



# **Ultraclean sterile transfer solutions**

FOR THE GLOBAL BIOPHARMACEUTICAL INDUSTRY



# Your partner for ultraclean sterile transfer solutions in the global pharmaceutical industry

## Co-development with pharma to better address unmet needs

ABC Transfer has been created by aseptic industry experts in co-development with pharma and isolator companies. This collaboration began with conducting a feasibility study which revealed more than 70 opportunities for improvement in Rapid Transfer Systems: GMP compliance, ease of cleaning, sterility assurance and ultra-cleanliness, lifecycle cost, maintenance, ergonomics, productivity, health and safety in production and social and environmental impacts, amongst others.



### Thierry Girard

Thierry has 30 years' experience as an executive in mid-size industrial companies, including the pharmaceutical and medical device sectors, and managing complex international B2B relationships.

Both Thierry and Jean-Luc have worked for the market leader of transfer technology in Vendôme (France). Thierry as President and Sales Manager for over 5 years and Jean-Luc as R&D Manager.

They have strong knowledges and background in the pharmaceutical industry and have complementary competencies (expertise) allowing them to structure the business development in the best conditions. Our new products are designed from scratch with the reference market but are compatible to the different RTP in the sector.



### Jean-Luc Schneider

Jean-Luc has 25 years' experience as Product Manager, Design Office Manager and Industrial organization Manager.

“

We have developed a range of high-quality Rapid Transfer Systems (RTS) solutions in cooperation with pharma companies. Patient safety, increased regulation, vital requirements for manufacturing new generation pharmaceutical drugs (cell therapy, nanopowders, new anticancer, etc.), automatization, plus other trends are among the many challenges the pharmaceutical industry has to address.

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Thierry Girard & Jean-Luc Schneider

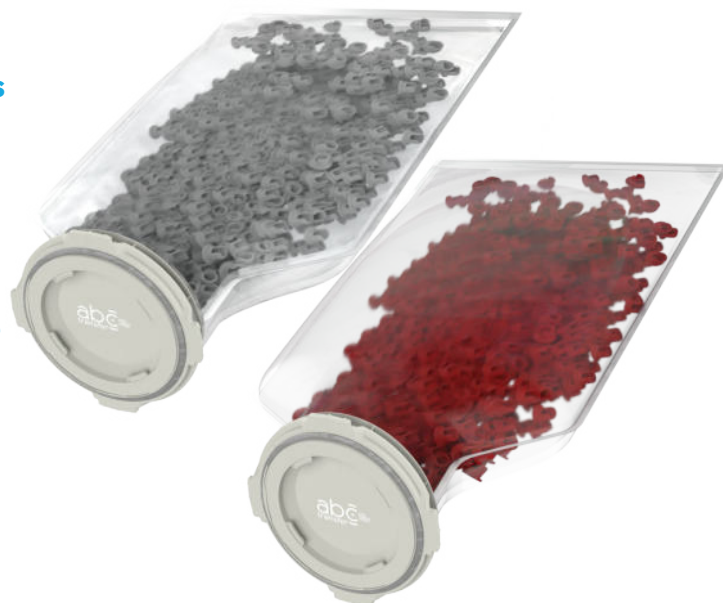


# ABC Transfer® Betacleanbag™

A REVOLUTION IN THE DESIGN OF SINGLE-USE PORTED BAGS

**Our range of next generation single-use ported bags brings significant improvements to sterility assurance and operator ergonomics.**

**Designed specifically for parenteral product applications, our single-use Betacleanbag™ can be used for many more. Their design is future-proof and can accommodate any type of film material. They can be gamma, steam, and ETO sterilized.**



## Gloveless Transfers Enabled

**The ABC Transfer® system complies with new Annex 1 of the European GMP. This new regulation imposes extra level of precautions in the management of sterile production. It has major consequences in the design of Isolators and RABS, in particular the elimination of glove ports when possible.**

- A complete line optimized for Gloveless transfer**

The revolutionary ABC Transfer® Alpha Port has been designed to eliminate manual operations inside the isolator.

ABC Transfer® Betacleanbag™ and handling trolleys have been specially designed to take advantage of those features.

The ABC Transfer® connector has been specially designed for gloveless transfers.

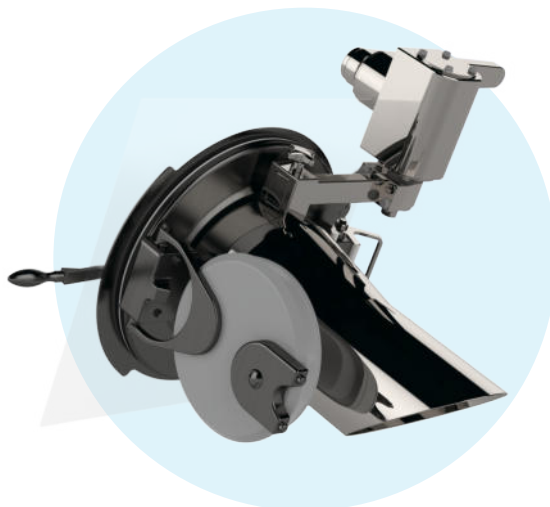
It has been shaped to eliminate sharp edges and facilitate the flow of components. The beta door does not rotate when opening, which reduces the production of particles.

The connector is made of PPO, high performance polymer. It contains no traces of endocrine disruptors and can be in direct contact with your components.



○ The ABC Ultra™: UltraSterile, UltraModern, UltraGloveless

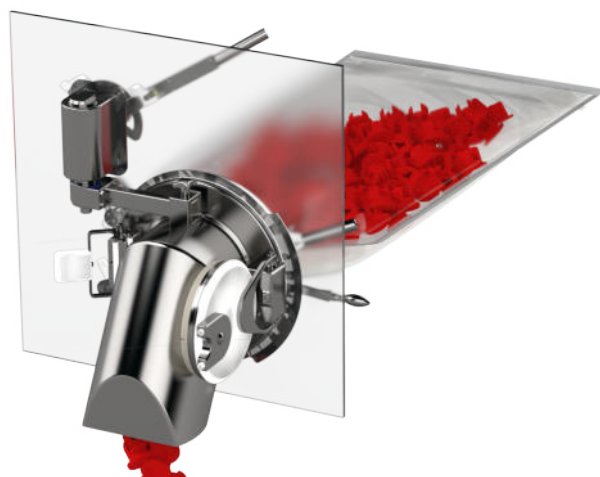
A simple, and manually operated stainless steel channel covers the ring of concern and guides the components to the hopper. The channel is operated from outside of the isolator and can be motorized. There is no need for power supply or complex software to validate.



ABC Ultra™- Vertical isolator wall



Gloveless Alpha Port closed

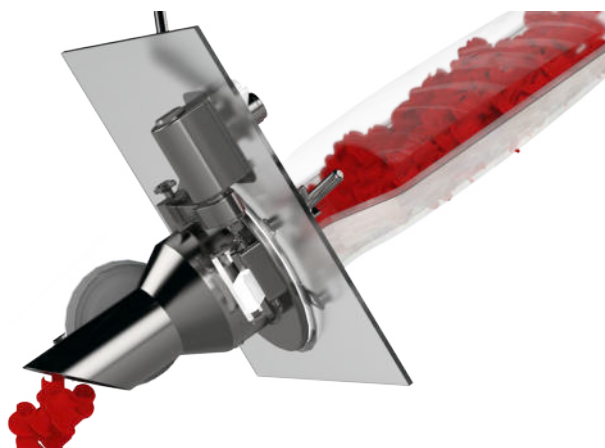


Gloveless Alpha Port opened

ABC Ultra™- 45° isolator wall



Gloveless Alpha Port closed



Gloveless Alpha Port opened

## Improved Patient Safety

The Betacleanbags™ from ABC Transfer have been designed to provide the highest level of patient safety from their production to their utilization. The risk of accidental contamination has been greatly reduced during storage, transportation or utilization.

### ● Easyglide™ inside

The ABC Transfer® single-use Betacleanbag™ integrate the Easyglide™ revolutionary seal.

The leak rate of the connector has been reduced to  $5 \times 10^{-4} \text{ Pam}^{-3}/\text{s}$  at 2500 Pa. That is the equivalent to a leak produced by a 7  $\mu\text{m}$  pinhole and is 10 times better than existing systems.

The ring of concern has been virtually eliminated with a surface of 119mm<sup>2</sup> on a 190 diameter port, which is 4 times less than on conventional products.

As for all the ABC Transfer® products, the Easyglide™ seal is firmly gripped in position and cannot move during the Alpha-Beta connection. The risk of accidental leak is eliminated.



### ● No welding

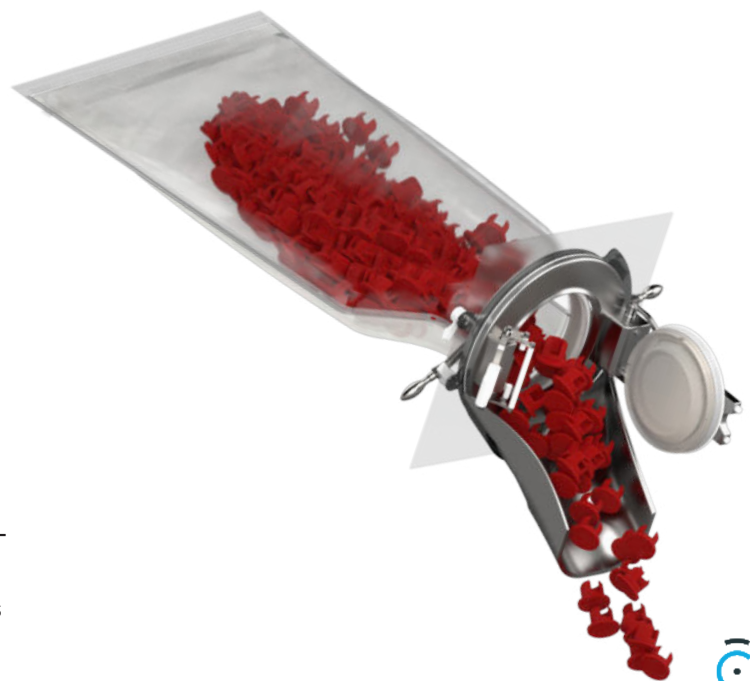
The ABC Transfer® Betacleanbag™ uses a very innovative assembly method, which does not require any welding of the film on the connector. This significantly decreases the stress to which the film is subjected. It thus reduces the risk of creating micro-leaks and increases the mechanical resistance of assembly.

### ● Standardized position of the connector

The ABC Transfer® Betacleanbag™ assembly method makes it possible to standardize the position of the connector at the end of the bag, regardless of the film material. This enables you to standardize the transfer process in your factory.

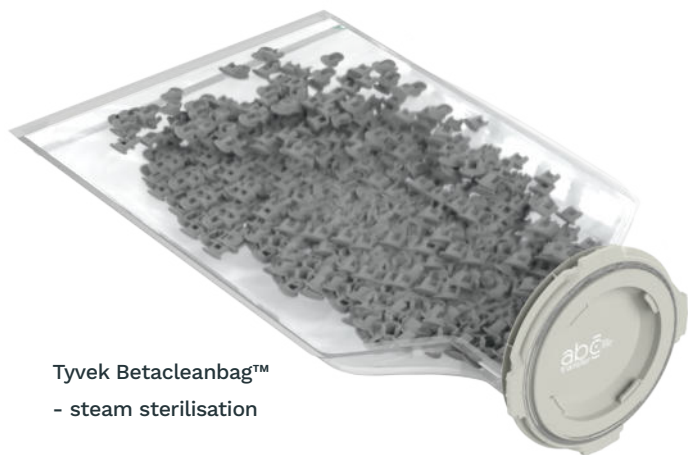
### ● Reduced risks of film puncture thanks to better ergonomics.

Thank to a much more ergonomic component transfer process, the risk of film puncture is reduced, especially on steam sterilized Betacleanbag™. A special purpose built tool and transfer trolley have been designed to help your operators throughout the transfer process.



○ **Guaranteed Alpha-Beta leaktightness**

The connector is made of medical grade PPO. This plastic material ensures very good dimensional tolerances as well as long term mechanical stability, regardless of the storage conditions. The Alpha-Beta connection remains leaktight longer. The risk of accidental contamination is reduced.



Tyvek Betacleanbag™  
- steam sterilisation



○ **Standardized connector position**

Regardless of the sterilization method, the connector always sits at the end of the bag. Transfer of components is therefore simplified and possible with the ABC Transfer® Gloveless Alpha Port, in a single or double wall configuration.

## Ultra Clean by Design

**The ABC Transfer® system and supply chain have been designed to avoid the contamination of your components by the packaging and during transfer operations. Stoppers are kept clean from production to injection.**

○ **Optimized manufacturing**

The connector is constructed with no sharp edges, which can shock the components and generate micro-particles.

The door opening motion has been optimized to remove the rotation found on conventional systems. Particles production during connection is thus reduced to a minimum.

The bags original cleanliness is protected by the absence of mechanical interference with the inner layer during the assembly process. Final assembly of the ABC Transfer® Betacleanbag™ is performed under ultraclean conditions.

○ **Minimum risk-taking**

The entire supply chain has been designed to minimize particulate and Biodurden contamination during production and transportation. When possible, production processes have been automated to reduce human contact. At all production steps, gowning has been studied to keep the risks of contamination to a minimum.

Strict quality control and batch release procedures, aligned with cGMP, ensure performance and consistency.



## Fully Compliant

The ABC Transfer® range of Betacleanbag™ complies with all the current and planned international regulations.



### Material compliance

All plastic materials comply with FDA 21 CFR and USP class 6 regulations.

We have chosen plastic resins which do not utilize endocrine disruptors during their production process, ahead of a likely evolution of the REACH regulation. Our Betacleanbag™ are bisphenol and phthalate-free.



Extractable studies carried out by ABC Transfer provide you with extra chemical contamination safety.



### Environmental responsibility

We endeavour to reduce our products' impact on the environment and contribute to the objective of carbon neutrality.

ABC Transfer® Betacleanbag™ utilizes 50% less plastic than conventional solutions.

Furthermore, the modular construction of the products, combined with the absence of welding enable the recyclability of all their components.

Because we believe that more can be done, we compensate 100% of our CO2 production. One tree is planted in a french forest everytime 10 ABC Transfer® Betacleanbag™ are produced.



## Easy to use Handling Trolley

### Manufactured to the highest standard and simple to operate

This product is the result of years of drug manufacturing experience in cramped and heavy-duty cleanroom environments.

### Compliant with gloveless transfers

The ABC Transfer® trolley has been designed to be operated with the ABC Transfer® Gloveless Alpha Port and sleeveless ABC Transfer® Betacleanbag™.



# The ABC Transfer brand

## 70 identified opportunities for improvement

- GMP compliance, patient safety
- GMP compliance, Ultra-cleanliness
- Ergonomy, Operations
- Ergonomy, Maintenance
- Industry responsibility, continuity of supply
- Environmental Responsibility, raw materials consumption
- Social Responsibility, endocrine disruptors

## A brand for sterile processes

- GMP & USP Class 6 compliance
- Ultracleanliness & Performance
- Ergonomy and risk reduction
- Future proof design
- Environmental and Social responsibility

## Environnemental & Social responsibility

### From design to recycling, we prioritize lowering the environmental impact of our products:

- No Bisphenols and no Phtalates in our single-use ported bags
- 50% fewer plastics
- 30% less stainless steel
- All our products are 100% recyclable

## Fighting global warming by offsetting our carbon footprint

More can be done to reduce our impact on the environment. ABC Transfer has subscribed to an environmental program, Reforest'Action, to compensate for our residual carbon emissions. That program is executed in France and its timely implementation is permanently controlled.







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