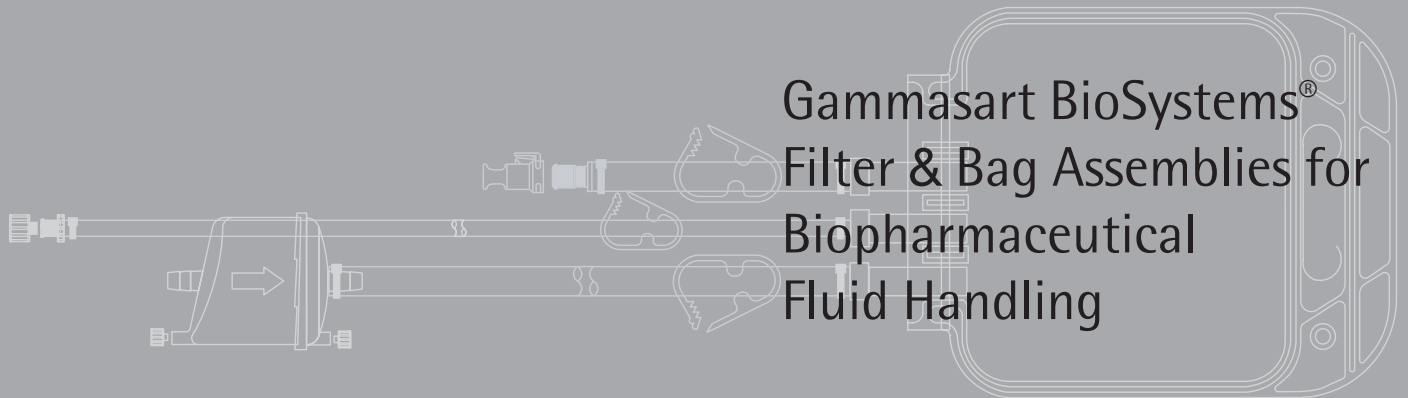


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Gammasart BioSystems®
Filter & Bag Assemblies for
Biopharmaceutical
Fluid Handling

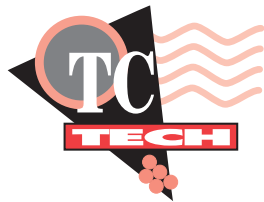
TC Tech | Sartorius Alliance

The TC Tech | Sartorius Alliance combines the resources of two industry-leading suppliers resulting in an unparalleled ability to deliver value-added fluid processing and storage solutions to the biopharmaceutical manufacturing market.

By delivering bioprocess filters & bags as sterilized assemblies TC Tech | Sartorius eliminates the time, cost and risk associated with on-site filter & bag assembly.

Available as standard items for a wide range of fluid volumes, assemblies are carried in inventory and are available for rapid delivery. Also available are customized assemblies engineered for specific application requirements.

Call us today for the specialist in your area and discover why pharmaceutical companies worldwide are making TC Tech | Sartorius a supplier of choice.



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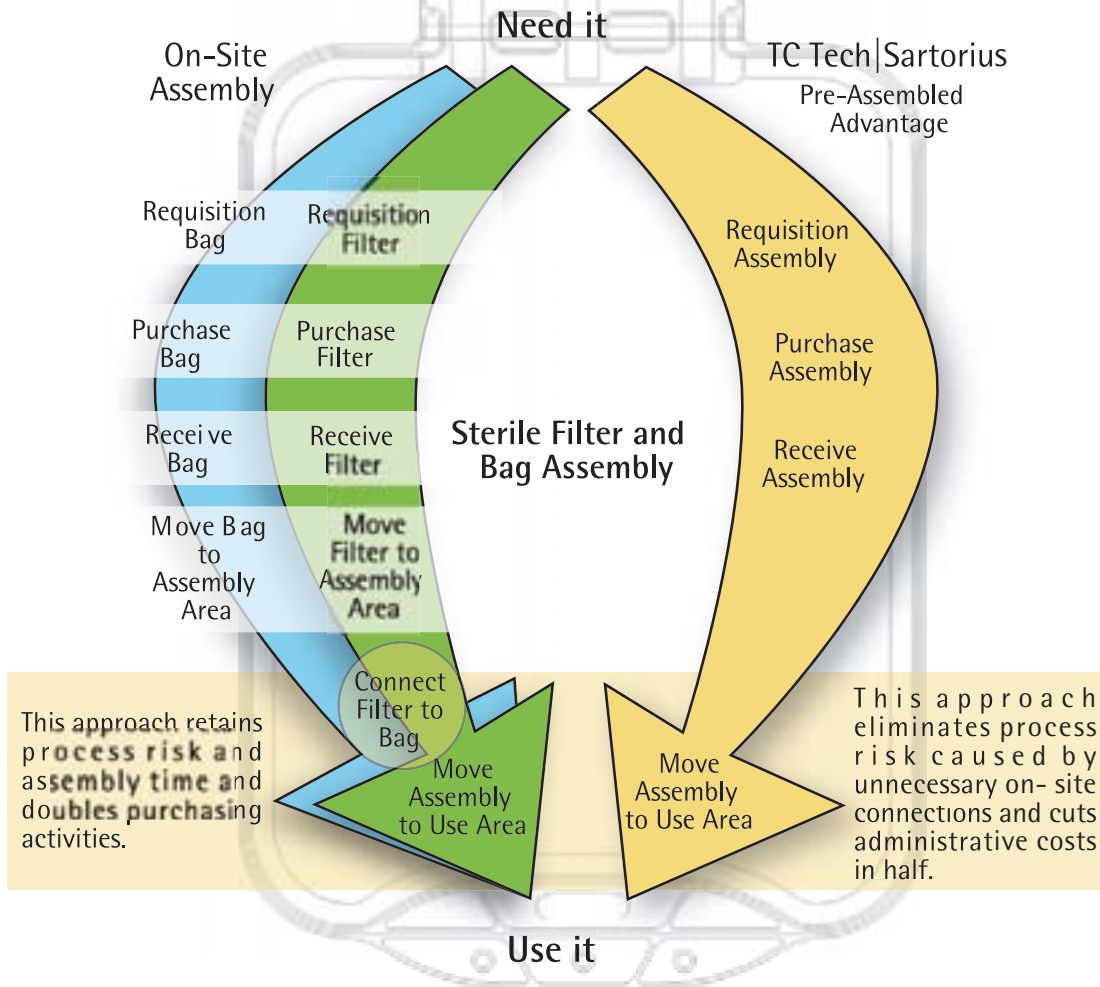


Single-Source Integrated Fluid Handling Solutions

The use of disposable processing systems has many well established benefits for bioprocessors:

- Single use eliminates cross contamination risk
- Pre-sterilized components reduce on site sterilization requirements
- Elimination of cleaning and cleaning validation reduces:
 - Direct Labor
 - Downtime
 - WFI usage
 - Steam usage
 - Waste streams from cleaning
- Reduced capital investment
- Quick & easy scale up

The TC Tech|Sartorius alliance now enhances these benefits by making pre-sterilized, custom and standard filter & bag assemblies available through a single source. Pre-assembled filter and bag assemblies eliminate unnecessary aseptic connections, reducing contamination risk and enhancing production efficiency. Purchasing filter and bag assemblies through a single source cuts lead times, procurement activities and the trouble of coordinating it all.



Gammasart BioSystem SA[®]

Standard Filter & Bag Assemblies In Stock to Serve Your Immediate Needs

Gammasart BioSystem SA Standard Filter and Bag Assemblies

Standard assemblies have been designed, manufactured and gamma sterilized and are in stock to provide maximum flexibility for your immediate needs. Available with variety of bag sizes, each standard assembly incorporates a Sartopore 2[®] 0.2 μm , sterilizing grade filter capsule sized for most filtration requirements. C-Flex[®] tubing allows the use of tubing welders and sealers and a QDC and female luer provide connection flexibility. Fluid containment is provided by pinch clamps on each tubing run.



Gammasart BioSystem SA1 - 1 liter
Standard Filter and Bag Assembly



Gammasart BioSystem SA2 - 2 liter
Standard Filter and Bag Assembly



Gammasart BioSystem SA5 - 5 liter
Standard Filter and Bag Assembly



Gammasart BioSystem SA10 - 10 liter
Standard Filter and Bag Assembly

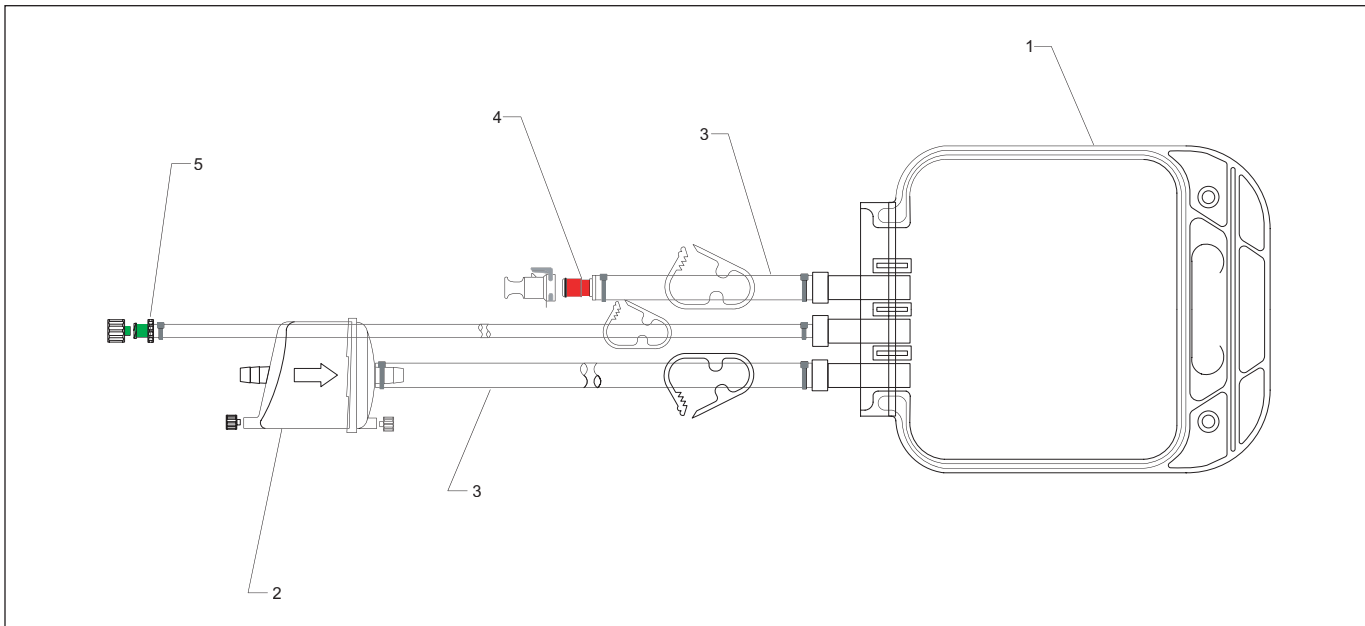


Gammasart BioSystem SA20 - 20 liter
Standard Filter and Bag Assembly



Gammasart BioSystem SA50 - 50 liter
Standard Filter and Bag Assembly

Standard Filter & Bag Assemblies (continued) In Stock to Serve Your Immediate Needs



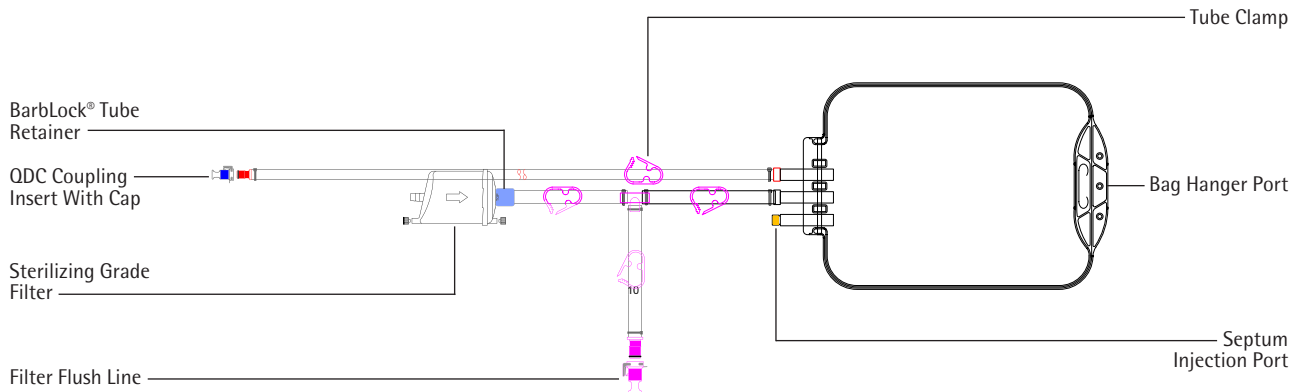
Ordering Information

Assembly P/N	Description	Item 1 Bag Chamber	Item 2 Bag Port 1 - Filter (Tubing Length)	Item 3 Tubing	Item 4 Bag Port 2 (Tubing Length)	Item 5 Bag Port 3
TC-145001	Gammasart BioSystem SA1	1 liter	5441307H4G-00, Sartopore 2 0.2µm, 150 cm ² , Gamma Capsule (18")	C-Flex® Clear 082 1/4" x 7/16"	QDC Insert with Cap (6")	36" SCD® Tubing with Female Luer & Plug
TC-145002	Gammasart BioSystem SA2	2 liter with Handle	5441307H4G-00, Sartopore 2 0.2µm, 150 cm ² , Gamma Capsule (18")	C-Flex® Clear 082 3/8" x 5/8"	QDC Insert with Cap (6")	36" SCD® Tubing with Female Luer & Plug
TC-145005	Gammasart BioSystem SA5	5 liter with Handle	5441307H5G-00, Sartopore 2 0.2µm, 300 cm ² , Gamma Capsule (18")	C-Flex® Clear 082 3/8" x 5/8"	QDC Insert with Cap (6")	36" SCD® Tubing with Female Luer & Plug.
TC-145010	Gammasart BioSystem SA10	10 liter with Handle	5441307H5G-00, Sartopore 2 0.2µm, 300 cm ² , Gamma Capsule (18")	C-Flex® Clear 082 3/8" x 5/8"	QDC Insert with Cap (6")	36" SCD® Tubing with Female Luer & Plug
TC-145020	Gammasart BioSystem SA20	20 liter with Handle	5441307H5G-00, Sartopore 2 0.2µm, 300 cm ² , Gamma Capsule (18")	C-Flex® Clear 082 3/8" x 5/8"	QDC Insert with Cap (6")	36" SCD® Tubing with Female Luer & Plug
TC-145050	Gammasart BioSystem SA50	50 liter	5441307H7G-S0, Sartopore 2 0.2µm, 1/2 ft ² Gamma Capsule (36")	C-Flex® Clear 082 1/2" x 3/4"	QDC Insert with Cap (6")	36" SCD® Tubing with Female Luer & Plug
TC-145100	Gammasart BioSystem SA100	100 liter	5441307H8G-S0, Sartopore 2 0.2µm, 1 ft ² Gamma Capsule (36")	C-Flex® Clear 082 1/2" x 3/4"	QDC Insert with Cap (6")	36" SCD® Tubing with Female Luer & Plug
TC-145200	Gammasart BioSystem SA200	200 liter	5441307H8G-S0, Sartopore 2 0.2µm, 1 ft ² Gamma Capsule (36")	C-Flex® Clear 082 1/2" x 3/4"	QDC Insert with Cap (6")	36" SCD® Tubing with Female Luer & Plug

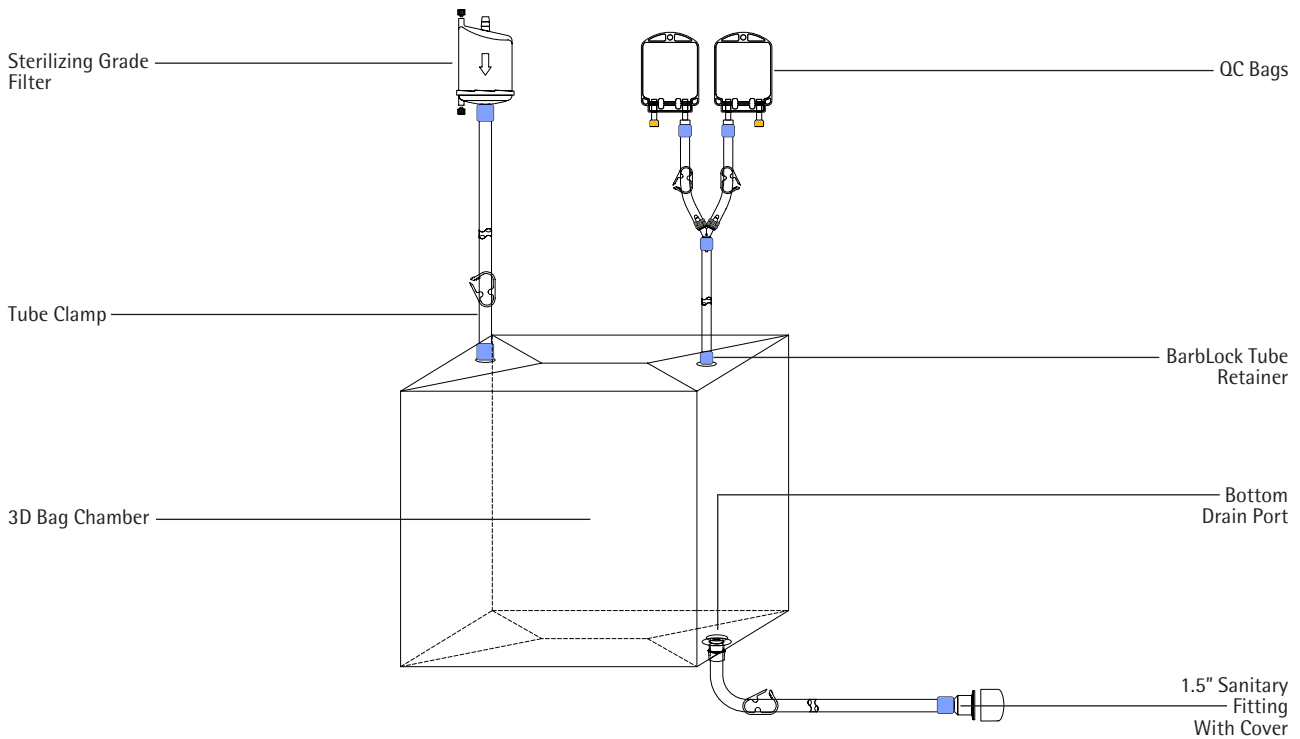
Custom Filter & Bag Assemblies

TC Tech|Sartorius will work with you to design a filter & bag system that optimizes use in your specific process. The TC Tech|Sartorius design team will provide drawings of custom assemblies for your review. Choose from a variety of USP Class VI tubing, connectors & accessories.

- 2D & 3D Bag Styles Available
- Assembly sizes for 60 ml – 2000+ Liter Fluid Volumes
- Can be Designed to fit your Existing Container



20 Liter Bag with Sartopore 2 Filter & Flush Port



1000 Liter Bottom Drain Bag with Sartopore 2 Filter & QC Bags

Custom Filter & Bag Components

Quick Disconnect



QDC Coupling Insert



QDC Sealing Cap



QDC Coupling Body



QDC Sealing Plug



QDC 3/4"
Coupling Body



QDC 3/4"
Coupling Insert

Sanitary



3/4" Mini Sanitary
Fitting



1.5" Sanitary Fitting

Luer



Male Luer



Female Luer Plug



Female Luer



Male Luer Plug

Accessories



SIP Bag Connector



BarbLock® Tubing
Retainer



"Y" & "T" Connectors



Reducers



Port Covers



BioClamp

Accessories (continued)



Tube Clamp

Pharmaceutical Grade Tubing



C-Flex® Tubing,
Clear Formulation 082, 050



Tygon® Silicone Tubing,
Formulation 3350



PharMed® Long-Life
Pump Tubing



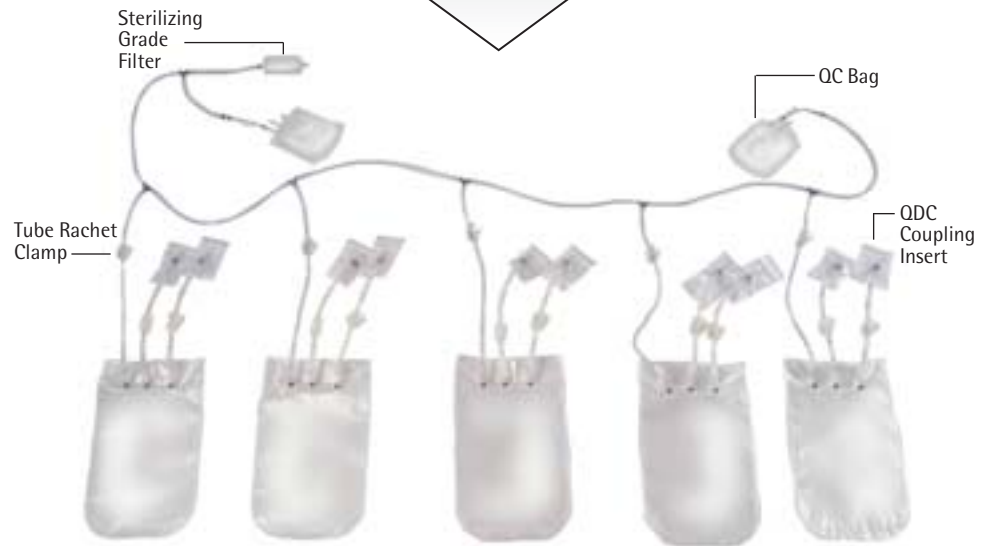
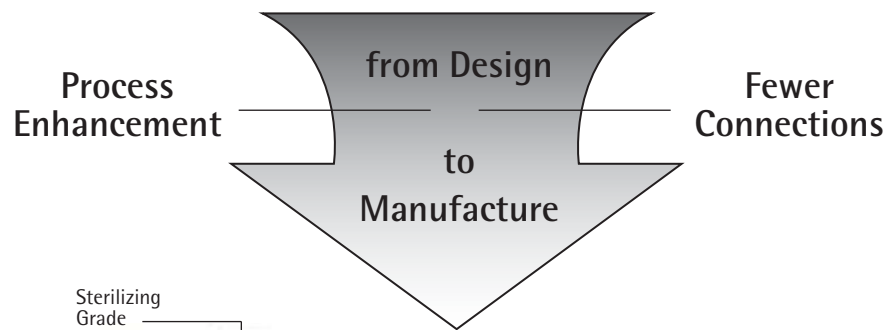
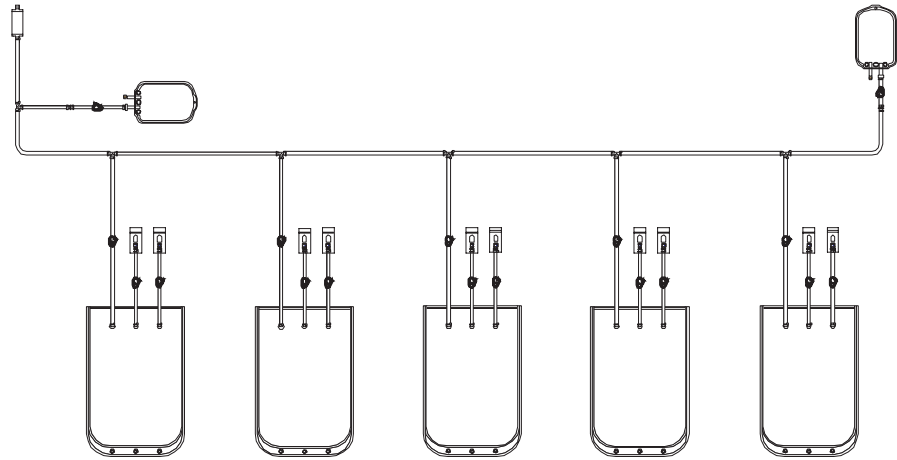
C-Flex® Tubing
Opaque Formulation 001, 072



Platinum Cured
Silicone Tubing

Filter & Bag Manifolds

Filter & Bag Manifolds allow the user to filter into multiple bags while making only a single connection. Designed to optimize your specific process virtually any number of bags can be assembled. Tube ratchet clamps allow for filling bags in any order. Typical design incorporates a 1 Liter QC bag in the manifold system.





TC Tech Sterile Fluid Handling Bags

Description

TC Tech Sterile Fluid Handling Bags are designed for storage of upstream & downstream biopharmaceutical fluids. They are provided sterilized via 25kGy-40kGy Gamma irradiation.

Applications

Typical applications for TC Tech Sterile Fluid Handling Bags with Sartopore 2 Sterilizing Grade capsules include:

- Pharmaceuticals
- Biologicals
- Media Filtration & Storage
- Buffer Filtration & Storage
- Intermediate & Final Product Filtration & Storage

Compatibility

Bag chambers utilize a LDPE fluid contact surface. LDPE offers broad chemical compatibility from pH 1 to pH 14 making it ideally suited for a wide range of applications in the biopharmaceutical field.



Performance

Multi-layer films include layers of LDPE, EVOH and Nylon resulting in outstanding biocompatibility, strength, and resistance to permeation. Additionally TC Tech films have demonstrated very low extractable levels over a broad range of solutions.

TC Tech Sterile Fluid Handling Bag Component Descriptions

Bag Chamber Film

LDPE Fluid Contact Surface
EVOH Gas Barrier Layer
Nylon Strength Layers
LLDPE Tie Layers

Standard Chamber Sizes

60ml	20 Liter
300ml	50 Liter
1 Liter	100 Liter
5 Liter	200 Liter
2 Liter	500 Liter
10 Liter	1000 Liter

Chamber Port Material

Polyethylene

Tube Clamp Material

Polypropylene

Retainers

BarbLock[®] - 1/8" - 5/8" - Polypropylene
Cable Ties - Nylon, Tefzel[®]

Bio Clamp Material

Fiberglass Reinforced Nylon

Connectors

Quick Disconnect 1/4", 3/8", 1/2" - Polycarbonate or Polysulfone
Quick Disconnect 3/4" - Polysulfone
Sanitary Fitting - 3/4" mini, 1", 1.5" - Polypropylene or PVDF
Luer Fittings - 1/8" - 1/4" - Polycarbonate or Nylon
T & Y Connectors - 1/8" - 5/8" - Polypropylene or Polycarbonate
SIP Connector - 3/8" & 1/2" Barb - 3/4" & 1.5" Sanitary - Polysulfone

Tubing

C-Flex[®] Formulation 082 - Translucent - Shore A, 60
Platinum Cured Silicone - Translucent - Shore A, 50
Tygon[®] Silicone Tubing - Translucent - Shore A, 50
PharMed[®] Tubing - Opaque - Shore A, 64
C-Flex[®] Formulation 050 - Translucent - Shore A, 50
C-Flex[®] Formulation 072 - Opaque - Shore A, 60
C-Flex[®] Formulation 001 - Opaque - Shore A, 50

Component Documentation

All fluid contact components used in the manufacture of TC Tech Sterile Fluid Handling Bags meet USP <88> Class VI guidelines. Additional documentation is available for most components in the areas of cytotoxicity, pyrogenicity, and extractables. See TC Tech for further information on component documentation.

Sartopore 2 Sterilizing Grade and Mycoplasma Retentive γ -Irradiatable Filter Capsules



Description

Sartopore 2- γ -irradiatable filter capsules are designed for sterilizing grade filtration and mycoplasma removal in filter & bag assemblies. Prior or after connection to flexible-bag-container-systems they can be sterilized by γ -irradiation \leq 50 kGy.

Applications

Typical applications for 0.2 μ m rated Sartopore 2- γ -irradiatable capsules include sterilizing grade filtration of:

- Pharmaceuticals
- Biologicals
- Cell Culture Media
- Culture Media Components
- Serum
- Buffers
- Diagnostic Reagents

Typical applications for 0.1 μ m rated Sartopore 2- γ -irradiatable capsules include combined sterilizing grade and mycoplasma removal from:

- Cell Culture Media
- Culture Media Components
- Serum

Sartopore 2- γ -capsules 0.1 μ m rated are ideally suited for bioprocessed pharmaceuticals and any other applications requiring sub 0.2 μ m filtration for enhanced sterility assurance.

Compatibility

Sartopore 2- γ -capsules are designed for sterilization by gamma irradiation \leq 50 kGy irradiation dosage. The Polyethersulfone membrane of the Sartopore 2- γ -capsules offers a broad chemical compatibility from pH 1 to pH 14 making them ideally suited for a broad range of applications in the Pharma | Biotech field.

Performance

Due to the superior construction including a "built-in" prefiltration by a heterogeneous double layer membrane, Sartopore 2- γ -capsules achieve outstanding total throughputs and excellent flow rates.

Flexibility

Sartopore 2- γ -capsules are available with filtration areas



from 0.015 m² | 0.45 m² for easy adaption to any filter & bag assembly independent from the batch size.

Microbiological Retention

Sartopore 2- γ -capsules are fully validated as sterilizing grade filters according to HIMA/ASTM F-838-83 guidelines and for mycoplasma removals for 0.1 μ m rated Sartopore 2- γ -capsules with a Log Reduction Value(LRV) of 7 for *Acholeplasma laidlawii*.

Quality Control

Each element is tested for integrity prior to release, assuring absolute reliability.

Documentation

Sartopore 2- γ -capsules are designed, developed and manufactured in accordance with a ISO 9001 certified Quality Management System. A Validation Guide is available for compliance with regulatory requirements.

Specifications for Sartopore 2- γ -Irradiatable Capsules

Materials:

Prefilter Membrane:	Polyethersulfone, asymmetric
Endfilter Membrane:	Polyethersulfone, asymmetric
Support Fleece:	Polypropylene
Core:	Polypropylene
End Caps:	Polypropylene
Capsule Housing:	Polypropylene

Pore Size:

0.45 μ m + 0.2 μ m
0.2 μ m + 0.1 μ m

Available Sizes | Filtration Area:

Size 4	0.015 m ² 0.15 ft ² (0.2 μ m rated)
Size 5	0.03 m ² 0.3 ft ² (0.2 μ m rated)
Size 7	0.05 m ² 0.5 ft ²
Size 8	0.1 m ² 1 ft ²
Size 9	0.2 m ² 2 ft ²
Size 0	0.45 m ² 5 ft ²

Available Connectors:

SS, SO, OO

Operating Parameters:

Max. Allowable	4 bar 58 psi at 20 °C
Differential Pressure:	2 bar 29 psi at 80 °C
Max. Allowable Back Pressure:	2 bar 29 psi at 20 °C

Extractables:

Sartopore 2- γ -capsules meet, or exceed the requirements for WFI quality standards set by the current USP.

Regulatory Compliance:

Individually integrity tested
Integrity test correlated to HIMA/ASTM F 838-83 Bacteria Challenge Test
Non pyrogenic according to USP Bacterial Endotoxins
Pass USP Plastic Class VI Test
Non fiber releasing according to 21 CFR

Sterilization:

γ -irradiation \leq 50 kGy irradiation dosage

Autoclaving:

134 °C, 2 bar | 29 psi, 30 min
No In-Line Steam Sterilization

Sterilization Cycles:

γ -Irradiation:	Maximum 1
Autoclaving:	Maximum 3

Technical References

Validation Guide:

SPK5734-e

Extractables Guide:

SPK5740-e

Integrity Test Limits for 0.2 μ m

Maximum Allowable Diffusion at 2.5 bar / 36 psi and 20 °C

Capsule Size	Maximum Diffusion	Minimum Bubble Point
Size 4	1 ml / min	3.2 bar 46 psi
Size 5	2 ml / min	3.2 bar 46 psi
Size 7	4 ml / min	3.2 bar 46 psi
Size 8	5 ml / min	3.2 bar 46 psi
Size 9	7 ml / min	3.2 bar 46 psi
Size 0	14 ml / min	3.2 bar 46 psi

Integrity Test Limits for 0.1 μ m

Maximum Allowable Diffusion at 4.0 bar / 58 psi and 20 °C

Capsule Size	Maximum Diffusion
Size 7	4 ml / min
Size 8	6 ml / min
Size 9	9 ml / min
Size 0	18 ml / min

Validated product specific integrity test limits can be established for your products. Contact your Sartorius representative for details.

Films & Validation

Films

Sterile Fluid Handling Bags are constructed of multi-layer film(s). Each film layer has been specifically engineered to maximize overall performance of the bag. The following materials are utilized in the manufacture of multi-layer films for TC Tech|Sartorius bags.

Fluid Contact Layer – Low Density Polyethylene (LDPE)

Offers excellent biocompatibility as well as chemical compatibility with a wide range of solutions. This material is used as the Fluid Contact Layer throughout the TC Tech|Sartorius product line thereby facilitating full product line validation.

Gas Barrier Layer – Ethyl Vinyl Alcohol – (EVOH)

Provides outstanding performance as a barrier to atmospheric gasses.

Strength Layer – Nylon

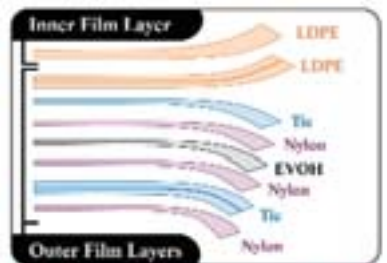
Offers excellent strength properties for bags that have the potential to be used or manipulated outside a cylindrical tank or tote.

Tie Layer – Linear Low Density Polyethylene

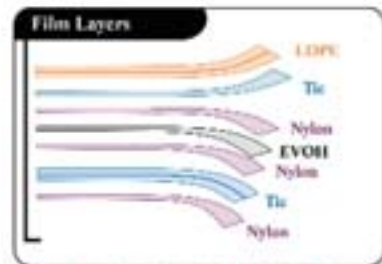
Material provides outstanding layer fusion. Material contributes to overall bag strength and gas barrier properties. USP <88> Class VI material.

Validation

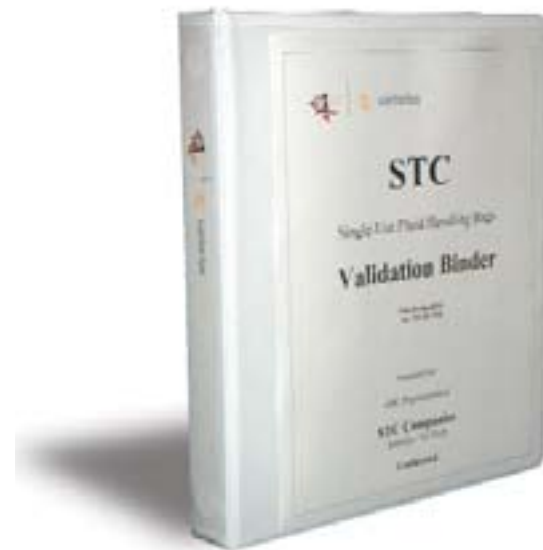
TC Tech|Sartorius has conducted extensive biological, chemical, physical testing on its full line of Sterile Fluid Handling Filters & Bags. TC Tech|Sartorius makes this data available to customers in the form of Validation Guides. These documents contain study data as provided TC Tech|Sartorius by test service providers. Availability of this data facilitates validation of filter & bag assemblies and reduces validation costs to pharmaceutical manufacturers.



5 Liter – 1000 Liter – Sterile Fluid Handling Bags



60 ml – 2 Liter Sterile Fluid Handling Bags



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