



Biosafe® Aseptic Transfer Bags

Aseptic Transfer Systems



Features and Benefits

Aseptic and contained single-use technology	Enhanced sterility assurance
Various bag materials & sizes	High flexibility
Standard Biosafe® bag	Short delivery leadtime
Multiple manufacturing sites	High security of supply

Introduction

A complete range of Biosafe® aseptic transfer Bags is designed to best fit your requirements for aseptic transfer of components into clean rooms, isolators or RABS and for contained transfer of potent powders.

For use with the Biosafe® aseptic transfer Bags, the Biosafe® aseptic transfer Ports are available in a variety of design to meet specific needs and applications.

Applications

The Biosafe® range of aseptic transfer Bags is designed to best fit your requirements for aseptic transfer of stoppers, pumps, tools, QC test devices between two environments with different classifications and for contained transfer of highly potent powders from isolator to vessel. They provide a single-use alternative to traditional stainless steel rigid transfer containers in a large variety of applications.

Applications

Prefillable syringe components
Vial & Cartridge components

Biosafe® Aseptic Transfer Bag Configurations

Gamma sterile

Prefilled and Ready-to-Use (RTU) components¹
Prefilled and Ready-to-Use (RTU) components²
Bulk components discharged from the autoclave processor into a Biosafe® aseptic transfer Bag with double-connector

Autoclavable

Prefilled and Ready-to-Sterilize (RTS) components¹
Prefilled and Ready-to-Sterilize (RTS) components²
Bulk components to be processed and autoclaved by end-user

Application	Configuration	Gamma sterile	Autoclavable
QC Test devices	IN	Prefilled Petri dishes ³	N A
	OUT	Sequential removal of Petri dishes	N A
Waste	OUT	Removal	N A
Samples	OUT	Removal	N A
Tools Filling parts	IN	N A	Entry
	OUT	Removal	N A
Powders	IN OUT	Filling from an isolator and discharging into a formulation vessel of high potent powders in a Biosafe® aseptic transfer Bag with double-connector	N A

Gamma sterilizable Biosafe® Bag can be supplied upon request.

¹ Exclusively supplied in BD TSCF™ packaging with components chosen by the end-user

² Supplied by component suppliers who validated the Biosafe® aseptic transfer Bags (West Pharma, Stelmi, Helvöet)

³ Supplied gamma sterile and validated by AES Chemunex

Cost reduction and risk reduction

Single-Use Biosafe® aseptic transfer Bags improve process safety as they reduce the risk of cross contamination from batch-to-batch and product-to-product. Cost and time consuming cleaning and sterilization required for traditional transfer containers are eliminated.

Safety and ease of use

The Biosafe® aseptic transfer Bags feature an inner sleeve that is deployed in the critical area to guide the components during their passage in the Biosafe® Port while covering the critical line (ring of concern). Over protective pouch around the Biosafe® connector protects from particle contamination up to connection.

The Biosafe® aseptic transfer Bag connector assemblies are 100% air leak tested.

Aseptic Transfer lines of products

Besides the Biosafe® aseptic transfer Bags for transfer of components and powders, the SART System™ and the Biosafe® RAFT system allow for aseptic transfer of liquids between area with different classifications.

Technology Integration Support

Sartorius Stedim Biotech supports users at the preliminary design phase of a new production facility with the most comprehensive program to ensure 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

Biosafe® aseptic transfer Bags are designed, developed and manufactured in accordance with a ISO 9001 and ISO 13485 Quality Management. Manufacture and Gamma sterilization processes are conducted under conditions that mirror Biopharmaceutical operations and meet cGMP requirements.

Specifications

Biosafe® Aseptic Transfer Bag Gamma sterile

Description		Biosafe® Bag BIO324	Biosafe® Bag BIO365	Biosafe® Bag BIO346
Dimensions	Film (L × W)	1200 × 300 mm 47.2 × 11.8 in.	740 × 475 mm 29.1 × 18.5 in.	2400 × 180mm 94.5 × 7.0 in.
	Passage diameter	110 mm 4.3 in.		
Material of construction	Film	PE PA PE ¹ 100 µm	STD71 ² 300 µm	PE PA PE ¹ 80 µm
	Connector	ABS ⁴ port, HDPE ⁵ ring		
	Inner sleeve	N A	N A	N A
Biosafe® connector		× 1	× 1	× 1
Working volume		23 L	50 L	16 L
Sterilization		Gamma sterile		

Description		Biosteam® P Bag BIO360	Biosteam® P Bag BIO364	Biosteam® S Bag BIO377TRMM
Dimensions	Film (L × W)	2000 × 300 mm 78.7 × 11.8 in.	2000 × 300 mm 78.7 × 11.8 in.	1000 × 350 mm 39.4 × 11.8 in.
	Passage diameter	110 mm 4.3 in.		
Material of construction	Film	LDPE ³ anti static	LDPE ³ anti static	PE PA PE ¹ 100 µm
	Connector	ABS ⁴ port, HDPE ⁵ ring		
	Inner sleeve	LDPE ³ anti static	LDPE ³ anti static	HDPE ⁵
Biosafe® connector		× 2	× 1	× 2
Working volume		10 L	10 L	25 L
Sterilization		Gamma sterile		

¹ PE | PA | PE: Polyethylene | Polyamide | Polyethylene

² STD71: Stedim 71 film

³ LDPE: Low Density Polyethylene

⁴ ABS: Acrylonitrile Butadiene Styrene

⁵ HDPE: High Density Polyethylene

⁶ PC: Polycarbonate

Biosafe® Aseptic Transfer Bag Autoclavable

Description		Biosafe® Bag BIO352	Biosafe® Bag BIO352TY	Biosafe® Bag BIO352MM	Biosafe® Bag BIO352TYMM
Dimensions	Film (L × W)	1100 × 400 mm 43.3 × 15.7 in.			
	Passage diameter	110 mm 4.3 in.			
Material of	Film	DuPont™ Tyvek® and HDPE ⁵ 80 µm			
	Connector	PC ⁶ port, HDPE ⁵ ring			
	Inner sleeve	N A	DuPont™ Tyvek®, HDPE ⁵	N A	DuPont™ Tyvek®, HDPE ⁵
	Protective cover	N A	N A	DuPont™ Tyvek®	DuPont™ Tyvek®
Biosafe® connector	× 1				
Working volume	30 L				
Sterilization	One steam sterilization cycle at 121 °C for 30 minutes				

Description		Biosafe® Bag BIO352TR	Biosafe® Bag BIO352TRMM	Biosafe® Bag BIO363	Biosafe® Bag BIO363TY
Dimensions	Film (L × W)	1100 × 400 mm 43.3 × 15.7 in.			
	Passage diameter	110 mm 4.3 in.			
Material of	Film	DuPont™ Tyvek® and HDPE ⁵ 80 µm			
	Connector	PC ⁶ port, HDPE ⁵ ring			
	Inner sleeve	PC ⁶	PC ⁶	N A	DuPont™ Tyvek®, HDPE ⁵
	Protective cover	N A	DuPont™ Tyvek®	N A	N A
Biosafe® connector	× 1				
Working volume	35 L	35 L	30 L	30 L	
Sterilization	One steam sterilization cycle at 121 °C for 30 minutes				

Description		Biosafe® Bag BIO363TYMM	Biosafe® Bag BIO363TR	Biosafe® Bag BIO363TRMM	Biosafe® Bag BIO363MM
Dimensions	Film (L × W)	800 × 450 mm 31.4 × 17.5 in.			
	Passage diameter	110 mm 4.3 in.			
Material of	Film	DuPont™ Tyvek® and HDPE ⁵ 80 µm			
	Connector	PC ⁶ port, HDPE ⁵ ring			
	Inner sleeve	DuPont™ Tyvek®, HDPE ⁵	PC ⁶	PC ⁶	N A
	Protective cover	DuPont™ Tyvek®	N A	DuPont™ Tyvek®	DuPont™ Tyvek®
Biosafe® connector	× 1				
Working volume	30 L				
Sterilization	One steam sterilization cycle at 121 °C for 30 minutes				

¹ PE | PA | PE: Polyethylene | Polyamide | Polyethylene

² STD71: Stedim 71 film

³ LDPE : Low Density Polyethylene

⁴ ABS: Acrylonitrile Butadiene Styrene

⁵ HDPE: High Density Polyethylene

⁶ PC: Polycarbonate

Ordering Information

Order Code	Designation	Application	Pack Size (Pieces)
BIO324	Biosafe [®] Aseptic Transfer Bag Gamma sterile	Removal of components	30
BIO365	Biosafe [®] Aseptic Transfer Bag Gamma sterile	Removal of waste	24
BIO346	Biosafe [®] Aseptic Transfer Bag Gamma sterile	Removal of Petri dishes	30
BIO377TRMM	Biosafe [®] Aseptic Transfer Bag with double-connector Gamma sterile	Discharging and transfer of components	20
BIO360	Biosafe [®] Aseptic Transfer Bag with double-connector Gamma sterile	Filling & discharging of powders	30
BIO364	Biosafe [®] Aseptic Transfer Bag Gamma sterile	Discharging of powders	20
BIO352	Biosafe [®] Aseptic Transfer Bag autoclavable	Entry of components	36
BIO352TY	Biosafe [®] Aseptic Transfer Bag autoclavable with inner sleeve	Entry of components	36
BIO352MM	Biosafe [®] Aseptic Transfer Bag autoclavable with protective cover	Entry of components	36
BIO352TYMM	Biosafe [®] Aseptic Transfer Bag autoclavable with inner sleeve and protective cover	Entry of components	36
BIO352TR	Biosafe [®] Aseptic Transfer Bag autoclavable with inner sleeve	Entry of components	20
BIO352TRMM	Biosafe [®] Aseptic Transfer Bag autoclavable with inner sleeve and protective cover	Entry of components	20
BIO363	Biosafe [®] Aseptic Transfer Bag autoclavable	Entry of components	24
BIO363TY	Biosafe [®] Aseptic Transfer Bag autoclavable with inner sleeve	Entry of components	24
BIO363MM	Biosafe [®] Aseptic Transfer Bag autoclavable with protective cover	Entry of components	24
BIO363TYMM	Biosafe [®] Aseptic Transfer Bag autoclavable with inner sleeve and protective cover	Entry of components	24
BIO363TR	Biosafe [®] Aseptic Transfer Bag autoclavable with inner sleeve	Entry of components	20
BIO363TRMM	Biosafe [®] Aseptic Transfer Bag autoclavable with inner sleeve and protective cover	Entry of components	20

Library

Further documentations are available upon request:

- Biosafe[®] Aseptic Transfer Ports
- Biosafe[®] Rapid Aseptic Fluid Transfer (RAFT) System
- SART System™

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