The DPTE® System
The original Rapid Transfer Port
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 Leak tight 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).

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 port 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.

Lip seals keep sterility in and contaminants out

**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 reusable DPTE® Beta containers for bi-directional transfer, in stainless steel and PolyEthylene (PE).

**Container benefits**

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

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 HAPiPs (Highly Active Pharmaceutical Ingredients), typically powder or in powder form.

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

4 levels of stainless steel containers are proposed from standard to customized. Refer page 19.
DPTE-BetaBag®
A flexible single-use option to increase productivity

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.

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 ergonomy for operators

Flexibility is key
Although typically the DPTE-BetaBag® is made of either multi-layer Poly-Ethylene, PolyUrethane or Tyvek™, the size, shape and material of the bag vary according to application and production parameters. 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.

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
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.

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.

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

Many single-use applications

Waste removal from an isolator using a DPTE-BetaBag®

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)

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

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 Singe-Use Technology”, Trisha Glad, Pharmaceutical Online, 12 August 2015
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.

Over 50 years of transfer solutions
A legacy of sterility
**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® Transfer Leak Tester TLT**

Wireless and pipeless

We know customers are under pressure from ever-increasing demands on testing for integrity. Getinge’s TLT is designed to meet these demands and provide easy testing for DPTE® Alpha and Beta parts.

- Full traceability compliant to FDA 21 CFR part 11 and EU annex 11
- A modern tool compliant to the Guidelines and Annex 1 of the GMP
- Pipeless and wireless (no pipes or cables between the remote head and the main unit)
- Based on a concept of inflatable gaskets allowing for testing different sizes of DPTE® Alpha and Beta parts
- Uses pressure decay method according to ISO 14644-7
- Possible future integration of an RFID* reader of remote head

* Radio Frequency Identification

During contained transfer of materials into or out of isolators or other classified environments, or during aseptic container storage between processes, the user-friendly TLT allows you to secure the integrity of the DPTE® systems prior to or after the production cycles, using the pressure decay method with reliable and accurate repeatability.
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 leak-tight.

- 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

**DPTE® Beta Stainless Steel Containers: 4 Levels**

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<th>Container Level</th>
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<th>Length 300 mm</th>
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* Ø 105 and Ø 460 are part of our range, please contact our Sales Team

**DPTE® Product Range**

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**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

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

TP5E® Beta stainless steel container Ø 190 with standard autoclavable insert

Customized autoclavable stainless steel and plastic insert
Getinge is a global provider of innovative solutions for operating rooms, intensive care units, sterilization departments and for life science companies and institutions. Based on our firsthand experience and close partnerships with clinical experts, healthcare professionals and medtech specialists, we are improving everyday life for people – today and tomorrow.

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