



Biosafe[®] 110

Single-Use Aseptic
Transfer Systems

Simplifying Progress

SARTORIUS

Biosafe® 110 Ports and Bags



The Highest Quality Assurance

- Manufactured in ISO 9001 certified facilities
- 100% quality control on Biosafe® 110 ports – Dimensional and leak testing
- 100% quality control on Biosafe® 110 bag connector assemblies
- Biosafe® 110 bags assembled in Class C (ISO 7) cleanrooms

The Biosafe® 110 Port

The Biosafe® range of aseptic transfer ports offers reliable and easy-to-use solutions that meet your specific needs and applications. The unique design of the Biosafe® 110 system enables the secure transfer of components, fluids and powders while maintaining the integrity of the critical area.



Dummy Service Connector
For sterilization and maintenance of the Biosafe® 110 ports.

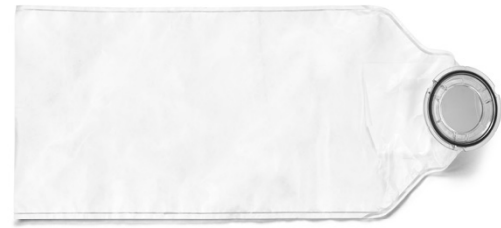
A Complete Range of Bags for a Variety of Applications

The Biosafe® range of bags is designed to best fit your requirements for aseptic transfer of stoppers, pumps, tools, QC test devices, fluids and powders into critical processing areas.



Gamma Irradiated Double-Connector Biosafe® 110 Bags

Specifically designed for the two-step transfer of components from autoclave (using the Biosafe® Biosteam® port) into an isolator.



Autoclavable Biosafe® 110 Bags

- Open autoclavable Biosafe® 110 bags are filled on-site prior to autoclave sterilization and aseptic transfer.
- Prefilled autoclavable Biosafe® 110 bags are delivered ready-to-sterilize by your component supplier.
- Entry of stoppers, tools, pump into isolators, RABS and cleanrooms.



Gamma Irradiatable Biosafe® 110 Bags

- Prefilled Biosafe® bags are delivered gamma sterilized by your component supplier for the entry of stoppers (prefillable syringe, vial, carpule), QC test devices and any other gamma sterilizable parts.
- Gamma irradiated Biosafe® 110 bags are used for the removal of waste, tools, pumps and QC test devices from critical areas.

Gamma Sterile RAFT Biosafe® 110 Bags

- Rapid Aseptic Fluid Transfer (RAFT) System is a sterile system designed for the aseptic transfer of liquids.



Biosafe® Biosteam® Port

- When installed on autoclaves, the steamable version of the Biosafe® 110 port allows reliable aseptic discharging of bulk stoppers from the autoclave into double-connector gamma irradiated bags prior to transfer into an isolator.
- Allows the contained addition of powders into formulation vessels.

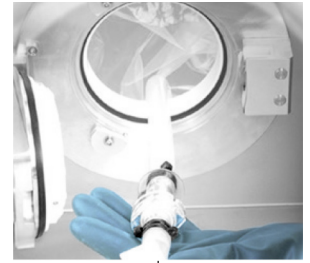


Biosafe® 110 Port

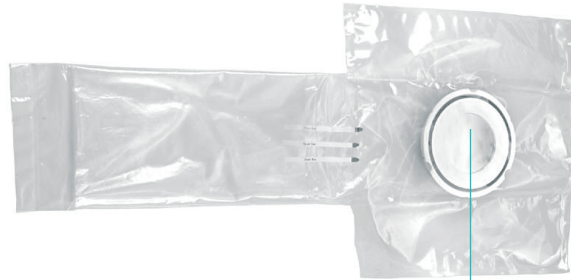
For the aseptic transfer of components and fluids into isolators, RABS and cleanrooms.

Services to Filling Line in Aseptic Processing

Applied to filling lines, the Biosafe® technology is the answer to a variety of aseptic transfer applications around the filling process.

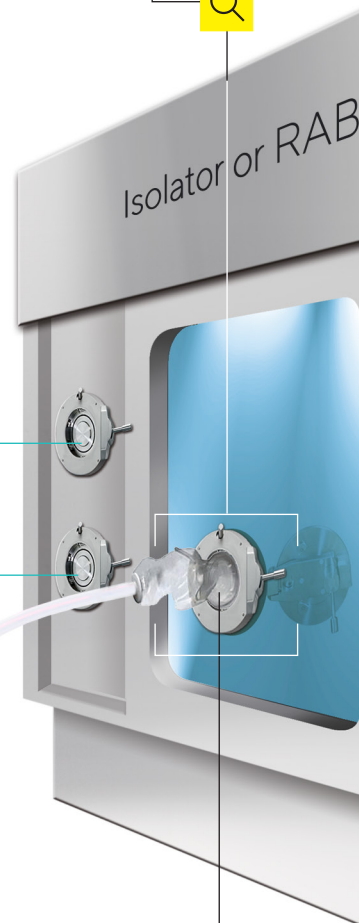


Inside view



Removal of waste

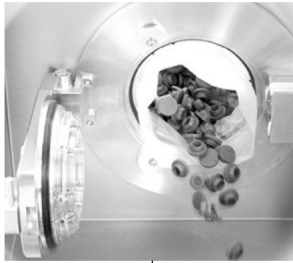
Removal of
Petri dishes



Entry of sterile fluid



The RAFT System is used for the aseptic transfer of bulk final product onto the filling line within an isolator, RABS or cleanroom.

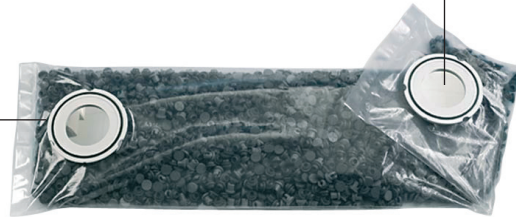


Inside view

The inner sleeve of Biosafe® 110 bags guides the components during transfer.



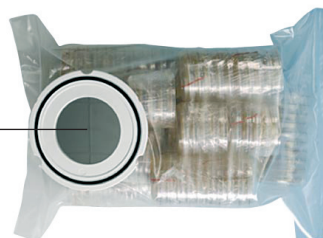
Bulk autoclave discharging with the Biosafe® Biosteam® port on the autoclave.



Entry of stoppers or caps



Entry of stoppers or caps

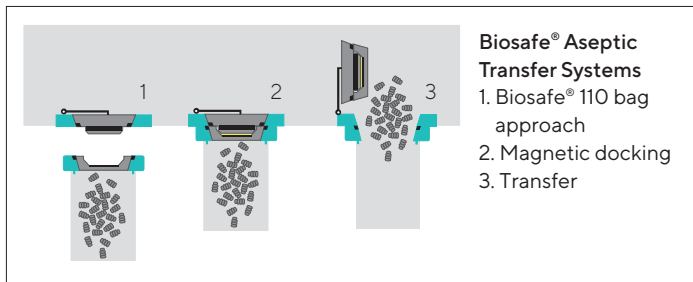


Entry of QC test devices



Entry of tools

Achieving Safe, Easy-to-Use & Reliable Aseptic Transfer



| In Out Aseptic Transfer into | Clean-room | Isolator | RABS | Auto-clave | Formulation vessel |
|--------------------------------|------------|----------|------|------------|--------------------|
| Biosafe® 110 port | ■ | ■ | ■* | | |
| Biosafe® 110 Biosteam® port | | | | ■ | ■ |

* The Biosafe® 110 port with outside opening is the best choice to prevent air turbulence in RABS

Enhanced Sterility Assurance in Aseptic Processing

- Offers a contained and single-use technology for safer aseptic transfer.
- Limits the number and complexity of personnel interventions in the aseptic processing area.
- Offers a completely closed aseptic process.

Safer Processing of Potent Drugs

- Maintains the barrier integrity of RABS and isolators and security of operators.

Ease-of-Use

- The magnet on the port allows easy centering and secure docking of the Biosafe® 110 bottle-shaped bags.

Process Safety and Maximum Robustness

- Mechanical interlock securities prevent door opening when a Biosafe® 110 bottle-shaped bag is not connected or from disconnecting a bag if the Biosafe® 110 port is not closed.
- The Biosafe® 110 bottle-shaped bags feature an over-molding of the Biosafe® film onto the connector flange, ensuring highest robustness of the resulting final product.

Flexible Portfolio

- The range of Biosafe® 110 systems is designed to best fit a variety of applications while ensuring a high level of containment.
- Biosafe® is a unique technology for the aseptic transfer of components, fluids and powders.

Simplified Maintenance and Sterilization

- When connected to the Biosafe® 110 port, the dummy service connector facilitates the sterilization of the critical area, the inner side of the Biosafe® 110 port and maintenance operations.

Proven Containment

- Biosafe® 110 ports and connectors are leak tested during production.
- Packaging Biosafe® 110 bags under vacuum can offer an additional guaranty of integrity.

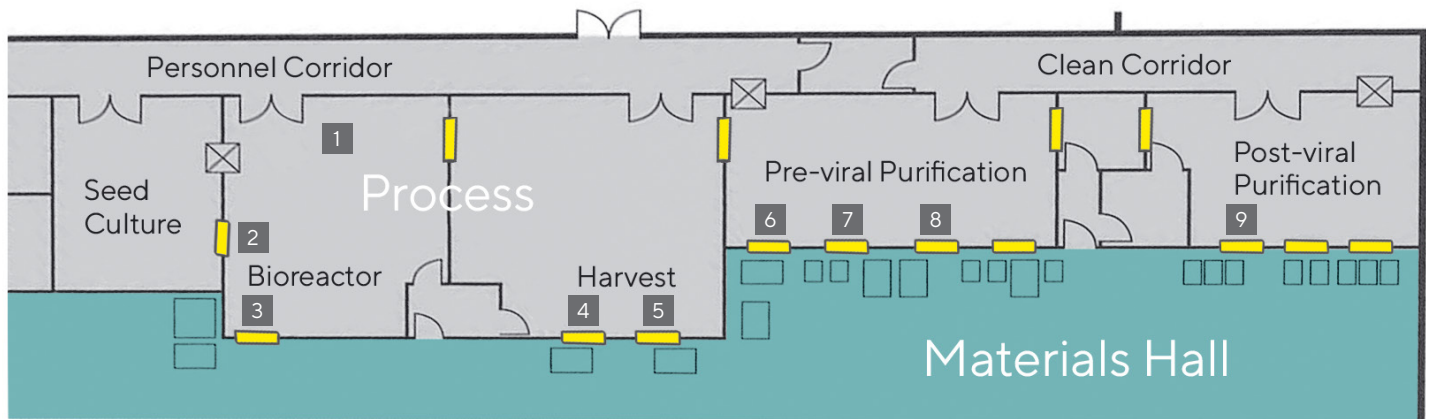
Practical and Economical Benefits

- The Biosafe® 110 bags eliminate cleaning and sterilization required for traditional transfer containers.
- The RAFT System simplifies facility layout and reduces higher classification cleanroom area by keeping large volume support solutions outside the cleanroom.



Upstream & Downstream Processing

The RAFT System provides easy-to-use and reliable through-the-wall aseptic transfer of fluids between biomanufacturing zones. The attached diagram demonstrates segregation of media and buffer solutions maintained in the materials hall, enabling substantial reduction of higher classification cleanroom areas.



1. Product transfer
2. Seed transfer
3. Transfer of cell culture media and other solutions to bioreactor
4. Transfer of buffers for centrifugation and clarification

5. Transfer of buffers to chromatography
6. Transfer of buffers to purification
7. Transfer of buffers to recovery operation
8. Transfer of buffers to chromatography column
9. Transfer of buffers to UF | DF system

The Biosafe RAFT System is customized upon request:

- different sizes
- bags
- filters and connections




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