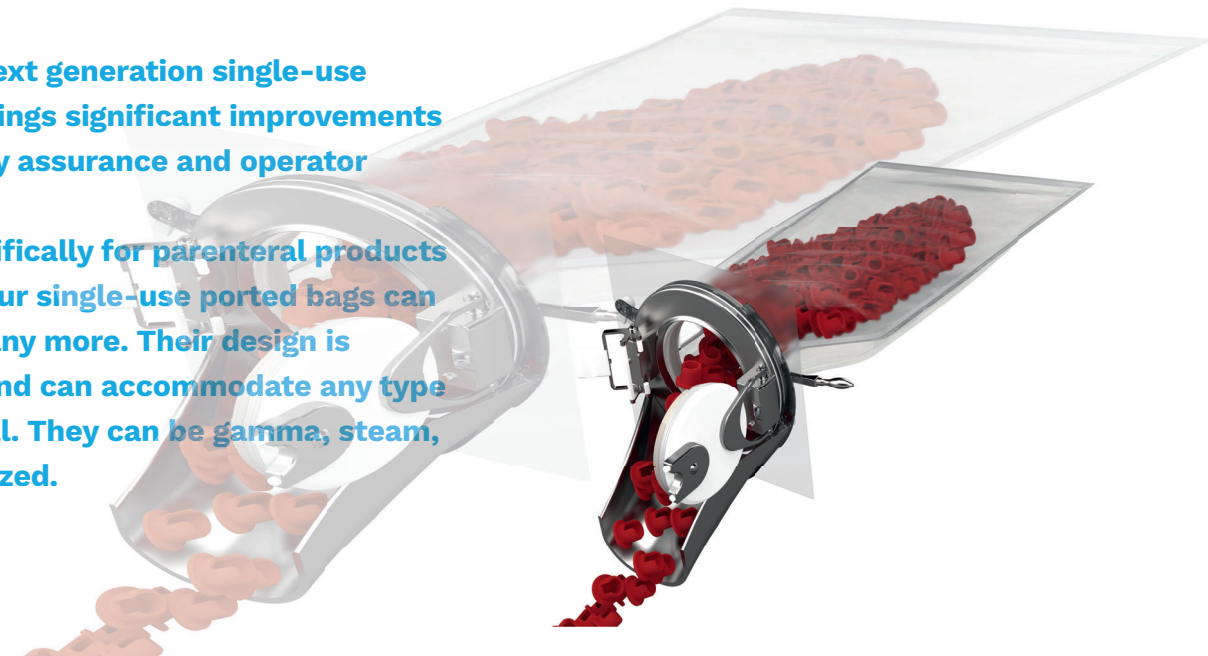


# ABC Transfer® single-use ported bags

A REVOLUTION IN THE DESIGN OF PORTED BAGS

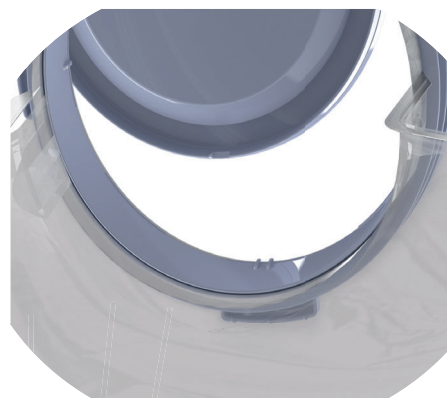
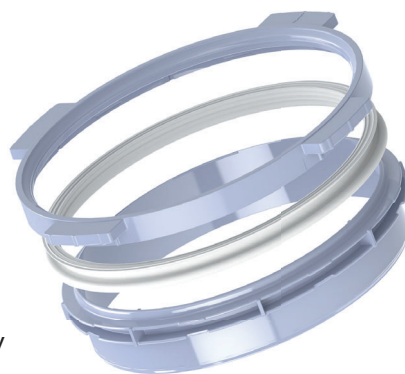
**Our range of next generation single-use ported bags brings significant improvements to your sterility assurance and operator ergonomics.**

**Designed specifically for parenteral products applications, our single-use ported bags 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.**



## Ultra clean by design

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



## Improved patient safety

- The ABC Transfer® single use ported bags integrate the Easyglide™ revolutionary seal.  
The leak rate has been reduced to  $5 \times 10^{-5} \text{Pam}^3\text{s}^{-1}$  at 2500 Pa. That is the equivalent to a leak produced by a 3  $\mu\text{m}$  pin hole and is 10 times better than existing systems.

- The ring of concern has been virtually eliminated with a surface of  $119\text{mm}^2$  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.



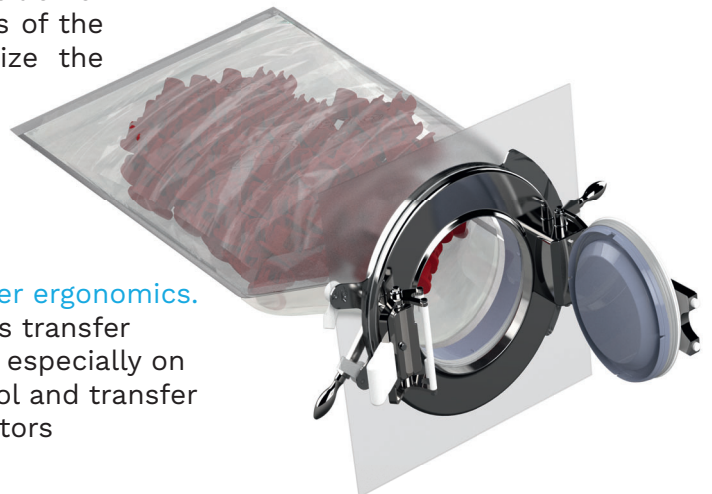
- No welding of the film on the connector  
The ABC Transfer® single-use ported bags use a very innovative assembly method, which does not require any welding of the film on the connector. This significantly decreases the stress to which the film is subjected. It thus reduces the risk of creating micro-leaks and increases the mechanical resistance of the assembly.  
For example a 190-PE/EVOH/PE single-use ported bag can hold up to 80 kg without any damages.

- Standardized position of the connector at the end of the bag

The ABC Transfer® Single-use ported bags 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.

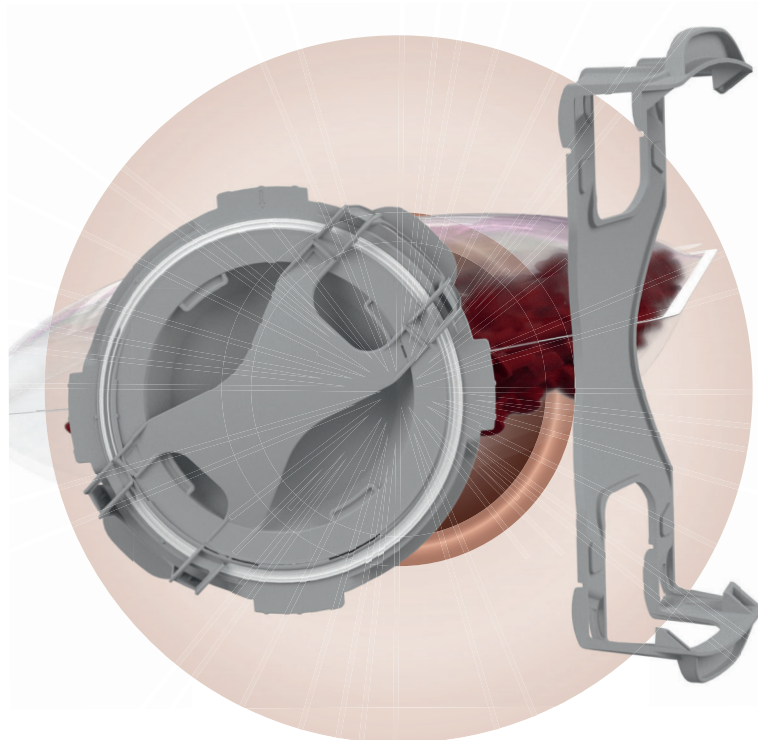
Thank to a much more ergonomic components transfer process, the risk of film puncture is reduced , especially on steam ported bags. A special purpose built tool and transfer trolley have been designed to help your operators throughout the transfer process.



- **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.

- The connector's protective cover acts as a pressure cover, and adds an extra level of sterility assurance. This is a very important feature for air transport since air pressure inside an aircraft decreases by 20000 Pa once airborne.



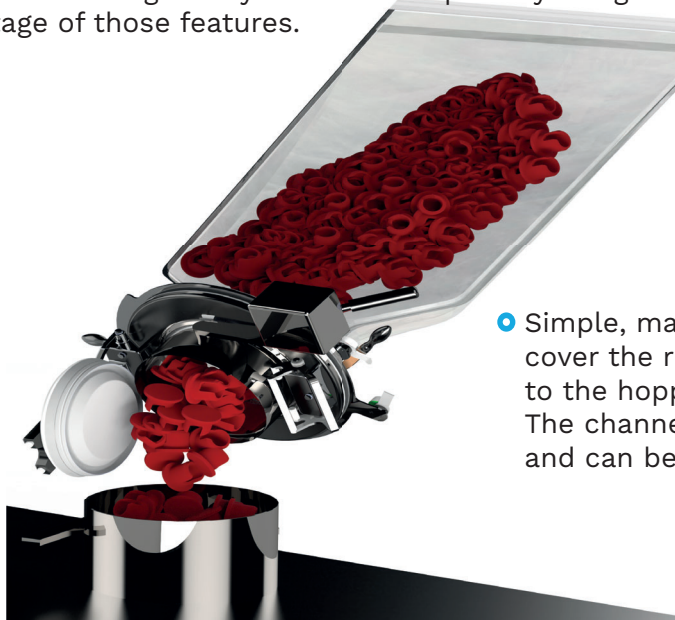
## Gloveless Transfers enabled

- The ABC Transfer® system has been designed to **comply with the future 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.

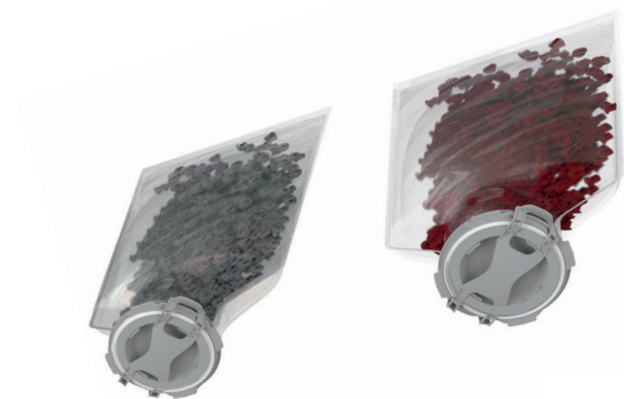
- **Glove-free transfer of components by design.**

The revolutionary ABC Transfer® Alpha port has been designed to eliminate manual operations inside the isolator. ABC Transfer® ported bags and handling trolleys have been specially designed to take advantage of those features.



- Simple, manually operated stainless steel channel to cover the ring of concern and guide the components to the hopper. The channel is operated from outside of the isolator and can be motorized



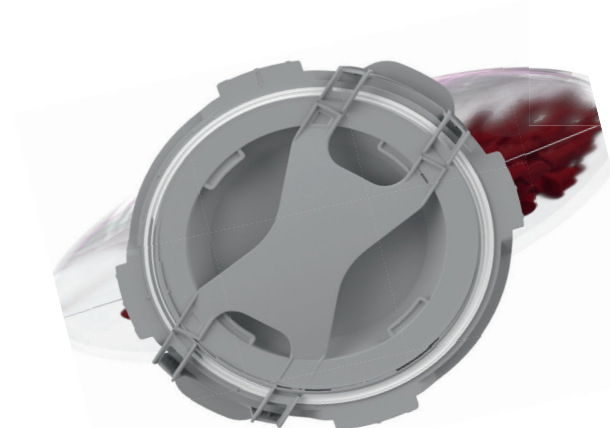


- **Standardized connector position**

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® external opening alpha, in a single or double wall configuration.

- **Optimized for gloveless transfers**

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

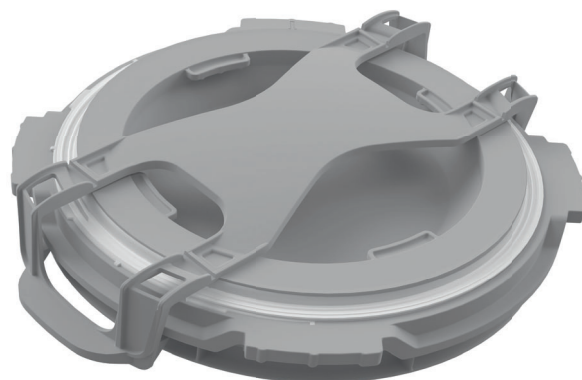


- **Reduced ring of concern**

The Easyglide seal™ reduces the size of the ring of concern and associated risk of contamination. A specially designed and manually operated channel can cover it and totally eliminate the risk.

## Fully compliant

- The ABC Transfer® range of ported bags complies with all the current and planned international regulations.
- All plastic materials comply with [FDA 21 CFR](#) and [USP class 6 regulations](#).
- Extractable studies carried out by ABC Transfer® provide you with extra chemical contamination safety.



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



- The ABC Transfer® Brand is environmentally responsible. We endeavour to reduce our impact on the environment and contribute to the objective of carbon neutrality.



- ABC Transfer® ported bags utilize 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® ported bags are sold.



## A comprehensive range of handling accessories

- Manufactured to the highest standard and simple to operate. These products are the result of years of drug manufacturing experience in cramped and heavy-duty cleanroom environments.
- Compliant with gloveless transfers. The ABC Transfer® handling accessories have been designed to be operated with the ABC Transfer® external opening alpha port and sleeveless ABC Transfer® ported bags.



# Availability

CONNECTOR		COVER MATERIAL	SEAL MATERIAL	BAG			STERILIZATION METHOD			SAMPLES BY	VALIDATION BY
Ø	MATERIAL			MATERIAL	VOLUME	CHUTE?	GAMMA	STEAM	ETO <sup>1</sup>		
190	PPO	PPO	LSR	PE/ EVOH/PE	10 20 30 50 100 <sup>2</sup> 150 <sup>2</sup>	Y	Y	N	N	Q3 2021	Q2 2022 Q2 2022 Q2 2022 Q4 2022 On request On request
					10 20 30 50 100 <sup>2</sup> 150 <sup>2</sup>	N	Y	N	N	Q3 2021	Q3 2022 Q3 2022 Q3 2022 Q1 2023 On request On request
				TYVEK HDPE DOUBLE BAG	10 25	N	N	Y	Y	Q3 2021	Q2 2022 Q2 2022
				TYVEK/ HDPE	10 30 50 80 <sup>2</sup>	Y	N	Y	Y		Q4 2023 Q2 2023 Q2 2024 On request
				TYVEK/ HDPE	10 30 50 80 <sup>2</sup>	N	N	Y	Y	Q3 2021	Q1 2023 Q4 2022 Q1 2024 On request

CONNECTOR		COVER MATERIAL	SEAL MATERIAL	BAG			STERILIZATION METHOD			SAMPLES BY	VALIDATION BY
Ø	MATERIAL			MATERIAL	VOLUME	CHUTE?	GAMMA	STEAM	ETO <sup>1</sup>		
105	PPO	PPO	LSR	PE/ EVOH/PE	10 20 30	Y	Y	N	N	Q3 2022	Q4 2023 Q4 2023 Q3 2023
					10 20 30	N	Y	N	N	Q3 2022	Q2 2023 Q3 2023 Q2 2023

Footnote 1: although Tyvek films can be ETO sterilized, this method requires a specific validation

Footnote 2: when these high volume bags are requested, we will need to perform a risk analysis to decide whether validation activities are required

Note 1: the packaging of all 190 bags, 10l, 20l, 25l, 30l, and 50l is identical, ie 3 layers of 3 bags per carton

Note 2: the packaging of the other bags has not yet been determined