



AMSTAR

CAPE Europe Rapid Transfer System

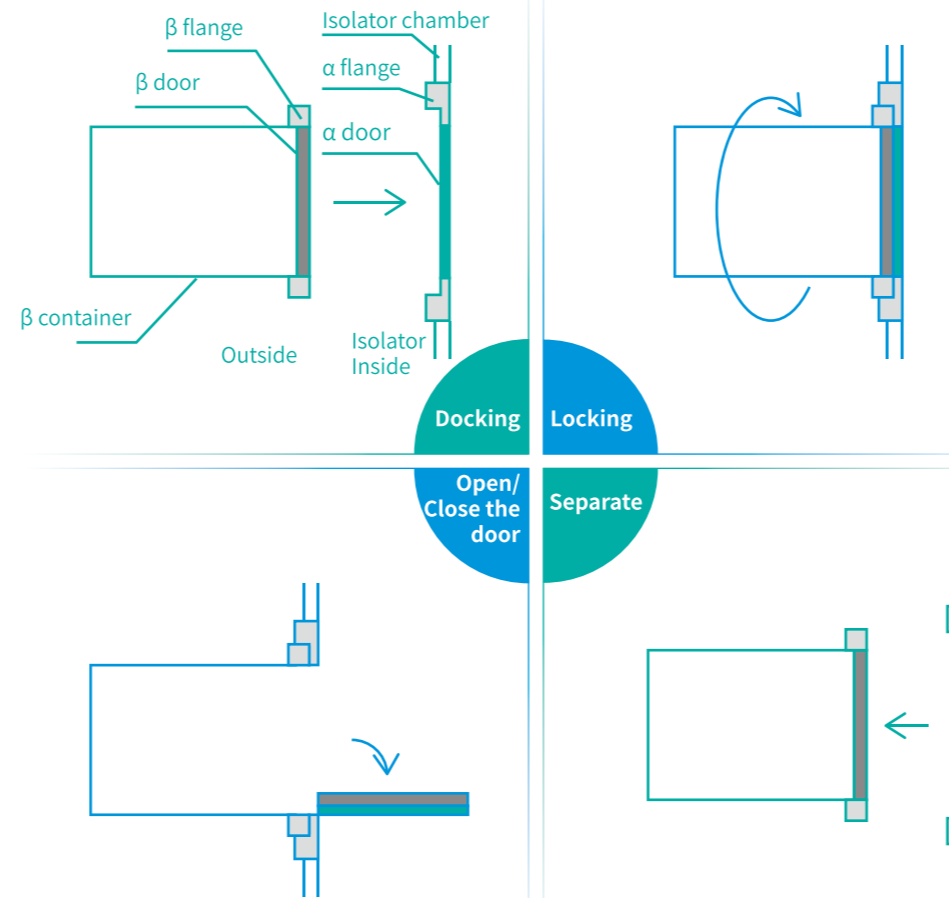
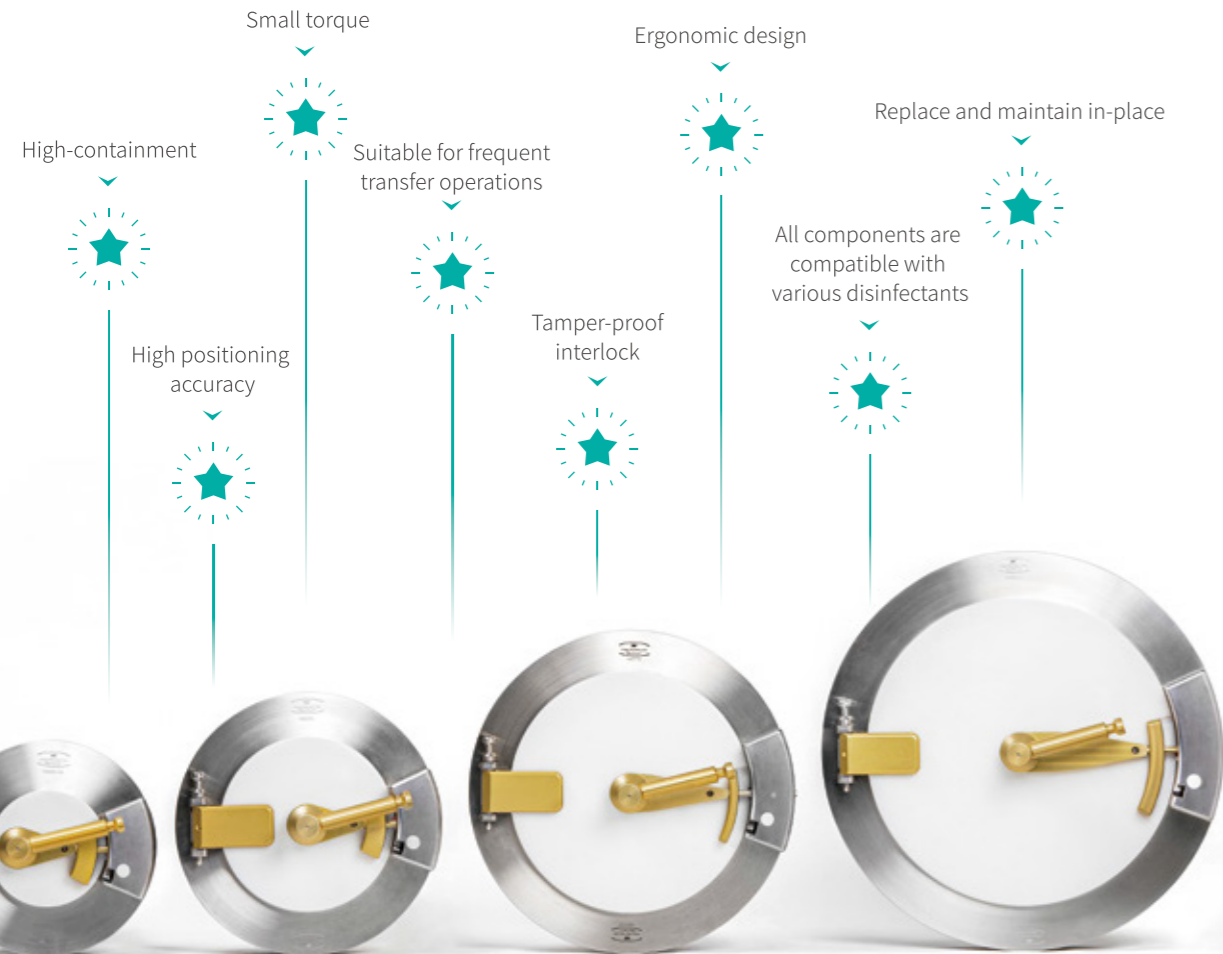
Containment

RTP (Rapid Transfer Ports)

Aseptic contained system and sterile material transfer are very important in pharmaceutical production. The CAPE Optima^{TS} Rapid Transfer system (RTP system) has become the standard of pharmaceutical industry.

RTP uses various beta components to transfer materials to isolators, filling lines, RABs, biosafety cabinets or clean rooms through alpha ports with interlocking safety mechanisms.

Advantages of RTP



Specifications

Optima^{TS} Alpha Ports

Available in a variety of sizes

- Standard size: 190mm, 270mm, 350mm
- Customized: 120mm, 460mm

Optima^{TS} Beta Ports

Available in a variety of combining forms

- SS (stainless steel)
- HDPE (High density polyethylene)
- PE (Polyethylene)
- LDPE (Low density polyethylene)

Pictures	Combining forms	Sterilization	Applications
	SS Beta+HDPE/ Tyvek bag	Steam sterilization	For small quantity items transfer (stoppers, caps)
	PE Beta+HDPE/ Tyvek bag	Steam sterilization	For large quantities and batches of items transfer (stoppers, caps)
	SS Container	Steam sterilization	For small quantity items transfer (stoppers, caps, key components, and tools), liquid transfer, removal of highly toxic or active waste.
	PE Beta+ PE Bag	Irradiation sterilization	For disposable sterile liquid transfer and waste removal

RTP Features

Leak test

- Alpha flange < 1.6 Pa/min at 1000 Pa
- Beta flange < 50 Pa /min for a test pressure of 3800 Pa

Surface finish

- < 0.6 Ra (1.6µm complaint to ISO 1302)

Compliance

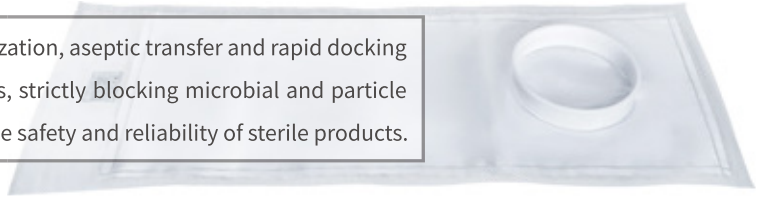
- Compliance with FDA, EU GMP and cGMP regulatory requirements
- Guaranteed low contamination during transfers in grade A aseptic processing environments in a grade C or D background
- Applicable to BSL3 facilities
- Suitable for containment transfer of high toxicity and activity products

Normal operating conditions

- Temperature: +16°C to +30°C
- Normal operating pressure range: +/- 500 Pa
- Maximum permissible pressure: +3800 Pa
- Relative humidity: 10 to 80% @ 25°C

RDB (Rapid Docking Bag)

RDB was developed for the sterilization, aseptic transfer and rapid docking requirements of critical materials, strictly blocking microbial and particle contamination, and protecting the safety and reliability of sterile products.



RDB features and advantages

- Apply to ISO clean environment class 5
- Low thermal, low bacterial endotoxin
- Reduce potential contamination of sealing components
- Transfer sterile materials without leakage and contamination (The background environment with class C or D)
- Regulatory Compliance

The rapid docking bag complies the United States Pharmacopoeia, USP <87> In vitro biological response testing.

The rapid docking bag complies the United States Pharmacopoeia ,USP <88> In vivo biological response testing.

The rapid docking bag complies the European pharmacopoeia, EP 3.1.3 'polyolefin' .

Raw materials complies FDA 21 CFR 177.1520(c) 2.2 requirements for contact with food.

Raw materials complies the EU No. 10/2011 for contact with food.

No risk of transmission of BSE (bovine spongiform encephalopathy) and TSE (transmissible spongiform encephalopathy).

Applications

Components



Alpha and Beta connected



Material transfer



Picture	Product models	Products description	Volume (L)	Size of interfaces (mm)	Packing
	RDB-N19005A	HDPE/Tyvek, Side Docking	10	190	1 EA/pack
	RDB-N19002A	HDPE/Tyvek, Side Docking	25	190	1 EA/pack
	RDB-N19003A	HDPE/Tyvek, Side Docking	35	190	1 EA/pack

* Custom specifications are acceptable



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