

**The DPTE<sup>®</sup> system**  
The original Rapid  
Transfer Port



# Complying with today's GMP regulations

## Annex 1 on the use of rapid transfer port in pharmaceutical production

Today's manufacturing technologies are pushing productivity further with even higher demands on throughput, while manufacturers are also exploring more targeted treatments, immunotherapies, biologics, and cell therapies which require manufacturing flexibility. As the market evolves, GMP requirements are also getting stricter.

Annex 1 requires pharmaceutical companies to minimize the risk of microbial and particle contamination while keeping up the pace of production. As a result, isolators are used 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 – is the industry standard.



# The original DPTE® rapid transfer port

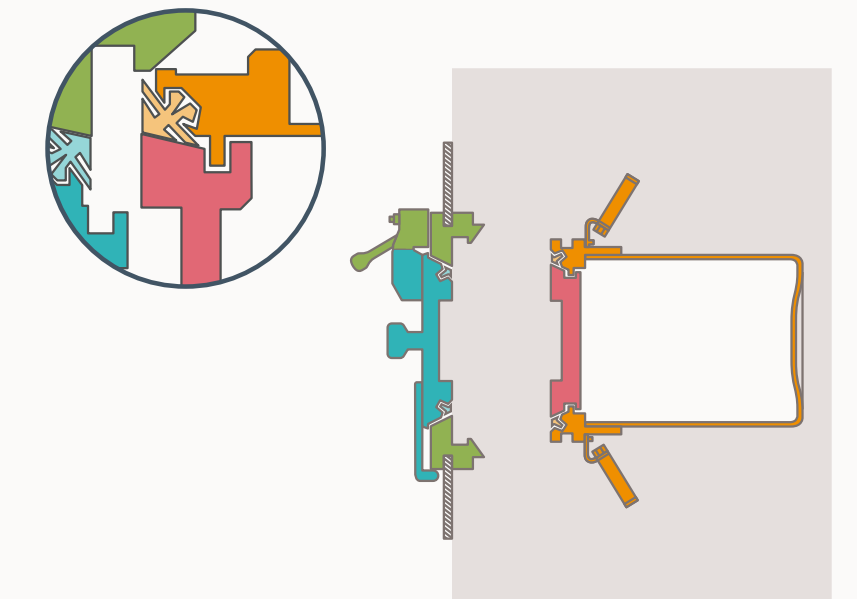
For secure aseptic transfer, only the DPTE® system – the original rapid transfer port – brings you the confidence you want and the quality you need.

The DPTE® system is recognized as the safest method for bi-directional transfer in aseptic or toxic working areas, without breaking containment or sterility.

How does it work?

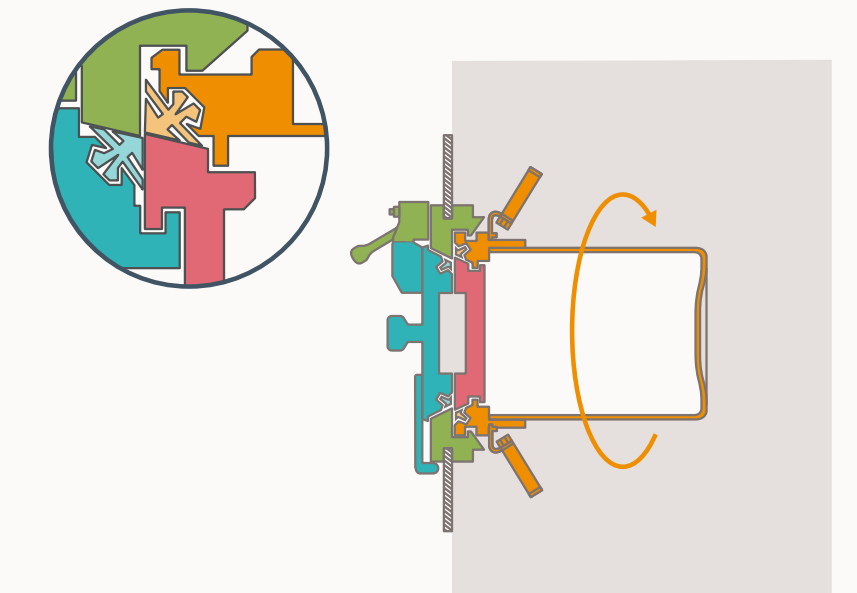
## 1. Line up the DPTE® Alpha and Beta parts

- The Alpha part is mounted on a support – commonly an isolator, RABS, BSC, or cleanroom.
- The Beta part consists of a container, bag, or other Beta device used for the transfer of components, solids, or liquids.



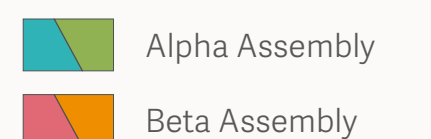
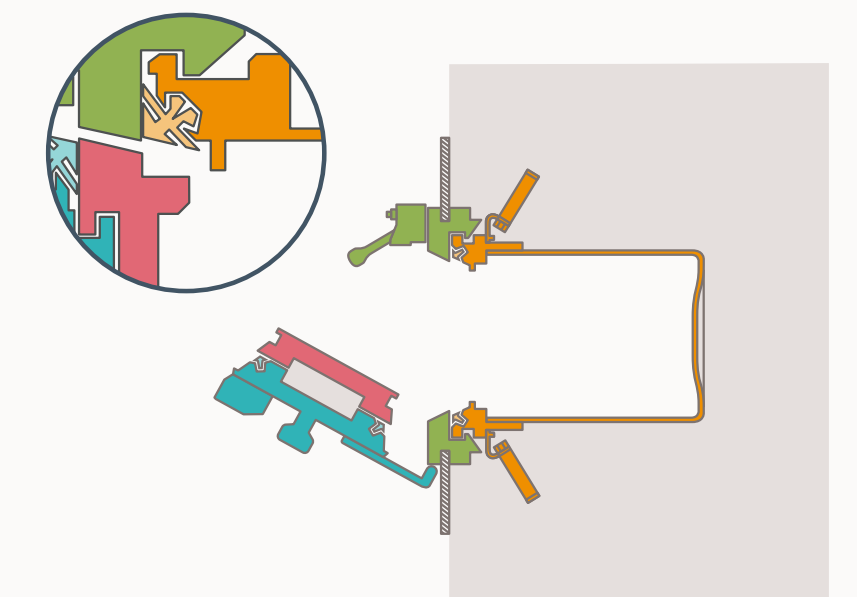
## 2. Rotate the Beta part 60° to ensure a leak tight seal

- The Alpha part and Beta part are connected by a manual 60° rotation that detaches the doors from their supports and joins them together.
- Leak tightness is secured by the lip seal of the new assembly.



## 3. Open the doors without breaking sterility or containment

- The doors can now be opened without breaking sterility or containment.
- Only the combination of the DPTE® Alpha and DPTE® Beta parts is a validated solution. Used together, they provide highly secure transfer and protect your production.

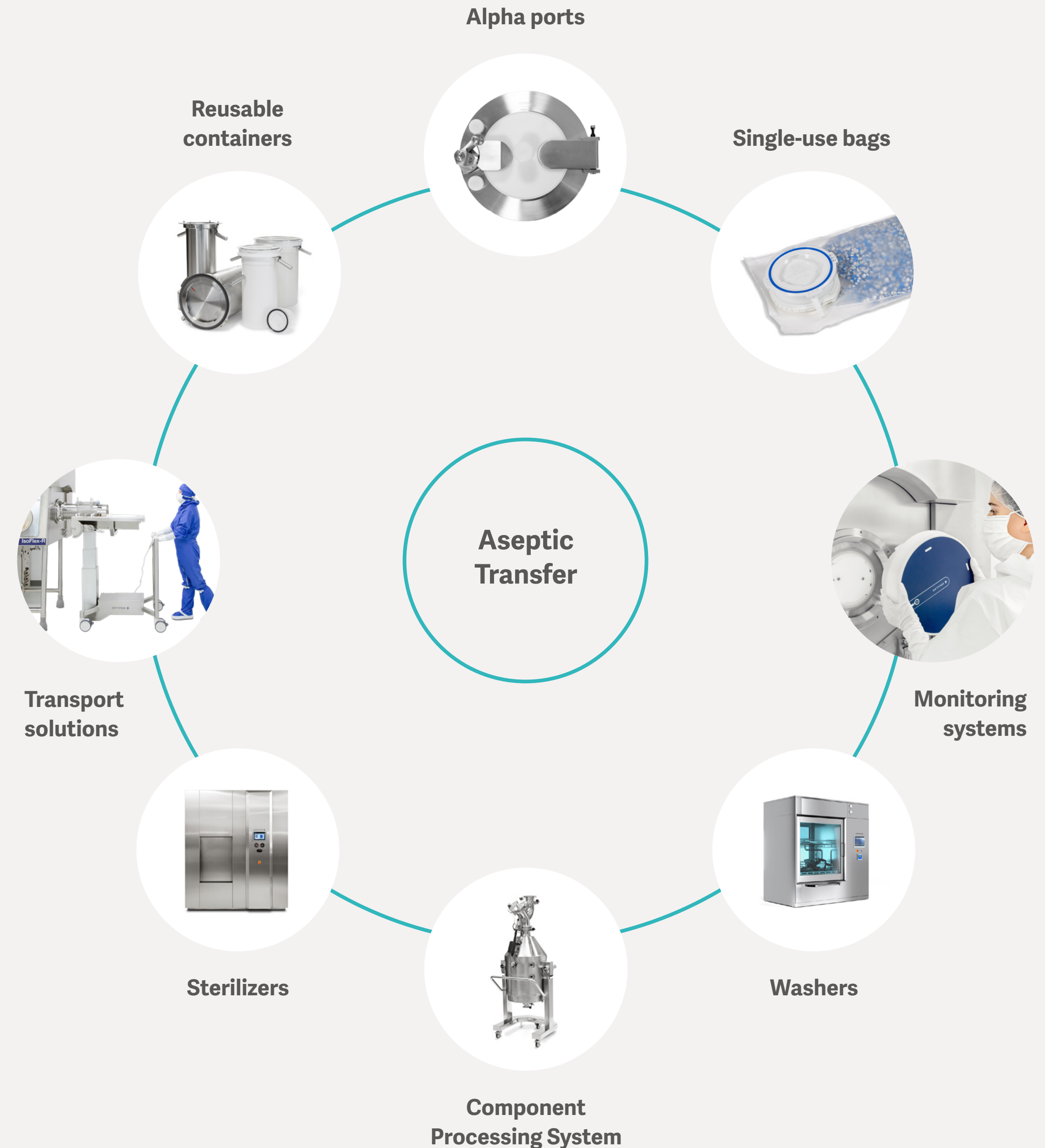


# The complete aseptic transfer solution from Getinge

As leaders in the life-science industry, we work closely with you to tailor your solution to your needs

The DPTE® Alpha and DPTE® Beta equipment work perfectly together as a fully validated solution that greatly improves process efficiency and minimizes the risk of contamination. By installing a complete DPTE® system, you eliminate the need to invest resources and time in attempting to validate a unique combination of Alpha and Beta parts.

**Matching your DPTE® Alpha port with the right Beta part from Getinge is a cost-effective way to guarantee your product and/or operator safety.**



The DPTE® system

# More than 60 years of DPTE® innovation



—

Around 45,000 DPTE® Alpha units are currently in operation worldwide, and Getinge has sold around 2 million DPTE-BetaBag® units

Getinge manufactures both Alpha and Beta parts as well as accessories in our factory in Vendôme, France, where the DPTE-BetaBag® range is assembled in ISO 5 and ISO 7 environments for ultra-clean production. In 2021, a new cleanroom opened in Merrimack, US, for the production of the DPTE-BetaBag®.

**Two production sites enables:**

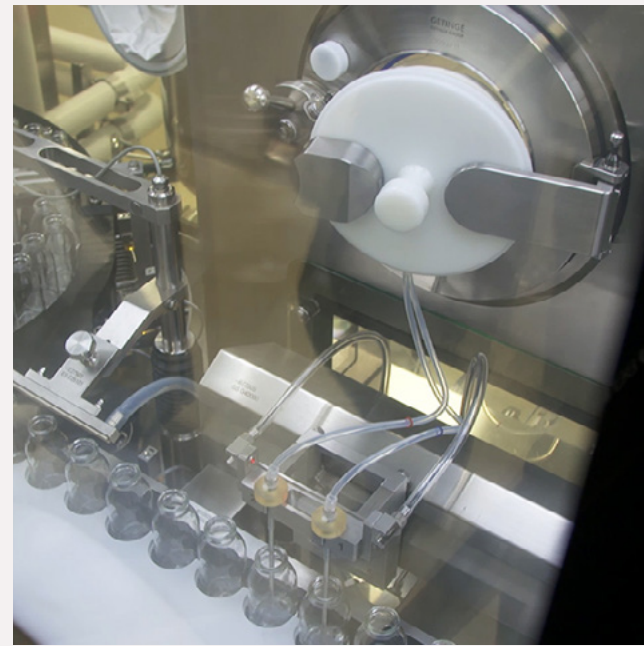
- + Flexibility to keep up with market demand
- + Increased production capacity
- + Assurance of production continuity for our customers

Because we own our cleanrooms and internal production, we can also ensure greater quality control and consistency, so no matter where our customers are, they always receive products of the highest quality.

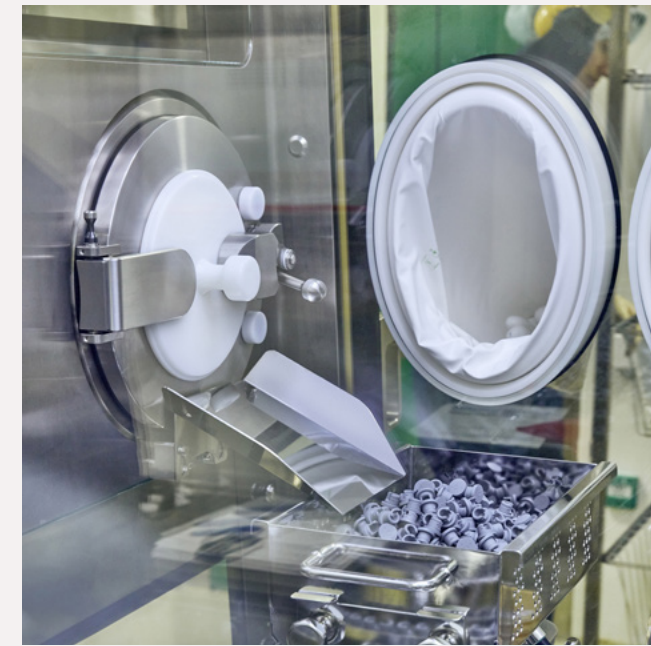


# The many applications of DPTE®

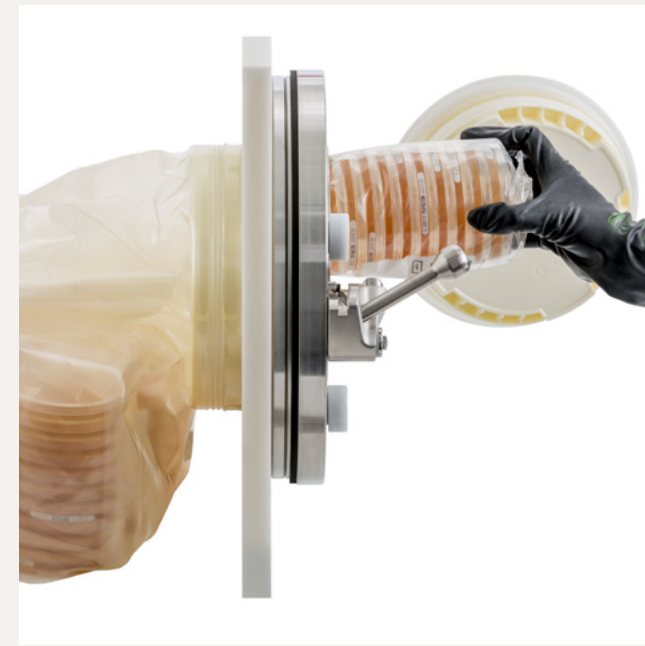
Validated to comply with international regulations, the DPTE® System is used in applications across aseptic and contained production



Liquid transfer



Component transfer



Environmental monitoring



Machine parts



Waste disposal



And many more...

# The first step towards a greener tomorrow in aseptic transfer

---

At Getinge, we are committed to helping you reach your sustainability goals.

As the first step in our carbon journey within the sterile transfer area, we are leading the way by replacing raw materials of the DPTE-BetaBag®. The change in polycarbonate raw material leads to a **13.3% reduction in CO<sub>2</sub> eq** over the life cycle of the product. The polycarbonate feedstock includes biogenic residuals that are considered life-cycle neutral. The difference between the product models is mainly due to the reduced use of fossil resources and the climate impact of incineration emissions.

An ambitious plan is in place to further reduce carbon emissions associated with our raw materials and production processes.



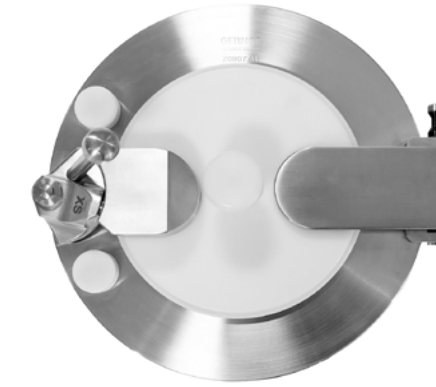
# DPTE® Alpha ports

The core of the DPTE® system is the Alpha port with its secure interlock enabling secure 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 numerous improvements. Due to technological progress along with evolving regulations and the demand for increased safety.



### DPTE®-XS

internally operated and manual RTP

– with an added degree of safety during connection and disconnection



### DPTE®-FLEX

externally operated and manual RTP

– with an external opening function to significantly reduce the risk of contamination



### DPTE®-EXO

externally operated and automated RTP

– with full connectivity and traceability



# DPTE®-XS

With more than 40,000 DPTE®-XS Alpha units installed worldwide, its reliability and safety have established it as the industry standard

## Leak-tight transfer

Once connected, the Alpha and Beta parts form a single unit. The DPTE® Alpha/Beta's safety interlocks and lip seals ensure reliable and leak-tight transfer. The assembly supports the safety of users and patients by minimizing the risk of contamination and ensuring the DPTE® system can be opened without breaking sterility or containment.

## Ultra-safe transfer

Simple and easy to use, the DPTE® system minimizes the risk of contamination. The DPTE® Alpha door cannot be opened when the DPTE® Beta part is not properly connected or if the double door is not closed. Additionally, the Alpha door cannot be opened if the Beta port is not equipped with the Beta part.

## Reliable and safe transfer

- + Comprehensive solution with Beta parts and accessories
- + Fully validated solution
- + Wide variety of applications



# DPTE®-FLEX

## Extra secure and flexible alpha port

The DPTE®-FLEX is a manual, extra-secure, and externally operable Alpha port developed to reduce human intervention in the barrier system, thereby minimizing the risk of contamination while enhancing ergonomics and productivity.

- + External gloveless transfer to reduce the risk of contamination
- + Easy to use and user-friendly
- + Totally mechanical, the DPTE®-FLEX is completely interlocked allowing for the safe connection/disconnection of the DPTE® Beta part
- + The external handles of the DPTE®-FLEX, which perform the double functions of unlocking/locking and opening/closing, are fully accessible from outside the enclosure
- + A configurable funnel to facilitate component transfer is available as an option. The funnel position is controlled using a handle accessible from outside the enclosure



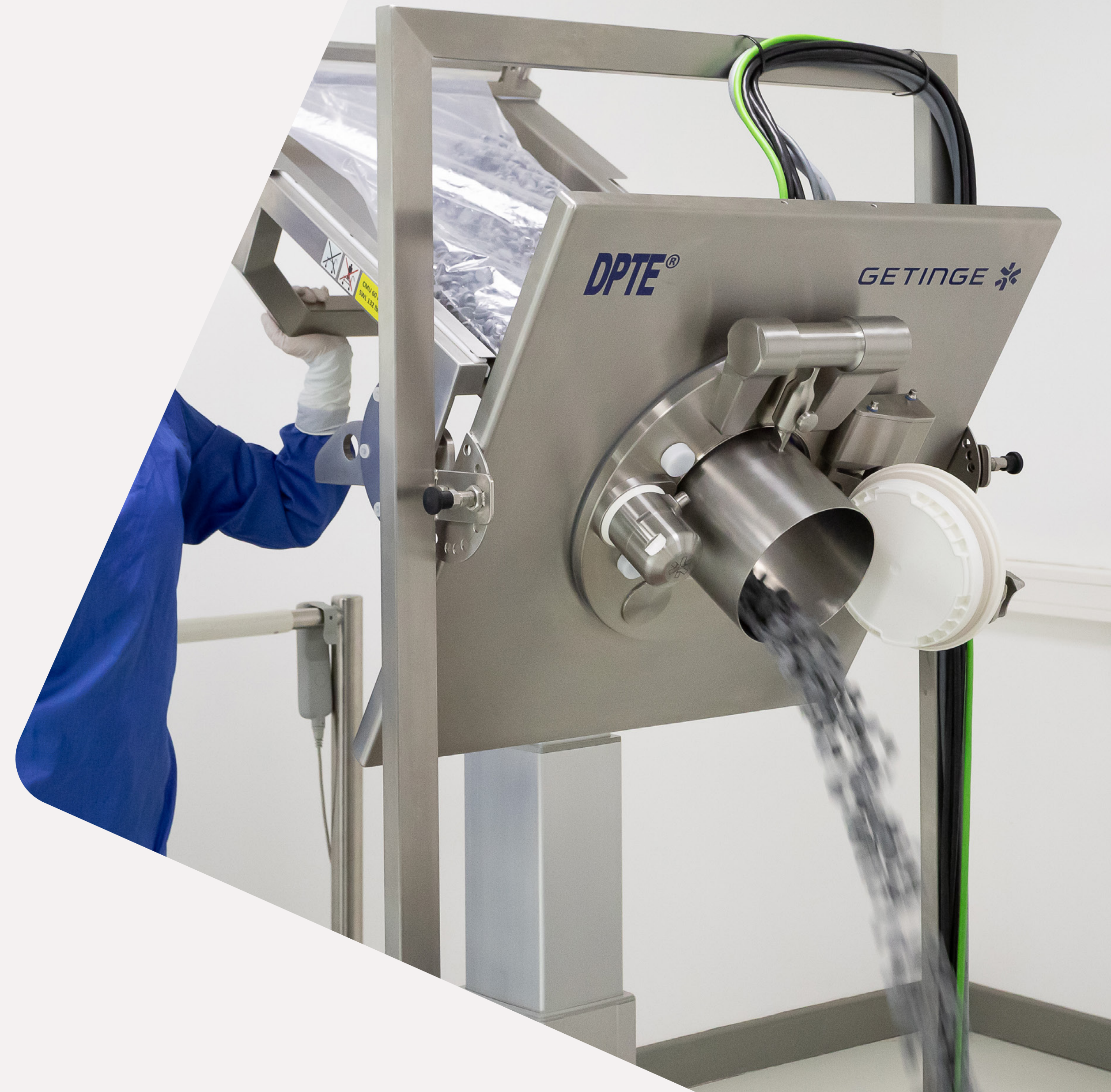
# DPTE®-EXO

Pharma 4.0 is revolutionizing production, with the industry shifting to integrated, automated, and gloveless systems

The DPTE®-EXO, an automated and externally operated rapid transfer port, ensures secure, reliable, and gloveless contamination-free transfers. Its design offers enhanced traceability and data analysis, providing full control over all movements.

Featuring configurable opening angles and funnel positions, the DPTE®-EXO allows for better control of the process environment. It tracks operational quality and monitors RTP status, operating hours, faults, and other events, offering a comprehensive view for auditing and preventive maintenance. The system also receives information from the filling line, such as emergency stops and safety light curtains, and connects seamlessly with the filling line's HMI.

- + Automated rapid transfer port with external opening
- + Improved operational efficiency
- + Greater degree of connectivity and transparency
- + Complete traceability and data analysis
- + New levels of flexibility
- + Easy to use and user-friendly



# DPTE-BetaBag®

## A flexible single-use option to increase productivity

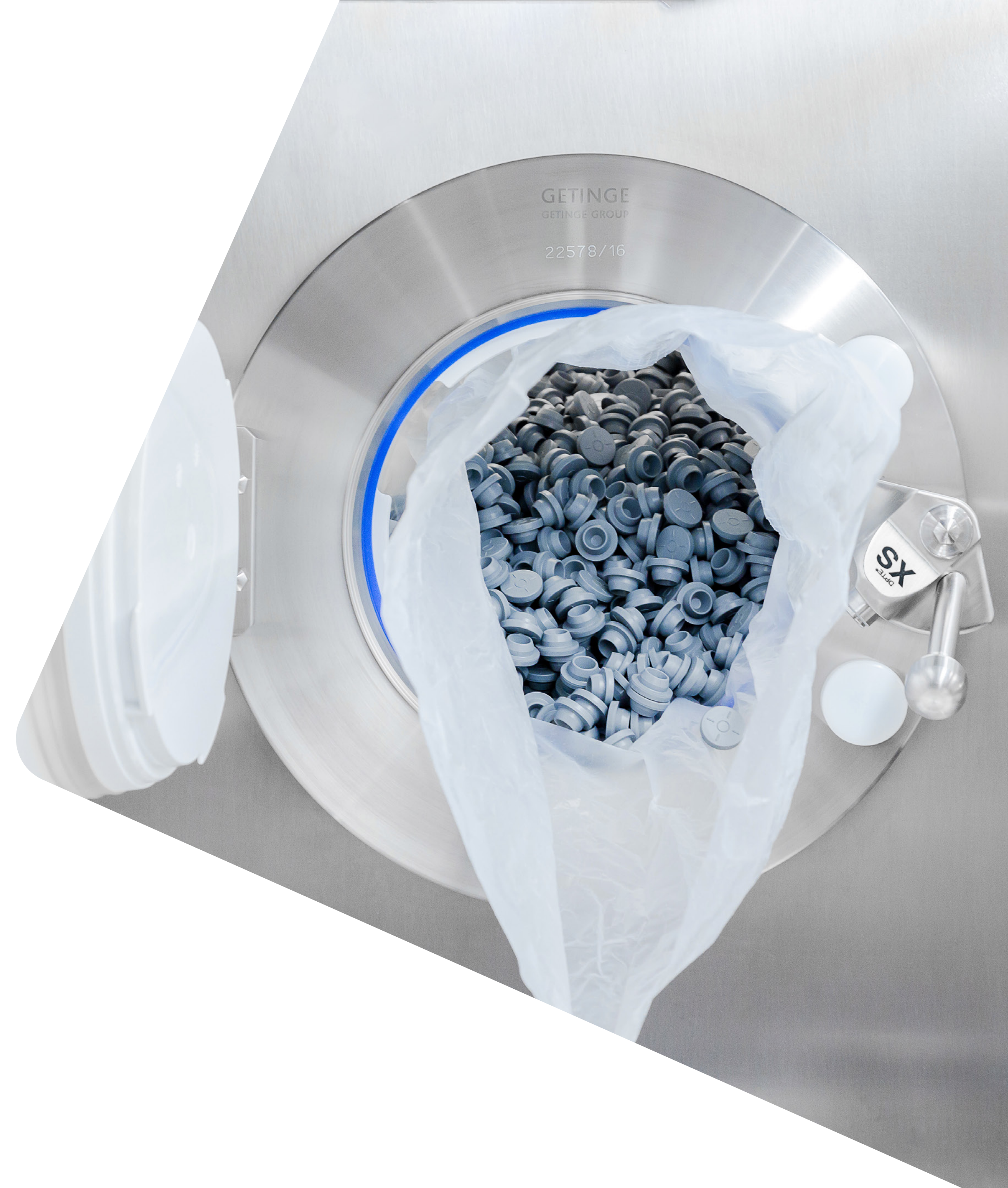
The DPTE-BetaBag® is a combination of a DPTE® Beta part and a bag for the safe transfer of sterile products or waste material. The DPTE-BetaBag® single-use range is designed for fast, contamination-free transfer to maintain high-speed production, increase flexibility and minimize validation costs.

### **Flexibility and long-term partnership are key**

Although the DPTE-BetaBag® is typically made of either multi-layer polyEthylene (PE), polyUrethane (PU) 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 manufacturing, sterilized inside the bag using the appropriate sterilization method (typically gamma, ethylene oxide or steam), and delivered ready to use to the pharmaceutical production site. Using quality control and modern tracing techniques, components are documented as sterile to provide a complete guarantee.



# DPTE® Beta containers

---

## The key to safe transfer

The 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 in stainless steel and polyethylene (PE) for bi-directional transfer.

- + Mechanical safety lock to prevent incorrect manipulation
- + Compatible with any DPTE® Alpha port of the same diameter
- + Bi-directional transfer system for the safe handling of sterile and toxic products
- + Re-usable, cleanable, cost-effective
- + Steam or gamma sterilization ready
- + H<sub>2</sub>O<sub>2</sub> 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.

# DPTE® Beta solutions

Single-use vs. reusable



## DPTE-BetaBag®

- + Fully validated and guaranteed transfer process
- + Minimizes transfers and handling
- + Significantly reduces the risk of biological and particulate contamination
- + Optimizes productivity
- + Save on validation and on-site cleaning times
- + Enables manufacturing flexibility



## DPTE® Beta Containers

- + High mechanical resistance
- + Transfer of heavy, complex parts
- + Product storage options
- + Transport products between sites
- + Options for occasional use and multiple loads
- + Sterilizable stainless steel version (by autoclave or hydrogen peroxide vapor)
- + Sterilizable PE version (by gamma)
- + Customizable solutions with inserts (stainless steel version)

# DPTE® Transfer Leak Testers

Stay compliant with DPTE® leak detection solutions

## Integrity testers for DPTE® Alpha and Beta containers

- + Safe production and process control with reliable, repeatable, and traceable leak detection systems
- + Simple and easy to install on both DPTE® Alpha and Beta containers
- + Wireless, paperless and pipeless
- + Full connectivity and traceability
- + Compliant with FDA 21 CFR part 11, EU Annex 11, and GAMP 5
- + Supports equipment integrity and preventive contamination control strategy

## Preventive maintenance

The DPTE® Transfer Leak Testers (TLT) support a preventive maintenance program. Check the leak tightness of your transfer system before and after production batches to ensure that your processes are compliant with international standards and regulations.



The DPTE® system

# DPTE® Transfer Trolley

The smart, mobile transfer platform for use with all DPTE® Beta solutions

Using the DPTE® Transfer Trolley safeguards optimum production efficiency and filling line uptime, guaranteeing the complete integrity of the product inside the DPTE® aseptic transfer system.

- + Easy to use
- + Enhanced ergonomics
- + Speed-up manual aseptic zone processes
- + Double the utility for multiple applications
- + Compact footprint

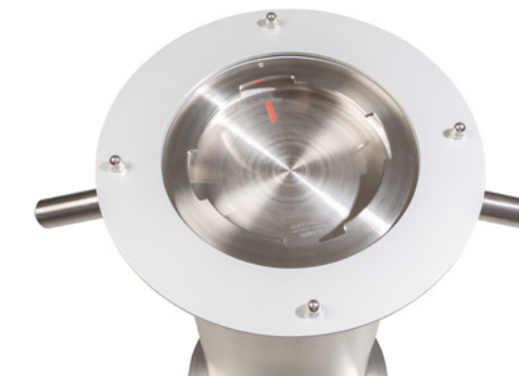




# DPTE® accessories

Do you have specific accessory needs?

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



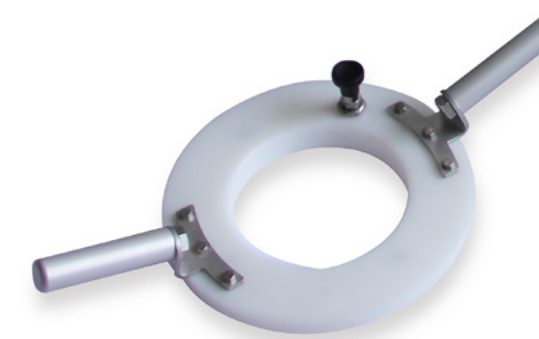
**Cover for autoclavable containers**  
Protects gasket during sterilization and manipulation



**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

# DPTE® Emergency Glove

On-demand interventions in your line for maintenance or emergencies

- + Connects to your line's DPTE® Alpha port for maintenance or emergencies
- + Enables quick intervention without halting production, saving time, minimizing downtime and reducing costs
- + Allows prompt issue resolution, preventing product contamination or quality deviations
- + Shows commitment to quality and safety, enabling swift emergency responses
- + Integrates seamlessly into existing production processes without requiring modifications
- + Maintenance-free, with no in-house testing or bio-decontamination needed, saving time and reducing chemical use
- + Delivered sterile, ready-to-use, and integrity-tested by our team



- + Proactive solution
- + Safeguard production integrity
- + Gain efficiency and flexibility
- + Maintain compliance
- + Cost savings

# DPTE®-Glove

---

## Safe, quick, reliable connections with the DPTE®-Glove System

The DPTE®-GLOVE system is based on a 240 Alpha Port and a glove. It is as easy and safe to use as the original DPTE® rapid transfer port system.

### **Reduce the risk of contamination**

Glove sleeves are weak points in barrier integrity, posing a contamination risk, and Annex 1 2022 recommends minimizing glove manipulations. The DPTE®-Glove System reduces the risk of contamination with quick, reliable, and safe on-demand glove connection/disconnection.

### **Gain time and save resources**

The DPTE®-Glove System is delivered sterile, ready-to-use, and integrity tested, so it is maintenance-free and requires no in-house testing or bio-decontamination. It enables on-demand intervention for maintenance and emergencies.

### **Reduce waste and overall cost**

Replacing fixed gloves with the DPTE®-Glove System reduces consumable consumption and waste. It also connects multiple times to different DPTE®-S 240 ports, reducing the volume that requires biodecontamination.

### **Save space and gain flexibility**

The DPTE®-Glove System eliminates the need for glove sleeve extenders, reducing the space occupied by gloves outside the line. With the system, you only need to connect gloves to your RABS or isolator when necessary.



# Technical data

## DPTE® Product Range

		105 mm	190 mm	270 mm	350 mm	460 mm	
<b>ALPHA</b>	DPTE®-XS Port	●	●	●	●	●	
	DPTE®-FLEX Port		●				
	DPTE®-EXO Port		●				
<b>BETA</b>	DPTE® Containers	Stainless Steel	●	●	●	●	●
		PolyEthylene	●	●	●	●	●
	DPTE-BetaBag®	Tyvek	●	●			
		PE/EVOH/PE	●	●			
		PolyUrethane	●	●	●		
	Sleeveless DPTE-BetaBag®	Tyvek		●			
		PE/EVOH/PE		●			

## DPTE® Beta Stainless Steel Containers: 4 Levels

Level	Ø	Length 300 mm	Length 400 mm	Length 500 mm	Length 600 mm	Length 700 mm
<b>1 Standard*</b>	190		●			
	270		●			
	350			●		
<b>2 Semi-standard</b>	190	●	●	●	●	●
	270	●	●	●	●	●
	350	●	●	●	●	●
<b>3 Configurable</b> using pre-designed parts	190	●	●	●	●	●
	270	●	●	●	●	●
	350	●	●	●	●	●
<b>4</b>	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
<b>Racks</b>	<b>Glide system</b>	●	●	●	●
	<b>Telescopic system</b>		●	●	●
	<b>Roller system</b>		●	●	●
	<b>Configurable rack</b>		●	●	●
	<b>Customized rack</b>		●	●	●

# Maintaining safe production

## Managing and protecting your investment

As a reliable partner, we are here by your side to help you 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 remain 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)





# GETINGE

PASSION FOR LIFE

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 12,000 people worldwide and the products are sold in more than 135 countries.

This information is intended for a professional audience. The information herein is for informational purposes only and should not be relied upon as a replacement of the Instructions for Use or service manual. Getinge shall bear no responsibility or liability for any action or omission by any party based upon this material, and reliance is solely at the user's risk.

Solutions or products mentioned may not be available or allowed in your country. Information may not be copied or used, in whole or in part, without written permission by Getinge.

© 2024 Getinge • Getinge and **GETINGE** \* are trademarks or registered trademarks of Getinge AB, its subsidiaries or affiliates • DMS-0007176 • All rights reserved.

Getinge Life Science France • 1 rue du Comté de Donegal • 41102 Vendôme cedex • France • Phone: +33 [0] 254 734 747 • E-mail: [info@getinge.com](mailto:info@getinge.com)