

CUSTOMER:

REFERENCE:

DPTE®-S TRANSFER SYSTEM

PRODUCT SPECIFICATION

PRODUCT

The DPTE®-S has been designed to avoid any mishandling which could interfere with the chain of containment during the transfer phases.

APPLICATION

The DPTE®-S transfer system is recognized as being the safest method for introducing and removing sterile and/or toxic material without breaking containment.

A single, easy to operate handle unlocks the door. The door hinge allows the door removal without tools, facilitating maintenance using gloves or half suit.

KEY FEATURES

The DPTE®-S is completely interlocked and allows safe connection/disconnection of the DPTE® Beta part. Its smooth design offers a cleanable fascia inside of the containment.

QUALITY STATEMENT

Confidence in the Getinge Group is the most important quality criteria. This must be the hallmark of all our external and internal commitments, activities and products. Products and services supplied by Getinge must conform to the agreed terms and expectations to ensure recommendations for further business. The achievement of these quality goals is the basis for continued competitive and successful enterprise.

STANDARDS & CODES

The DPTE®-S transfer system complies with all appropriate standards, codes and directives relevant to the region of installation. The equipment is manufactured according to industry requirements and standards. A sample declaration stating the relevant standards, codes and machine directives with which the equipment complies is available on request.



Additionally, GMP procedures and guidelines are followed throughout the project lifecycle and all documentation and validation support materials are issued accordingly.

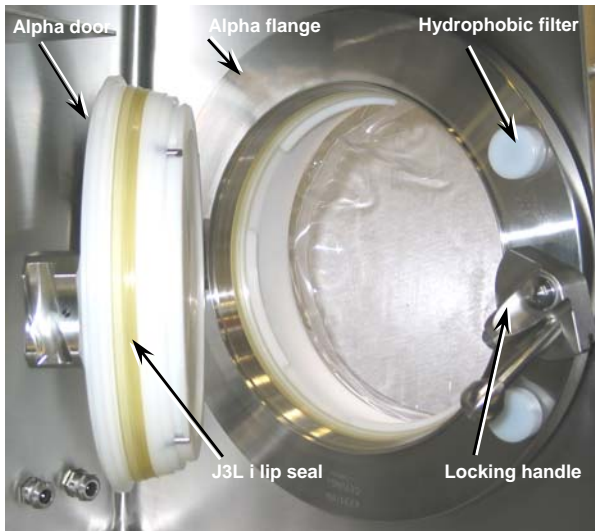
-
- Denotes optional features - Check boxes as required.
 - Commercial specifications only.
 - Pictures and drawings non-contractual.

DESCRIPTION

PRODUCT (OR SERIES) DESCRIPTION

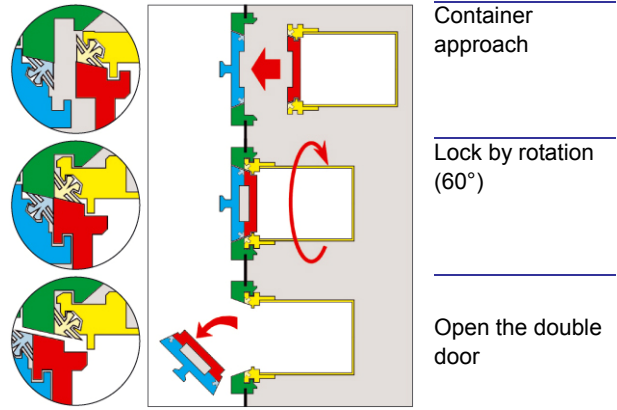
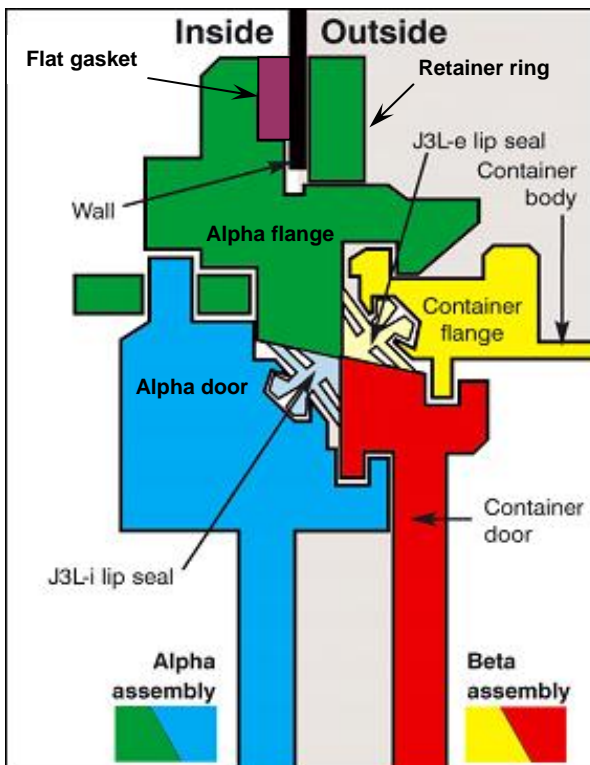
The assembly is comprised of three main parts.

- Alpha flange
- Alpha door
- J3L i lip seal



PRINCIPLE OF OPERATION

- 2 assemblies, Alpha and Beta
- 2 seals meeting at the juncture
- 4 elements mutually shielding each others surfaces, locked together by the rotation of the Beta or Alpha part



BASIC DESIGN FEATURES

Design features and material definition conform to the specification listed below, unless specifically mentioned as optional.

Alpha flange

The alpha flange is constructed from solid, high quality, stainless steel (type 316L or European equivalent). Surfaces are polished to facilitate cleaning (N7=Ra 1.6 µm in accordance with norm ISO 1302). The Alpha flange is composed of a body fixed onto the cleanroom wall or the isolator wall by a threaded retainer ring, the leak tightness on the wall is ensured by a flat gasket.

Alpha door

The Alpha door is manufactured of high molecular weight PEHD. Surfaces are polished to facilitate cleaning (N7=Ra 1.6 µm in accordance with norm ISO 1302).

J3L i lip seal

A J3L i lip seal made of PVC (polyvinyl chloride) is mounted onto the Alpha door.

- It ensures tightness between the Alpha door and Alpha flange.
- It ensures tightness between the Alpha and Beta doors when the container is opened.

Safety features

Four simple components ensure the following:

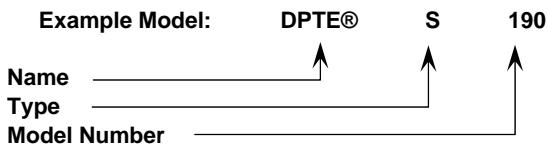
- The door cannot be opened unless a container with lid is properly connected.
- The double door cannot be opened when the DPTE® Beta is not equipped with a container door.
- Container cannot not be removed if the double door is not locked shut.

ORDERING

ORDERING

Description

Use the description below, with the dimension table to select the appropriate model.



DPTE®-S MODELS

- DPTE®-S 105
- DPTE®-S 190
- DPTE®-S 270
- DPTE®-S 350
- DPTE®-S 460

See also table of dimensions on page 4

SERVICES

Check

DPTE®-S is inspected before shipment.

This operation is carried out by our Inspection Quality Department.

Inspection sheets are signed by the Inspection Quality Department and the Quality Internal Validation Department.

Documentation

Standard:

- English language
- French language

For each unit, a certificate is delivered including:

- Material certificate
- Checks
- Statement of conformity

Option list:

- Other language
- Operating file includes:
 - Assembly drawing
 - Operation manual and recommendations
 - Factory acceptance procedure
 - Inspection note
 - Material certificate
 - Statement of conformity
- Microbiological qualification report
- Qualification report for particulate contamination

PACKING AND OPTIONS

Packaging identification

- Item reference
- Quantity
- Assembly

Packing method

The DPTE®-S is adjusted with polyurethane foam and placed in a wooden box.

Storage conditions

- Stored in a flat position
- Normal storage temperature (16°C and 24°C)

INSTALLATIONS

Limits of use / specification

Service conditions

- Operating temperature: between +16° C and +24° C

Operating pressure: between -150 Pa and +150 Pa (relative pressure)

Limits of resistance

- Range of temperature: 0° C / + 50° C
- Test pressure : - 4,000 Pa / + 4,000 Pa

Specifications for leak tightness

- The DPTE®-S is class 1 in accordance with standard ISO 10648-2

Cleaning

- Soft lint free cloth
- Cleaning agent (check for material compatibility)

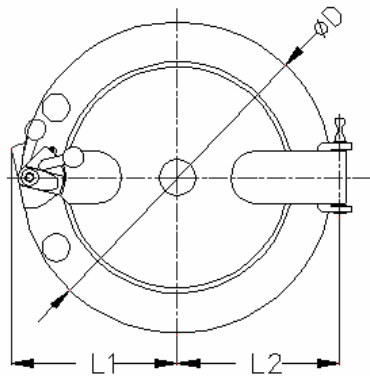
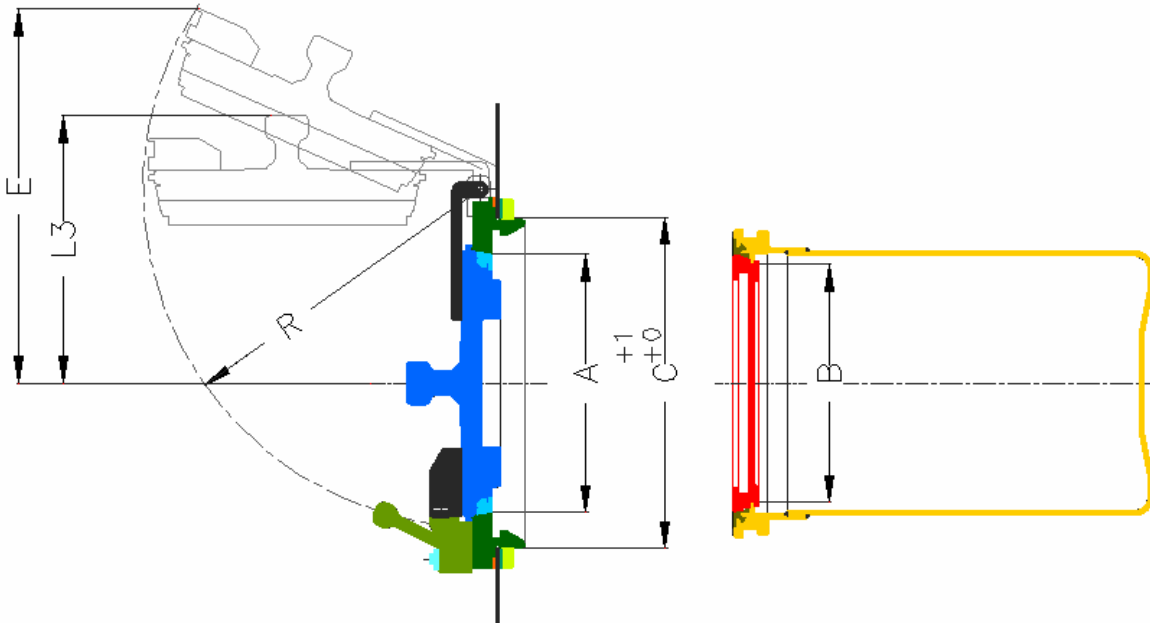
Minimum overall dimensions

The values in the table below are given according to the drilling axis of the wall.

These are the minimum values, which ensure the correct functioning of the DPTE®-S.

2 types of assembly are possible: left or right hand side hinge, obtained by rotating 180° and by returning to the hinge axis.

DIMENSIONS (mm)
(Diagrams or tables)



- A > Nominal diameter
- B > Useful diameter
- C > Bore diameter
- D > Overall diameter

Wall thickness: $2\text{mm} \leq E \leq 10\text{ mm}$

Models	A (mm)	B (mm)	C (mm)	D (mm)	E (mm)	R (mm)	L1 (mm)	L2 (mm)	L3 (mm)	Weight (kg)
105	105	95	152	226	203	192	120	123	180	8
190	190	170	268	317	325	277	169	166	220	17
270	270	250	348	390	394	355	208	203,5	260	21
350	350	330	428	480	474	440	248	249,2	305	29
460	460	440	542	586	570	545	302,5	301,7	365	36

ACCESSORIES

List of spare parts

	DPTE®-S models				
	Ø 105	Ø 190	Ø 270	Ø 350	Ø 460
Part number	26148C	15511C	18839C	18836C	18858C
Description	Part number				
J3L i lip seal	360C	373C	392C	401C	7357C
Flat gasket	26621	15513	18841	18797	18864
Hydrophobic filter		15308	15308	15308	15308
Set of Pin (ring, security axle, security roller, pins, locking finger and screw)	29015C	17463C	17463C	17463C	17463C
Gasket kit	29014C	17456C	17456C	17456C	17456C
Device for replacing the J3L lip seal.	21920				
Silicon oil (100 ml)	638C				
Particle-free cleaning.	19594				
*Kit for replacing the J3L i lip seal	23024C				

*Kit for replacing the J3L i lip seal includes one device for replacing the J3L i lip seal, procedure of replacement, particle-free cleaning paper and silicone bottle.

Frequency of replacement

Description	Frequency
J3L i lip seal	Once every 2 years
Flat gasket	(1)
Hydrophobic filter	Once a year

(1): Replace the gasket only when the DPTE®-S is disassembled.

Replacement of the J3L i lip seal

The J3L i lip seal must be replaced every 2 years. However, it is recommended to carry out a periodic visual inspection of the lip seal conditions and to proceed with a replacement if necessary.

Options

J3L i lip seal made of silicone for DPTE®-S

Compatible types of DPTE® Beta

- Autoclavable stainless steel container (Ø 105 to Ø 350)
- Polyethylene and false container (Ø 105 to Ø 460)
- Emergency container (Ø 190 to Ø 350)
- Transfer isolator (Ø 270 to Ø 460)
- DPTE-BetaBag® (Ø 105 to Ø 350)

- Transfer bin container (Ø 105 to Ø 270)

- DPTE-Tubing (Ø 105 to Ø 270)

GLOSSARY

DPTE®-S: safety double door transfer system (alpha flange + alpha door + J3L i)

DPTE® Beta: beta flange + beta door + J3L e

J3L i: internal 3 effect lip seal

J3L e: external 3 effect lip seal



Getinge provides complete solutions for effective and efficient cleaning, disinfection and sterilization in the healthcare and life science sectors. Our know-how comprises everything from architectural planning, production and handling equipment, to systems for full traceability of sterile goods. Our commitment covers expert advice, training and long-term technical support.

GETINGE

La Calhène

Getinge-La Calhène
1 rue du Comté de Donegal, F-41102 Vendôme, France
Tél.: +33 [0] 254 734 747
Fax : +33 [0] 254 734 748
www.lacalhene.com

GETINGE

THE GETINGE GROUP is a leading global provider of equipment and systems that contribute to quality enhancement and cost efficiency within healthcare and life sciences. Equipment, services and technologies are supplied under the brands **ARJO** for patient hygiene, patient handling and wound care, **GETINGE** for infection control and prevention within healthcare and life science and **MAQUET** for surgical workplaces, cardiopulmonary and critical care.