



# Biosafe® Aseptic Transfer Bags



## 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 irradiated

Prefilled and Ready-to-Use (RTU) components<sup>1</sup>  
Prefilled and Ready-to-Use (RTU) components<sup>2</sup>  
Bulk components discharged from the autoclave processor into a Biosafe® aseptic transfer Bag with double-connector

### Autoclavable

Prefilled and Ready-to-Sterilize (RTS) components<sup>1</sup>  
Prefilled and Ready-to-Sterilize (RTS) components<sup>2</sup>  
Bulk components to be processed and autoclaved by end-user

		Gamma irradiated	Autoclavable
QC Test devices	IN	Prefilled Petri dishes <sup>3</sup>	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 irradiatable Biosafe® Bag can be supplied upon request.

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

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

<sup>3</sup> Supplied gamma irradiated 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 irradiation processes are conducted under conditions that mirror Biopharmaceutical operations and meet cGMP requirements.

## Specifications

### Biosafe® Aseptic Transfer Bag Gamma irradiated

Description		Biosafe® Bag BIO324	Biosafe® Bag BIO365	Biosafe® Bag BIO346	Biosafe® Bag BIO304	Biosafe® Bag BIO360
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.	1200 × 300 mm 47,2 × 11,8 in.	2000 × 300 mm 78,7 × 11,8 in.
	Passage diameter	110 mm / 4,3 in.				
Material of construction	Film	PE/PA/PE <sup>1</sup> 100 µm	STD71 <sup>2</sup> 300 µm	PE/PA/PE <sup>1</sup> 80 µm	PE/PA/PE <sup>1</sup> 100 µm	LDPE <sup>3</sup> anti static
	Connector	ABS <sup>4</sup> port, HDPE <sup>5</sup> ring				
	Inner sleeve	N/A	N/A	N/A	N/A	LDPE <sup>3</sup> anti static
Biosafe® connector		× 1	× 1	× 1	× 2	× 2
Working volume		23 L	50 L	16 L	23 L	10 L
Sterilization		Gamma Irradiated				

### Biosafe® Aseptic Transfer Bag Autoclavable

Description		Biosafe® Bag BIO336	Biosafe® Bag BIO336TY	Biosafe® Bag BIO336MM	Biosafe® Bag BIO336TYMM
Dimensions	Film (L × W)	760 × 400 mm 30 × 15,7 in			
	Passage diameter	110 mm / 4,3 in.			
Material of construction	Film	Tyvek® and HDPE <sup>5</sup> 80 µm			
	Connector	PC <sup>6</sup> port, HDPE <sup>5</sup> ring			
	Inner sleeve	N/A	Tyvek®, HDPE <sup>4</sup>	N/A	Tyvek®, HDPE <sup>4</sup>
	Protective cover	N/A	N/A	Tyvek®	Tyvek®
Biosafe® connector		× 1			
Working volume		26 L			
Sterilization		One steam sterilization cycle at 121 °C for 30 minutes			

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 construction	Film	Tyvek® and HDPE <sup>5</sup> 80 µm			
	Connector	PC <sup>6</sup> port, HDPE <sup>5</sup> ring			
	Inner sleeve	N/A	Tyvek®, HDPE <sup>4</sup>	N/A	Tyvek®, HDPE <sup>4</sup>
	Protective cover	N/A	N/A	Tyvek®	Tyvek®
Biosafe® connector		× 1			
Working volume		30 L			
Sterilization		One steam sterilization cycle at 121 °C for 30 minutes			

<sup>1</sup> PE | PA | PE: Polyethylene | Polyamide | Polyethylene

<sup>2</sup> STD71: Stedim 71 film

<sup>3</sup> LDPE : Low Density Polyethylene

<sup>4</sup> ABS: Acronytryle Butadiene Styrene

<sup>5</sup> HDPE: High Density Polyethylene

<sup>6</sup> PC: Polycarbonate

## Ordering Information

Order Code	Designation	Application	Pack Size (Pieces)
BIO324	Biosafe® Aseptic Transfer Bag Gamma irradiated	Removal of components	30
BIO365	Biosafe® Aseptic Transfer Bag Gamma irradiated	Removal of waste	24
BIO346	Biosafe® Aseptic Transfer Bag Gamma irradiated	Removal of Petri dishes	30
BIO304	Biosafe® Aseptic Transfer Bag with double-connector Gamma irradiated	Discharging and transfer of components	18
BIO360	Biosafe® Aseptic Transfer Bag with double-connector Gamma irradiated	Filling & discharging of powders	30
BIO336	Biosafe® Aseptic Transfer Bag autoclavable	Entry of components	36
BIO336TY	Biosafe® Bag autoclavable with inner sleeve	Entry of components	36
BIO336MM	Biosafe® Aseptic Transfer Bag autoclavable with protective cover	Entry of components	36
BIO336TYMM	Biosafe® Aseptic Transfer Bag autoclavable with inner sleeve and protective cover	Entry of components	36
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

For order processing, please contact  
Sartorius Stedim Aseptics S.A., Z.I. de Saux,  
Rue Ampère, 65100 LOURDES (France)  
Tel : +33 5 62.42.73.73  
Fax: +33 5 62.42.08.44

## Library

Further documentations are available upon request:  
– Biosafe® Aseptic Transfer Ports  
– Biosafe® Rapid Aseptic Fluid Transfer (RAFT) System  
– SART System™

Sartorius Stedim Biotech GmbH  
August-Spindler-Strasse 11  
37079 Goettingen, Germany  
Phone +49.551.308.0  
Fax +49.551.308.3289  
www.sartorius-stedim.com  
USA Toll-Free +1.800.368.7178  
UK +44.1372.737159  
France +33.442.845600  
Italy +39.055.63.40.41  
Spain +34.91.3586102  
Japan +81.3.3740.5407

Specifications subject to change  
without notice. Printed and copyrighted  
by Sartorius Stedim Biotech GmbH  
W/sart-000 - G  
Publication No.: SPP2003-e08061  
Order No.: 85034-535-58