



## DPTE<sup>®</sup>-EXO with Sleeveless DPTE-BetaBag

Automated and externally operated alpha port  
for secure and optimized aseptic transfer





# Open the door to the future

## Supporting the pharma industry transition

Your organization is facing increased demands on throughput and automation while GMP requirements become stricter.

Pharma 4.0 is changing the way goods are produced, and the pharmaceutical industry is now increasingly shifting to integrated and automated production systems.

The industry evolves: the next generation of pharmaceutical manufacturing needs greater flexibility to switch production quickly from one drug to another, gloveless processes to reduce human intervention in the aseptic environment, and connected traceable solutions compliant with the latest regulations.

The total solution DPTE-EXO with sleeveless DPTE-BetaBag is an automated and externally operated rapid transfer port and provides a secure, reliable, and automated transfer solution. Its external opening function was designed to significantly reduce the risk of contamination while its connectivity offers a greater degree of traceability and data analysis.

Discover how the DPTE-EXO with sleeveless DPTE-BetaBag supports your efforts to build a safe, automated, and compliant filling line.



# Reducing the risk of contamination

## with automated aseptic transfer

### Automated processes improve operational efficiency

The alpha port with automated external opening combined with an optional funnel provides operational efficiency by reducing manual intervention.

DPTE-EXO has a number of smart controls governing its safe and efficient door opening and closing and funnel movements. It also features a specific program with an open door and funnel position suitable for the enclosure bio-decontamination cycle.

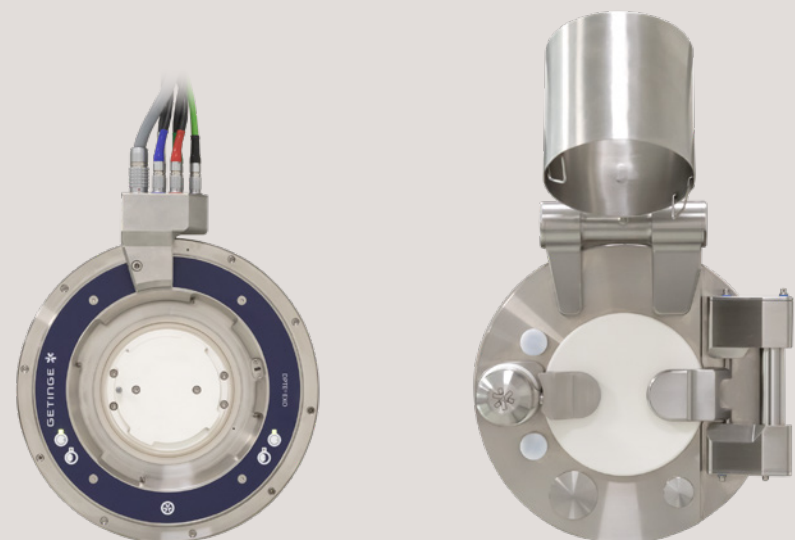
The motorized process automates the repetitive opening of alpha doors with precise angles unique to your aseptic zone environment. The repeatable movements offer better control of the line and process environment. Easy to use, it requires minimal training for your operator to take advantage of its full potential.

### Be certain with full data traceability

Take the guesswork out of monitoring and preventive maintenance by improving connectivity and transparency. Depending on your need, DPTE-EXO is fully integrated, mechanically and electrically, with or without data communication with the filling line's HMI.

Using the line's HMI or the optional portable maintenance display, DPTE-EXO can track operational quality and monitor RTP's status, operating hours, faults, and other events to provide a comprehensive view of operations for auditing and preventive maintenance.

Speed-up your decision-making and gain full access to the system with full traceability and data analysis.



DPTE®-EXO WITH SLEEVELESS DPTE-BETABAG

### Improved responsiveness for increased safety

DPTE-EXO was designed for product, process, and operator safety. Both digital and mechanical precautions are in place to prevent unauthorized or accidental access, and process contamination is avoided in the event of improper connections, power failures, or safety issues.

With the DPTE-EXO, Getinge is taking the safety of the DPTE System to the next level with a new patented safety feature. Each of the 4 lugs of the Beta flange will be individually detected during the connection to avoid any improper connections and further improve sterile transfer security.

All the movements performed by the DPTE-EXO and its optional funnel are fully controlled. The DPTE-EXO is configured to receive information from the filling line such as an emergency stop and/or safety light curtains. The automated process is interrupted when meeting an obstacle ensuring both process and operator safety. In addition, the alpha port can be switched from automatic to manual mode using the optional portable maintenance display for corrective or preventive maintenance or in case of an emergency.



DPTE®-EXO WITH SLEEVELESS DPTE-BETABAG

# Traceable and validated solution for safe and compliant production

## Extensive validation to ensure compliance

With DPTE-EXO you can remain compliant with evolving regulatory requirements. We perform a thorough validation process – including leak testing, endurance testing, shipping testing, particle generation, and H<sub>2</sub>O<sub>2</sub> resistance testing – to ensure that your filling line meets all relevant criteria.

The alpha port is designed to be integrated into an architecture in accordance with FDA 21 CFR part 11 – “Electronic Records, Electronic Signatures – Scope and Application” and Annex 11 – EU Guidelines to Good Manufacturing Practices for Medicinal Products for Human and Veterinary Use “Computerized Systems”. DPTE-EXO is GAMP 5 compliant, ensuring that your automated processes run smoothly and securely.

## Creating new levels of flexibility

With different port configurations, optional funnels, and an adaptable door opening speed and angle, the total solution gives you the flexibility to optimize your production according to your specific needs.

- Door opening to the right or the left
- Funnel located on top or at the bottom of the port
- Different recipes can be managed using the portable maintenance display enabling specific speed and position control for each actuator (funnel, door, lock)

## Full documentation package

- Functional specifications
- Assembly Drawing
- Electrical file (electrical diagram, parameters file)
- Manuals (technical, installation, user), spare parts list
- Vendor data sheets for electrical components
- Control system specifications
- Material certificates
- Other standard and optional documentation



## Key takeaways

- Automated aseptic process
- Improved operational efficiency
- Efficient bio-decontamination
- Full filling line integration including optional data communication
- Greater degree of connectivity and transparency
- Easy to use
- Validated and compliant
- Higher levels of flexibility
- Complete traceability and data analysis
- Ensuring product, process, and operator safety
- Enhanced security and quick process recovery



# Interlocking elements ensure secure connection

– Preserve sterility and containment

To support the need for gloveless processes, Getinge has developed a sleeveless DPTE-BetaBag. The sleeve has been removed and replaced by the funnel reducing human intervention in the aseptic environment.

The DPTE-EXO with sleeveless DPTE-BetaBag is a fully validated and interlocked system. Together with the dismantlable funnel, it offers a total transfer solution from the outside of the aseptic filling area to the processing area.



## Sleeveless DPTE-BetaBag

Beta and alpha ports join to form a single validated unit when connected by rotation. The FDA compliant silicone lip seals form a secure connection, allowing the door to be safely opened without breaking sterility or containment. The manually connected sleeveless DPTE-BetaBag comes in RTS (Ready to Sterilize) or RTU (Ready to Use) depending on the bag material for minimum human intervention, increased efficiency, simplified component transfer, and reduced risk of contamination.



Available in:

- + Tyvek or PE-EVOH-PE
- + Diam. 190

## Optional dismantlable funnels

The DPTE-EXO is the first and only RTP (Rapid Transfer Port) with a fully integrated funnel. To meet specific needs we offer a high and a low-profile funnel. The funnel protects the alpha/beta seals and its patented FAST system (Funnel Add-on for Smooth Transfer) allows efficient component transfer to the process area (feeder / bowl). It can be positioned above or below the DPTE door. The dismantlable funnel can be easily, safely, and quickly released with one hand, and the assembly is fully autoclavable.



# A complete solution for sterile transfer

## – Compatible accessories

Dedicated accessories streamline processes while improving operator safety and ergonomics.

### DPTE Transfer Leak Tester (TLT)

Patient safety is ensured with an unbroken chain of sterility throughout the process. Quality of production batches must be secured during every step. Transfer integrity in rapid transfer ports is essential not only to keep track of the system's lifecycle and its components but also to account for normal wear and tear.

The wireless and operator-friendly DPTE Transfer Leak Tester (TLT) allows you to check the integrity of the DPTE systems before starting the manufacturing batch to ensure safe production and process control.



### DPTE Transfer Trolley

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.

Its ergonomic, power-assisted design enables easy handling of heavy and fragile loads within confined spaces, while its smart functions help speed-up manual aseptic zone processes. Its ease of maneuverability reduces aseptic zone disruption and increases production uptime. Operators gain full command of fine-tuned positioning to achieve the elevations and tilts they need, and can store precise alignments to its onboard memory.



### Additional accessories:

- + Handles for 190 PE DPTE-BetaBag
- + Dummy container



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.

**Getinge AB** · Lindholmspiren 7 · P.O. Box 8861 · SE-417 56 · Göteborg · Sweden

[www.getinge.com](http://www.getinge.com)