

Biosafe® 110 Bottle-Shaped Bags

Product Information

Our complete range of Biosafe® 110 bottle-shaped bags offers reliable and easy-to-use solutions for the secure transfer of components and materials while maintaining the integrity of the critical area in isolators, RABS, and cleanrooms.

Used in conjunction with the Biosafe® 110 port, the Biosafe® 110 bottle-shaped bags are available in multiple configurations that meet the specific needs of a variety of applications.



Features and Benefits

Aseptic and contained single-use transfer technology	Enhanced sterility assurance and safety
Bag chamber overmolding to the connector	Maximum robustness
Automated bag manufacturing process	High cleanliness
Bottle-shaped bag design	Material transfer efficiency
Flexible portfolio with different configurations	Highly adaptable for various process needs and sterilization types

Applications

Biosafe® 110 bottle-shaped bags allow the transfer of stoppers, plungers, seals, plastic bottles | components, and various other components between two environments with different air quality classifications. The Biosafe® 110 aseptic transfer bags are the single-use alternative to traditional stainless steel rigid transfer containers in a large variety of applications. This transfer is done thanks to the Biosafe® 110 port, which is installed on the wall of the critical area.

Enhanced sterility assurance and safety

Single-use Biosafe® 110 bags improve process safety by reducing the risk of cross-contamination from batch to batch and product to product. The ports also eliminate the need for costly and time consuming cleaning and sterilization procedures that are required with traditional transfer containers.

Maximum robustness for the bag and the connection

The overmolding of the bottle-shaped bag film directly onto the flange of the connector results in a very robust attachment.

The bottle-shaped bags have been extensively qualified to ensure the highest robustness of the container in comparison with the real use conditions of the Biosafe® 110 bags when they are filled with components.

High cleanliness

The manufacturing process of the Biosafe® 110 bottle-shaped bags has been improved to bring automation to the most critical assembly steps, resulting in a high cleanliness level of the final product.

Improved material transfer efficiency

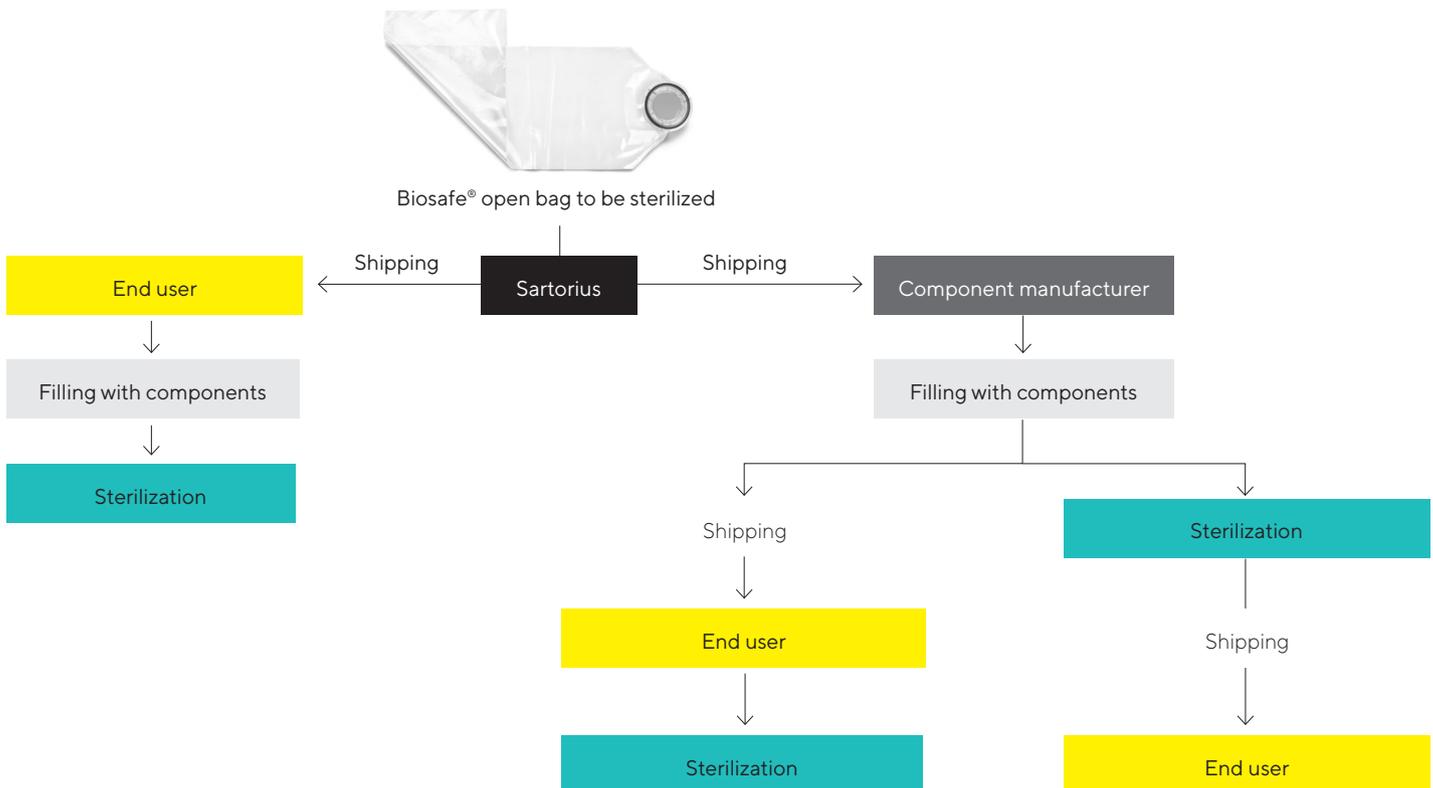
The bottle shape of the Biosafe® 110 bag allows for the efficient and simple transfer of components to the critical area.

Highly adaptable for various applications and sterilization types

The Biosafe® 110 aseptic transfer bags can be manufactured with several optional add-ons to best fit your requirements. An inner flexible sleeve or rigid collar can be deployed in the critical area to guide the components during their passage through the Biosafe® 110 port. A protective cover over the Biosafe® 110 connector protects it from particle contamination prior to docking the bag.

Applications	Biosafe® 110 bottle-shaped bag configuration(s)
Closure component transfer: for pre-fillable syringes	<ul style="list-style-type: none"> ▪ Steam gamma-sterilizable bags ▪ Prefilled by component manufacturer; ▪ Filled by end user; ▪ Sterilized by component manufacturer or end user
Closure component transfer: for vials & cartridges	<ul style="list-style-type: none"> ▪ Steam gamma-sterilizable bags ▪ Prefilled by component manufacturer; ▪ Filled by end user; ▪ Sterilized by component manufacturer or end user
Tools Filling parts entry	<ul style="list-style-type: none"> ▪ Steam-sterilizable bags ▪ Filled by end user; ▪ Steam sterilized by end user

Diagram of the different sales processes for Biosafe® bags



Technical Data

Specifications

Construction material		
Type of bag	Autoclavable	Gamma sterilizable
Film	DuPont™ Tyvek® HDPE ¹ 80 µm	PE PA PE ² 120 µm
Connector	PC ³ port, HDPE ¹ overmolding 110 mm useful diameter	PC ³ port, HDPE ¹ overmolding 110 mm useful diameter

Options available		
Rigid collar for use without glove*	PC ³	PC ³
Protective cover	DuPont™ Tyvek®	DuPont™ Tyvek®
Flexible sleeve for use with glove	DuPont™ Tyvek® HDPE ¹ 100 µm	LDPE ⁴

* The rigid collar is the best adapted for external opening configuration to avoid the use of any glove inside the enclosure equipment.

Reference	Bag dimensions	Sterilization	Working volume	Options		
				Rigid collar	Protective cover	Flexible sleeve
Biosafe® 110 bags – autoclavable						
BIO1502IR	850 × 370 mm	One steam sterilization cycle at max. 123°C for 30 minutes	25 L			
BIO1502MMIR	850 × 370 mm	One steam sterilization cycle at max. 123°C for 30 minutes	25 L		■	
BIO1502TRIR	850 × 370 mm	One steam sterilization cycle at max. 123°C for 30 minutes	25 L	■		
BIO1502TRMMIR	850 × 370 mm	One steam sterilization cycle at max. 123°C for 30 minutes	25 L	■	■	
BIO1502TYIR	850 × 370 mm	One steam sterilization cycle at max. 123°C for 30 minutes	25 L			■
BIO1502TYMMIR	850 × 370 mm	One steam sterilization cycle at max. 123°C for 30 minutes	25 L		■	■
Biosafe® 110 bags – gamma sterilizable						
BIO1002	1000 × 350 mm	To be gamma sterilized at 45 kGy max.	31 L			
BIO1002MM	1000 × 350 mm	To be gamma sterilized at 45 kGy max.	31 L		■	
BIO1002TR	1000 × 350 mm	To be gamma sterilized at 45 kGy max.	31 L	■		
BIO1002TRMM	1000 × 350 mm	To be gamma sterilized at 45 kGy max.	31 L	■	■	
BIO1002T	1000 × 350 mm	To be gamma sterilized at 45 kGy max.	31 L			■
BIO1002TMM	1000 × 350 mm	To be gamma sterilized at 45 kGy max.	31 L		■	■

¹ HDPE: High-Density Polyethylene

² PE | PA | PE: Polyethylene | Polyamide | Polyethylene

³ PC: Polycarbonate

⁴ LDPE: Low-Density Polyethylene

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Ordering Information

Reference	Description	Pack size
BIO1502IR	Biosafe® 110 bottle-shaped bag autoclavable	28
BIO1502MMIR	Biosafe® 110 bottle-shaped bag autoclavable with protective cover	28
BIO1502TRIR	Biosafe® 110 bottle-shaped bag autoclavable with rigid collar	20
BIO1502TRMMIR	Biosafe® 110 bottle-shaped bag autoclavable with rigid collar and protective cover	20
BIO1502TYIR	Biosafe® 110 bottle-shaped bag autoclavable with flexible sleeve	28
BIO1502TYMMIR	Biosafe® 110 bottle-shaped bag autoclavable with flexible sleeve and protective cover	28
BIO1002	Biosafe® 110 bottle-shaped bag gamma sterilizable	28
BIO1002MM	Biosafe® 110 bottle-shaped bag gamma sterilizable with protective cover	28
BIO1002TR	Biosafe® 110 bottle-shaped bag gamma sterilizable with rigid collar	20
BIO1002TRMM	Biosafe® 110 bottle-shaped bag gamma sterilizable with rigid collar and protective cover	20
BIO1002T	Biosafe® 110 bottle-shaped bag gamma sterilizable with flexible sleeve	28
BIO1002TMM	Biosafe® 110 bottle-shaped bag gamma sterilizable with flexible sleeve and protective cover	28

Library

Further documentation is available on request:

- Biosafe® 110 Bottle-shaped Bags Validation Guide
- Biosafe® 110 User Manual
- Biosafe® 110 Ports Datasheet

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