



Biosafe® Ports

Contained aseptic transfer of components, fluids and powders

Fluid Management Technologies



Description

The Biosafe® range of Aseptic Transfer Ports offers reliable and easy-to-use solutions for the secure transfer of components, fluids and powders while maintaining the integrity of the critical area – isolators, RABS and cleanrooms.

Features & Benefits

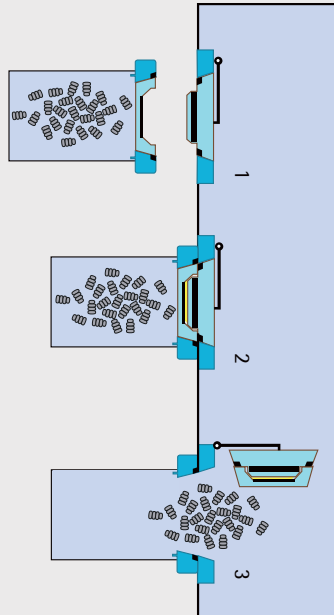
- Enhanced sterility assurance and viral segregation in aseptic processing
- Easy to use
- Process safety
- Versatile technology
- Simplified maintenance and sterilization
- Cost effective

Applications	Upstream and Downstream Processing		Aseptic Processing	
Applications	Transfer of large volume support solutions held in lower classified environments to higher classification process zones. Examples of applications: - Media feed to N-2 N-1 bioreactor - Buffer feed to chromatography columns - Transfer out of higher classified zones: - fraction collection - bulk intermediates - bulk final product transferring out of purification	Transfer into formulation vessel - Powder (buffer and media)	Discharge from autoclave - Stoppers	Transfer into isolators or RABS - Drug products - Entry of stoppers - Entry and removal of QC test devices, tools and pumps - Waste removal
Biosafe® 110 Monolever Port	•	—	—	• ¹
Biosafe® 110 Automatic Port	—	—	—	• ¹
Biosafe® Biosteam® P Port	—	•	—	—
Biosafe® Biosteam® S Port	—	—	•	—
Biosafe® Bags (All Biosafe® Bags are designed for connection to any Biosafe® Port.)	Rapid Aseptic Fluid Transfer (RAFT) Systems preassembled with other Sartorius Stedim Biotech technologies such as Flexel® 3D and Flexboy® system. Complete assembly is Gamma sterile.	Closed Gamma sterile	Double connector Gamma sterile	- Open autoclavable to be filled by end-users prior to autoclave sterilization and aseptic transfer. - Prefilled autoclavable delivered ready-to-sterilize via component suppliers. - Prefilled delivered Gamma sterile by component suppliers. - Closed Gamma sterile for the removal of waste, tools, pumps and QC test devices.

¹ Biosafe® Port with outside opening is the best choice to prevent air turbulence in RABS and glove usage in isolator.

Operating Sequences

Connecting a Biosafe® Bag



Approach

- Wipe down the Biosafe® Port
- Open package of the Biosafe® Bag and remove the protecting pouch

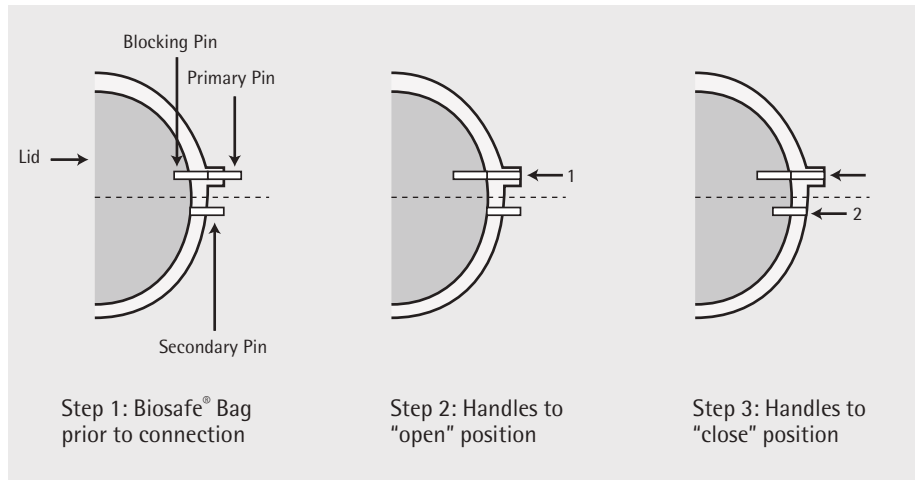
Docking

- Docking is secured by magnetic guidance on the Biosafe® Port
- The magnetic connection is further secured by mechanical locks.

Opening and Transfer

- Open the double-door either from inside or outside the critical area.
- Aseptic transfer of components, fluids or powders.

Prior to the connection, the pins on the Biosafe® connector are in the "out" position (see beside). This is a proof that the Biosafe® Bag is ready to be connected to the Port and that it has not been used before.



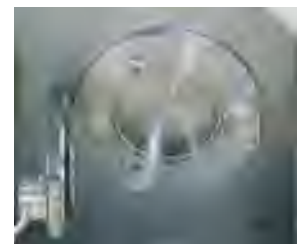
Maintenance, decontamination and sterilization of the Biosafe® Port

When connected to the Biosafe® Port, the dummy service connector allows the door to be opened for the sterilization of the critical area and the inner side of the Biosafe® Port as well as for maintenance operations such as gasket replacement.

Outside View



Inside View



Specifications

	Biosafe® 110 Monolever Port	Biosafe® 110 Automatic Port	Biosafe® Biosteam® P Port	Biosafe® Biosteam® S Port
Installation Requirements	Wall thickness: 2–8 mm 0.08–0.31 in.	Wall thickness: 2–8 mm 0.08–0.31 in.	N A	N A
	<ul style="list-style-type: none"> – If the wall thickness exceeds 8 mm 0.31 in., the Biosafe® Port must be installed on a Biosafe® support which is then integrated into the wall. – If outside opening is chosen, the Biosafe® Port is systematically supplied on a Biosafe® support which is then integrated into the wall. 		N A	N A
	<ul style="list-style-type: none"> – We highly recommend setting the port below or on a window so that the operator can see the other side. – Height of port for accessibility: for good access, the port axis must be 1.1 m to 1.4 m (43.3 in. to 52.12 in.) high from the operator standing reference. 		N A	N A
Weight (approx.)	15 KG 33.07 lb.	45 KG 99.21 lb.	80 KG 176.37 lb.	80 KG 176.37 lb.
Operating Temp Range	5°C to 30°C 41°F to 86°F	10°C to 30°C 50°F to 86°F	5°C to 30°C 41°F to 86°F	5°C to 30°C 41°F to 86°F
Maximum Temp During Autoclave Cycle	N A	N A	150°C 302°F	150°C 302°F
Pressure Range During Autoclave Cycle	N A	N A	–1 to +6 bars	–1 to +3 bars
Power Requirements (Europe and U.S.)	100 V to 240 V; 50 to 60 Hz (required only if the vacuum option is chosen)	90 V to 240 V; 50 to 60 Hz	N A	N A
Materials of Construction ¹	Stainless Steel 316L; PETP; Silicone EPDM for gaskets			Stainless Steel 316L; PETP; PEEK; EPDM for gaskets
Passage Diameter	110 mm 4.3 in.	110 mm 4.3 in.	110 mm 4.3 in.	110 mm 4.3 in.
Quality Standards	<ul style="list-style-type: none"> – All materials are compliant with 21 CFR Part 177.2600 (EPDM Silicone), 21 CFR Part 177.1630 (PETP) and 21 CFR Part 177.2470 (PEEK) – The Biosafe® Biosteam® P and S Ports meet the requirements given by European Pressure Equipment directive 97/23/EC and the European explosive atmosphere Directive 94/9/EC 'ATEX' – Vacuum box meets the requirements for Low Voltage European Directive 73/23/EC – Automatic Port meets the requirements for Machinery Directive 98/37/EC; Low Voltage European Directive 73/23/EC; Electromagnetic Compatibility Directive 89/336/EC 			
FAT SAT	<p>Factory Acceptance Tests (FAT) and Site Acceptance Tests (SAT) are performed on each Biosafe® Port.</p> <ul style="list-style-type: none"> – Only during FAT, air tightness is performed at several points of control: gasket, locking screws, handles positioning, vacuum circuit (if the option is chosen) – Functional: positioning of gasket, positioning and manipulation of external and internal handle(s), lockers, mechanical securities 			
Cleaning and Decontamination Agents	<ul style="list-style-type: none"> – Purified water (WFI) or any neutral pH detergent – Ethanol or isopropyl alcohol (70% v v) – Peracetic acid solution (2% v v) – Hydrogen peroxide solution (2% v v) 			

¹ The list provides construction materials in contact with the critical area (isolators, RABS, cleanrooms).

Ordering information

Biosafe® Ports

FAA109722	Biosafe® 110 Monolever Port ¹
FAA109860	Biosafe® 110 Monolever Port ²
FAA109861	Biosafe® 110 Monolever Port ³
FAA109862	Biosafe® 110 Monolever Port ⁴
FAA109723	Biosafe® 110 Automatic Port ¹
FAA109869	Biosafe® 110 Automatic Port ²
FAA109871	Biosafe® 110 Automatic Port ³
FAA109872	Biosafe® 110 Automatic Port ⁴
FAA109728	Biosafe® Biosteam® P Port
FAA113645	Biosafe® Biosteam® S Port

Accessories, options & support for Biosafe® ports

FAA109724	Biosafe® Dummy Service Connector for Manual Port
FAA109725	Biosafe® Dummy Service Connector for Automatic Port
FAA112940	Biosafe® Dummy Service Connector for Biosafe® Biosteam® P Port
FAA113646	Biosafe® Dummy Service Connector for Biosafe® Biosteam® S Port
FAA114793	Biosafe® vertical support device for Biosafe® 110 Monolever Port
FAA112077	Biosafe® inclined support device for Biosafe® 110 Monolever Port
FAA112081	Biosafe® inclined support device for Biosafe® 110 Automatic Port
FAA109726	Biosafe® Vacuum Box

For further information or details on Site Acceptance Tests (SAT) and training at final customers, please contact your local Service representative.

- ¹ Inside right opening ³ Outside right opening
² Inside left opening ⁴ Outside left opening

Spare Parts for Biosafe® Ports

Upon order of Biosafe® Ports, you will receive a complete technical package including the list and prices of spare parts.

Trademarks

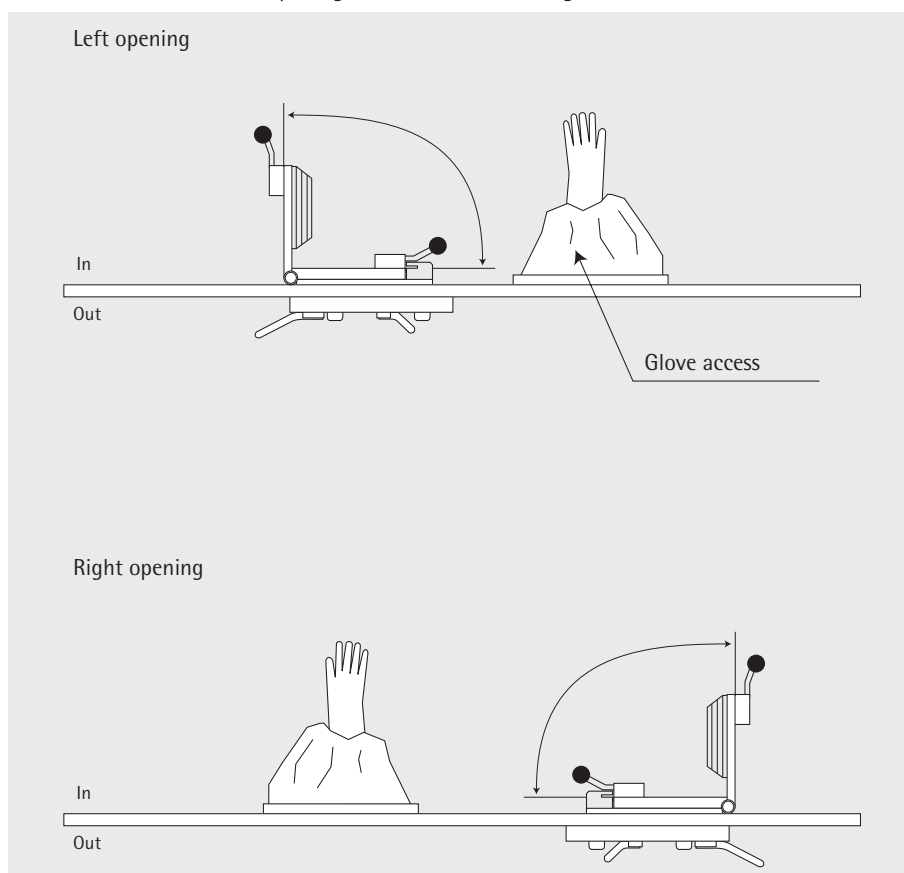
Biosafe and Biosteam are Sartorius Stedim Aseptics registered trademarks.

Summary of Biosafe Ports configurations and options

	Right Opening	Left Opening	Inside Opening	Outside Opening	Vacuum Option
Biosafe 110 Monolever Port	Available	Available	Available	Available	Optional
Biosafe 110 Automatic Port	Available	Available	Available	Available	Available

Left or right-hand side opening

You can choose to have an opening on the left or on the right-hand side as shown below:



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 +34.90.2110935
 Russian Federation +7.812.327.5.327
 Japan +81.3.4331.4300