WHITE PAPER

Increasing Security in Aseptic Transfer

Considerations for Mixing Rapid Transfer Ports Across Manufacturers

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Increasing Security in Aseptic Transfer

Abstract

In pharmaceutical and biopharmaceutical environments, the secure transfer of materials between controlled areas is a critical component of contamination control. The DPTE® transfer system, pioneered by Getinge, was designed to maintain leak tightness and microbial integrity through the combination of its Alpha and Beta ports. However, the growing availability of standalone transfer ports from different suppliers, along with claims of cross-compatibility has led some users to mix components.

This white paper examines the risks associated with combining Alpha and Beta ports from different manufacturers, including compromised leak tightness, poor ergonomics, inconsistent performance, and regulatory challenges. It reinforces the importance of using fully qualified, single-source systems for sterile transfer operations and outlines the robust testing behind the DPTE® system's global standard of performance.

Introduction

First developed in the 1960s for the secure handling of hazardous nuclear materials, the DPTE® (Double Porte de Transfert Etanche) Double Door Transfer System was created to provide a leak-tight method for transferring contaminated materials. As containment demands evolved through the 1970s, the DPTE® system was adapted for the pharmaceutical industry to support sterile and high-potency applications that required safe, repeatable material transfers.

Today, with over 40,000 systems installed worldwide, the DPTE® system is recognized as the global benchmark for secure and sterile transfer technology. Its unique design enables connection between two controlled environments (sterile and/or toxic) without introducing risk of contamination to the surrounding environment or operator exposure. The foundation of this performance lies in the exclusive pairing of the DPTE® Alpha and Beta ports, which are mechanically and microbiologically qualified as a complete system.

While advances in manufacturing have introduced a growing number of transfer port options, including standalone alpha and beta components from a variety of manufacturers, the assumption that these parts are interchangeable, or compatible with ports from other manufacturers, presents serious risks. This white paper examines the design intent, qualification principles, and performance results that demonstrate why mixing alpha and beta components from different sources can jeopardize leak tightness, microbiological control, and regulatory compliance and risk management.

The DPTE® Alpha and Beta ports: Designed as One

From its inception, the DPTE® system has been based on a closed, integrated design. The Alpha port is never intended to be used independently; its leak-tight performance depends entirely on its precise mechanical and dimensional integration with the Beta component.

Getinge has adopted a qualification strategy aligned with Annex 15 of Good Manufacturing Practices (GMP), which states: "It is a GMP requirement that manufacturers control the critical aspects of their particular operations through qualification and validation."[1] This strategy revolves around four key pillars:

- Leak tightness
- Docking operations
- Robustness
- Dimensional Control

Each pillar reinforces the importance of qualifying the full transfer system, not just individual components, to ensure reliable, repeatable performance throughout the system lifecycle.

Leak Tightness: The Cornerstone of Containment

Leak tightness is the defining performance characteristic of the DPTE® system. Qualification tests simulate real-world conditions to validate the seal integrity between Alpha and Beta components. These tests ensure that contamination risk is minimized not just during initial installation, but across repeated use cycles.

However, significant uncertainties are introduced when transfer systems are compiled using components from different suppliers. Systems built using mixed-brand components almost inevitably have unpredictable dimensional mismatches that can lead to minute leaks, which compromise the process and impact reproducibility. Performance cannot be guaranteed when unvalidated combinations are introduced. The DPTE® system avoids this risk by qualifying the entire system as a unit.

Docking Operations: Ensuring Consistency and Ergonomics

Docking and undocking the Alpha and Beta must be easy for operators and consistent across system lifespans. Qualification includes torque testing to evaluate the force required to dock and undock the DPTE® Beta from the DPTE® Alpha, ensuring ergonomic usability and connection reliability.

When ports from different suppliers are combined, operators may encounter strong resistance during rotation, misalignment, or even separation of components. These problems compromise not only usability but also safety and containment.

Robustness: Time Tested Validation

As part of the qualification program, the robustness of the DPTE® system is evaluated throughout the product's life cycle. This process, among which shelf-life testing for Beta parts, involves periodic performance assessments at defined intervals. At each stage, key tests, such as leak tightness and docking operations, are repeated to ensure continued compliance with specifications.

For the DPTE® Alpha, robustness is further validated through endurance testing, which examines tightness, safety features, and the physical integrity of components. This involves subjecting the system to repeated operations on a dedicated test bench to verify that critical aspects are maintained over time. These tests are conducted using both Alpha and Beta ports to simulate real-world usage conditions.

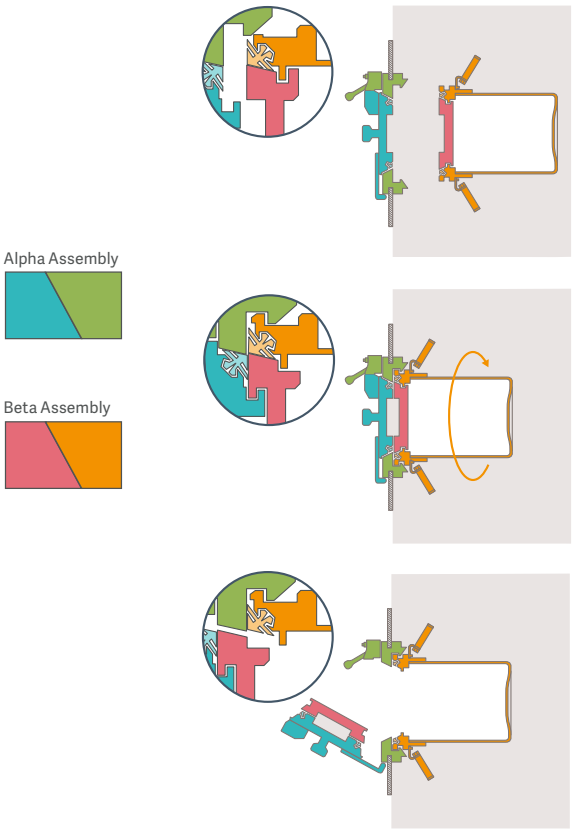
This full-system approach is essential; if only individual parts are tested, there is no assurance the combination will hold up under actual production demands.

The Ring of Concern: Understanding Dimensional Control

A visible annular surface known as the "ring of concern" can appear when transfer ports are docked. If not properly managed, this surface can become a point of contamination.

Getinge mitigates this risk through precise control of dimensional tolerances in both Alpha and Beta parts, ensuring a clean interface and reliable aseptic performance.

Such assurance cannot be achieved when components are sourced from multiple vendors.



Microbial and Particulate Qualification

Maintaining sterility during transfer is only possible when the mechanical seal is perfectly aligned and qualified. Microbiological studies, such as those conducted by the French National Institute for Agricultural Research (INRA), have confirmed that the DPTE® system maintains microbial integrity even in high-challenge environments.[2]

While leak tightness and microbiological contamination prevention are crucial, the system performance against particulate contamination is equally critical. Particulate containment performance of the DPTE® system has been similarly proven in rigorous tests at the French Nuclear Safety Institute (IPSN).

Instead of microorganisms, the test used a Uranine solution, which generates particulates with a diameter of 0.15 µm. The rigorous test conditions mirrored those of the microbiological studies.

The results were conclusive: the efficiency ratio, comparing Uranine contamination levels between two enclosures separated by the DPTE® system, was calculated at 6.10^6. This performance exceeds the 99.999% efficiency of a HEPA filter for 0.3 µm particles, clearly demonstrating the DPTE® system's exceptional ability to isolate particulate contamination.

These results reflect the complete system's effectiveness, not that of isolated components.

The tests were carried out in the same enclosures used for microbiological validation, ensuring consistency in methodology and conditions.

Compatibility Claims: Risk Without Guarantee

Some suppliers offer parts that they claim are compatible with other manufacturers' alpha or beta ports. This perceived flexibility is misleading. As demonstrated throughout this paper, all performance testing, validation data, and regulatory compliance documentation for the DPTE® system are based on full-system testing. Mixing components from different origins introduces uncertainty into the process.

Risks when systems are built from non-validated combinations include, failures in leak tightness, poor fit, premature wear, and operator injury. The consequences of these failures, from batch contamination to patient harm, can be catastrophic.

Furthermore, in the event of a deviation or product recall, identifying the root cause becomes far more complex when the system contains components that were never designed or tested to work together.

The Importance of a Single-Source System

By choosing a validated, single-source transfer system, manufacturers ensure compatibility, reduce risk, and simplify qualification. Getinge offers a complete portfolio of DPTE® Beta solutions to match a wide range of applications, all designed and qualified to perform with DPTE® Alpha ports.

Single-source systems:

- Guarantee mechanical and microbiological compatibility
- Prevent contamination and system failure
- Provide robust validation data and reduce end-user qualification burden
- Improve ergonomics and operator safety
- Protect patient safety and regulatory compliance

When looking for a system, a top consideration should be finding an experienced manufacturer who not only designs high-quality transfer systems, but also offers full system validation that guarantees performance. Another consideration is to find a system that offers a wide range of beta options to fit a variety of application needs.

As a proven and validated method of aseptic transfer, the Getinge DPTE® system offers numerous benefits over other transfer devices, including: reduced manual interventions, decreased possible sources of contamination, and better protection of the operator and the product from hazardous materials. There are no third-party transfer solutions that are guaranteed to be compatible with the Getinge rapid transfer port system.

DPTE® Alpha port standard diameters:
105, 190, 270, 350, 460

Conclusion

Leak-tight performance, sterility assurance, and operator safety all rely on the complete compatibility of transfer port systems. As shown throughout this paper, mixing Alpha and Beta components from different suppliers can compromise system integrity and undermine both microbiological control and regulatory compliance.

The DPTE® system from Getinge is backed by decades of qualification data, precise engineering tolerances, and proven performance in the most demanding aseptic and containment applications.

By choosing a single-source, fully qualified transfer system, pharmaceutical manufacturers can reduce contamination risk, safeguard operator safety, and maintain the regulatory confidence essential to pharmaceutical and biopharmaceutical manufacturing processes.

Leading the Industry

Getinge has led the industry in rapid transfer port systems for more than 60 years.

Our isolator technology and patented DPTE® rapid transfer port systems are trusted worldwide to protect products, operators, and the surrounding environment while enabling compliance with the most stringent regulatory standards. From design to qualification, every Getinge solution is engineered to perform as part of a validated, single-source system, delivering the certainty your critical processes demand.

Discover how Getinge can support contamination prevention and upstream bioprocessing for your specific application.

Pharmaceutical Production Solutions

Through large-scale cultivation, cGMP cleaning and sterilization, isolation technology, and aseptic transfer, Getinge's goal is to ensure contamination-free and scalable processes while fulfilling the strictest compliance requirements.

Learn more: getinge.com/int/products-and-solutions/pharmaceutical-production/

References:

1. European Commission Directorate-General For Health And Food Safety. "EU Guidelines for Good Manufacturing Practice for Medicinal Products for Human and Veterinary Use Annex 15: Qualification and Validation." (2) European Commission, March 30, 2015. https://health.ec.europa.eu/system/files/2016-11/2015-10_annex15_0.pdf.

2. A 2012 independent study by the French National Institute for Agricultural Research (INRA) of the Getinge-La Calhène DPTE transfer system proved continued containment during transfers despite a hostile environment with numerous constraints. Anneke Evers, Nolwenn Brunet, and Cyril Mounier. "DPTE® SYSTEM The transfer system that guarantees safety." May 2012.

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DMS-0013360 Considerations for Mixing Alpha and Beta Ports Across Manufacturers