

Gammasart BioSystem SA®

Preassembled, Sterile Filter and Bag Assemblies



Description

The Gammasart BioSystem SA line of ready to use, preassembled sterile filter and bag assemblies is designed for sterilizing grade filtration, storage and transport of biopharmaceutical solutions. Each assembly incorporates a Sartopore 2 sterilizing grade filter capsule with broad chemical and pH compatibility, scaled to handle a wide range of biopharmaceutical products.

Applications

Typical applications include sterile filtration, storage and transport of:

- Cell Culture Media
- Buffers
- Bulk Harvest
- Intermediates
- WFI

Easy to Use

Gammasart BioSystem SA's are delivered preassembled and sterile, ready for immediate use. There is no need for assembling individual components on site. Gammasart BioSystem SA's are integrated systems that minimize installation time and operator errors.

Flexibility

Gammasart BioSystem SA's are available in a variety of filter and bag sizes allowing easy adaption to process volume and media. Two different outlet connections are provided for flexible incorporation into your process. The quick disconnect can be attached directly or adapted to a variety of connections. The female luer fitting may be used for direct connection or sampling. A 36" length of heat weldable tubing is provided for use with a Sterile Connection Device (SCD).

Cost and Risk Reduction

Disposable bag assemblies incorporating filter capsules reduce the risk of cross contamination from batch-to-batch and product-to-product dramatically. Cost and time consuming CIP&SIP operations are eliminated. This results in significant cost savings throughout the entire manufacturing process. Additionally, Gammasart BioSystem SA presterilized, preassembled single use Filter and Bag Assemblies eliminate the risk of on site aseptic connections.

Available from Stock

Gammasart BioSystem SA's are standard products available from stock, avoiding lead times associated with the design and fabrication of custom designs.

Specifications

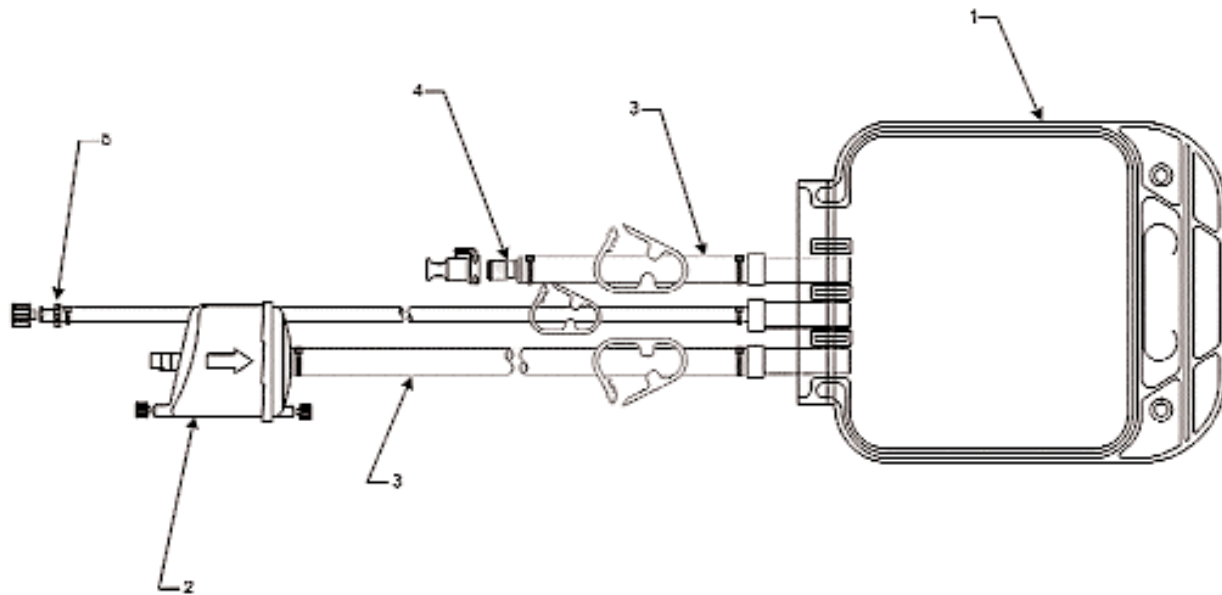
Components

Filter Capsule:	Sartopore 2, 0.2µm Sterilizing Grade Gamma Capsule
Bag Chamber:	LDPE Fluid Contact Surface EVOH Gas Barrier Layer Nylon strength Layer
Tubing:	C-Flex 082 Heat Sealable / Weldable
Outlet Fittings:	Quick Disconnect Female Luer

Available Sizes | Filter Size

1 Liter	Size 4, 150cm ² / .15 ft ²
2 Liter	Size 4, 150cm ² / .15 ft ²
5 Liter	Size 5, 300cm ² / .3 ft ²
10 Liter	Size 5, 300cm ² / .3 ft ²
20 Liter	Size 5, 300cm ² / .3 ft ²
50 Liter	Size 7, 500cm ² / 1/2 ft ²
100 Liter	Size 8, 1000cm ² / 1 ft ²
200 Liter	Size 8, 1000cm ² / 1 ft ²

Filter and Bag Assemblies



Assembly P/N	Description	Item 1 Bag Chamber	Item 2 Bag Port - Filter (Tubing Length)	Item 3 Tubing	Item 4 Bag Port 2 (Tubing Length)	Item 5 Bag Port 3	Case Qty
TC-145001	Gammasart BioSystem SA1	1 liter	5441307H4G-OO, Sartopore2 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 w/ Female Luer & Plug	5
TC-145002	Gammasart BioSystem SA2	2 liter with Handle	5441307H4G-OO, Sartopore2 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 w/ Female Luer & Plug	5
TC-145005	Gammasart BioSystem SA5	5 liter with Handle	5441307H5G-OO, Sartopore2 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 w/ Female Luer & Plug	5
TC-145010	Gammasart BioSystem SA10	10 liter with Handle	5441307H5G-OO, Sartopore2 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 w/ Female Luer & Plug	5
TC-145020	Gammasart BioSystem SA20	20 liter with Handle	5441307H5G-OO, Sartopore2 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 w/ Female Luer & Plug	5
TC-145050	Gammasart BioSystem SA50	50 liter	5441307H7G-SO, Sartopore2 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 w/ Female Luer & Plug	3
TC-145100	Gammasart BioSystem SA100	100 liter	5441307H8G-SO, Sartopore2 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 w/ Female Luer & Plug	3
TC-145200	Gammasart BioSystem SA200	200 liter	5441307H8G-SO, Sartopore2 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 w/ Female Luer & Plug	2

Specifications

Extractables

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

Sterilization

Presterilized by Gamma Irradiation

Regulatory Compliance

Filters Capsules: 100% Integrity Tested

Filter integrity test correlated to HIMA/ASTM F838-83 bacterial Challenge Test.

All materials Non-Pyrogenic according to USP Bacterial Endotoxins

All materials pass USP Class VI Test

Filter is non-fiber releasing according to 21 CFR

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