SARTORIUS

Product Datasheet

Biosafe® 110 Ports

Contained Aseptic Transfer of Components and Fluids

Benefits

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

Product Information

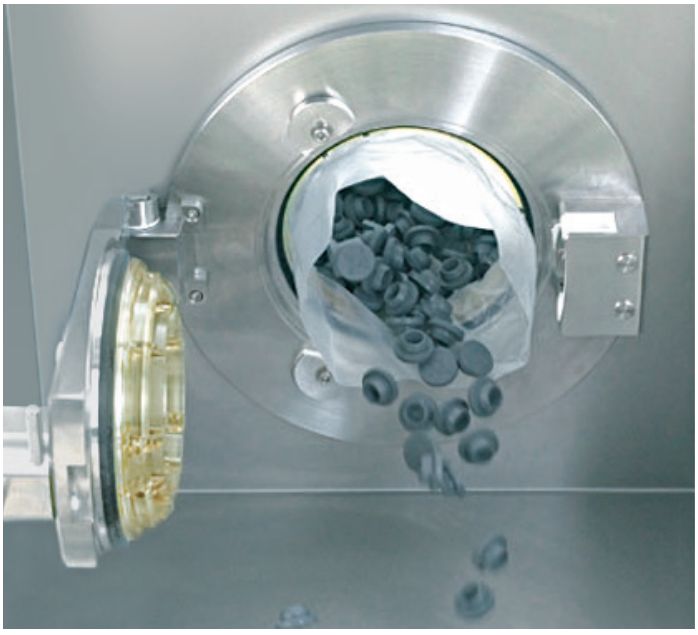
The Biosafe® 110 range of aseptic transfer ports offers reliable and easy-to-use solutions for the secure transfer of components and fluids while maintaining the integrity of the critical area – isolators, RABS and cleanrooms.

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
		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

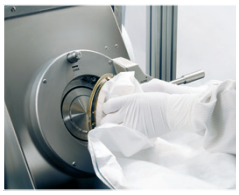
Biosafe® 110 port	☑	–	☑[1]
Biosafe® Biosteam® S port	–	☑	–
Biosafe® 110 bags (All Biosafe® bags are designed for connection to any Biosafe® 110 port.)	Rapid Aseptic Fluid Transfer (RAFT) systems preassembled with other Sartorius technologies such as Flexsafe® 3D and Flexboy® system. Complete assembly is 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.

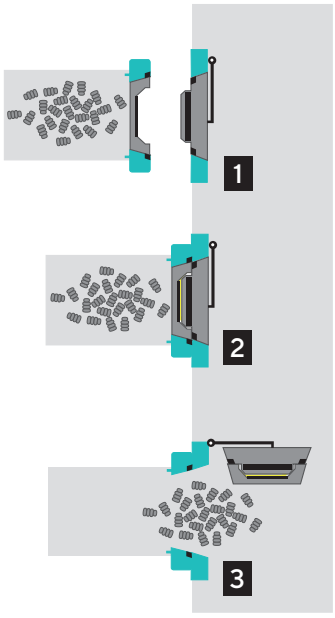
[1] Biosafe® 110 port with outside opening is the best choice to prevent air turbulence in RABS and glove usage in isolator.



Operating Sequences

Connecting a Biosafe® 110 Bag



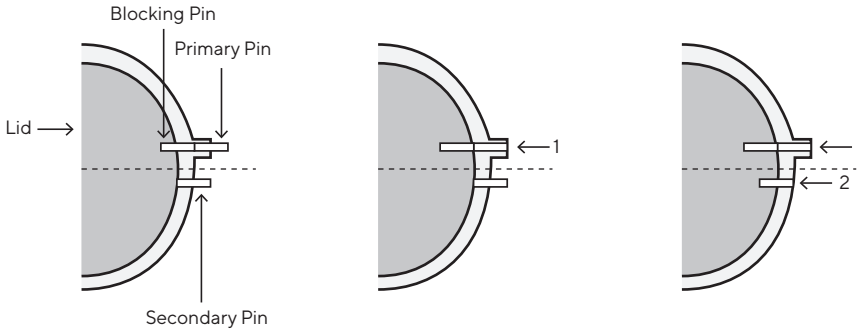


Approach
- Wipe down the Biosafe® 110 port
- Open package of the Biosafe® 110 bag and remove the protecting pouch

Docking
- Docking is secured by magnetic guidance on the Biosafe® 110 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® 110 bag is ready to be connected to the Biosafe® 110 port and that it has not been used before.



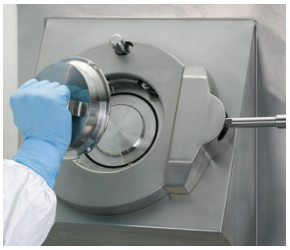
Step 1: Biosafe® bag prior to connection

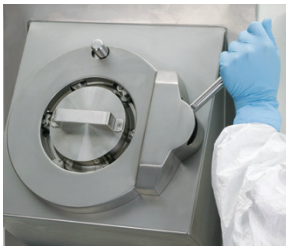
Step 2: Handles to "open" position

Step 3: Handles to "close" position

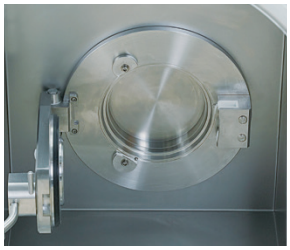
Maintenance, Decontamination and Sterilization of the Biosafe® 110 Port
When connected to the Biosafe® 110 port, the dummy service connector allows the door to be opened for the sterilization of the critical area and the inner side of the Biosafe® 110 port as well as for maintenance operations such as gasket replacement.

Outside View





Inside View



Specifications

	Biosafe® 110 Port	Biosafe® Biosteam® S Port
Installation Requirements	Wall thickness: 3–8 mm | 0.08–0.31 in.	N | A
	▪ If the wall thickness exceeds 8 mm | 0.31 in.,the Biosafe® 110 port must be installed on a Biosafe® support which is then integrated into the wall. ▪ If outside opening is chosen, the Biosafe® 110 port is systematically supplied on a Biosafe® support which is then integrated into the wall.	N | A
	▪ 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
Weight (approx.)	15 KG | 33.07 lb.	80 KG | 176.37 lb.
Operating Temp Range	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	150 °C | 302°F
Pressure Range During Autoclave Cycle	N | A	–1 to +3 bars
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.
Quality Standards	▪ 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)	
FAT | SAT	Factory Acceptance Tests (FAT) and Site Acceptance Tests (SAT) are performed on each Biosafe® 110 port. ▪ Only during FAT, air tightness is performed at several points of control: gasket, locking screws, handles positioning ▪ Functional: positioning of gasket, positioning and manipulation of external and internal handle(s), lockers, mechanical securities	
Cleaning and Decontamination Agents	▪ 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 port[1]
FAA109860	Biosafe® 110 port[2]
FAA109861	Biosafe® 110 port (w/ support)[3]
FAA109862	Biosafe® 110 port (w/ support)[4]
FAA308155	Biosafe® 110 port - 90° lever[1]
FAA308156	Biosafe® 110 port - 90° lever[2]
FAA308157	Biosafe® 110 port - 90° lever (w/o support)[3]
FAA308158	Biosafe® 110 port - 90° lever (w/o support)[4]
FAA113645	Biosafe® Biosteam® S port

[1] Inside right opening
[2] Inside left opening
[3] Outside right opening
[4] Outside left opening

Accessories, Options & Support for Biosafe® Ports

FAA109724	Biosafe® dummy service connector for Biosafe® 110 port
FAA113646	Biosafe® dummy service connector for Biosafe® Biosteam® S port
FAA114793	Biosafe® vertical support device for Biosafe® 110 port
FAA112077	Biosafe® inclined support device for Biosafe® 110 port

With each port ordered, please indicate the wall thickness on which the port will be installed, as this information is mandatory to proceed with manufacturing.

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

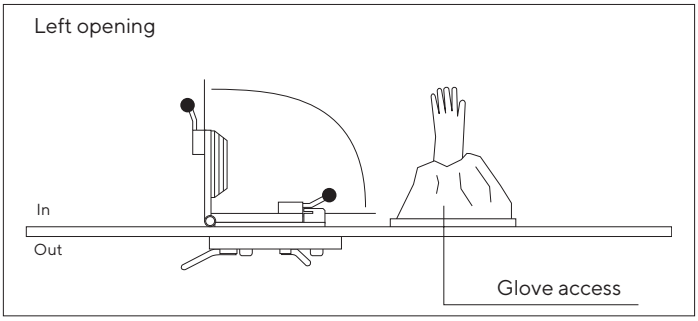
Spare Parts for Biosafe® 110 Ports

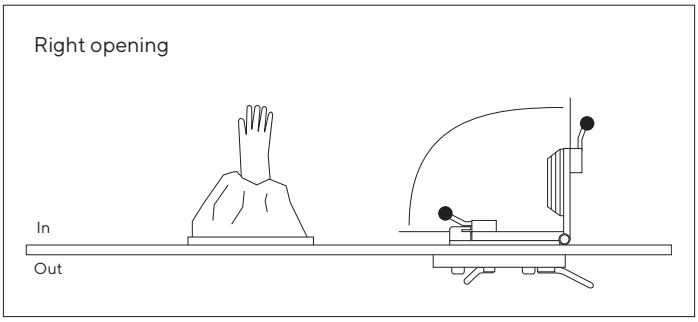
Upon order of Biosafe® 110 ports, you will receive a complete technical package including the list and prices of spare parts.

Trademarks
Biosafe and Biosteam are Sartorius Stedim Aseptics registered trademarks.

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:





Lever on the Right or 90° Lever

You can choose to have the monolever on the right of the port or at 90° compared to the port as shown in the picture below:

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