	Short	55 mm	Stainless Steel 304 and TPE	Bead Blasted	100 × 55 mm	596 g
Filter Holder Long 55 mm	FXC301583	Long	55 mm			500 × 55 mm	1,519 g
Filter Holder Short 75 mm	FXC301584	Short	75 mm			100 × 75 mm	672 g
Filter Holder Long 75 mm	FXC301585	Long	75 mm			500 × 75 mm	1,596 g
Filter Holder Short 100 mm	FXC301586	Short	100 mm			100 × 100 mm	735 g
Filter Holder Long 100 mm	FXC301587	Long	100 mm			500 × 100 mm	1,658 g

Accessories

Accessories	Powder Transfer System
	Tubing Holder
	Filter Holder
	pH Reader Holder and pH Bag Holder

pH Reader Holder and pH Bag Holder

Description	Part number	Material	Surface finish	Dimensions	Weight
Palletank for Mixing pH Reader Holder	FXA304214	Stainless Steel 304 and elastomer	Bead Blasted	245 × 170 × 181 mm	1,499 g
Palletank for Mixing pH Bag Holder	FXA304215			160 × 181 × 212 mm	1,519 g

Design, Application Development and Validation Services

Design Configuration Options

Should our Pre-designed Solutions need to be adjusted to more specific requirements, they can serve as a base for adjusting your specific design using our Corporate Configurator and configure to Order (CTO) solutions.

Our Engineered to order (ETO) solutions allows the selection of a larger variety of solutions with added features, lines, manifolds, filters, connectors and sampling systems.

Please contact our sales representatives and application specialist to support you with the selection and design of your best solution for your specific process and application.

Application Support

Our expert FMT Application Specialists provide global support for:
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- Process design with standard and custom solutions
- Filter selection and sizing optimization study
- SOP development, process validation and operator training
- Technology transfer and process optimization

Validation Service

Our global validation services network offers:
- Installation start up, FAT, IQ & OQ, calibration and maintenance
- Consultancy service and process specific validation studies including
- Extractables | leachables,
- Chemical compatibility
- Bacterial challenge test
- Particle shedding

Please contact www.sartorius–stedim.com or your local sales representative for more information.

Sales and Service Contacts

For further contacts, visit www.sartorius-stedim.com

Europe

Germany
Sartorius Stedim Biotech GmbH
August-Spindler-Strasse 11
37079 Goettingen

Phone +49.551.308.0

Sartorius Stedim Systems GmbH
Robert-Bosch-Strasse 5 – 7
34302 Guxhagen

Phone +49.5665.407.0

France
Sartorius Stedim FMT S.A.S.
ZI des Paluds
Avenue de Jouques – CS 91051
13781 Aubagne Cedex

Phone +33.442.845600

Sartorius Stedim France SAS
ZI des Paluds
Avenue de Jouques – CS 71058
13781 Aubagne Cedex

Phone +33.442.845600

Austria
Sartorius Stedim Austria GmbH
Modecenterstrasse 22
1030 Vienna

Phone +43.1.7965763.18

Belgium
Sartorius Stedim Belgium N.V.
Rue Colonel Bourg 105
1030 Bruxelles

Phone +32.2.756.06.80

Hungary
Sartorius Stedim Hungária Kft.
Kagyló u. 5
2092 Budakeszi

Phone +36.23.457.227

Italy
Sartorius Stedim Italy S.r.l.
Via dell'Antella, 76/A
50012 Antella-Bagno a Ripoli (FI)

Phone +39.055.63.40.41

Netherlands
Sartorius Stedim Netherlands B.V.

Phone +31.30.60.25.080

filtratie.nederland@sartorius-stedim.com

Poland
Sartorius Stedim Poland Sp. z o.o.
ul. Wrzesinska 70
62-025 Kostrzyn

Phone +48.61.647.38.40

Russian Federation
LLC "Sartorius Stedim RUS"
Vasilyevsky Island
5th line 70, Lit. A
199178 St. Petersburg

Phone +7.812.327.53.27

Spain
Sartorius Stedim Spain, S.A.U.
Avda. de la Industria, 32
Edificio PAYMA
28108 Alcobendas (Madrid)

Phone +34.913.586.098

Switzerland
Sartorius Stedim Switzerland AG
Ringstrasse 24 a
8317 Tagelswangen

Phone +41.52.354.36.36

U.K.
Sartorius Stedim UK Ltd.
Longmead Business Centre
Blenheim Road, Epsom
Surrey KT19 9 QQ

Phone +44.1372.737159

Ukraine
LLC "Sartorius Stedim RUS"
Post Box 440 "B"
01001 Kiev, Ukraine

Phone +380.44.411.4918

Africa

Republic of South Africa
Sartorius South Africa (Pty) Ltd
Unit 4, Alphen Square South
853 16th Road
Midrand 1685, RSA

Phone +27.11.315.5444

Americas

USA
Sartorius Stedim North America Inc.
565 Johnson Avenue
Bohemia, NY 11716

Toll-Free +1.800.368.7178

Argentina
Sartorius Argentina S.A.
Int. A. Ávalos 4251
B1605ECS Munro
Buenos Aires

Phone +54.11.4721.0505

Brazil
Sartorius do Brasil Ltda
Avenida Senador Vergueiro 2962
São Bernardo do Campo
CEP 09600-000 - SP- Brasil

Phone +55.11.4362.8900

Mexico
Sartorius de México, S.A. de C.V.
Libramiento Norte de Tepotzotlan s/n,
Colonia Barrio Tlacateco,
Municipio de Tepotzotlan,
Estado de México,
C.P. 54605

Phone +52.55.5562.1102

leadsmex@sartorius.com

Asia | Pacific

Australia
Sartorius Stedim Australia Pty. Ltd.
Unit 5, 7-11 Rodeo Drive
Dandenong South Vic 3175

Phone +61.3.8762.1800

China
Sartorius Stedim (Shanghai)
Trading Co., Ltd.
3rd Floor, North Wing, Tower 1
No. 4560 Jinke Road
Zhangjiang Hi-Tech Park
Pudong District
Shanghai 201210, P.R. China

Phone +86.21.6878.2300

Sartorius Stedim (Shanghai)
Trading Co., Ltd.
Beijing Branch Office
No. 33 Yu'an Road
Airport Industrial Park Zone B
Shunyi District, Beijing 101300

Phone +86.10.8042.6501

Sartorius Stedim (Shanghai)
Trading Co., Ltd.
Guangzhou Branch Office
Room 1105
Xing Guang Ying Jing Building
No. 119, Shui Yin Road
Yue Xiu District, Guangzhou 510075

Phone +86.20.3836.4193

India
Sartorius Stedim India Pvt. Ltd.
#69/2-69/3, NH 48, Jakkasandra
Nelamangala Tq
562 123 Bangalore, India

Phone +91.80.4350.5250

Japan
Sartorius Stedim Japan K.K.
4th Fl., Daiwa Shinagawa North Bldg.
8-11, Kita-Shinagawa 1-chome
Shinagawa-ku, Tokyo, 140-0001 Japan

Phone +81.3.4331.4300

Malaysia
Sartorius Stedim Malaysia Sdn. Bhd.
Lot L3-E-3B, Enterprise 4
Technology Park Malaysia
Bukit Jalil
57000 Kuala Lumpur, Malaysia

Phone +60.3.8996.0622

Singapore
Sartorius Stedim Singapore Pte. Ltd.
10 Science Park Rd
The Alpha #02-13/14
Singapore Science Park II
Singapore 117684

Phone +65.6872.3966

South Korea
Sartorius Korea Biotech Co., Ltd.
8th Floor, Solid Space B/D,
PanGyoYeok-Ro 220, BunDang-Gu
SeongNam-Si, GyeongGi-Do, 463-400

Phone +82.31.622.5700

www.sartorius–stedim.com

Palletank for storage

Benefits

Qualified system
Perfect fit and protection of the Flexsafe® | Flexel® 3D Bag in its Palletank

Stackable version
Space saving containment system

Technology integration support
For a successful Single-Use manufacturing implementation and validation

Product Information

The Palletank for storage are stainless steel containers designed for the safe and robust storage of biopharmaceutical fluids contained in Flexsafe® | Flexel® 3D Bags. They are available in volumes of 50 L, 200 L and 500 L. The Flexsafe® | Flexel® 3D Bags are manufactured according to a qualified design that precisely fits the Palletank.

Applications
The Palletank for storage that incorporate Flexsafe® | Flexel® 3D Bags have been designed for the safe processing and storage 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

Space-saving
The stackable version of the Palletank for storage enables users to meet the complex in-process demands as well as the high requirements for storage while maximizing the utilization of the available clean room area. It saves up to 50% of the space required for cylindrical drums.

Safety
Flexsafe® | Flexel® 3D Bags coupled with the rigid structure of Palletank provide a stable and secure solution for processing, storage and in-house transportation of buffers, media, intermediates and final bulk products.

Palletank family
Besides the Palletank for storage, the product range of Palletank container includes the following lines specifically developed for the various application requirements on fluid management in the biopharmaceutical industry:
– Palletank for shipping
– Palletank for in-process fluid handling
– Plastic Palletank for storage
– Palletank for Mixing

Technology Integration Support

Sartorius Stedim Biotech supports users from 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.

Quality Assurance

The Palletank for storage are designed, developed and manufactured in accordance with a ISO 9001 certified Quality Management System. They undergo extensive testing before shipping.

Technical Data

Specifications

1. Palletank for storage

Description	Palletank 200 L for storage	Palletank 500 L for storage
Bag Volume(s)	100 L or 200 L	500 L
Construction Material	304 L Stainless Steel	304 L Stainless Steel
Surface Finishing	Bead Blasted	Bead Blasted
Dimensions (W × D × H)	792 × 592 × 892 mm (31 × 23 × 35 in)	1192 × 792 × 1008 mm (46 × 31 × 39 in)
Weight	48 kg (106 lb)	100 kg (220 lb)
Bottom Gate	1	1
Stackability	No	No

2. Palletank for storage stackable

Description	Palletank 50 L for storage stackable[1]	Palletank 200 L for storage stackable	Palletank 500 L for storage stackable
Bag Volume(s)	50 L	100 L or 200 L	500 L
Construction Material	304 L Stainless Steel	304 L Stainless Steel	304 L Stainless Steel
Surface Finishing	Bead Blasted	Bead Blasted	Bead Blasted
Dimensions (W × D × H)	490 × 490 × 750 mm (19 × 19 × 29 in)	792 × 592 × 929 mm (31 × 23 × 36 in)	1135 × 792 × 1044 mm (44 × 31 × 41 in)
Weight	25 kg (55 lb)	70 kg (154.3 lb)	110 kg (242 lb)
Bottom Gate | Sliding Gate	1	1	1
Stackability (Static)	3 high	3 high	2 high

[1] The 50L volume only available with Flexel® 3D Bag

3. Ancillary products
3.1. Dolly

Description	Dolly for Palletank 50 L for Storage and Shipping	Dolly for Palletank 200 L for Storage and Shipping	Dolly for Palletank 500 L for Storage and Shipping
Construction Material	304L and polyamide (wheels)	304L and polyamide (wheels)	304L and polyamide (wheels)
Surface Finishing	Glass Bead blasted	Glass Bead blasted	Glass Bead blasted
Dimensions (W × D × H)	490 × 490 × 185 mm (19.3 × 19.3 × 7.3 in)	815 × 615 × 188 mm (32.1 × 24.2 × 6.4 in)	1215 × 815 × 161 mm (47.8 × 32.1 × 6.4 in)
Weight (approx.)	7 kg (15.4 lb)	10 kg (22 lb)	18 kg (39.7 lb)

3.2. Weighing platforms

The IFS4 flat-bed scales are entirely constructed of stainless steel and have an extremely low height, making it ideally suited for floor installation without a pit or anchoring. The ramp is securely attached to the scale using special retainers for prevention of force shunt. This high-quality platform can be connected to any of a wide range of indicators, for use as a Class III legal measuring instrument or without legal verification. The CIS1 Combics 1 indicator allows strain gauge weighing with flat bed scales as well as with load cells to be connected.

	IFS4-150GG-I	IFS4-300LI-I	IFS4-1000RN-I
Weighing capacity	150 kg (330.7 lb)	300 kg (661.4 lb)	1000 kg (2204.6 lb)
Platform size	600 × 600 mm (23.6 × 23.6 in)	1000 × 800 mm (39.3 × 31.5 in)	1500 × 1250 mm (59 × 49.2 in)
Height	Standard: 35 mm	Standard: 35 mm	Standard: 45 mm
Load Plate	AISI304 │ 1.4301 (V2A) bead-blasted	AISI304 │ 1.4301 (V2A) bead-blasted	AISI304 │ 1.4301 (V2A) bead-blasted
Resolution	30.000 d	30.000 d	30.000 d
Readability	5 g	10 g	50 g
Suitable with Palletank Storage and Storage Stackable	50 L	200 L	500 L

Refer to specific Sartorius datasheet for Combics indicators ranges, printers and other accessories specifications and ordering information.

Integrated features

Features	Benefits	Palletank for storage	Palletank for storage stackable
Level marks	allow rapid visual monitoring of the fluid level in the bag	•	•*
Integrated pallet	allows easy carriage by pallet-jack or forklift	•	•
Tubing & Fitting Tray	simplifies fluid handling operations & provides a convenient and secure place for inlet & outlet tubing assemblies during transport	•	•
Lid	protects the bag against dust and light		•*
Bottom gate | Sliding gate	allows passage of large bore tubing, 1,5" tri clamps, QC bags and filters; facilitates bag positioning and maintain in position	•	•
Stacking corner	enables the stacking of the Palletank in order to maximise the utilisation of available clean room area		•
Dolly (accessory)	facilitates the movement of material throughout a facility	•	•

* Except 50 L volume

Ordering Information

| Order Code	Description
FXC110888	Palletank 200 L for storage
FXC110889	Palletank 500 L for storage
FXC113946	Palletank 50 L for storage stackable
FXC110733	Palletank 200 L for storage stackable
FXC110734	Palletank 500 L for storage stackable
FXA113988	Dolly for Palletank 50 L for storage
FXS102254	Dolly for Palletank 100 L | 200 L for storage & shipping
FXS102256	Dolly for Palletank 500 L for storage & shipping

Configurable Flexsafe® 3D Bioprocessing Bags

for Palletank 100 L – 1,000 L

Product Information

Flexsafe® bags ensure consistent cell growth, robustness and ease of use and are extensively validated for all process steps, from cell culture and downstream purification of drug substance to final formulation and filling of drug product. Characterization of resins and establishing supply contracts for the resins and the film ensure compliance, reliable assurance of supply and change control.
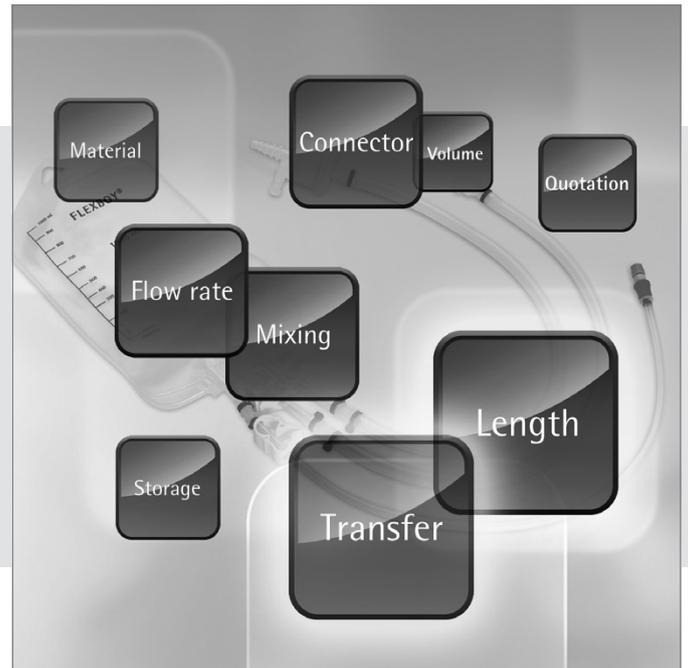
Description

Configurable Flexsafe® 3D Bags are designed from a database of pre qualified components and proven functionalities, using a web-based and interactive Product Configurator tool. The user friendly Product Configurator tool provides the flexibility needed for the application-based single use configuration whilst improving design and quotation turn around times, manufacturing lead times, security of supply, product reliability, safety and robustness.

Applications

The multi-layer, PE and EVOH based S80 film 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 filtration & storage

– Bulk harvest

– Product pooling

– Fraction collection

– Sample collection

– Bulk intermediate filtration & hold

– Final product storage and transport

Flexibility

Configurable Flexsafe® 3D Bags are configured from pre-qualified components and proven functionalities including a variety of tubing, connectors, filter and sampling methods for a streamlined incorporation into your process. Multiple configurations are available with thermoweldable TPE tubing, compatible with BioWelder® and BioSealer® for aseptic connection|disconnections, silicone TuFlux® tubing compatiblewith Clipster® Aseptic Disconnector and qualified for peristaltic pumping and EVA tubing for RF sealing with Vante™ Sealers. An extensive range of filters (Sartopore® 2, Sartopore® Platinum, Sartopore® 2 XLG, XLM and Sartoguard NF) are proposed with an optional flush bag. Needle free sampling port or sampling bags may be used for easy and convenient sampling. Quick couplers, tri-clamps, Steam thru valves and Sterile-to sterile connectors are provided for optimal connection flexibility in a production environment.

Features	Benefits
Pre-qualified component database and proven functionalities	Quality by design for improved product reliability
Standard components & manufacturing methods	Save on development and engineering costs
Instant design with a web-based Product Configurator	Shorten lead time for drawing & quotes
CTO dedicated supply chain and manufacturing capability	Shorten lead-time for products
Offer a large range of standardized configurable products	Reduce complexity and risks by Standardization
Product Configurator tool with preconfigured options & functionalities	Flexibility for optimal design tailored to the application needs
Most commonly used components and solutions in the market	Compatibility with end user process requirements

Robust Performance and Assurance of Supply

Flexsafe® 3D bags are designed for safe storage and shipping of biopharmaceutical solutions in Palletank containers. Flexsafe® bags ensure consistent cell growth robustness and ease of use and are extensively validated for all process steps, from cell culture and downstream purification of drug substance to final formulation and filling of drug product. Characterization of resins and establishing supply contracts for the resins and the film ensure compliance, reliable assurance of supply and change control.

Cell Growth

The resins and additives used for the film of Flexsafe® bags are optimized to reduce extractables and to ensure excellent and reproducible growth. The control of our entire process guarantees consistent lot-to-lot cell growth after short and long term media storage.

Robustness & Ease of Use

The combined thickness, strength and flexibility of Flexsafe® bags make them suitable for all process steps and applications and reduce the risk of damage due to inappropriate handling. Flexsafe® 3D bags in Palletank are validated with the most stringent ASTM D4169 shipping test regime to offer safe transportation of critical drug substances. The flexibility enables convenient installation and self-deployment of the bag in its container.

Consistent Extractable Profile

Specification and control of the resin and the film ensure well characterized and consistent extractables. Extractable data is readily available for risk assessment, thus saving end-users the time and money required for generating validation data. The validation established on extractables and|or leachable studies and toxicological analysis remains valid and reproducible from lot to lot.

Validation

Flexsafe® 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 Configurable Flexsafe® 3D Bags with data representing the widest 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. Design, Manufacture and Sterilization processes are conducted under conditions that mirror biopharmaceutical operations and meet cGMP requirements. Flexsafe® 3D Bags for Palletank are tested for compliance to:

– USP <85>: Bacterial endotoxins

– 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

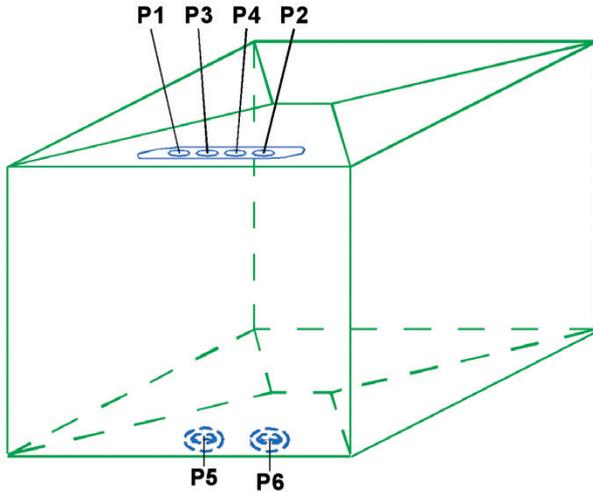– ISO 11137: Sterilization of Medical Devices

Supply Chain

Configurable Flexel® 3D Bags for Palletank are available as Configured to Order products. Pre-configured products based on application knowledge allow savings on engineering time and production preparation, thus providing reduced lead-times compared to classical fully customized processes.

Configurable Flexsafe® 3D for Palletank

Bag Chamber	Multiple layer film, including EVOH gas barrier layer and PE contact layer S80 film
Tubing	Silicone Tuflux® or Silicone (Pt) compatible with Clipster® Aseptic Disconnector, TPE compatible with BioWelder® and BioSealer®
End Connectors	Quick Couplers Triclamp and Mini-Triclamp Steam thru valves for SIP connections Sterile-to-sterile connectors, including Opta® sterile connector
Filters	Sartopore® 2 0.2µm Gamma MidiCaps® and T-Styles MaxiCaps® Capsules Sartopore® Platinum 0.2 µm Gamma MidiCaps® and T-Styles MaxiCaps® Capsules Sartopore® 2 XLG 0.8/0.2 µm Gamma MidiCaps® and T-Styles MaxiCaps® Capsules Sartopore® 2 XLM 0.2/0.1 µm MidiCaps® and T-Styles MaxiCaps® Capsules Sartoguard NF MidiCaps® and T-Styles MaxiCaps® Capsules With optional flush bag
Sampling	Needleless sampling site Manifolded Flexboy® or Flexel® sampling bags TPE tubing for tube-to-tube welding
Volumes	100 L – 1,000 L
Number of Ports	100 L – 500 L: 4 top ports – 1 bottom port 1,000 L: 4 top ports – 2 bottom ports
Sterilization	By Gamma Irradiation

Technical Data

Generic Description

Specifications

Volume
100 L, 200 L, 500 L, 1,000 L

Number of Ports
– 4 top ports for all bag volumes
– 1 central bottom port (P5) for 100 L, 200 L and 500 L
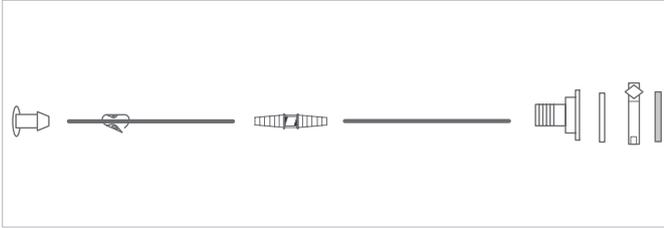– 2 bottom ports (P5 & P6) for 1,000 L

Type of Ports
– 1 top UPS4 port with 1 to 4 hose barb
  (¼", ⅜", ½", ¾", plug)
– 1 bottom UPS1 with 1 hose barb
  (¼", ⅜", ½", ¾", plug)

Functionalities
– Storage application
– Shipping application

Type of Lines

Port	P1	P2	P3	P4	P5	P6
Line	Line 1	Line 2	Line 3	Line 4	Line 5	Line 6
Function	Fill	Addition	Addition	Addition | Sampling	Drain	Drain
Normal Flow Rate	●	●	●	●	●	●
Normal Flow Rate with Sampling Bags	●					
Normal Flow Rate with Filter	●					
Normal Flow Rate with Filter and Sampling Bags	●					
Small Flow Rate	●	●	●	●	●	●
Small Flow rate with Sampling Bags	●					
High Flow Rate	●	●	●	●	●	●
Very Small Flow Rate		●	●			
Sampling				●		
Transfer to Filter					●	●
Not Used		●	●	●	●	●

Line Type "Normal Flow Rate"

Generic Description

Functionalities
– Bag filling or bag drainage
– Transfer with a peristaltic pump or by gravity
– Tube to tube welding
– Tube sealing
– Aseptic connection
– Generic connection with a Triclamp or a Quick Coupler

Specifications

Flow Rate
Maximum flow-rate with a peristaltic pump = 780 L/hr.
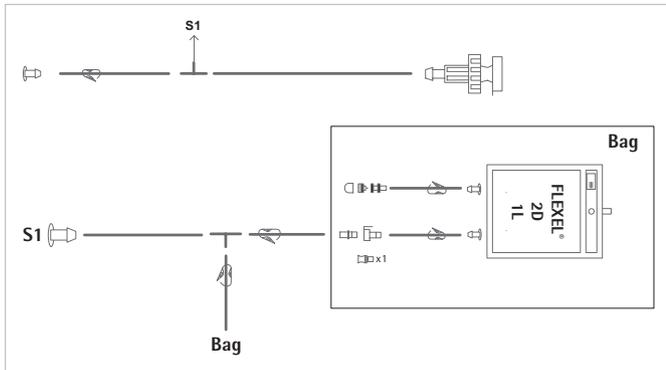Flow rate varies with discharge pressure, suction and viscosity.

Type of tubing	Tubing Diameters	Tubing lengths	Disconnection	Function
Silicone TuFlux® or Silicone (Pt)	ID × OD = ½" × ¾" (12.70 mm × 19.05 mm)	300 mm (12") 500 mm (19") 1,000 mm (39") 1,500 mm (59") 3,000 mm (118") 5,000 mm (197")	Clipster® disconnection on Silicone (Pt) ≥ 1,000 mm length	Transfer with Peristaltic pumping ≥ 1,000 mm length (10 hr maximum)
TPE Tubing (not for bottom lines P5 or P6)	ID × OD = ½" × ¾" (12.70 mm × 19.05 mm)	500 mm (19") 1,000 mm (39") 1,500 mm (59") 3,000 mm (118")	BioSealer® or Biowelder® or Clipster® disconnection ≥ 1,000 mm length	Transfer after tube-to-tube welding
Silicone TuFlux® or Silicone (Pt) with TPE tubing extension	ID × OD = ½" × ¾" (12.70 mm × 19.05 mm)	1,000 mm (39") silicone + 500 mm (19") TPE 2,500 mm (98") silicone + 500 mm (19") TPE 4,500 mm (177") silicone + 500 mm(19") TPE	BioSealer® or Biowelder® or Clispter® disconnection ≥1,000 mm length	Transfer with Peristaltic pumping ≥ 1,000 mm length (10hr maximum) for silicone tubing

Distal Connectors
– TriClamp (1 ½" or ¾" flange) with or without a triclamp cap, gasket and union
– Quick Coupler with plug – MPX (Male or Female or Double Female)
– OPTA® SFT – aseptic connection (Male or Female)
– STC & STC II - CPC Steamthru™ connection –
   (with 1 ½" and ¾" triclamp flanges or with ¾" × ¾" triclamp flanges)
– Aseptiquick® Genderless HT
– Plug (for TPE only)
– KPC HT – Male or Female – Kleenpak™ Sterile Connectors
   (Disclaimer: Please refer to the third party user
   manual and validation documentation)

Line Type "Normal Flow Rate with Sampling Bags"

Generic Description

Functionalities
– Bag filling
– Transfer with a peristaltic pump or by gravity
– Tube to tube welding
– Tube sealing
– Aseptic connection
– Generic connection with a Triclamp or a Quick Coupler
– On line sampling in bags

Specifications

Flow Rate
Maximum flow-rate with peristaltic pumping = 780 L/hr.
Flow rate varies with discharge pressure, suction and viscosity
and product filterability.

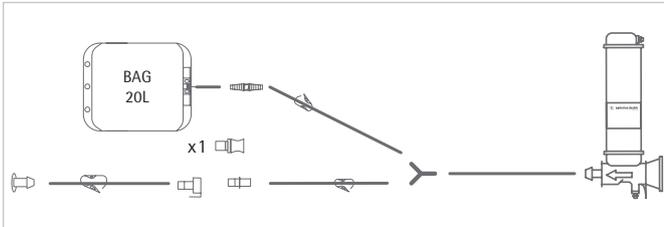| Type of tubing	Tubing Diameters	Tubing lengths	Disconnection	Function
Silicone TuFlux® or Silicone (Pt)	ID × OD = ½″ × ¾″ (12.70 mm × 19.05 mm)	1,000 mm (39″) 1,500 mm (59″) 3,000 mm (118″) 5,000 mm (197″)	Clipster® disconnection on Silicone (Pt) ≥ 1,000 mm length	Transfer with Peristaltic pumping ≥1,000 mm length (10 hr maximum)
Silicone TuFlux® or Silicone (Pt) with TPE tubing extension	ID × OD = ½″ × ¾″ (12.70 mm × 19.05 mm)	1,000 mm (39″) silicone + 500 mm (19″) TPE 2,500 mm (98″) silicone + 500 mm (19″) TPE 4,500 mm (177″) silicone + 500 mm (19″) TPE	BioSealer® or Biowelder® or Clispter® disconnection on Silicone (Pt) ≥1,000 mm length	Transfer with Peristaltic pumping ≥1,000 mm length (10hr maximum) for silicone tubing

Distal Connectors
– TriClamp (1 ½″ or ¾″ flange) with or without a triclamp cap,
  gasket and union
– Quick Coupler with plug – MPX
  (Male or Female or Double Female)
– OPTA® SFT – aseptic connection (Male or Female)
– STC & STC II - CPC Steamthru™ connection –
  (with 1 ½″ and ¾″ triclamp flanges or with ¾″ × ¾″
  triclamp flanges)
– Aseptiquick® Genderless HT
– Plug (for TPE only)
– KPC HT – Male or Female – Kleenpak™ Sterile Connectors
  (Disclaimer: Please refer to the third party user
  manual and validation documentation)

Sampling bags
– 2 or 4 × 50 mL Flexboy®
– 2 or 4 × 150 mL Flexboy®
– 2 or 4 × 500 mL Flexboy®
– 2 × 1,000 mL Flexboy®
– 2 or 4 × 150 mL Flexel®
– 2 or 4 × 500 mL Flexel®
– 2 × 1,000 mL Flexel®

Line Type "Normal Flow Rate with Filter"

Generic Description

Functionalities
– Filling trough large choice of filters
– Optional filter flush bag
– Filter disconnection with a MPX Quick Coupler (additional MPX plug provided in a PE pouch) or filter disconnection with tube sealing
– Filter removal with Clipster® aseptic disconnection system

Specifications

Flow Rate
Maximum flow-rate with peristaltic pumping = 780 L/hr.
Flow rate varies with discharge pressure, suction and viscosity and product filterability.

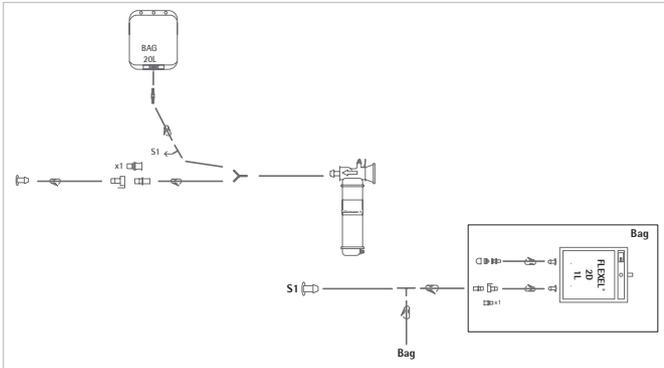| Type of tubing	Tubing Diameters	Tubing lengths	Disconnection	Function
Silicone TuFlux® or Silicone (Pt)	ID × OD = ½" × ¾" (12.70 mm × 19.05 mm)	800 mm (32") 1,500 mm (59") 3,000 mm (118") 5,000 mm (197")	Clipster® disconnection on Silicone (Pt) ≥ 1,000 mm length	Transfer with Peristaltic pumping ≥1,000 mm length (10 hr maximum)
TPE Tubing	ID × OD = ½" × ¾" (12.70 mm × 19.05 mm)	500 mm (19") 1,000 mm (39") 1,500 mm (59") 3,000 mm (118") 5,000 mm (197")	BioSealer® or Biowelder® or Clispter® disconnection on Silicone (Pt) ≥1,000 mm length	Transfer after tube-to-tube welding

Filter range with inlet TriClamp flange 1–½"

Filter type	Size of filter
Sartopore® 2 0.2 µm Gamma	MidiCaps® sizes 7, 8, 9, 0 MaxiCaps® T-Style sizes 1, 2, 3
Sartopore® Platinum 0.2 µm Gamma	MidiCaps® sizes 7, 8, 9, 0 MaxiCaps® T-Style sizes 1, 2, 3
Sartopore® XLG 0.8/0.2 µm Gamma	MidiCaps® sizes 7, 8, 9, 0 MaxiCaps® T-Style sizes 1, 2, 3
Sartopore® XLM 0.2/0.1 µm Gamma	MidiCaps® sizes 7, 8, 9, 0 MaxiCaps® T-Style sizes 1, 2, 3
Sartoguard NF	MidiCaps® sizes 8, 9, 0 MaxiCaps® T-Style sizes 1, 2, 3

With optional flush bags: 5 L, 10 L & 20 L

Line Type "Normal Flow Rate with Filter and Sampling Bags"

Generic Description

Functionalities
– Filling trough large choice of filters
– Optional filter flush bag
– Filter disconnection with a MPX Quick Coupler (additional MPX plug provided in a PE pouch) or filter disconnection with tube sealing
– Filter removal with Clipster® aseptic disconnection system

Specifications

Flow Rate
Maximum flow-rate with peristaltic pumping = 780 L/hr.
Flow rate varies with discharge pressure, suction and viscosity and product filterability.

Type of tubing	Tubing Diameters	Tubing lengths	Disconnection	Function
Silicone TuFlux® or Silicone (Pt)	ID × OD = ½" × ¾" (12.70 mm × 19.05 mm)	1,500mm (59") 3,000mm (118") 5,000mm (197")	Clipster® disconnection on Silicone (Pt) ≥ 1,000 mm length	Transfer with Peristaltic pumping ≥1,000 mm length (10 hr maximum)
TPE Tubing	ID × OD = ½" × ¾" (12.70 mm × 19.05 mm)	1,500mm (59") 3,000mm (118") 5,000mm (197")	BioSealer® or Biowelder® or Clispter® disconnection ≥1,000 mm length	Transfer after tube-to-tube welding

Filter range with inlet TriClamp flange 1–½"

| Filter type	Size of filter
Sartopore® 2 0.2 μm Gamma	MidiCaps® sizes 7, 8, 9, 0 MaxiCaps® T-Style sizes 1, 2, 3
Sartopore® Platinum 0.2 μm Gamma	MidiCaps® sizes 7, 8, 9, 0 MaxiCaps® T-Style sizes 1, 2, 3
Sartopore® XLG 0.8/0.2 μm Gamma	MidiCaps® sizes 7, 8, 9, 0 MaxiCaps® T-Style sizes 1, 2, 3
Sartopore® XLM 0.2/0.1 μm Gamma	MidiCaps® sizes 7, 8, 9, 0 MaxiCaps® T-Style sizes 1, 2, 3
Sartoguard NF	MidiCaps® sizes 8, 9, 0 MaxiCaps® T-Style sizes 1, 2, 3

With optional flush bags: 5L, 10L & 20L

Sampling bags
– 2 or 4 × 50 mL Flexboy®
– 2 or 4 × 150 mL Flexboy®
– 2 or 4 × 500 mL Flexboy®
– 2 × 1,000 mL Flexboy®
– 2 or 4 × 150 mL Flexel®
– 2 or 4 × 500 mL Flexel®
– 2 × 1,000 mL Flexel®

Line Type "Small Flow Rate"

Generic Description
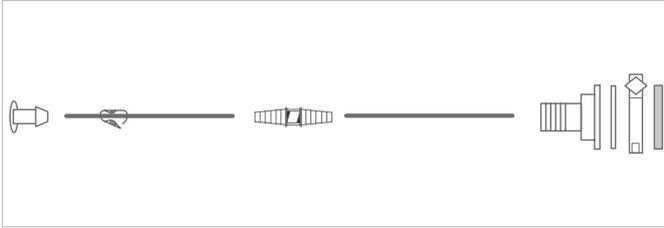
Functionalities
– Bag filling or bag drainage
– Transfer with a peristaltic pump or by gravity
– Tube to tube welding
– Tube sealing
– Aseptic connection
– Generic connection with a Triclamp or a Quick Coupler
– Disconnection with Clipster® aseptic disconnection system

Specifications

Flow Rate
Maximum flow-rate with a peristaltic pump = 420 L/hr.
Flow rate varies with discharge pressure, suction and viscosity.

Type of tubing	Tubing Diameters	Tubing lengths	Disconnection	Function
Silicone TuFlux® or Silicone (Pt)	ID × OD = ³⁄₈" × ⁵⁄₈ (9.53 mm × 15.88 mm)	300 mm (12") 500 mm (19") 1,000 mm (39") 1,500 mm (59") 3,000 mm (118") 5,000 mm (197")	Clipster® disconnection on Silicone (Pt) or Silicone TuFlux® ≥ 1,000 mm length	Transfer with Peristaltic pumping ≥ 1,000 mm length (10 hr maximum)
TPE Tubing	ID × OD = ³⁄₈" × ⁵⁄₈ (9.53 mm × 15.88 mm)	500 mm (19") 1,000 mm (39") 1,500 mm (59") 3,000 mm (118")	BioSealer® or Biowelder® or Clipster® disconnection ≥ 1,000 mm length	Transfer after tube-to-tube welding
Silicone TuFlux® or Silicone (Pt) with TPE tubing extension	ID × OD = ³⁄₈" × ⁵⁄₈ (9.53 mm × 15.88 mm)	1,000 mm (39") silicone + 500 mm (19") TPE 2,500 mm (98") silicone + 500 mm (19") TPE 4,500 mm (177") silicone + 500 mm (19") TPE	BioSealer® or Biowelder® or Clispter® disconnection ≥1,000 mm length	Transfer after tube-to-tube welding

Distal Connectors
– TriClamp (1 ½" or ¾" flange) with or without a triclamp cap, gasket and union
– Quick Coupler with plug – MPX (Male or Female or Double Female)
– OPTA® SFT – aseptic connection (Male or Female)
– STC & STC II - CPC Steamthru™ connection –
   (with 1 ½" and ¾" triclamp flanges or with ¾" × ¾" triclamp flanges)
– Aseptiquick® Genderless HT
– Plug (for TPE only)
– KPC HT – Male or Female – Kleenpak™ Sterile Connectors
– Lynx® Valve ST ½" – Lynx® ST Connector
   (Disclaimer: Please refer to the third party user
   manual and validation documentation)

Line Type "Small Flow rate with Sampling Bags"
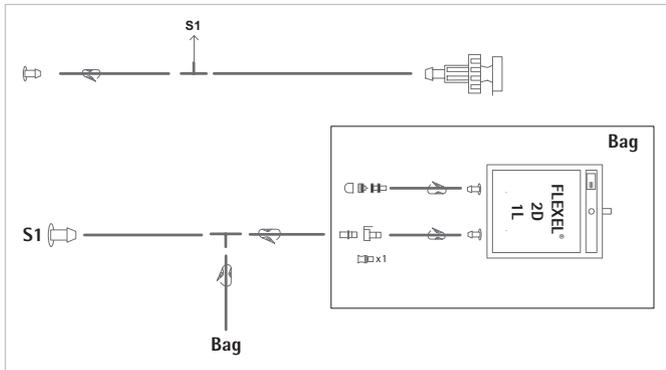
Generic Description

Functionalities
– Bag filling
– Transfer with a peristaltic pump or by gravity
– Tube to tube welding
– Tube sealing
– Aseptic connection
– Generic connection with a Triclamp or a Quick Coupler
– On line sampling in bags
– Disconnection with Clipster® aseptic disconnection system

Specifications

Flow Rate

Maximum flow-rate with a peristaltic pump = 420 L/hr.
Flow rate varies with discharge pressure, suction and viscosity.

| Type of tubing	Tubing Diameters	Tubing lengths	Disconnection	Function
Silicone TuFlux® or Silicone (Pt)	ID × OD = ³/₈" × ⁵/₈ (9.53 mm × 15.88 mm)	1,000 mm (39") 1,500 mm (59") 3,000 mm (118") 5,000 mm (197")	Clipster® disconnection on Silicone (Pt) or Silicone TuFlux® ≥ 1,000 mm length	Transfer with Peristaltic pumping ≥ 1,000 mm length (10 hr maximum)
Silicone TuFlux® or Silicone (Pt) with TPE tubing extension	ID × OD = ³/₈" × ⁵/₈ (9.53 mm × 15.88 mm)	1,000 mm (39") silicone + 500 mm (19") TPE 2,500 mm (98") silicone + 500 mm (19") TPE 4,500 mm (177") silicone + 500 mm (19") TPE	BioSealer® or Biowelder® or Clispter® disconnection ≥1,000 mm length	Transfer after tube-to-tube welding

Distal Connectors
– TriClamp (1 ½" or ¾" flange) with or without a triclamp cap, gasket and union
– Quick Coupler with plug – MPX (Male or Female or Double Female)
– OPTA® SFT – aseptic connection (Male or Female)
– STC & STC II - CPC Steamthru™ connection – (with 1 ½" and ¾" triclamp flanges or with ¾" × ¾" triclamp flanges)
– Aseptiquick® Genderless HT
– Plug (for TPE only)
– KPC HT – Male or Female – Kleenpak™ Sterile Connectors
– Lynx® Valve ST ½" – Lynx® ST Connector (Disclaimer: Please refer to the third party user manual and validation documentation)

Sampling bags
– 2 or 4 × 50 mL Flexboy®
– 2 or 4 × 150 mL Flexboy®
– 2 or 4 × 500 mL Flexboy®
– 2 × 1,000 mL Flexboy®
– 2 or 4 × 150 mL Flexel®
– 2 or 4 × 500 mL Flexel®
– 2 × 1,000 mL Flexel®

Line Type "High Flow Rate"

Generic Description
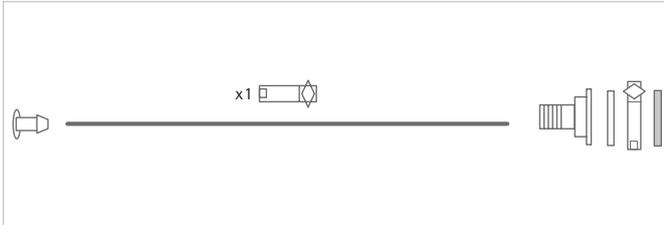
Functionalities
– Bag filling or bag drainage
– Transfer with a peristaltic pump or by gravity
– Generic connection with a Triclamp or a Quick Coupler

Specifications

Flow Rate
Maximum flow-rate with a peristaltic pump = 1,500 L/hr.
Flow rate varies with discharge pressure, suction and viscosity.

Tubing Diameters
ID × OD = ¾" × 1 ⅛" (19.05 mm × 28.58 mm)

Tubing Materials
– Silicone TuFlux® or Silicone (Pt) for 10 hr maximum operation
  with a peristaltic pump

Tubing Lengths
– 300 mm (12")
– 1,000 mm (39")
– 1,500 mm (59'')
– 3,000 mm (118")

Distal Connectors
– TriClamp (1 ½" or ¾" flange) with or without a triclamp cap,
  gasket and union
– Quick Coupler with plug – MPU (Male or Female)
– Opta® SFT - Aseptic connection (Male or Female)
– Aseptiquick® Genderless HT

Accessory
– External pinch clamp

Line Type "Very Small Flow Rate"

Generic Description
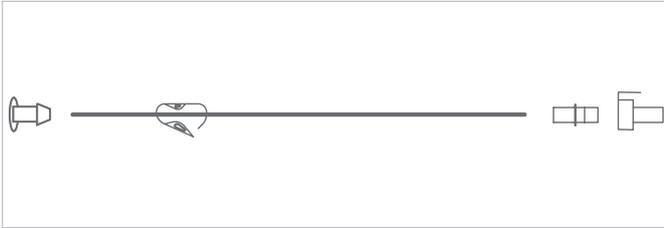
Functionalities
– Solution addition
– Transfer with a peristaltic pump or by gravity
– Tube to tube welding
– Tube sealing
– Generic connection with a Quick Coupler

Specifications

Flow rate
Maximum flow-rate with peristaltic pumping 240 L/hr.
Flow rate vary with discharge pressure, suction and viscosity.

Tubing Diameters
ID × OD = ¼" × ⁷⁄₁₆" (6.35 mm × 11.11 mm) Silicone TuFlux® or
Silicone (Pt) tubing ¼" × ³⁄₈" (6.35 mm × 9.53 mm) TPE tubing

Tubing Materials
– Silicone TuFlux® or Silicone (Pt) for 10 hr maximum operation
  with a peristaltic pump
– TPE (thermoplastic tubing) for tube sealing and welding operations

Tubing Lengths
– 1,500 mm (59")

Distal Connectors
– Quick Coupler with plug – MPC, Male (Only Silicone TuFlux®
  or Silicone (Pt))
– Plug (Only TPE)

Line Type "Sampling"

Generic Description
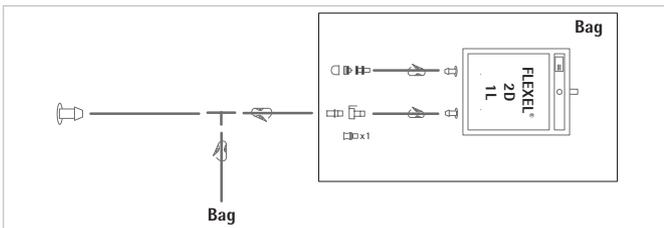
Functionalities
– Sampling from the top of the Flexel® Bag
– Needleless sampling port
– Tube welding
– Sampling bags

Specifications

Tubing diameter
ID × OD = ¼" × ⁷⁄₁₆" (6.35 mm × 11.11 mm)
Silicone TuFlux® or Si(Pt)tubing ¼" × ³⁄₈" (6.35 mm × 9.53 mm)
TPE tubing

Tubing Materials
– Silicone TuFlux® or Si(Pt) for needleless sampling port
– TPE (thermoplastic tubing) for welding, sampling, sealing
  operations
– EVA section for sealing sampling bags

Distal Connectors
– Needleless sampling port (Silicone TuFlux® or Si(Pt))
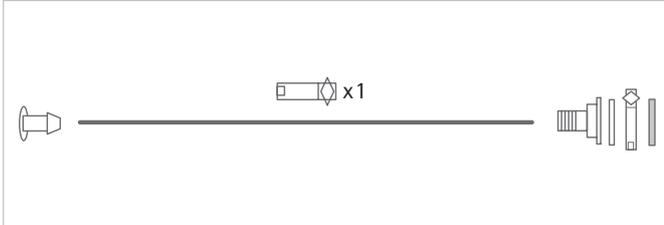– Plug (TPE only)

Tubing Lengths
– 100 mm (4") for Si(Pt) TuFlux® or Si(Pt)
– 150 mm for sampling bag volume <1L
– 300 mm for sampling bag volume =1L
– 1,000 mm (39") for TPE tubing

Sampling bags
– 2 or 4 × 50 mL Flexboy®
– 2 or 4 × 150 mL Flexboy®
– 2 or 4 × 500 mL Flexboy®
– 2 × 1,000 mL Flexboy®
– 2 or 4 × 150 mL Flexel®
– 2 or 4 × 500 mL Flexel®
– 2 × 1,000 mL Flexel®

Line Type "Transfer to Filter"

Generic Description

Functionalities
– Drain and transfer with a peristaltic pump to a filter
  (pressure rating of the line: 1.5 bar maximum)

Specifications

Flow Rate
Maximum flow-rate with a peristaltic pump = 780 L/hr.
Flow rate varies with discharge pressure, suction and viscosity
and product filterability.

Tubing Diameters
$ID \times OD = \frac{1}{2}" \times \frac{7}{8}"$ (12.7 mm $\times$ 22.2 mm)

Tubing Materials
– Specifically formulated platinum-cured silicone tubing for
  peristaltic pump applications, providing up to six times
  the pump life of standard platinum-cured silicone tubing.

Tubing Lengths
– 1,500 mm (59'')
– 3,000 mm (118")

Distal Connectors
– TriClamp (1 ½" flange) with a triclamp cap, gasket and union
– OPTA® SFT – aseptic connection (Male or Female)

Configurable Flexsafe® for Palletank 100 L – 1,000 L

	Normal Flow Rate	Normal Flow Rate with Sampling	Normal Flow Rate with Filter	Normal Flow Rate with Filter & Sampling
Function	Fill Drain Addition	Fill Drain Addition Sampling	Sterile Fill	Sterile Fill sampling
Port	P1 – 6	P1, P5	P1	P1
Tube Dim.	½" – ¾"	½" – ¾"	½" – ¾"	½" – ¾"
Tube Length mm	300 (12") 500 (19") 1,000 (39") 1,500 (59") 3,000 (118") 5,000 (197")	1,000 (39") 1,500 (59") 3,000 (118") 5,000 (197")	800 (32") 1,000 (39") 1,500 (59") 3,000 (118") 5,000 (197")	1,500 (59") 3,000 (118") 5,000 (197")
Tubing Materials	Si(Pt) TuFlux® Si(Pt) TPE Si(Pt) TuFlux® + TPE Si(Pt) + TPE	Si(Pt) TuFlux® Si(Pt) Si(Pt) TuFlux® + TPE Si(Pt) + TPE	Si(Pt) TuFlux® Si(Pt) TPE	Si(Pt) TuFlux® Si(Pt) TPE
Standard Connectors	TC 1 ½ TC ¾ MPX - M/F/FF Plug	TC 1 ½ TC ¾ MPX - M/F/FF Plug		
Aseptic Connectors	Opta® SFT-M/F Aseptiquick® STC 1 ½, ¾ STC ¾, ¾	Opta® SFT-M/F Aseptiquick® STC 1 ½, ¾ STC ¾, ¾		
Other Connectors	KPC HT – M/F	KPC HT – M/F		
Sampling bags on top		– 2 or 4 × 50 mL Flexboy® – 2 or 4 × 150 mL Flexboy® – 2 or 4 × 500 mL Flexboy® – 2 × 1,000 mL Flexboy® – 2 or 4 × 150 mL Flexel® – 2 or 4 × 500 mL Flexel® – 2 × 1,000 mLFlexel®		– 2 or 4 × 50 mL Flexboy® – 2 or 4 × 150 mL Flexboy® – 2 or 4 × 500 mL Flexboy® – 2 × 1,000 mL Flexboy® – 2 or 4 × 150 mL Flexel® – 2 or 4 × 500 mL Flexel® – 2 × 1,000 mL Flexel®
Sampling bags on bottom		– 2 or 4 × 50 mL Flexboy® – 2 or 4 × 150 mL Flexboy® – 2 × 150 mL Flexel®		

High Flow Rate	Small Flow Rate	Small Flow Rate with Sampling	Very Small Flow Rate	Sampling	Transfer to Filter
Fill Drain Addition	Fill Drain Addition	Fill Drain Addition Sampling	Addition	Sampling	Drain to filter
P1 – 6	P1 – 6	P1, P5	P2, P3	P4	P5, P6
$3/4$"–$1\,1/8$"	$3/8$"–$5/8$"	$3/8$" – $5/8$"	$1/4$" $\times$ $7/16$" or $1/4$" $\times$ $3/8$"	$1/4$" $\times$ $7/16$"	$1/2$ "–$7/8$"
300 (12") 1,000 (39") 1,500 (59") 3,000 (118")	300 (12") 500 (19") 1,000 (39") 1,500 (59") 3,000 (118") 5,000 (197")	1,000 (39") 1,500 (59") 3,000 (118") 5,000 (197")	1,500 (59")	100 (4") 150 (6") 300 (12") 1,000 (39")	1,500 (59") 3,000 (118")
Si(Pt) TuFlux® Si(Pt)	Si(Pt) TuFlux® Si(Pt) TPE Si(Pt) TuFlux® + TPE Si(Pt) + TPE	Si(Pt) TuFlux® Si(Pt) Si(Pt) TuFlux® + TPE Si(Pt) + TPE	Si(Pt) TuFlux® Si(Pt) TPE	Si(Pt) TuFlux® Si(Pt) TPE Si(Pt) + EVA	Si(Pt)
TC 1 ½ TC ¾ MPU- M/F Opta® SFT M/F Aseptiquick®	TC 1 ½ TC ¾ MPX - M/F/FF Plug	TC 1 ½ TC ¾ MPX - M/F/FF Plug	MPC-M Plug	Clave Plug	TC 1 ½+cap
	Opta® SFT-M/F Aseptiquick® STC 1 ½, ¾ STC ¾, ¾	Opta® SFT-M/F Aseptiquick® STC 1 ½, ¾ STC ¾, ¾			Opta® SFT-M/F
	KPC HT – M/F Lynx® ST M/F	KPC HT – M/F Lynx® ST M/F			
		– 2 or 4 × 50 mL Flexboy® – 2 or 4 × 150 mL Flexboy® – 2 or 4 × 500 mL Flexboy® – 2 × 1,000 mL Flexboy® – 2 or 4 × 150 mL Flexel® – 2 or 4 × 500 mL Flexel® – 2 × 1,000 mL Flexel®		– 2 or 4 × 50 mL Flexboy® – 2 or 4 × 150 mL Flexboy® – 2 or 4 × 500 mL Flexboy® – 2 × 1,000 mL Flexboy® – 2 or 4 × 150 mL Flexel® – 2 or 4 × 500 mL Flexel® – 2 × 1,000 mL Flexel®	
		– 2 or 4 × 50 mL Flexboy® – 2 or 4 × 150 mL Flexboy® – 2 × 150 mL Flexel®			

	Normal Flow Rate with Filter **Normal Flow Rate with Filter & Sampling**
Filters	Sartopore® 2 0.2 µm Gamma MidiCaps® sizes 7, 8, 9, 0 MaxiCaps® T-Style sizes 1, 2, 3
	Sartopore® Platinum 0.2 µm Gamma MidiCaps® sizes 7, 8, 9, 0 MaxiCaps® T-Style sizes 1, 2, 3
	Sartopore® XLG 0.8│0.2 µm Gamma MidiCaps® sizes 7, 8, 9, 0 MaxiCaps® T-Style sizes 1, 2, 3
	Sartopore® XLM 0.2│0.1µm Gamma MidiCaps® sizes 7, 8, 9, 0 MaxiCaps® T-Style sizes 1, 2, 3
	Sartoguard® NF MidiCaps® sizes 8, 9, 0 MaxiCaps® T-Style sizes 1, 2, 3
Flush bag	5 L, 10 L & 20 L

Microsart® ATMP Mycoplasma

Rapid Real-time PCR Mycoplasma Detection Kit for testing ATMPs

User Benefits

– Highest Level of Security

– Designed for ATMP Testing

– Easy Handling

Product Information

A standard DNA extraction followed by a TaqMan® probe real-time qPCR is used for the detection of Mycoplasma DNA. 200 µl sample volume can be used as starting material for DNA preparation. The isolated DNA is amplified in a qPCR cycler and the evaluation can be performed with the standard cycler software.

Introduction
Microsart® ATMP Mycoplasma utilizes quantitative, real-time PCR (qPCR) as the method of choice for sensitive and reliable detection of Mycoplasma contamination in autologous cell transplant culture. The Microsart® ATMP Mycoplasma kit was validated according EP 2.6.7 in combination with EP 2.6.21 with respect to detection limit for all listed Mycoplasma species, specificity and robustness for autologous cell transplants (e.g. chondrocytes).

Applications
The Microsart® ATMP Mycoplasma real-time PCR kit is especially designed for all hospitals, institution and companies which are involved in testing Mycoplasma contamination according to EP 2.6.7 in cell-based therapeutics like autologous chondrocyte transplants (ATMPs – advanced therapy medical products).

High Performance
The Microsart® ATMP Mycoplasma kit has been developed for EP complaint Mycoplasma testing in autologous cell transplants. A detection limit of less than 10 cfu/ml for all Mycoplasma species mentioned in the European Pharmacopoeia fulfills the requirements for the needed sensitivity and specificity.

Fast Result
The Microsart® ATMP Mycoplasma kit is a fast and easy to use real-time PCR kit. The total procedure from DNA extraction to PCR result takes only a few hours.

TaqMan® Probes
The use of TaqMan® probes adds specificity to the PCR detection system. The analysis is performed during the cycling process – no melting curve analysis is needed.

Contamination Prevention

The kit contains dUTP instead of dTTP, so the option is available to degrade amplicons form previous analyses by use of uracil-DNA glycosylase (UNG). Thus the occurrence of false-positive results can be minimized. UNG is not inculded in the kit.

Summary

The Microsart® ATMP Mycoplasma kit is the optimal solution for all QC labs which performing Mycoplasma testing of cell-based therapeutics like autologous chondrocyte transplants.

Unlike competitive PCR Detection kits, the Microsart® ATMP Mycoplasma kit is dedicated for the specific application in regard to sample volume, sensitivity , robustness and specificity.

Technical Specifications

Each Kit contains all required reagents for 25 or 100 reactions including polymerase as part of the Mycoplasma Mix. The expiry date of the unopened package is specified on the package label. The kit components are to be stored until use at +2 to +8°C and must be stored after opening and rehydration below −18°C. The lot specific Certificate of Analysis can be downloaded from the manufacturer's website (www.minerva-biolabs.com).

Kit Component	25 Reactions	100 Reactions
Order No.	SMB95-1003	SMB95-1004
Mycoplasma Mix	1 × lyophilized	4 × lyophilized
Rehydration Buffer	1 × 1.0 ml	4 × 0.5 ml
Positive Control	1 × lyophilized	1 × lyophilized
Internal Control	1 × lyophilized	4 × lyophilized
PCR grade Water	1 × 1.5 ml	4 × 1.5 ml

Order Information

Description	Quantity	Order No.
Mycoplasma Kits		
Microsart® ATMP Mycoplasma	25	SMB95-1003
Microsart® ATMP Mycoplasma	100	SMB95-1004
Accessories		
Microsart® AMP Extraktion	50 extractions	SMB95-2003
Related Products		
Microsart® AMP Mycoplasma	25	SMB95-1001
Microsart® AMP Mycoplasma	100	SMB95-1002
Microsart® RESEARCH Mycoplasma	25	SMB95-1005
Microsart® RESEARCH Mycoplasma	100	SMB95-1006

Microsart® ATMP
Bacteria/Fungi/Sterile Release
Microsart® RESEARCH Bacteria/Fungi

Rapid detection of total fungi in ATMPs prior treatment

User Benefits

- All critical bacterial and fungal contaminents detected in one test
- 3h-result: prior to treatment
- Specific TaqMan® probes reduce false-positives
- Non-infectious validation standards
- Less pipetting: controls already included

Product Information

Microsart® ATMP: Contaminated ATMPs pose life-threatening risks for immunocompromised patients. Microbial release test results prior to treatment are critical to patient safety. Microsart® ATMP Bacteria and Fungi or combined Microsart® ATMP Sterile Release that is ready prepared for single samples, enables the detection of bacterial and fungal contamination within 3 hours validated according to EP 5.1.6 and EP 2.6.27. During kit validation sensitivity (5 to 99 CFU/ml) was proven for 18 bacterial and 7 fungal species including 6 standard USP and EP strains. Comparability to the compendial method was demonstrated. The kit is not suitable to replace sterility testing according EP 2.6.1 or USP <71> yet. The Microsart® ATMP kits should be used as pre-check test to get rapid QC results for ATMPs.

Microsart® RESEARCH Bacteria and Fungi are used for fast and reliable direct detection of microbial contamination in cell cultures, cell culture supernatants and cell media components in research and development or whenever there is no need for regulation conform testing (i.e. according to EP/USP/JP).

Kit components and storage
Each kit contains all required reagents for the qPCR reaction. Due to lyophilization they are less temperature sensitive and ensure highest performance stability. Color-coded tubes with master mix, buffers, positive control and negative control, make the handling as simple as possible. For details, see kit components table on page 2.

The expiry date and the storage conditions of the unopened package are noted on the package label. The kit components are stored until use at +2° C to +8° C and must be stored after rehydration or opening at < -18° C. Please note: The master mix, also called Bacteria|Fungi Mix, should be protected from light all the time.

Test Principle
Microsart® ATMP|RESEARCH utilizes real-time PCR. The detection procedure can be performed within 3 hours, including less than 1 hour hands-on time. In contrast to the detection by cell cultivation method, samples do not need to contain vital bacteria.

The assay can be performed with any type of real-time PCR cycler able to detect the fluorescence dyes FAM™ and ROX™.

Bacteria or fungi are specifically detected by amplifying a highly conserved 16S|18S rRNA coding region in the bacterial|fungal genome. The amplification is detected at 520 nm (FAM™ channel). The kit includes primer and FAM™ labeled TaqMan® probes which allow the specific detection of more than 95% of all known bacterial and fungal species so far described as contaminants of cell cultures and media components. Eukaryotic DNA is not amplified by this primer | probe system.

False negative results due to PCR inhibitors or improper DNA extraction are detected by the internal amplification control which is part of the PCR master mix. The amplification of the internal amplification control is detected at 610 nm (ROX™ channel).

Product versions

a. Microsart® ATMP Sterile Release—contains all reagents for testing 10 patient samples for bacterial and fungal contamination including DNA extraction
b. Microsart® ATMP Bacteria—contains all reagents for 100 qPCR reactions to test for bacterial contamination without DNA extraction
c. Microsart® ATMP Fungi—contains all reagents for 100 qPCR reactions to test for fungal contamination without DNA extraction

d. Microsart® RESEARCH Bacteria—contains all reagents for 25|100 qPCR reactions to test for bacterial contamination without need of DNA extraction
e. Microsart® RESEARCH Fungi—contains all reagents for 25|100 qPCR reactions to test for fungal contamination without need of DNA extraction

The lot specific Certificate of Analysis can be downloaded from the manufacturer's website (www.minerva-biolabs.com).

Kit components

Order No.	Cap color	Microsart® ATMP Sterile Release SMB95-1007 (10 patient samples)	Microsart® ATMP Bacteria SMB95-1008 (100 rxn)	Microsart® ATMP Fungi SMB95-1012 (100 rxn)	Microsart® RESEARCH Bacteria (25|100) SMB95-1009 (25 rxn) SMB95-1010 (100 rxn)	Microsart® RESEARCH Fungi (25|100) SMB95-1014 (25 rxn) SMB95-1013 (100 rxn)
ATMP Bacteria Mix	red	10 x lyophilized	4 x lyophilized	–	4 x lyophilized	–
ATMP Fungi Mix	orange	10 x lyophilized	–	4 x lyophilized	–	4 x lyophilized
Rehydration Buffer	blue	10 x 0.5 ml	4 x 0.5 ml	4 x 0.5 ml	4 x 0.5 ml	4 x 0.5 ml
Positive Control DNA	green	10 x lyophylized	1 x lyophilized	1 x lyophilized	1 x lyophilized	1 x lyophilized
Internal Control DNA	yellow	10 x lyophilized	4 x lyophilized	4 x lyophilized	4 x lyophilized	4 x lyophilized
PCR grade Water	white	20 x 1.5 ml	5 x 1.5 ml	5 x 1.5 ml	5 x 1.5 ml	5 x 1.5 ml
Lysis Buffer	transparent	10 x 1.8 ml	–	–	–	–
Suspension Buffer	violet	10 x 1.5 ml	–	–	–	–
Processing Tubes	–	10 x 3	–	–	–	–

Related products

DNA Extraction kits

Order No.	Description	Quantity
SMB95-2001	Microsart® ATMP Extraction	Reagents for 50 extractions
SMB95-2003	Microsart® AMP Extraction (only for Mycoplasma qPCR)	Reagents for 50 extractions

Mycoplasma Detection Kits for qPCR

Order No.	Description	Quantity
SMB95-1001|1002	Microsart® AMP Mycoplasma	25|100 reactions
SMB95-1003|1004	Microsart® ATMP Mycoplasma	25|100 reactions
SMB95-1005|1006	Microsart® RESEARCH Mycoplasma	25|100 reactions

Microsart® Validation Standard according to EP 2.6.7 and USP <63> for Mycoplasma species and EP 2.6.1, EP 2.6.27 and USP <71> for other bacteria

3 vials with10 CFU/vial for Mycoplasma species and 6 vials with 99 CFU/vial for other bacteria and all fungi

Order No.	Description
SMB95-2005	Bacillus subtilis
SMB95-2006	Pseudomonas aeruginosa
SMB95-2007	Kocuria rhizophila
SMB95-2008	Clostridium sporogenes
SMB95-2009	Bacteroides vulgatus
SMB95-2010	Staphylococcus aureus
SMB95-2011	Mycoplasma arginini
SMB95-2012	Mycoplasma orale
SMB95-2013	Mycoplasma gallisepticum
SMB95-2014	Mycoplasma pneumoniae
SMB95-2015	Mycoplasma synoviae
SMB95-2016	Mycoplasma fermentans
SMB95-2017	Mycoplasma hyorhinis
SMB95-2018	Acholeplasma laidlawii
SMB95-2019	Spiroplasma citri
SMB95-2020	Mycoplasma salivarium
SMB95-2037	Candida albicans
SMB95-2038	Aspergillus brasiliensis
SMB95-2039	Aspergillus fumigatus
SMB95-2040	Penicillium chrysogenum
SMB95-2041	Candida glabrata
SMB95-2042	Candida krusei
SMB95-2043	Candida tropicalis

Microsart® Calibration Reagent, 1 vial, 108 genomes/ vial for all bacteria and 106 genomes/vial for all fungi

Order No.	Description
SMB95-2021	Mycoplasma arginini
SMB95-2022	Mycoplasma orale
SMB95-2023	Mycoplasma gallisepticum
SMB95-2024	Mycoplasma pneumoniae
SMB95-2025	Mycoplasma synoviae
SMB95-2026	Mycoplasma fermentans
SMB95-2027	Mycoplasma hyorhinis
SMB95-2028	Acholeplasma laidlawii
SMB95-2029	Spiroplasma citri
SMB95-2030	Bacillus subtilis
SMB95-2031	Pseudomonas aeruginosa
SMB95-2032	Kocuria rhizophila
SMB95-2033	Clostridium sporogenes
SMB95-2034	Bacteroides vulgatus
SMB95-2035	Staphylococcus aureus
SMB95-2036	Mycoplasma salivarium
SMB95-2044	Candida albicans
SMB95-2045	Aspergillus brasiliensis
SMB95-2046	Aspergillus fumigatus
SMB95-2047	Penicillium chrysogenum
SMB95-2048	Candida glabrata
SMB95-2049	Candida krusei
SMB95-2050	Candida tropicalis

User–supplied equipment and material
- For DNA extraction we recommend the DNA-free Microsart® ATMP Bacteria kit, Order No. SMB95-2001
- DNA-free PCR reaction tubes for the specific qPCR device
- Microcentrifuge for 1.5 ml reaction tubes, i.e. Centrisart A-14, Order No. A-14-1EU
- Pipettes with DNA-free filter tips (10, 100 and 1000 μl)
- qPCR device with filter sets for the detection of the fluorescence dyes FAM™ and ROX™ and suitable for 25 μl reaction volume

For PCR support and recommendation please contact PCR@Sartorius.com.

Sales and Service Contacts

For further contacts, visit www.sartorius.com

Europe

Germany
Sartorius Lab Instruments
GmbH & Co. KG
Otto-Brenner-Strasse 20
37079 Goettingen

Phone +49.551.308.0

France & Suisse Romande
Sartorius France
2, rue Antoine Laurent de Lavoisier
ZA de la Gaudrée
91410 Dourdan

Phone +33.1.70.62.50.00

Austria
Sartorius Austria GmbH
Modecenterstrasse 22
1030 Vienna

Phone +43.1.7965760.0

Belgium
Sartorius Belgium N.V.
Rue Colonel Bourg 105
1030 Bruxelles

Phone +32.2.756.06.90

Finland & Baltics
Sartorius Biohit Liquid Handling Oy
Laippatie 1
00880 Helsinki

Phone +358.9.755.951

Hungary
Sartorius Hungária Kft.
Kagyló u. 5.
2092 Budakeszi

Phone +3623.457.227

Ireland
Sartorius Ireland Ltd.
Unit 41, The Business Centre
Stadium Business Park
Ballycoolin Road
Dublin 11

Phone +353.1.8089050

Italy
Sartorius Italy S.r.l.
Via Torino 3/5
20814 Varedo (MB)

Phone +39.0362.5557.11

Netherlands
Sartorius Netherlands B.V.

Phone +31.30.60.53.001

info.netherlands@sartorius.com

Poland
Sartorius Poland sp.z o.o.
ul. Wrzesinska 70
62–025 Kostrzyn

Phone +48.61.6473830

Russian Federation
LLC "Sartorius RUS"
Vasilyevsky Island
5th line 70, Lit. A
199178 St. Petersburg

Phone +7.812.327.53.27

Spain & Portugal
Sartorius Spain, S.A.
Avda. de la Industria, 32
Edificio PAYMA
28108 Alcobendas (Madrid)

Phone Spain +34.913.586.095
Phone Portugal +351.800.855.800

Switzerland
Sartorius Mechatronics Switzerland AG
Ringstrasse 24a
8317 Tagelswangen (ZH)

Phone +41.44.746.50.00

U.K.
Sartorius UK Ltd.
Longmead Business Centre
Blenheim Road, Epsom
Surrey KT19 9QQ

Phone +44.1372.737159

Ukraine
LLS "Sartorius RUS"
Post Box 440 "B"
01001 Kiev, Ukraine

Phone +380.44.411.4918

Americas

USA
Sartorius Corporation
565 Johnson Avenue
Bohemia, NY 11716

Phone +1.631.254.4249
Toll-free +1.800.635.2906

Argentina
Sartorius Argentina S.A.
Int. A. Ávalos 4251
B1605ECS Munro
Buenos Aires

Phone +54.11.4721.0505

Brazil
Sartorius do Brasil Ltda
Avenida Senador Vergueiro 2962
São Bernardo do Campo
CEP 09600-000 - SP- Brasil

Phone +55.11.4362.8900

Canada
Sartorius Canada Inc
1173 North Service Road West, D4
Oakville, ON L6M 2V9

Phone +1.905.569.7977
Toll-Free +1.800.668.4234

Mexico
Sartorius de México, S.A. de C.V.
Libramiento Norte de Tepotzotlan s/n,
Colonia Barrio Tlacateco,
Municipio de Tepotzotlan,
Estado de México,
C.P. 54605

Phone +52.55.5562.1102

leadsmex@sartorius.com

Asia | Pacific

Australia
Sartorius Australia Pty. Ltd.
Unit 5, 7–11 Rodeo Drive
Dandenong South Vic 3175

Phone +61.3.8762.1800

China
Sartorius (Shanghai) Trading Co., Ltd.
3rd Floor, North Wing, Tower 1
No. 4560 Jinke Road
Zhangjiang Hi-Tech Park
Pudong District
Shanghai 201210, P.R. China

Phone +86.21.6878.2300

Hong Kong
Sartorius Hong Kong Ltd.
Unit 1012, Lu Plaza
2 Wing Yip Street
Kwun Tong
Kowloon, Hong Kong

Phone +852.2774.2678

India
Sartorius Weighing India Pvt. Ltd.
#69/2–69/3, NH 48, Jakkasandra,
Nelamangala Tq
562 123 Bangalore, India

Phone +91.80.4350.5250

Japan
Sartorius Japan K.K.
4th Fl., Daiwa Shinagawa North Bldg.
8-11, Kita-Shinagawa 1-chome
Shinagawa-ku, Tokyo, 140-0001 Japan

Phone +81.3.6478.5200

Malaysia
Sartorius Malaysia Sdn. Bhd
Lot L3-E-3B, Enterprise 4
Technology Park Malaysia
Bukit Jalil
57000 Kuala Lumpur, Malaysia

Phone +60.3.8996.0622

Singapore
Sartorius Singapore Pte. Ltd
10 Science Park Rd
The Alpha #02-13/14
Singapore Science Park II
Singapore 117684

Phone +65.6872.3966

South Korea
Sartorius Korea Ltd.
8th Floor, Solid Space B/D,
PanGyoYeok-Ro 220, BunDang-Gu
SeongNam-Si, GyeongGi-Do, 463–400

Phone +82.31.622.5700

Thailand
Sartorius (Thailand) Co. Ltd.
129 Rama 9 Road,
Huaykwang
Bangkok 10310

Phone +66.2643.8361–6

www.sartorius.com

NutriFreez® D10 Cryopreservation Medium

Powerful cryopreservation media optimized for various cells and tissues

NutriFreez® D10 Cryopreservation Medium is an optimized freezing solution designed and validated for the cryopreservation of various tissue and cell types, including but not limited to sensitive cell types such as hESCs, iPSCs, and MSCs. NutriFreez® D10 Medium maintains defined and animal component-free conditions during cryopreservation, essential to maintaining consistency when culturing cells in a xeno-free system. NutriFreez® D10 Medium is ready-to-use and pre-formulated with DMSO, providing a protective environment for cells during the freezing, storage, and thawing process. Cells preserved with NutriFreez® D10 Medium show excellent attachment (Figure 1) and maintain proper pluripotency marker expression after thawing, with superior results compared to both serum-containing freezing media, other serum-free solutions, and homebrew formulations[1].

- **High recovery post thaw**
- **Ready-to-use solution**
- **Serum-free and protein-free**
- **Chemically-defined**
- **cGMP-manufactured**
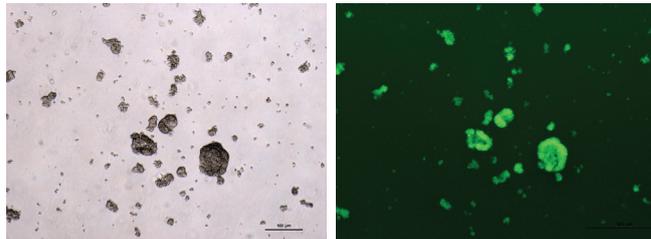
Figure 1: BG01V/hOG cells (an Oct4-GFP reporter hES cell line) frozen in NutriFreez® D10 Medium and thawed into NutriStem® hPSC Medium on Matrigel. Images taken just 1 hour post-thaw show excellent survival and attachment of the hES cells, with high expression of Oct4 (green).

Applicable Cell Types

- Human Embryonic Stem Cells
- Induced Pluripotent Stem Cells
- Human Mesenchymal Stem Cells
- Peripheral Blood Mononuclear Cells
- Human Endothelial Cells
- T cells, including Chimeric Antigen Receptor (CAR T) Cells and Tumor Infiltrating Lymphocytes (TILs)
- Neuron Cells
- Hybridomas
- CHO Cells
- Vero Cells
- Multiple mammalian cell lines:
MRC-5, HEK-293, HepG2, HeLaBSC-1, BGM3T3, MA-10BHK-21

Ordering Information

Cat. #	Product	Qty
05-713-1A	NutriFreez® D10 Cryopreservation Medium	500 mL
05-713-1B		100 mL
05-713-1E		50 mL
05-713-1C		20 mL
05-713-1D		10 mL
05-714-1A	NutriFreez® D10 Cryopreservation Medium, w/o phenol red	500 mL
05-714-1B		100 mL

1. Nishishita N, et al. An effective freezing/thawing method for human pluripotent stem cells cultured in chemically-defined and feeder-free conditions. AJSC 2015;4(1):38-49.

How to Order

Biological Industries | T. +972.4.9960595 | F. +972.4.9968896 | info@bioind.com

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Simplifying Progress

SARTORIUS

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Boosting business growth

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- Monitor in real time and swiftly detect deviations. With SIMCA you can model your ideal process from your collected data. Transferred into SIMCA-online, the model acts as a valuable reference for your current production.

- Predict with confidence. You can predict final quality from the properties of the raw material and the process parameters as well as forecast the final quality.

- Control at a glance. SIMCA-online uses an 'ideal process' model to anticipate the effect of changes and recommend immediate adjustments. This will ensure product performance according to specifications and optimize throughput.

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SIMCA-online has been adopted widely in many different industries, including pharma & chemical, pulp & paper and food & beverage.

Our customers have seen excellent results in cost savings, efficiency and product quality. For instance:

- A multi-national paper company reduced costs, achieved a more consistent product quality and gained a deeper understanding of their data.

- A major food processing company saved over USD 3 million each year in production costs.

- A pharmaceutical company paid for their investment several-fold in recovered batches alone.

SIMCA-online at a glance:

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- Root-cause-analysis
- Predicting final quality attributes
- Soft sensing
- Real-time supervisory control

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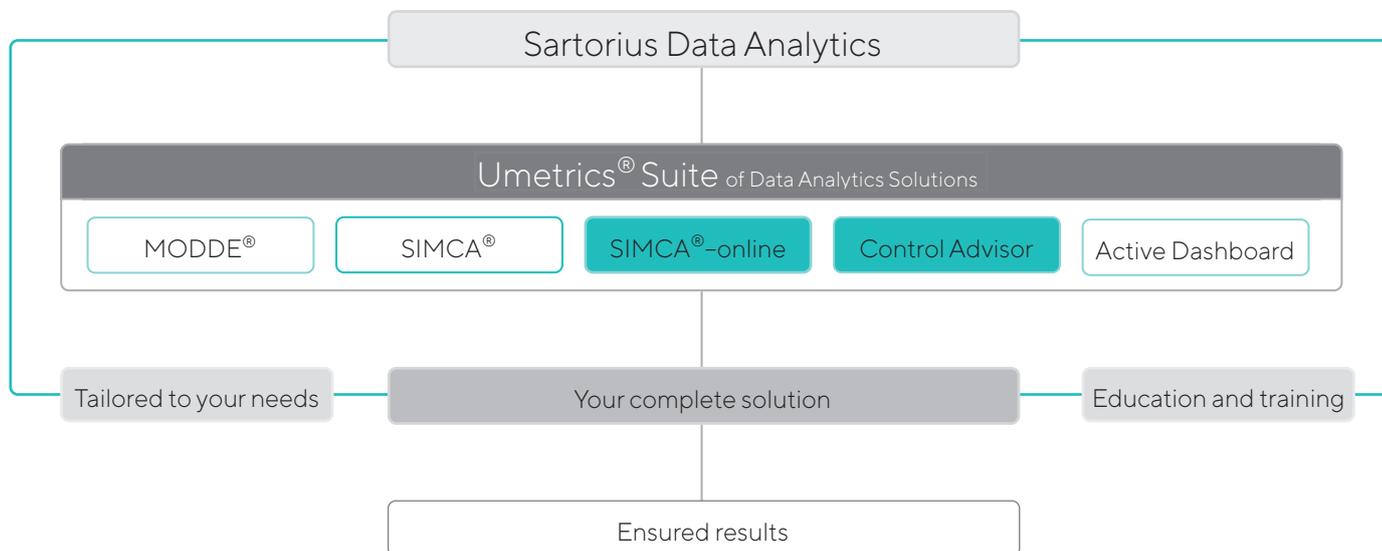
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As our customer, you'll have access to supporting documents, templates, training and consultation to address your specific business challenges. Our courses and webinars help over a thousand people every year develop expertise and confidence in data analytics.

" SIMCA-online improves overall understanding of process and equipment

A complete suite for business growth

The Umetrics Suite is a family of proven data analytics solutions that work seamlessly together.
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- Control Advisor
  Predictive capabilities to be able to forecast the output
- Active Dashboard
  Interactive performance insight

These solutions give you control and confidence in your processes at every stage - from development to manufacturing.
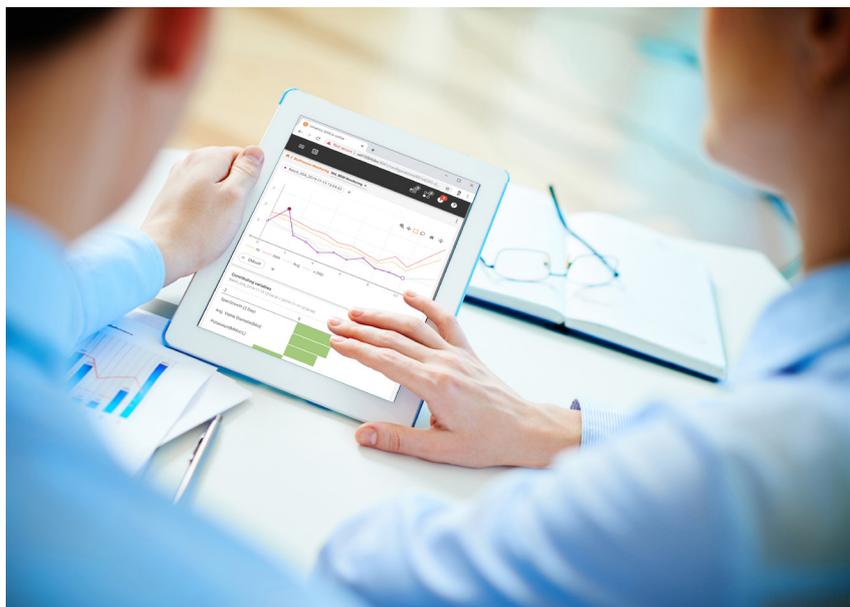
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