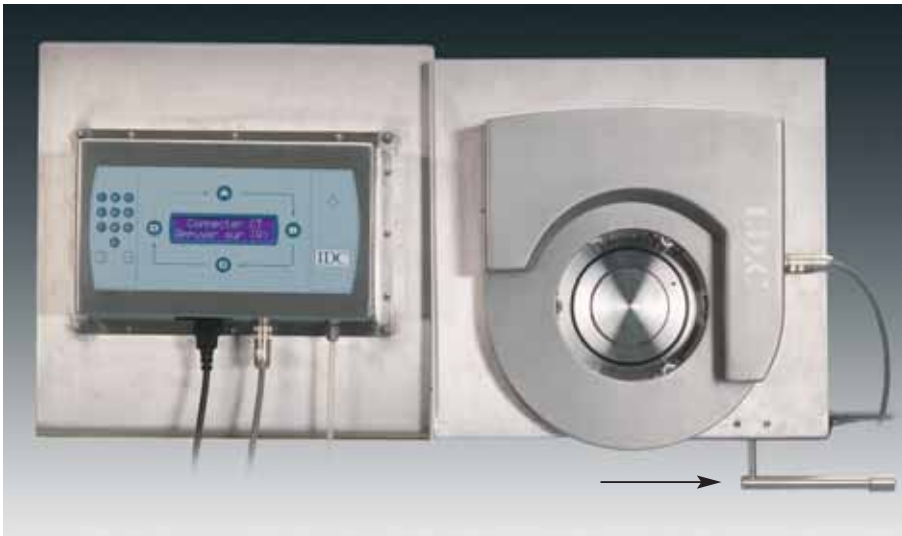




Biosafe® 110 Ports

Configuration and options



Outside Opening: Handle to allow the Biosafe Port opening from outside.



Inside Opening: Handle to allow the Biosafe Port opening from inside.

Inside or outside opening

You can choose to have an inside or an outside opening as shown in the example above. In isolator or RABS, Sartorius Stedim Biotech recommends the outside opening configuration which avoids the need for glove usage.

Notices

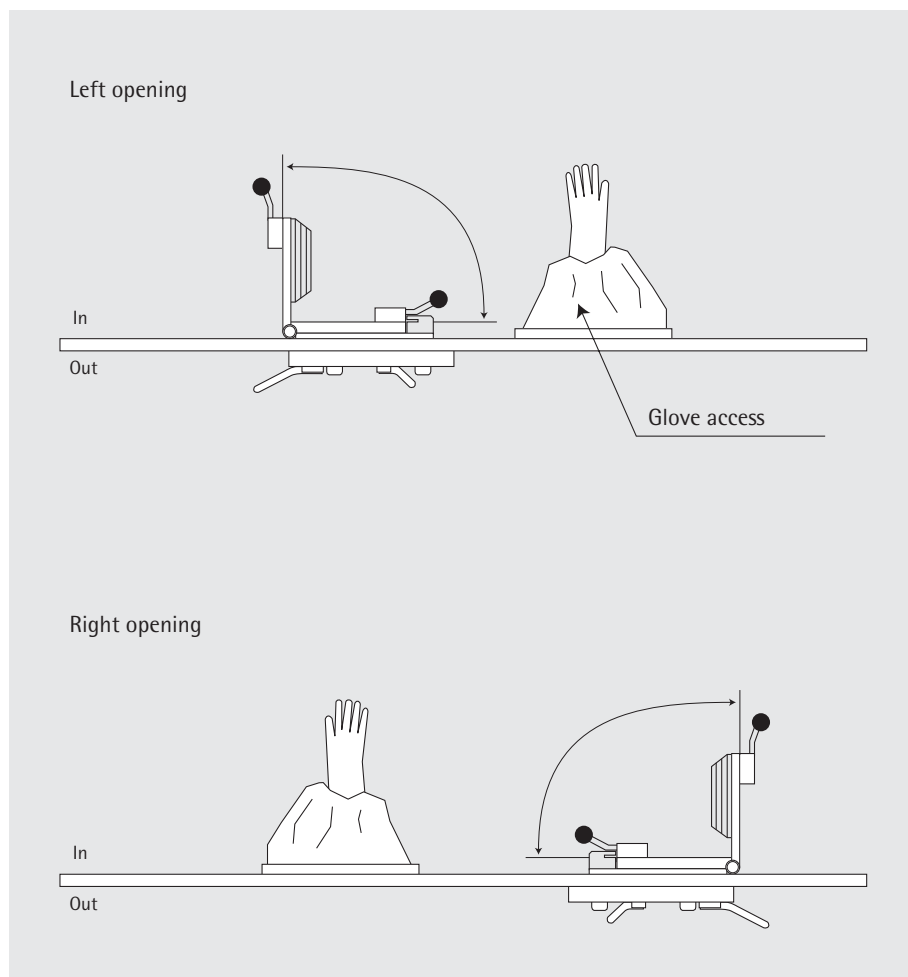
- If the outside opening is chosen, the Biosafe 110 Port has to be installed on a Biosafe Support which is then integrated into the wall.
- If the wall thickness is over 15 mm, the Biosafe 110 Port has to be installed on a Biosafe Support which is then integrated into the wall.

Summary of Biosafe Ports configurations and options

	Right Opening	Left Opening	Inside Opening	Outside Opening	Vacuum Option
Biosafe 110 Three-Lever PETP Port	Available	Available	Available	Not Applicable	Not Applicable
Biosafe 110 Three-Lever TTI Port	Available	Available	Available	Available	Optional
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 +1.800.3687178
 UK +44.1372.737100
 France +33.442.845600
 Italy +39.055.634041
 Spain +34.91.3586102
 Japan +81.3.37405407

Trademarks
 Biosafe is an IDC trademark

Specifications subject to change
 without notice. Printed and copyrighted
 by Sartorius Stedim Biotech GmbH
 W/sart-000 · G
 Publication No.: SPP2001-e07091
 Order No.: 85032-533-91



Biosafe® Ports

Contained aseptic transfer of components, fluids and powders



1. Biosafe 110 Monolever Port; 2. Biosafe 110 Automatic Port; 3. Biosafe 110 Three-lever Port; 4. Biosafe Biosteam® Port

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

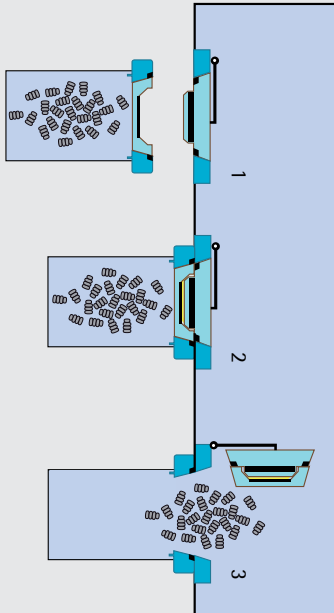
Applications	Upstream and Downstream Processing		Aseptic Processing	
Applications	Transfer of large volume support solutions held in lower classified environments to higher classification process zones. Examples of applications: - Media feed to N-2/N-1/bioreactor - Buffer feed to chromatography columns - 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 Three-lever Port	•	-	-	-
Biosafe 110 Monolever Port	•	-	-	• ¹
Biosafe 110 Automatic Port	-	-	-	• ¹
Biosafe Biosteam	-	•	•	-
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 irradiated.	Closed Gamma irradiated	Double connector Gamma irradiated	- 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 irradiated 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

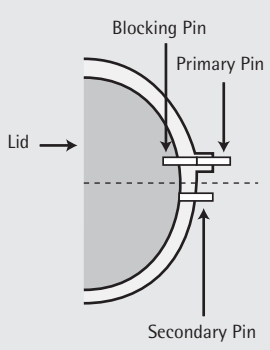
Docking

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

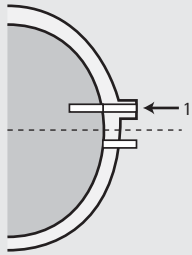
Opening and Transfer

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

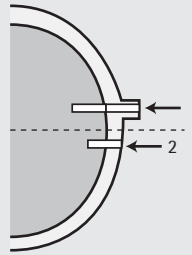
Prior to the connection, the pins on the Biosafe connector are in the "out" position (see beside). This is a proof that the Biosafe bag is ready to be connected to the Port and that it has not been used before.



Step 1: Biosafe bag prior to connection



Step 2: Handles to "open" position



Step 3: Handles to "close" position

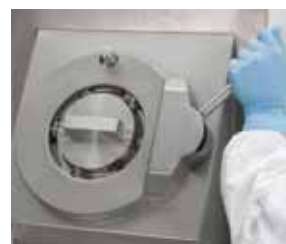
Maintenance, decontamination and sterilization of the Biosafe Port

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 Three-lever Port	Biosafe 110 Monolever Port	Biosafe 110 Automatic Port	Biosafe Biosteam Port
Installation Requirements	Wall thickness: 2-15 mm/0.08-0.59 in.	Delivered on a Biosafe support	Delivered on a Biosafe support	N/A
	<ul style="list-style-type: none"> - If the wall thickness exceeds 15 mm/ 0.59 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	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
Weight (approx.)	10 KG/22.05 lb.	15 KG/33.07 lb.	45 KG/99.21 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	10°C to 30°C 50°F to 86°F	5°C to 30°C 41°F to 86°F
Maximum Temp During Autoclave Cycle	N/A	N/A	N/A	130°C 266°F
Pressure Range During Autoclave Cycle	N/A	N/A	N/A	-1 to +6 barg
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
Materials of Construction ¹	Stainless Steel 316 L; PETP; Silicone/EPDM/PEEK (Biosafe Biosteam Port) (Gasket); EPDM (O-Ring)			
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 Port meets 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"> - Air-tightness 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

FAA109720	Biosafe 110 Three-lever TTI Port ¹
FAA109857	Biosafe 110 Three-lever TTI Port ²
FAA109856	Biosafe 110 Three-lever TTI Port ³
FAA109858	Biosafe 110 Three-lever TTI Port ⁴
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 Port

Accessories, options & support for Biosafe ports

FAA109724	Biosafe Dummy Service Connector for Manual Port
FAA109725	Biosafe Dummy Service Connector for Automatic Port
FAA109873	Biosafe Dummy Service Connector for Biosafe Biosteam Port
FAA109727	Biosafe Support for Biosafe Port
FAA109726	Biosafe Vacuum Box
SAT-TRAINING-ATS	Site Acceptance Tests (SAT) and training at final customers

¹ Inside right opening

² Inside left opening

³ Outside right opening

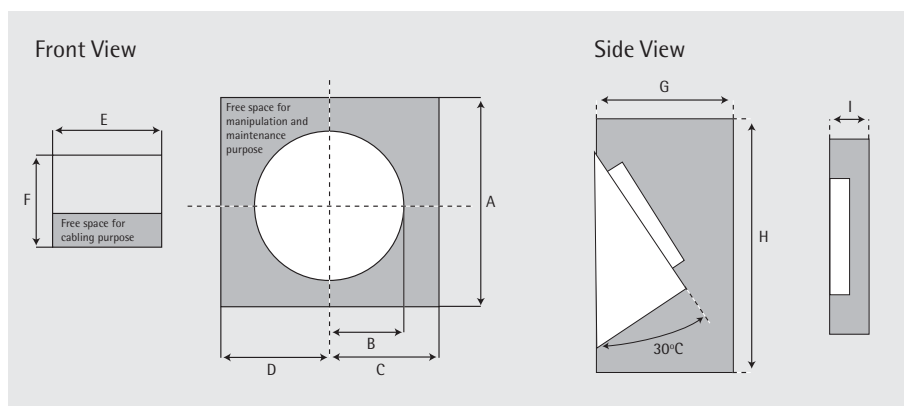
⁴ Outside left opening.

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.

Dimensions

	A	B	C	D	E	F	G	H	I
Biosafe 110 Three-lever Port	400 mm 15.7 in.	118 mm 4.65 in.	200 mm 7.9 in.	250 mm 9.8 in.	N/A	N/A	N/A	N/A	63 mm 2.5 in.
Biosafe 110 Monolever Port	500 mm 19.7 in.	–	375 mm 14.8 in.	245 mm 9.7 in.	N/A	N/A	320 mm 12.6 in.	500 mm 12.7 in.	N/A
Biosafe 110 Automatic Port	560 mm 22.1 in.	–	405 mm 15.9 in.	195 mm 7.7 in.	326 mm 12.8 in.	300 mm 11.8 in.	240 mm 9.5 in.	560 mm 22.0 in.	N/A



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 +1.800.3687178
 UK +44.1372.737100
 France +33.442.845600
 Italy +39.055.634041
 Spain +34.91.3586102
 Japan +81.3.37405407

Trademarks
 Biosafe and Biosteam are IDC
 registered trademarks.

Specifications subject to change
 without notice. Printed and copyrighted
 by Sartorius Stedim Biotech GmbH
 W/sart-000 - G
 Publication No.: SPP2000-e07091
 Order No.: 85032-533-90