SARTORIUS

Product Datasheet

Biosafe® Rapid Transfer Ports 110 – 200 mm

Contained Aseptic Transfer of Components and Fluids

Product Information

The Biosafe® Rapid Transfer Ports, available in 110 and 200 mm diameters, offer reliable and easy-to-use solutions for the secure transfer of components and fluids while maintaining the integrity of critical areas such as isolators, RABS, and cleanrooms.

In accordance with Annex 1 of the EU GMP guidelines, a contamination control strategy that addresses particle generation and gloveless intervention was incorporated into the quality-by-design process.

Features and Benefits

- Unique magnetic technology without rotation prevents particle generation
- Reduced potential risk of contamination by protection of the ring of concern by design
- Gloveless human intervention with an external opening port configuration
- Compact and space-efficient port fitting on isolators with a 90° lever option

Introduction

Relevant Applications

- Parenteral product applications
- Protein- and viral-based therapeutics
- Advanced therapies

Relevant Process Steps

- Aseptic processing and drug product repartition
- Upstream and downstream processing of drug substances

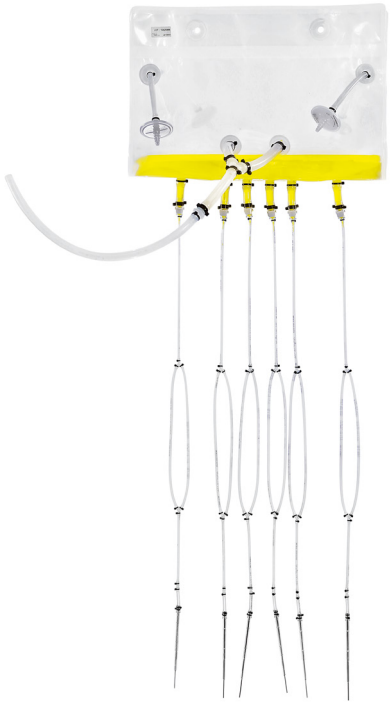
Applications

Biosafe® Rapid Transfer Ports can be used for any component or fluid transfer, such as:

- Transfer into isolators or RABS (entry of final filling set, entry of stoppers, and removal of QC plate, tools, and waste)
- Transfer of large volume support solutions held in lower classified environments to higher classification process zones (such as media feed to N-2 | N-1 | bioreactor, buffer feed to chromatography columns, or transfer out of high classified zone for post-viral area or final filling)

Aseptic Solid and Liquid Transfers via Biosafe® Rapid Transfer Port

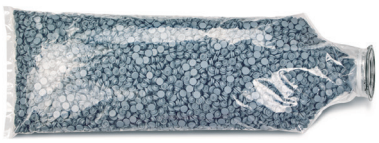
Transfer of final filling bag

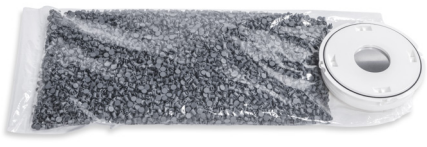


Transfer of final filling bag

Transfer of petri dishes, sterile tools, commodities, and removal of IPC samples and waste

Transfer of gamma or steam-sterilized stoppers, plungers, or seals





Key System Features

The Biosafe® system uses a proprietary concept and is developed and produced by a dedicated team of experts.

Biosafe® consists of several alpha ports (RTP) with 110 and 200 mm useful diameters (installed onto the wall of the isolator) and beta single-use bags fitting all needs for aseptic liquid and component transfer.

- Application 1: Transfer of components (stoppers | plungers | caps), Petri dishes, or tools, and removal of in-process control samples and waste **(A)**
- Application 2: Transfer of a filling set for drug product repartition **(B)**
- Application 3: Liquid zone-to-zone transfer between two different classified areas **(C)**

In accordance with the latest Annex 1 regulations, the new Biosafe® 200 addresses the main challenges of building an effective contamination control strategy. First, the unique magnetic technology allows the port to open with pin actuation without rotation, thereby avoiding particle generation. Second, the ring of concern has been integrated into the connector design. Finally, the external opening port configuration meets the need for gloveless stopper transfer and provides a compact, space-efficient fitting on isolators with a 90° lever.

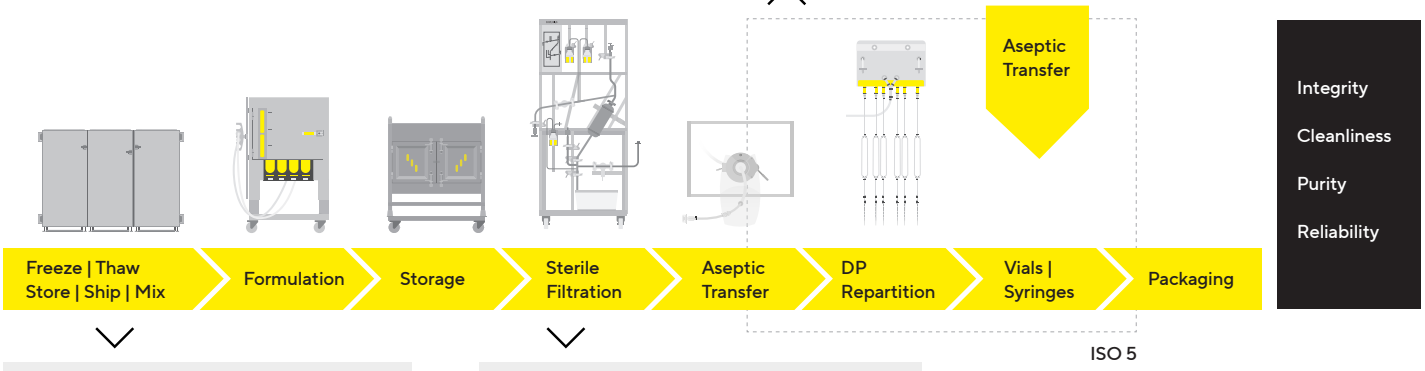
Platform and Synergies

Sartorius is a key fill finish partner, simplifying the drug substance processing infrastructure with a unique single-use portfolio that provides both rapid transfer ports and single-use filling repartition bags. Our strong knowledge, as well as supply assurance and quality support capabilities, offer a complete drug product platform from freezing to finishing, supported by a diverse portfolio including Celsius® freezers and containers, Biosafe® Rapid Transfer Port and beta-bag, Flexsafe® Pro Mixer equipment and bags, PUPSIT final filters and Octoplus FF® repartition bags.

Contamination Control Stratergy (CCS) Is the Cornerstone of the Entire Annex 1 for Drug Discovery Processing

DP Processing in PBT | VBT Workflow

The transfer of materials, equipment and components into the grade A or B areas should be carried out via undirectional process [...] Where sterilisation upon transfer of the items is not possible, a procedure which achieves the same objective of not introducing contamination should be validated (e.g. using rapid tranfer system for isolator...)

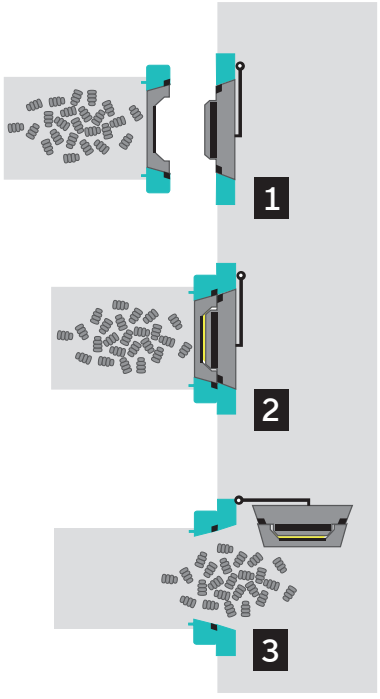


Aseptic manipulations should be minimized through the use of engineering solutions such as pre-assembled and sterilized equipment

The integrity of the sterilized filter assembly should be verified by integrity testing before use (PUPSIT). Any alternative should be justified

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 component or fluids

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 biodecontamination of the inner side of the Biosafe® port as well as for maintenance operations such as gasket replacement.

Technical Specifications

	Biosafe® 110 Port	Biosafe® 200 Port
Installation requirements	Wall thickness: 3–8 mm | 0.12–0.31"	Wall thickness: 3-12 mm | 0.12-0.47"
	▪ If the wall thickness exceeds 8 mm | 0.31" 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.	▪ For Biosafe® 200 all support accessories (vertical or inclined) shall be ordered separately
	▪ We highly recommend setting the port below or on a window so that the operator can see the other side. ▪ Height of port: for good access, the port axis must be 1.1 m to 1.4 m (43.3" to 52.12") high from the operator standing reference.	
Weight without support (approx.)	12 kg | 26.5 lb	16.3 kg | 35.9 lb
Operating temperature range	5 °C to 30 °C | 41 °F to 86 °F	
Materials of construction[1] Visible (outside class A)	**Port** – Stainless steel 1.4404 / 316L, Stainless steel 1.4305 / AISI 303, Stainless steel A2 / 304, PETP, EPDM **Dummy beta-connector** – Stainless steel 1.4404 / 316L, Stainless steel A2 / 304, PETP **Inclined support** – Stainless steel 1.4404 / 316L, Stainless steel A2 / 304	**Port** – Stainless steel 1.4404 / 316L, Stainless steel 1.4410, Stainless steel A2 / 304, Stainless steel 1.4305 / AISI 303, PETP, EPDM **Dummy beta-connector** – Stainless steel 1.4404 / 316L, Stainless steel A2 / 304, PETP **Inclined support** – Stainless steel 1.4404 / 316L, Stainless steel A2 / 304
Materials of construction[1] Visible (inside class A)	**Port** - Stainless steel 1.4404 / 316L, Stainless steel 1.4410, Stainless steel A2 / 304, PETP, PE **Dummy beta-connector** – Stainless steel 1.4404 / 316L, EPDM **Inclined support** – Stainless steel 1.4404 / 316L, Silicone	**Port** - Stainless steel 1.4404 / 316L, Stainless steel 1.4410, Stainless steel A2 / 304, PETP, PE, IGLIDUR® A350 **Dummy beta-connector** – PETP, EPDM **Inclined support** – Stainless steel 1.4404 / 316L, Silicone
Surface finishing	▪ External contact part finishing Ra ≤ 1,6 µm ▪ Internal contact part finishing Ra ≤ 0,8 µm	
Passage diameter	110 mm | 4.3"	200 mm | 7.87"
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® 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 decontaminant agents compatible	▪ 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)	
Accessories	▪ Vertical support recommended for liquid transfer and zone-to-zone transfer ▪ Inclined support recommended for stopper transfer, angle 30°	

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

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® Ports

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

Ordering Information

Biosafe® 110 mm Port	
FAA109722	Inside right opening – side lever
FAA109860	Inside left opening – side lever
FAA109861	Outside right opening with support – side lever
FAA109862	Outside left opening with support – side lever
FAA308155	Inside right opening – 90° lever
FAA308156	Inside left opening – 90° lever
FAA308157	Outside right opening without support – 90° lever
FAA308158	Outside left opening without support – 90° lever

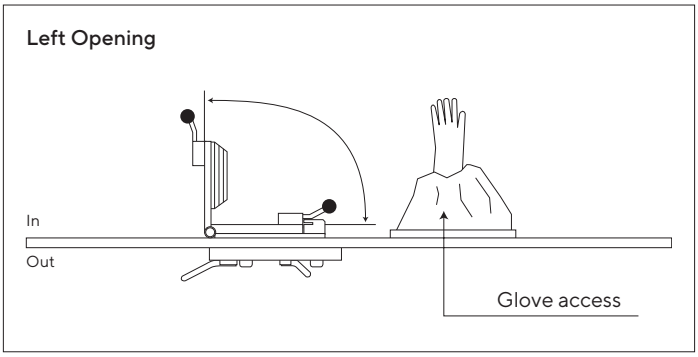
Biosafe® 110 mm Accessories	
FAA109724	Dummy service connector
FAA114793	Vertical support
FAA112077	Inclined support

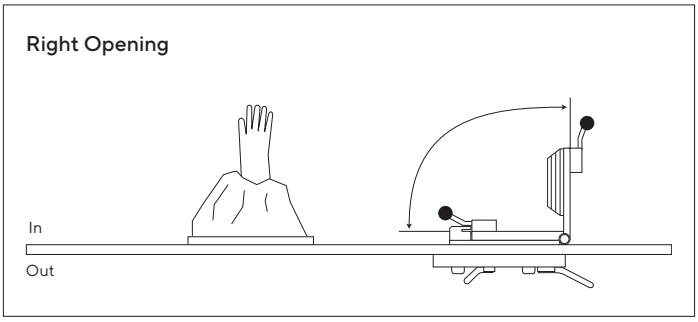
Biosafe® 200 mm Port	
FAA304524	Outside right opening without support – 90° lever
FAA304526	Outside left opening without support – 90° lever

Biosafe® 200 mm Accessories	
FAA304551	Dummy service connector
FAA304553	Inclined support

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:





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.

Lever on the Right or 90° Lever

For Biosafe 110mm Port, 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:

Related Products and Datasheets

Octoplus FF® for Final Filling Operations
Find out more

Biosafe® RAFT System – For Zone-to-Zone Rapid Aseptic Fluid Transfer (RAFT)
Find out more

Biosafe® 110 Bottle-Shaped Bags
Find out more

PUPSIT
Find out more

Flexsafe® 2D Advanced
Find out more

Microbial Air Monitoring
Find out more

Sustainability Commitment

We made the calculation of our Product Carbon Footprint to monitor our environmental impact. We design our products to minimize their environment impact at each stage of their life cycle using:

100% French Production and Supplier Proximity
Our products are entirely manufactured in France, ensuring that all suppliers are located close to each other, minimizing transportation emissions and supporting local economies.

Green Manufacturing Practices
Manufacturing and assembly take place in a Sartorius plant that utilizes certified green electricity, significantly reducing our carbon footprint and promoting renewable energy use.

Packaging Conception
We have implemented packaging made of 100% recyclable materials to reduce waste, and promote resource efficiency.

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