



The DPTTE[®] System

The original Rapid Transfer Port

GETINGE 

The benchmark for sterile transfer

The first choice for risk-free production



Manufacturing technologies are pushing productivity further with ever higher demands on throughput. GMP requirements are also getting stricter. Pharmaceutical companies must find methods to minimize microbial and particle contamination while keeping up the pace in production.

As a result, isolators are now the gold standard for the production of aseptic or toxic products in pharmaceutical factories and biomedical research. To maintain sterility during transfer of sterile products, specialized technology is needed. The DPTE®* system – the first sterile transfer system for validated aseptic transfer along the production chain – has become an industry standard.

* DPTE Double Porte pour Transfert Etanche (Double Door for Leaktight Transfer)

An industry standard

Developed originally to solve the problem of safe and secure transfer of nuclear waste, the DPTE® system is today the norm in the pharmaceutical production industry with more than 40,000 DPTE® Alpha units installed worldwide.

The system is still based on the ability to transfer components via a DPTE® Beta system into and out of an isolator, filling line, RABS*, BSC* or cleanroom via a secure lock with an Alpha Port, but has been continuously refined and developed over the decades.

*RABS Rapid Access Barrier System

*BSC BioSafety Cabinet

DPTE® technology in your production process



Minimized manual intervention
The major cause of microbial and particulate contamination in aseptic processes.



Higher productivity
Operators are not obliged to manipulate components directly and can be freed up for other tasks.



Risk-free production
Sterile transfer with a secure leak-tight interlock further reduces the risk of contamination.

Securing sterile transfer

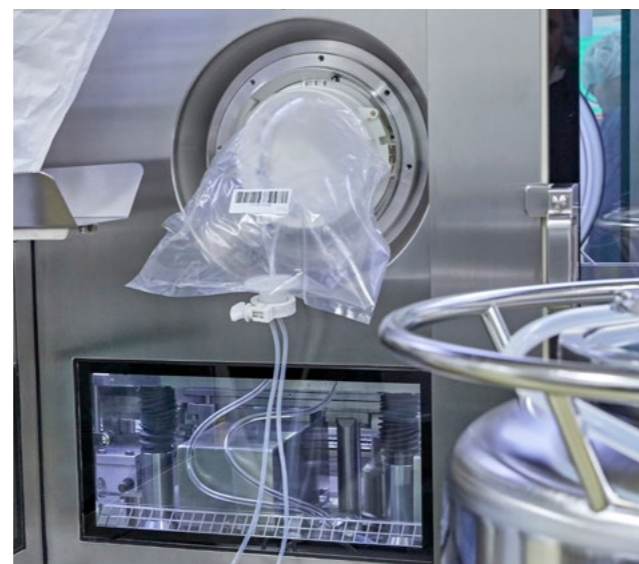
A variety of applications



The DPTE® system enables the user to introduce material into – or to extract material from – an enclosed zone or to connect two devices with identical environments without affecting their ambient characteristics.

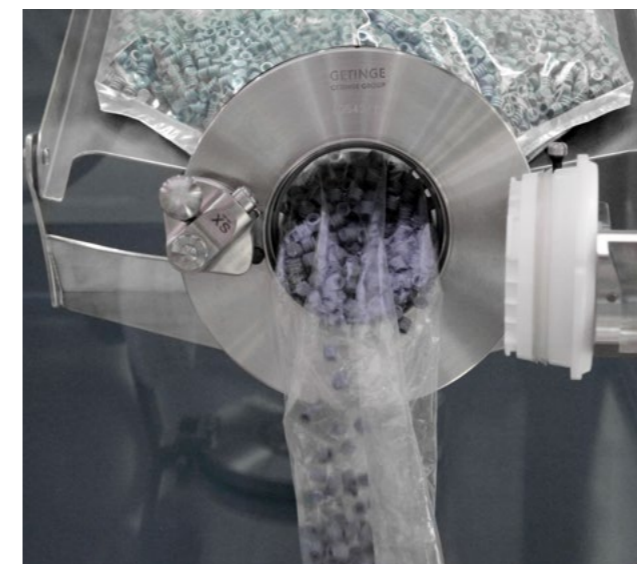
The transfer of components with proven leaktightness takes place after docking a Beta container or DPTE-BetaBag® to an Alpha port. The DPTE® system is secure and certified to eliminate any microbiological and particulate risks. A test program has proven that the DPTE® system is not contaminated even after multiple connections and disconnections.

The types of components that can be used for incoming transfers include - but are not limited to - plugs, syringes, pistons, capsules, injectors, stoppers, caps, bottles and plungers, and other medical products as well as toxic/potent products. Outgoing transfers include samples, miscellaneous equipment, waste and bulk products (powder).



Liquid transfer using the DPTE® system (courtesy Octapharma)

THE DPTE® SYSTEM



Sterile components transfer system

THE DPTE® SYSTEM



Component transfer at customer site (courtesy Octapharma)
DPTE-BetaBag® was first sterilized in a Getinge sterilizer.

DPTE® Alpha

The core of the system

The core of the DPTE® system is the Alpha part with its secure interlock enabling totally safe connections and disconnections.

The DPTE® system is based on the interaction of an Alpha part with a Beta part – each fitted with a door, a lock and a sealing function. The Alpha part is mounted on a support – commonly an isolator, RABS, BSC or cleanroom – while the Beta part consists of a container, bag or similar device used for the transfer of components, solids or liquids.

Continuous innovation

The DPTE® system was originally developed in 1963 and has since undergone several further improvements. Due to the demand for increased safety and changing regulations combined with technological progress, Getinge introduced the DPTE® XS – eXtra Safe with an added degree of safety during connection and disconnection.

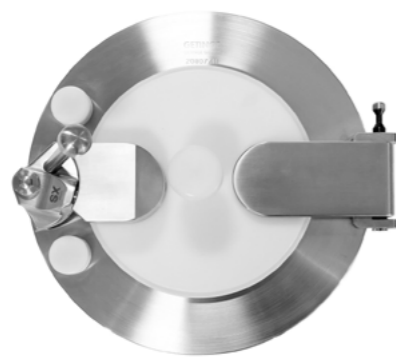
DPTE®-XS - eXtra Safe

DPTE®-XS - Manual 60° Rotation

The Alpha parts and Beta parts are connected by a manual 60° rotation which detaches the doors from their supports and joins them together. Tightness (corresponding to class 1 of 10648-2 standard) is secured by the lip seals of the new assembly. The doors can now be opened without breaking sterility or containment.



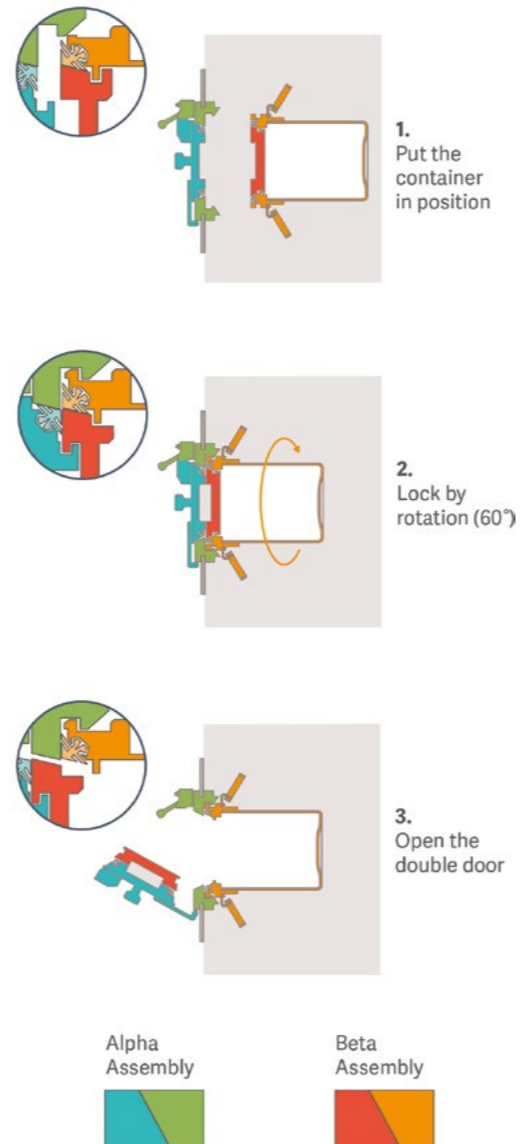
Operator Side



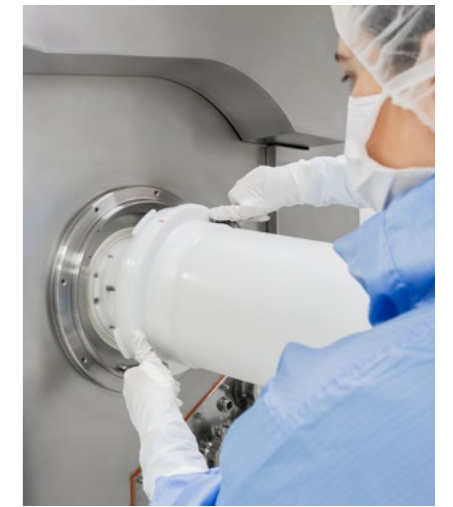
Barrier System Side

Original
DPTE®

Lip seals keep sterility in and contaminants out



DPTE®-XS Operating Principle



Diameters available (Alpha)

Nom. Dia

105 mm

190 mm

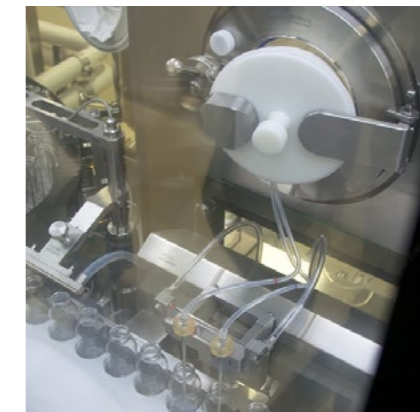
270 mm

350 mm

460 mm



Courtesy Octapharma



Liquid transfer



Microbiological and particulate contamination

The DPTE® system has been rigorously tested for potential microbiological contamination in a three-phase study at the French Agricultural Institute (INRA) in France. Following the same methodology an official study on particulate contamination was conducted at the French Nuclear Safety Institute (LECEV of IPSN) to quantify the efficiency of the DPTE® system.

The results from repeated transfers at higher pressure than used in regular operations showed no microbiological contamination, and – for particulate contamination – that the efficiency ratio for DPTE® was at a level higher than the efficiency of a HEPA* filter, demonstrating its capacity to effectively isolate particulate contamination.

*HEPA High Efficiency Particulate Air

DPTE® Beta containers

The key to safe transfer

Transfer of sterile and/or toxic products in and out of a barrier system is one of the most critical aspects of aseptic and confined production. We offer a wide range of re-usable DPTE® Beta containers for bi-directional transfer, in stainless steel and PolyEthylene (PE).



For aseptic and/or containment applications our reusable PE containers can be sterilized by gamma irradiation or biodecontaminated by H₂O₂. They can be used to transfer HAPIs (Highly Active Pharmaceutical Ingredients), typically powder or in powder form.



Steam sterilization ready

Gamma irradiation ready

Container benefits

- Mechanical safety lock to prevent incorrect manipulation
- Compatible with any DPTE® Alpha port of the same diameter
- Bi-directional transfer system for safe handling of sterile and toxic products
- Re-usable, cleanable, cost-effective
- Steam or gamma sterilization ready
- H₂O₂ biodecontamination ready
- Optional racks for steel canisters provide efficient manipulation and sterilization solutions

Getinge's stainless steel containers are used to sterilize material before bringing it into the aseptic zone or to remove material from a sterile environment.

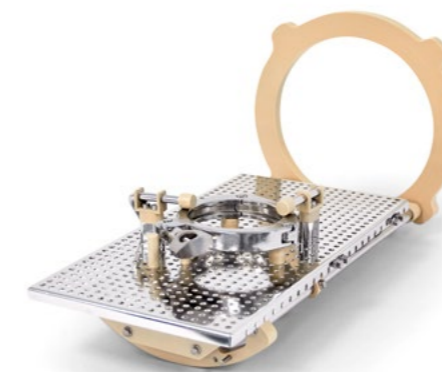
Various levels of stainless steel containers and racks are available, from standardized to fully customized. Refer table on page 19.



Hydrophobic filter for steam sterilization



Rounded basket for all levels of containers



Configurable Rack



Customized Rack

DPTE-BetaBag®

A flexible single-use option to increase productivity

Original
DPTE®

The DPTE-BetaBag® is a combination of a DPTE® Beta part and a bag for the safe transfer of sterile products or waste material. The DPTE-BetaBag® single-use range is designed for fast contamination-free transfer to maintain high-speed production, increase flexibility and minimize validation costs.



DPTE-BetaBag® 105, multi-layer Poly-Ethylene filled with components (plungers)

Flexibility and long-term partnership are key

Although typically the DPTE-BetaBag® is made of either multi-layer PolyEthylene, PolyUrethane or Tyvek®, the size, shape and material of the bag vary according to application and production parameters. This compatibility with various applications is based on long-term partnerships with industry leaders. The system also offers safe, bi-directional transfer, i.e. the product can be transferred from the DPTE-BetaBag® to the process zone and vice versa.

Ready-to-use

Components such as stoppers, caps, plastic bottles and plungers can be loaded into a single use DPTE-BetaBag® at the point of manufacture, sterilized inside the bag by the appropriate sterilization method (typically gamma, ethylene oxide or steam), and delivered to the pharmaceutical production site, ready to use. Using quality control and modern tracing techniques, components are documented as sterile, providing a complete guarantee to the client.

Benefits of the pre-filled, pre-sterilized single-use DPTE-BetaBag®

- Complete sterility guarantee
- Increased manufacturing flexibility and scalability
- Reduced risk of cross contamination
- One sterilization and multiple (up to 5) connections
- Process and production uptime improvement
- No requirement for in-house sterilization of components prior to bagging
- No requirement to biodecontaminate the bag before loading products into the aseptic zone
- No cleaning, washing operations needed so no cleaning process validation on site
- Reduced use of chemicals for cleaning
- Maintenance-free
- Minimized operator intervention
- Production surface (footprint) reduction
- Better ergonomics for operators

DPTE-BetaBag® 190 Tyvek® filled with components (caps)



Guaranteeing safe transfer

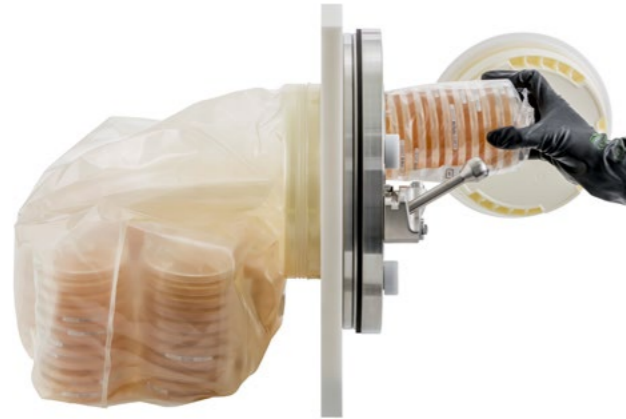
The validation of our DPTE-BetaBag® complies with international regulations and includes:

- Mechanical validation
 - Leak testing of DPTE® Beta unit
 - Leak testing of bag welded onto DPTE®
 - Seal strength of the bag
- Sterility validation (Gamma irradiation cycle between 25 and 50 kGy)
- Microbiological validation
 - Bioburden
 - Endotoxin level
- Particulate validation

Many single-use applications

Validated to comply with international regulations, the DPTE-BetaBag® is used in various applications in aseptic and contained production

The DPTE-BetaBag® is also used to transfer environmental monitoring items, cleaning materials and to handle waste, i.e. safely removing items such as toxic waste, broken vials, ampules, syringes and used wipes from the isolator or filling line.



Environmental monitoring items, pre-sterilized, ready-to-use plates (courtesy of Merck KGaA or its affiliates)



Cleaning materials, pre-sterilized, ready-to-use (courtesy of Texwipe)



Waste removal from an isolator using a DPTE-BetaBag®

The DPTE-BetaBag® contributes to safe transfer of liquids, maintaining sterility between the tank source and the point of filling.

In the aseptic filling process, replacement of all the parts in contact with the product, after use, significantly reduces the contamination risk. Getinge's partners have developed single-use assemblies which are pre-validated, pre-assembled, pre-sterilized systems with tubing, connectors, filters etc. placed inside a DPTE-BetaBag® for easy and secure insertion and removal around the aseptic filling line.



DPTE-BetaBag® for liquid transfer (courtesy of Merck KGaA or its affiliates)



DPTE-BetaBag® for liquid transfer (©2019 Saint-Gobain Life Sciences)



DPTE-BetaBag® for liquid transfer (Copyright Pall Corporation)



Sustainability

Is single-use technology viable from a sustainability perspective? Studies* show that single-use products, compared to re-usable stainless-steel products (for example), have "substantially lower energy and water requirements because of the elimination of extensive cleaning and sterilization between each batch production as well as chemicals used during that process".

*"Is Sustainability Possible with Single-Use Technology", Trisha Glad, Pharmaceutical Online, 12 August 2015



Nearly 60 years of transfer solutions

A legacy of sterility

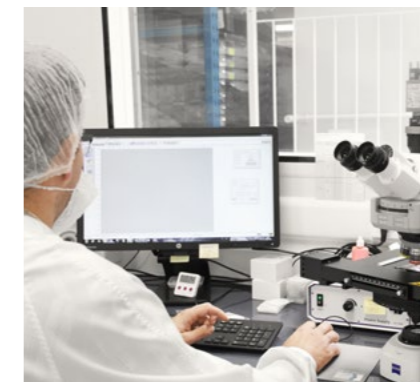
The DPTE® system is manufactured in Vendôme, France. All sterile transfer parts are rigorously tested and validated in the extended, ultra-modern Vendôme factory.

The first DPTE® system was developed for the nuclear industry in 1963. In the 1970s the pharmaceutical industry realized the potential in this sterile transfer solution, resulting in the production of the first DPTE-BetaBag® in 1998. Getinge manufactures both Alpha and Beta parts in the factory in Vendôme, where the DPTE-BetaBag® range is assembled in ISO 5 and ISO 7 environments for ultra-clean production.

During assembly in the factory, inspections are performed on 100% of production. Inspections consist of leak tests, visual inspection and mechanical and connection tests. Each DPTE-BetaBag® batch is delivered with a certificate of conformity based on total traceability in the supply chain.

The DPTE-BetaBag® is validated on gamma irradiation sterilization, on endotoxins, bioburden and particulate level according to the following standards: ISO 11137 1, 2 and 3, European Pharmacopeia 5th Edition Chapter 2.6.14 with additional constraints on fibers decided by Getinge.

Getinge has invested in ISO 5 cleanrooms in order to comply with the continuously evolving Good Manufacturing Practice (GMP) regulations and to ensure consistently high quality production. We are constantly working on the highest possible level of cleanliness, in order to remain at the forefront of sterile transfer technology, based on a permanent Continuous Improvement Programme.



DPTE® Accessories

To optimize your sterile transfer solution

We are constantly designing and developing accessories to streamline your process while improving operator safety and ergonomics.



DPTE® Tubing with heat sealing machine for removal of items from the sterile zone

DPTE® Transfer Trolley

Safe, Smart, Simple



The hygienically designed compact loading trolley safeguards production efficiency and the integrity of the product inside the DPTE® aseptic transfer system. Variable height and memorization of positions for DPTE® access improve ergonomics and safety.

DPTE® Transfer Leak Tester TLT

Wireless and pipeless

Check the integrity of your Beta container before and after use, with Getinge's wireless, pipeless leak tester. The equipment provides full traceability under FDA 21 CFR Part 11.



Cover for autoclavable containers
Protects gasket during sterilization and manipulation



DPTE® Alpha port with flexible membrane
Enables rotating Alpha



Lifting pressure cover
For steam sterilization in place of Beta part seal surface



DPTE® container locking/unlocking key
For secure opening/closing in aseptic zone



Dummy container
Use when decontaminating the seal on the Alpha part



Handles for DPTE-BetaBag®, 190 and 270, multi-layer PolyEthylene and PolyUrethane

Maintaining safe production

Managing and protecting your investment

As a reliable partner by your side, we help you to maintain and optimize the productivity of your equipment throughout its entire life cycle.

The DPTE® transfer system is a critical component preventing cross contamination in the aseptic process. Getinge proposes regular preventive maintenance of Alpha ports and Beta containers to ensure that your transfers are leaktight.

- Leak test before and after the maintenance operation
- Change the lip seal every year (Getinge recommendation)
- Visual inspection of flange and door (lip seal contact surface)
- Functional verification of all inner pins and replacement if needed
- Remounting
- Control of hydrophobic filter (autoclavable containers)



DPTE-BetaBag® Product Range



Direct delivery or via component manufacturers:

- Ready to sterilize (RTS)
- Ready to use (RTU)

Shelf-life:

- 24 months (average)

Bag volumes adapted to applications:

- from 10L to 150L

DPTE® Product Range

		105 mm	190 mm	270 mm	350 mm	460 mm	
ALPHA	DPTE®-XS PORT	•	•	•	•	•	
BETA	DPTE® Containers	Stainless Steel	•	•	•	•	
		PolyEthylene	•	•	•	•	•
	DPTE-BetaBag®	Tyvek®	•	•			
		PE/EVOH/PE	•	•			
		PolyUrethane	•	•	•		
	DPTE® Tubing PolyEthylene	•	•	•			
	DPTE® Dummy Container	•	•	•	•	•	

DPTE® Beta Stainless Steel Containers: 4 Levels

Level	Ø	Length 300 mm	Length 400 mm	Length 500 mm	Length 600 mm	Length 700 mm
1 Standard*	190		•			
	270		•			
	350					
2 Semi-standard	190	•	•	•	•	•
	270	•	•	•	•	•
	350	•	•	•	•	•
3 Configurable using pre-designed parts	190	•	•	•	•	•
	270	•	•	•	•	•
	350	•	•	•	•	•
4	Customized containers and racks, dimensions, parts and finishing to customers' requirements - contact our Sales Team					

* Ø 105 and Ø 460 are part of our range, please contact our Sales Team.

Containers and Racks compatibility

The rack design will match the diameter and length of the chosen container.

		Containers			
		1-Standard	2-Semi-Standard	3-Configurable	4-Customized
Racks	Glide system	✓	✓	✓	✓
	Telescopic system	✗	✓	✓	✓
	Roller system	✗	✓	✓	✓
	Configurable rack	✗	✓	✓	✓
	Customized rack	✗	✓	✓	✓



With a firm belief that every person and community should have access to the best possible care, Getinge provides hospitals and life science institutions with products and solutions aiming to improve clinical results and optimize workflows. The offering includes products and solutions for intensive care cardiovascular procedures, operating rooms, sterile reprocessing and life science. Getinge employs over 10,000 people worldwide and the products are sold in more than 135 countries.

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