



STERILE **TECHNOLOGY**

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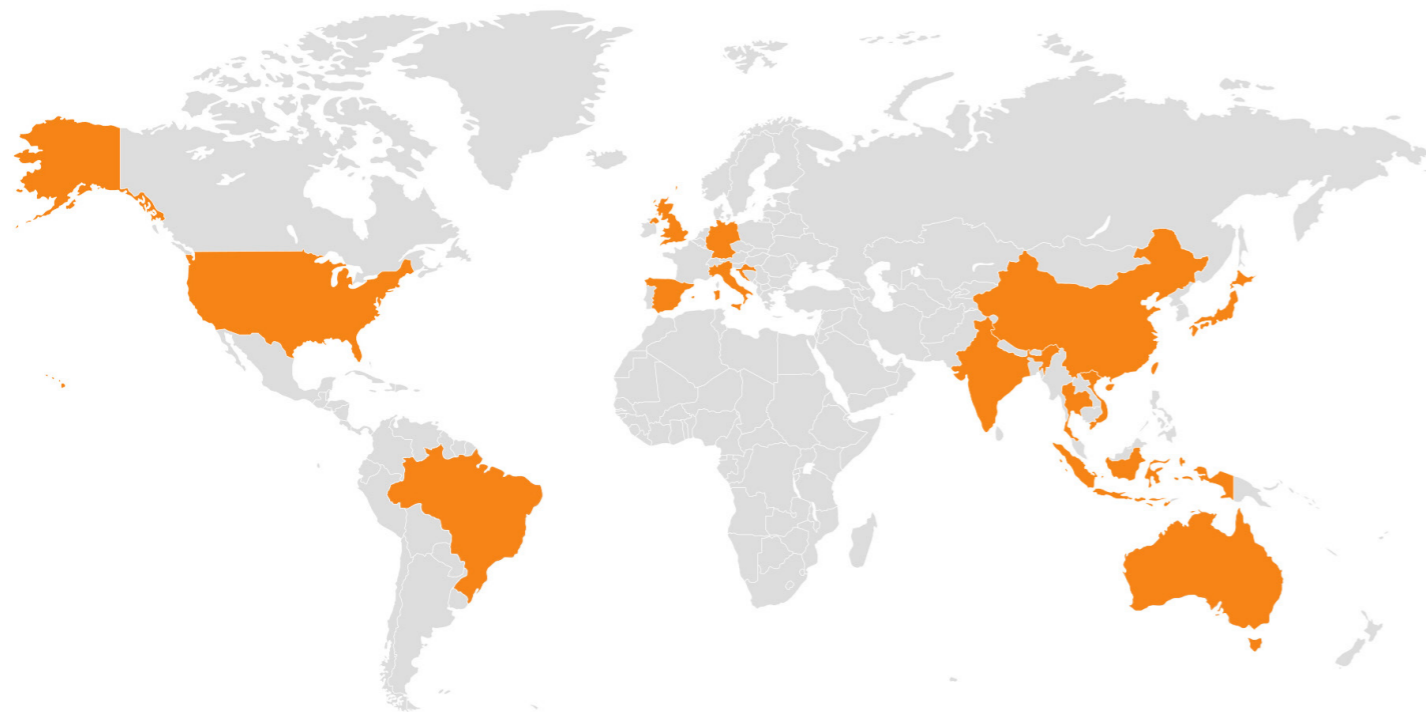
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Atec Pharmatechnik
Customized Equipment for Sterile Technology

Component Processing Systems
Powder Transfer
Transfer Equipment
Clean Room Lifts
Formulation Systems

www.atecgroup.de



Our Company

Founded in Germany in 1996, Atec Pharmatechnik specializes in the manufacturing of sterile processing and handling equipment for use in sterile production facilities. With over 120 installations worldwide, Atec is market leader for component processing and is known for the portfolio for custom aseptic solutions.

We continue to achieve customer satisfaction by building high quality machinery and offering competent service throughout each of our projects.

With

- over 150 employees
- worldwide distribution, customer and technology networks
- multiple patented innovations
- and a long business tradition based on reliability, unique problem-solving approaches and technical superiority

Atec has established its role as an industry leader and technical pioneer in solving aseptic processing challenges.

SERVICES

- Engineering
- Manufacturing
- FAT
- Installation
- SAT
- Cycle Development
- Qualification
- Maintenance

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Manufacturing and Quality Management

The implementation and ISO 9001 certification of our quality management system is one of our milestones.

Atec's ASME certification enables us to market Atec products worldwide and to meet the highest international safety standards.



- ▶ **Design Qualification (DQ)**
Verifies that the proposed design fulfills the design specification.
- ▶ **Installation Qualification (IQ)**
Verifies correct implementation of the design specification.
- ▶ **Operational Qualification (OQ)**
Verifies correct functionality of the equipment.
- ▶ **Performance Qualification (PQ)**
Verifies that the equipment performs correctly under operating conditions.

Project Implementation

DQ, IQ/OQ and PQ are an essential part of quality assurance throughout our equipment validation.



Component Processing

Quality is critical for primary product contact surfaces, especially for the final container and closure.

Clean and sterile components are needed at the filling line for sterile filling of parenteral drug products.

COMPONENTS SUCH AS

| Needle Shields



| Lined Seals



| Caps



| Stoppers



| Plungers

- Tip Caps
- Glass Beads
- Steel Beads
- and more!

- Endotoxin Reduction
- Particle Reduction
- Siliconization
- Sterilization
- Drying and Cooling

Advantages of Atec Component Processing

Highest quality components

- Effective washing (particle & endotoxin reduction)
- No risk of clumping or sticking
- Homogeneous siliconization
- Effective drying process for low moisture content



Safe and easy component handling

- Highest level of sterility
- Mobile vessels enables processing and transport
- Fully-automated processing & transfer to filling line



Cost-effective component preparation

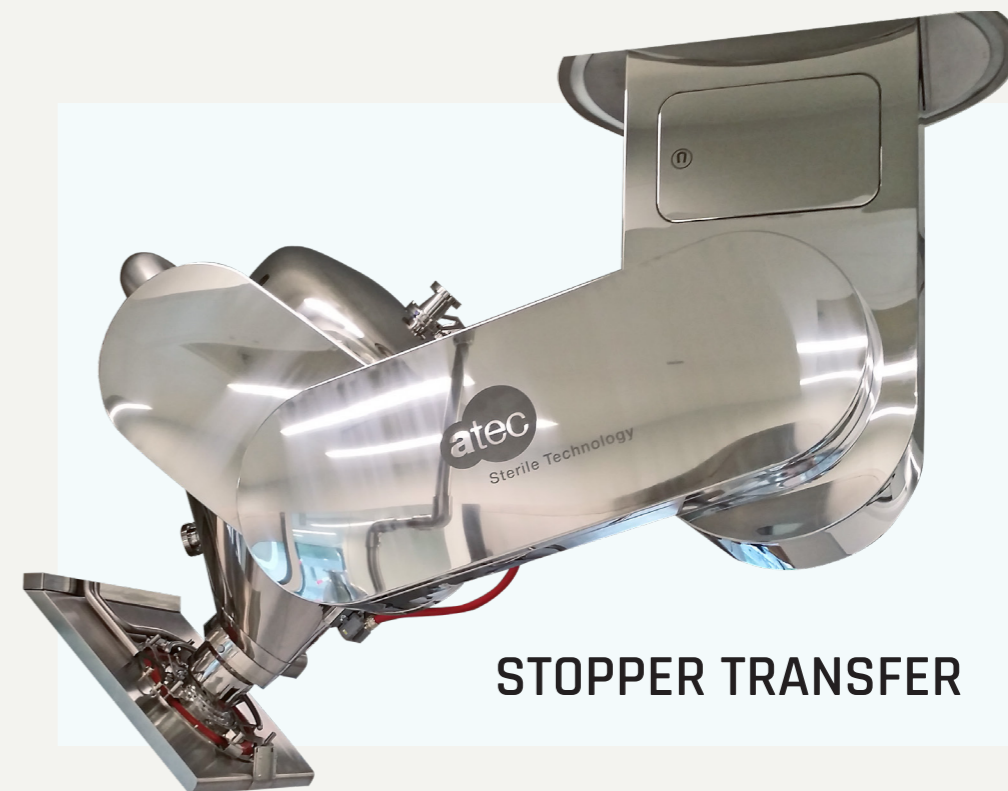
- Minimal worker intervention
- Large batch capacities possible

Atec Component Processing System

The system is comprised of three stations. To ensure that they are suitable for sterile filling, components are contained in a single vessel and transferred between the stations:



STOPPER LOADING



STOPPER TRANSFER



STOPPER PROCESSING



Atec Mini Processor

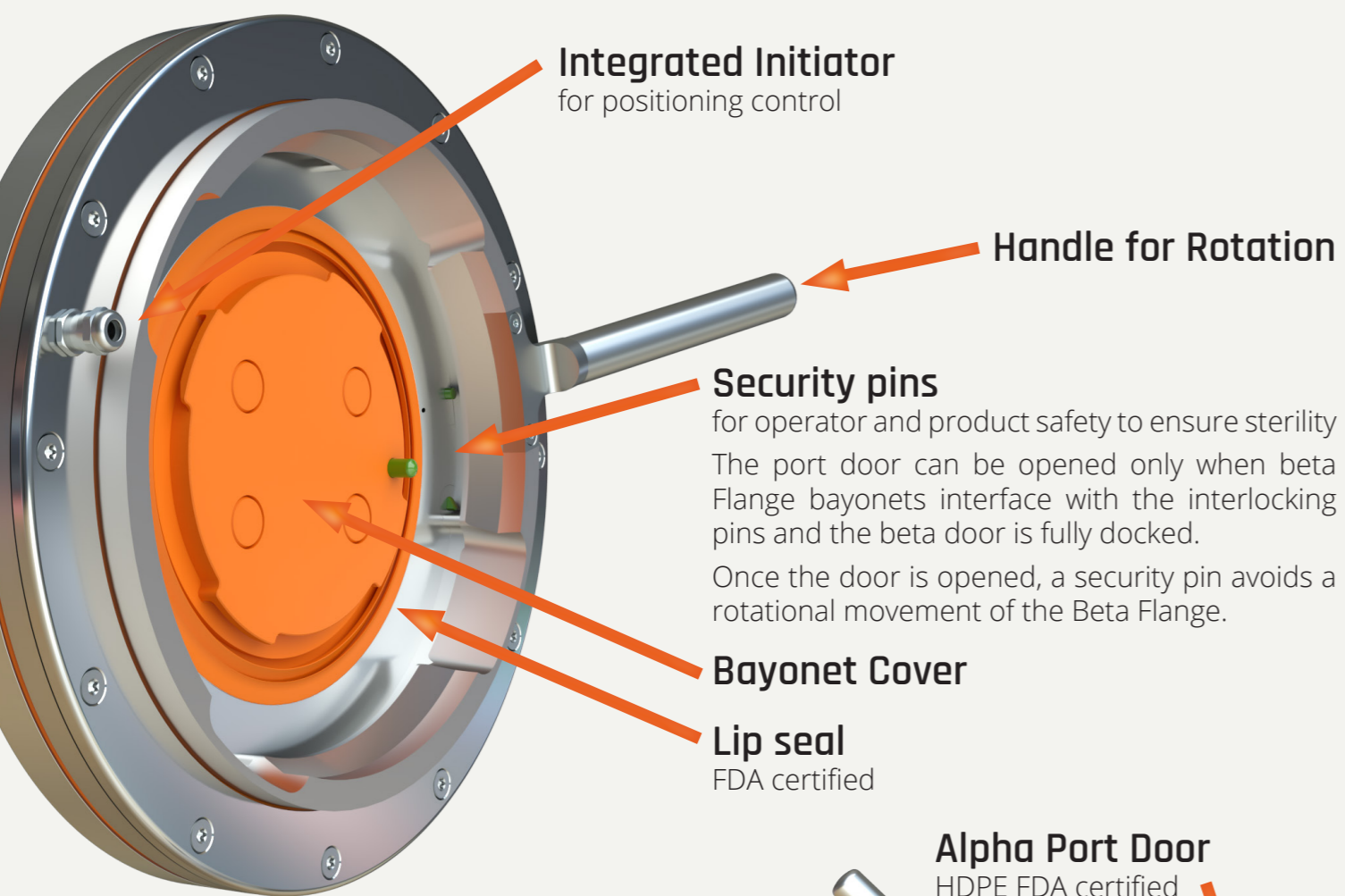
For small batch volumes of components Atec has developed a Mini Processor that can perform complete processing cycles including washing, siliconization, sterilization, drying and cooling.

To achieve sterile filling requirements, stoppers must undergo the following process steps:

- | | | |
|----------------|---|--------------------------------------|
| WASHING | ▶ | • Minimizes endotoxins & particles |
| SILICONIZATION | ▶ | • Applies homogeneous silicone layer |
| STERILIZATION | ▶ | • Reduces bioburden |
| DRYING | ▶ | • Ensures low moisture content |
| COOLING | ▶ | • Eliminates clumping and sticking |

Atec Transfer Port (ATP) Rotating or Non-Rotating

Atec Transfer Ports improve the handling of Component Bags and Beta Port Containers. Ergonomic handling is improved by combining both the lock and handle on the hinge of the door.

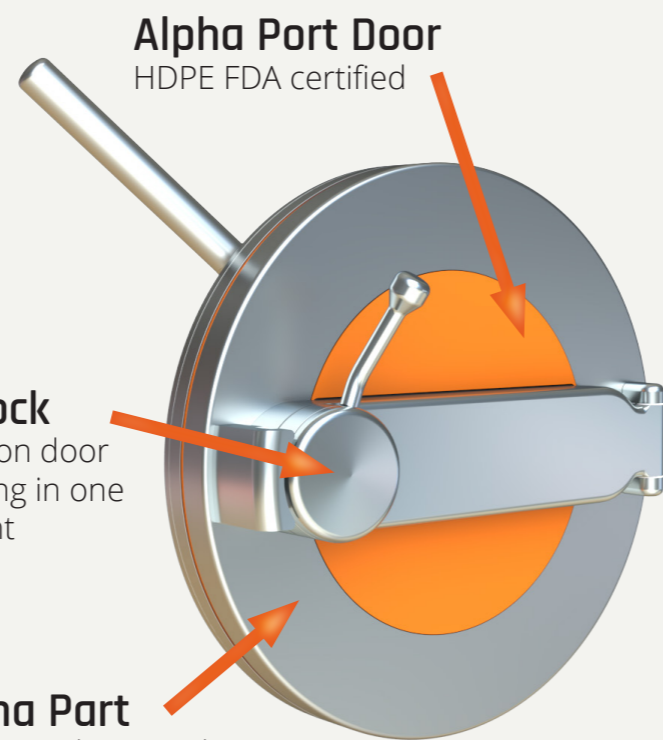


Optional: Automated Alpha Port

fully automated - no operator intervention required



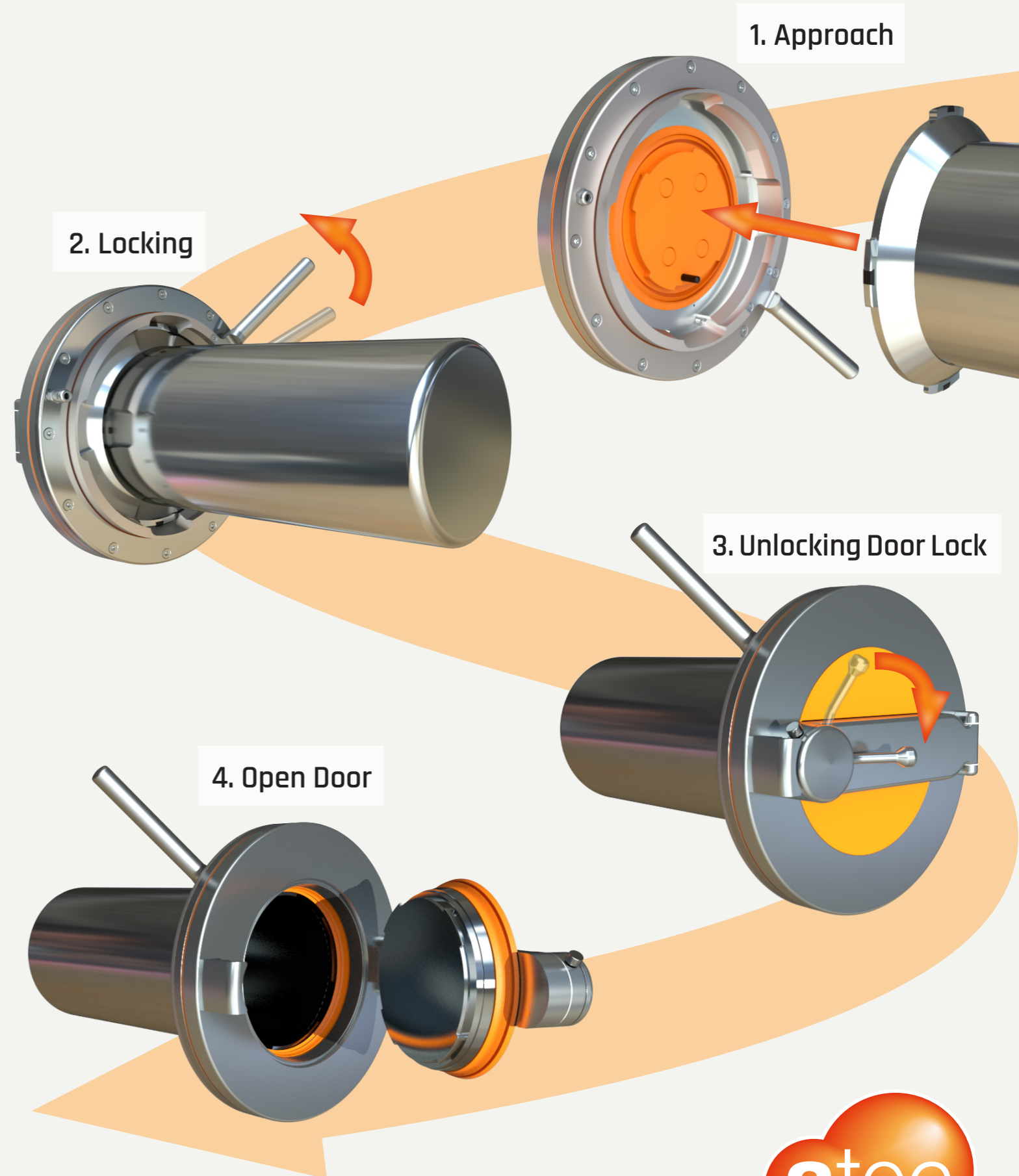
Automated Alpha Port
Electric motors integrated in door



Alpha Part
316L Stainless Steel
FDA approved material
fully VHP capable

Atec Transfer Port Rotating (ATPR)

The rotating Atec Transfer Port enables a complete connection by rotating the Alpha Port without moving the Beta Flange.



Atec Mobile Lift (AML)

Mobile lift system for containers and bags with electric functionality



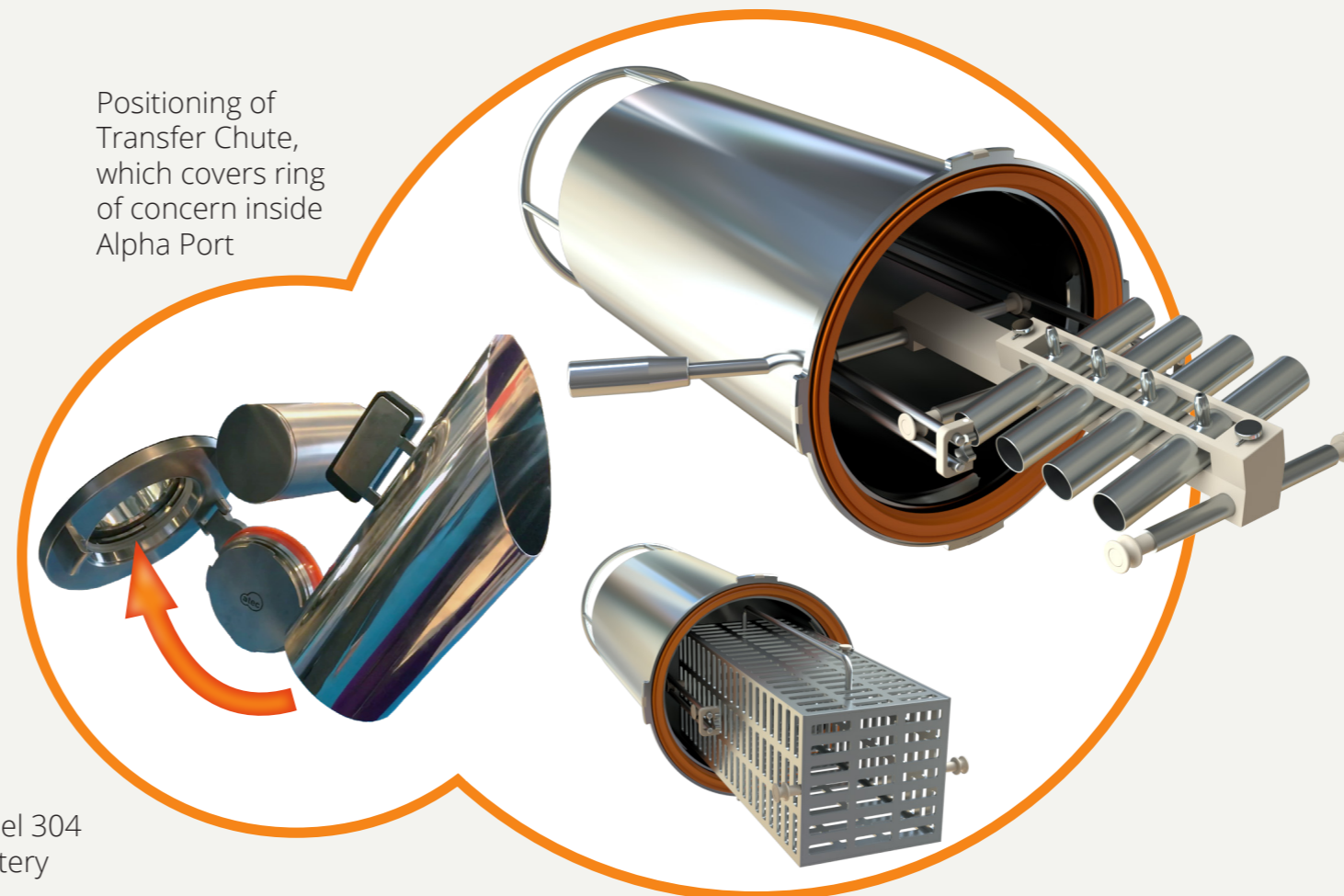
Atec Beta Port Container (ABC)

Customized aseptic solutions for autoclave sterilisation

Features

- 190mm butterfly valve for the retention of components during the docking process
- Empty weight of just 12,5kg
- 24L useful volume
- Container can be docked to an RTP using an Atec Handling Device
- Transfer Chute covers ring of concern

Customized drawers and baskets for transferring small components or machine parts into and out of the isolator



Autoclavable containers for stoppers and caps



Standard containers



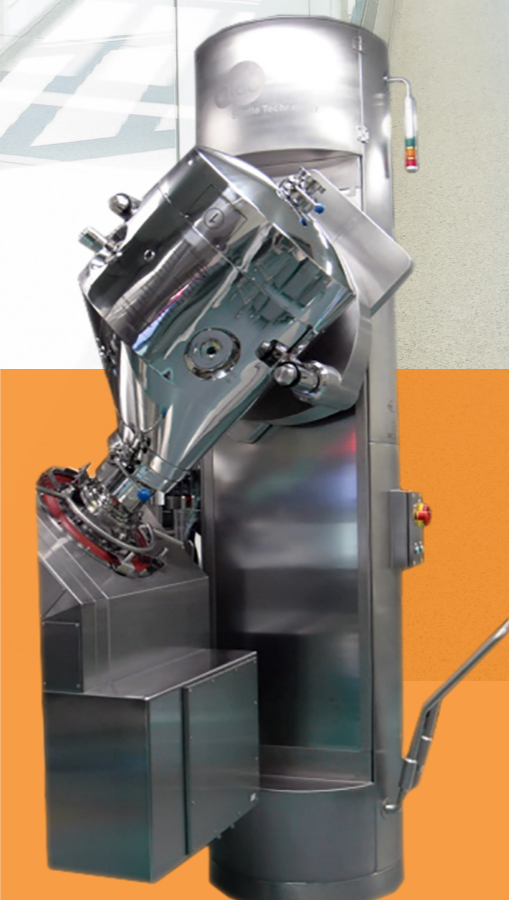
Cleanroom Lifts

The Atec Lifting Device is a unique lift system for operations in clean classified manufacturing environments.

Depending on the user requirements, each Lifting Device is individually customizable for

- transfer filling components, powder or liquid products to the filling line
- docking vessels, containers, cans or bags to RABS or isolators

The Lifting Device can be floor, wall or ceiling mounted and ensures a precise and flexible automated positioning.



Specifications & Options:

- Designed for cleanrooms with complete enclosure of all motors and sensors using stainless steel paneling
- Precise movement and positioning by gear drives using frequency-driven motors
- Safety assurance using motor brakes
- Flexibility using modular attachments for vessels, containers and bags
- Ceiling, floor or wall mounted
- Rotating lift column for three dimensional movement

Bag Filling Equipment

Components can be also transferred into bags

How It Works: An Automated Process

Components are transferred into the isolator through an RTP and fall into a vibrating chute. The operator only needs to attach a bag to the equipment. Bag opening, component dosing, bag closing and bag welding is done automatically. The bag then falls into a container that transfers the bag out of the isolator.

The filling process is weight-controlled and vibrational frequencies are used to dose a range of commodities:

- Aluminum Seals
- Plungers
- Stoppers

For applications where high-accuracy is needed, filling accuracy can be achieved down to $\pm 5g$.

System Features

- All materials inside the isolator are selected to meet the requirements for both aseptic- and VHP-compatibility.
- The Bag Filling Equipment can be designed to accommodate a range of different bag sizes.
- The system can be controlled independently or in conjunction with an Atec Lifting Device.

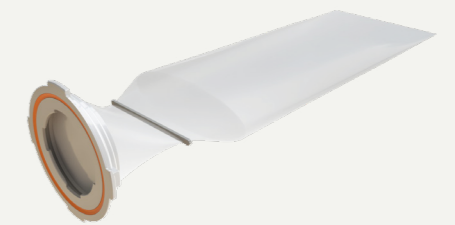
Tyvek Bag



Bag with Sartorius Port

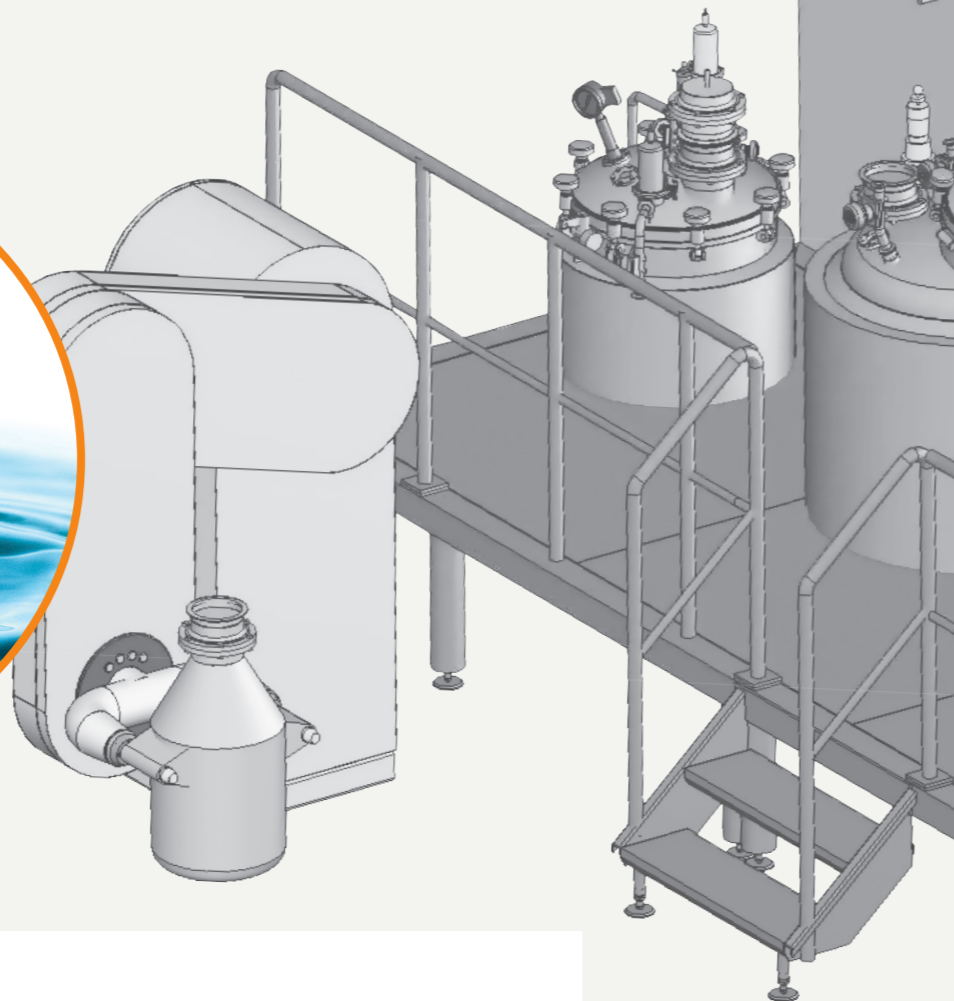


Component Bag



Atec Bag Filling Equipment integrated into an isolator





Formulation

Atec specializes in custom formulation vessels and systems for sterile filling operations.

Formulation process can contain following steps:

- API and excipients are suspended in water.
- Powder products can be added into the formulation vessel through an isolator via RTP or split butterfly valve.
- The formulation may be heated, cooled, mixed etc.
- The formulation undergoes sterile filtration for transfer in a sterile holding vessel.
- Sterile sampling is performed as needed.
- Transfer to the filling line can be done with fixed piping or RTP solutions.

Formulation systems can be supplied with mobile vessels or with fixed vessels.

Formulation Systems

Formulation vessels can be equipped with various fittings, such as

- sterile filters
- transfer ports
- manholes
- magnetic stirrers
- sight glasses
- measurement systems (e.g. temperature and pressure)
- etc.

Vessel volumes can be designed within the range of 10 to 2000 litres.

Formulation systems that utilize mobile vessels enhance aseptic handling by transferring treated products directly to the filling line using the transfer station. This prevents any risk of cross-contamination, since dedicated vessels can be used for each product. Flexibility and product integrity are thus maximized wherever multiple vessels are required.

FORMULATION AND CIP/SIP STATION



TRANSFER FROM STERILE HOLDING TANK TO FILLING LINE



FORMULATION WITH FIXED TANKS AND INTEGRATED CIP/SIP PROCESS



Powder Blending and Transfer

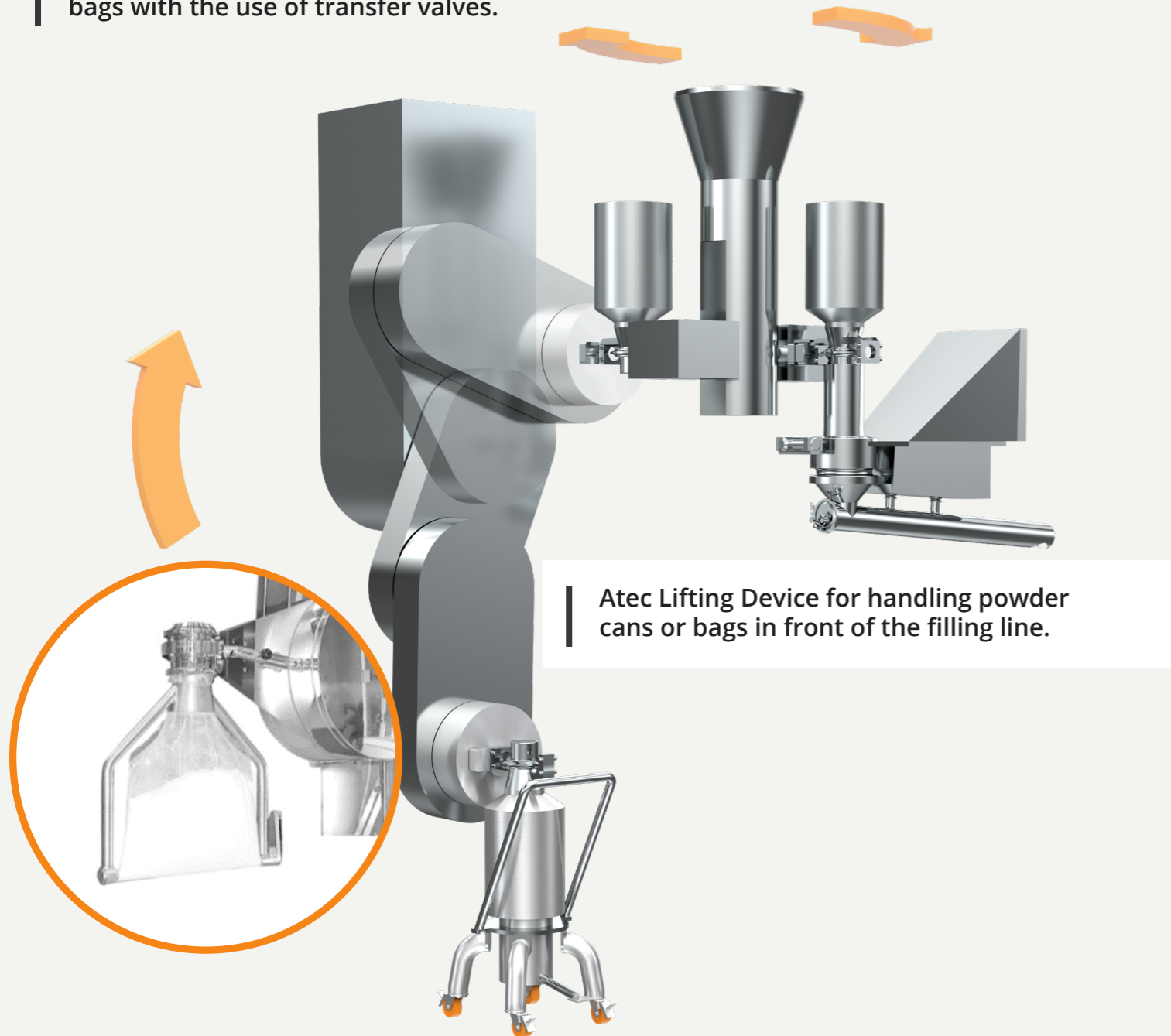
Increasingly, parenteral products are produced in powder form. Atec has developed systems for safe powder handling and transfer to the filling line.

These systems can handle both bags or cans, and can also include complete solutions such as powder blending plus transfer to the filling line within a contained vessel.



Handling System at the Filling Line

Fully-automated positioning of cans and bags with the use of transfer valves.



Atec Lifting Device for handling powder cans or bags in front of the filling line.

Powder Blending and Transfer

The Atec Powder Transfer System is designed for a contained powder handling from the spray drying to the vial filling line isolator with the followings steps:



Powder is charged from the spray dryer into a sterile blending vessel.

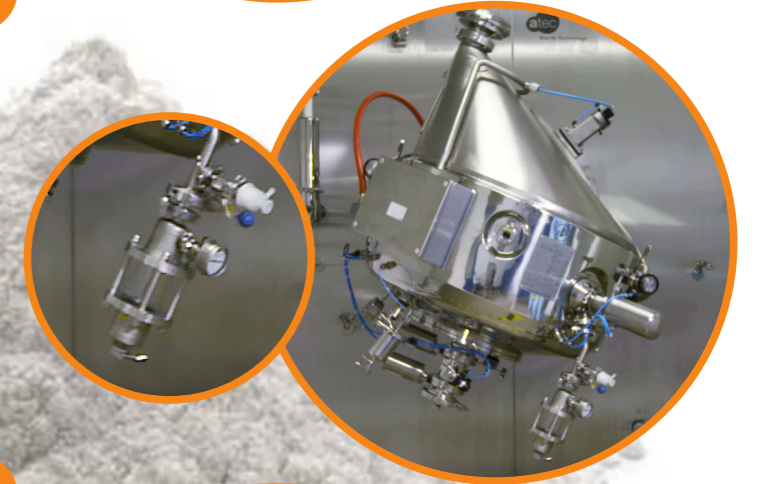
STEP 1



Various vessel volumes

Powder blending and sampling takes place at the blending station.

STEP 2



Powder transfer to the filling line is executed through a Rapid Transfer Port.

STEP 3



CIP and SIP of the equipment is executed at the blending station.

STEP 4

