



sartorius stedim  
biotech

## Biosafe® Single-Use Aseptic Transfer Systems



turning science **into solutions**

# The Biosafe® 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 system enables the secure transfer of components, fluids and powders while maintaining the integrity of the critical area.

**Biosafe Three-Lever Port**  
For the aseptic transfer of fluids into cleanrooms.



**Biosafe Monolever Port**  
For the aseptic transfer of components and fluids into isolators, RABS and cleanrooms.



**Biosafe Biosteam® Port**

- When installed on autoclaves, the steamable version of the Biosafe 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.



## The Highest Quality Assurance

- Manufactured in ISO 9001 and ISO 13485 certified facilities
- 100% quality control on Biosafe Ports – Dimensional and leak testing
- 100% quality control on Biosafe bag connector assemblies
- Biosafe bags assembled in Class C (ISO 7) cleanrooms

**Biosafe Automatic Port**  
Automated aseptic transfer of components into isolators and RABS.



# A Complete Range...

## Autoclavable Biosafe Bags

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

...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 Irradiatable Biosafe 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 bags are used for the removal of waste, tools, pumps and QC test devices from critical areas.
- Rapid Aseptic Fluid Transfer (RAFT) System is a sterile system designed for the aseptic transfer of liquids.

## Gamma Irradiated Double-Connector Biosafe Bags

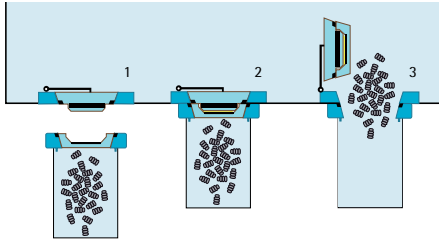
Specifically designed for the two-step transfer of components from autoclave (using the Biosafe Biosteam Port) into an isolator.

## Dummy Service Connector

For sterilization and maintenance of the Biosafe Ports.



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



## Biosafe Aseptic Transfer Systems

1. Biosafe bag approach
2. Magnetic docking
3. Transfer

### 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 bag.

### Process Safety

- Mechanical interlock securities prevent door opening when a bag is not connected or from disconnecting a bag if the Biosafe Port is not closed.
- Automatic inter-door vacuum integrity test of Biosafe Port and connector.

### Versatile Technology

- The range of Biosafe 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 Port, the dummy service connector facilitates the sterilization of the critical area, the inner side of the Biosafe Port and maintenance operations.

### Proven Containment

- Biosafe Ports and connectors are 100% leak tested during production.
- Packaging Biosafe bags under vacuum can offer an additional guaranty of integrity.

### Practical and Economical Benefits

- The Biosafe 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.

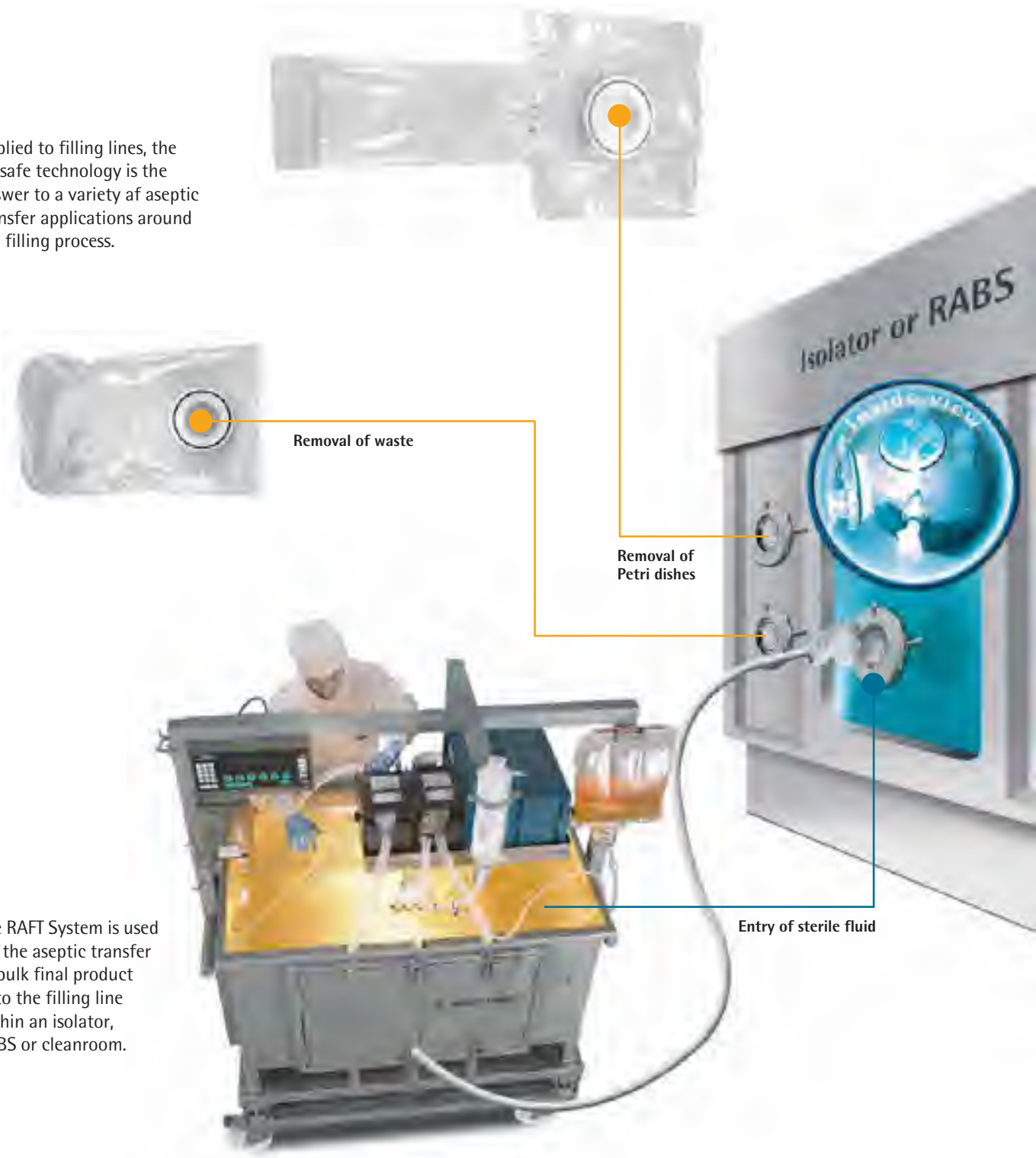
In   Out Aseptic Transfer into	Clean-room	Isolator	RABS	Auto-clave	Formulation vessel
Biosafe 110 Three-Lever TTI Port	•				
Biosafe 110 Monolever Port	•	•	•*		
Biosafe 110 Automatic Port		•	•*		
Biosafe 110 Biosteam Port				•	•

\* The Biosafe Port with outside opening is the best choice to prevent air turbulence in RABS



# 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.



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.

The inner sleeve of Biosafe 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

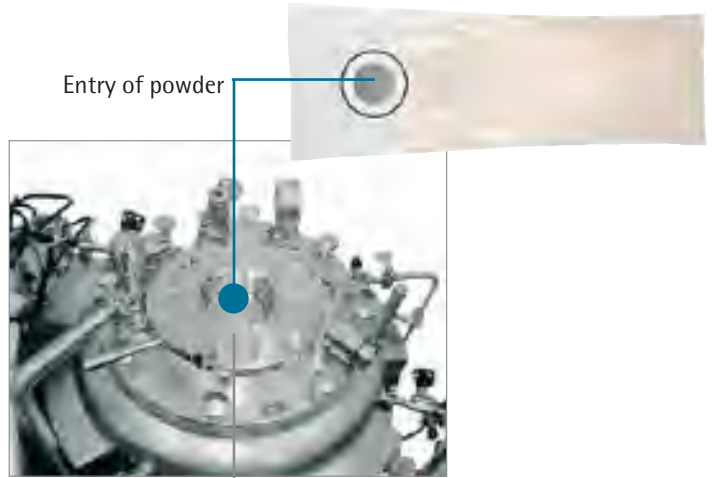


Entry of tools

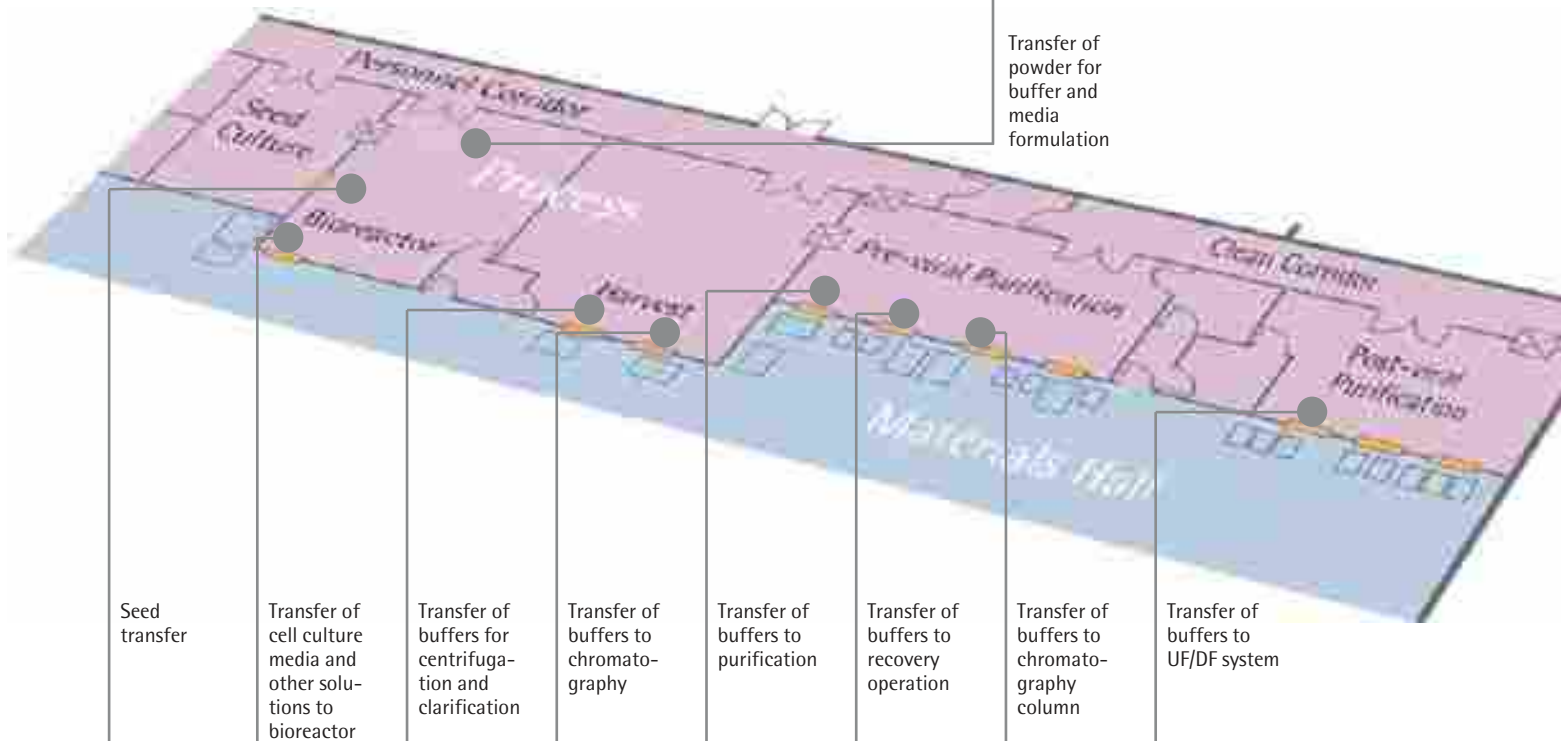


# Upstream & Downstream Processing

The Biosafe Biosteam Port can be cleaned and sterilized in-place along with the formulation vessel. The Biosafe bags are used for the contained transfer of powders for media and buffer preparation.



Transfer of powder for buffer and media formulation



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.

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