



ChargePoint   
AseptiSafe™

**CONTAINED ASEPTIC  
TRANSFER VALVES**

- Handling sensitive ingredients and components in aseptic processing
- Simple in process sterilization
- High containment performance for hazardous products

- Perform aseptic transfers that **maintain critical area integrity**.
- **Reduce risk of cross contamination** with closed transfers that limit manual intervention.
- Meet **GMP and product quality** requirements.
- **Remove high air class control areas and cumbersome PPE**.
- Process toxic powders, ensuring the **safety of your personnel** and a **dust free environment**.
- **Maximize yield** transferring poorly flowing and high value product.

## Applications

Contained filling and dispensing for all production processes.

Processes	Products
Vessel Charging Isolator / RABS filling and dispensing Dryer discharge Autoclave - component load/unloading Transfer to filling Line	Bulk Powders Intermediates Active Ingredients Components e.g. stoppers Toxic/potent materials

## Two solutions to meet specific process and facility design

Two alternative methods of sterilizing the product contact and sealing faces of the valve are available to meet the critical area and process set up. In both cases, patented split-valve technology will ensure a closed environment at the point of transfer and throughout the handling and storage process.

### ChargePoint® AseptiSafe™



#### Benefit

- Offers a simple upgrade to GMP requirements in existing or new facilities.
- Simple SIP step prior to material transfer.
- Can be utilized to store product, sealed under sterile conditions between processes – no need to break 'containment' before or after transfer.

#### Critical Area

Ideal for installation in higher grade cleanrooms with Isolator/RABS or existing LAF or other high air class control systems.

#### Sterilization method

Autoclave or/and SIP.

#### Application

Multiple batch transfers without the need for repeated SIP steps.  
 Or Single transfers in lower grade areas.

### ChargePoint® AseptiSafe™ bio



#### Benefit

- Can eliminate the need to construct large high air class control areas in new facilities.
- Optimised Biodecontamination cycle.

#### Critical Area

Ideal for lower grade cleanrooms to reduce the costs associated with the construction, validation and management of large clean areas.

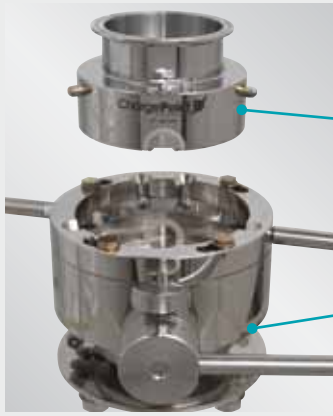
#### Sterilization method

Autoclave or/and  
 SIP & H<sub>2</sub>O<sub>2</sub> Biodecontamination.

#### Application

Single or multiple batch transfers.  
 Suitable for continuous process.

## Operation Sequence



### Passive (beta)

Attached to mobile product/  
component container

### Active (alpha)

Attached to process vessel/  
filling line

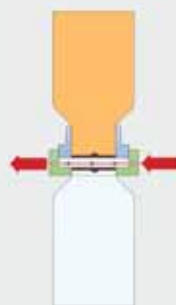
- Prior to the transfer process the Passive unit/container is pre-sterilized outside of the process.
- This is normally completed in an Autoclave and the critical interface that will be later exposed to the production area can be sealed with a GMP Cover.
- Each half of the valve contains one half of a butterfly valve disc. Each unit is sealed and cannot be opened unless they are docked together.

## ChargePoint® AseptiSafe™



- 1** OPTIONAL: The Active unit is sterilized in place (SIP) with the use of an SIP Passive unit. This step may not be required in processes that simply require a high level GMP contained transfer.
- 2** Two disc halves are locked in place to form a single sealed unit. The previously exposed interfaces are now sealed together to form a single butterfly valve disc.
- 3** The Active unit is the driving half of the valve. Once operated the disc will open to allow the transfer of material through the valve. The active and Passive interface is sealed to ensure no material can penetrate the critical area. Once the transfer has taken place the valve is closed.
- 4** The Active and Passive units are then unlocked and undocked revealing the previously closed interfaces ensuring a clean transfer.

## ChargePoint® AseptiSafe™ bio



- 1** The Active unit is sterilized in place (SIP) with the use of a SIP Passive unit.
- 2** Two disc halves are locked in place to form a single sealed unit. The previously exposed interfaces are now sealed together to form a single butterfly valve disc.
- 3** The disc faces are exposed to decontamination gases within a sealed chamber prior to the product transfer to ensure decontamination of all critical areas.
- 4** The Active unit is the driving half of the valve. Once operated the disc will open to allow the transfer of material through the valve. The active and Passive interface is sealed to ensure no material can penetrate the critical area. Once the transfer has taken place the valve is closed.
- 5** The Active and Passive units are then unlocked and undocked revealing the previously closed interfaces ensuring a clean transfer.

## Features & Benefits

### Enhanced sterility confidence

- Mechanical interlocks guarantee safety prior to, during and after material transfer
- Possible to store product/component container under sterile conditions.
- Metal-to-metal disc seal - No additional solid or inflatable seals that can provide a product trap ensure a simple GMP design

### Economic processing

- Remove requirement for large high grade control areas by maintaining critical area within valve
- Possible to perform multiple, repeated transfer without the need for continuous SIP steps or re-validation.
- Single use bag system eliminates cleaning and sterilization associated with rigid containers.

### Easy to operate and maintain

- Simple manual or automatic operation.
- Optimised sterilization cycles.
- Minimum parts design for quicker maintenance.

### Safer handling of potent or hazardous ingredients

- Nanogram level / OEB5 performance possible.
- Independently validated according to ISPE containment performance measurement (SMEPAC) guidelines.
- Maintains RABS and isolator containment integrity.

### Process Versatility

- Scalable technology for multiple process functions
- Powder filling and dispensing
  - Component handling
  - SIP / WIP
  - Sampling
  - Process inspection (Sightglass)

### Key validation features

- All materials are suitable for SIP and WFI.
- All materials are suitable for use with H<sub>2</sub>O<sub>2</sub> decontamination.
- The system kills organisms effectively and quickly.
- The decontamination phase is optimised.
- The product is protected from the decontamination gases.



## ChargeBag®

The ChargeBag® provides a cost effective single use method of handling powders.

- Manufactured under cleanroom conditions using an FDA approved high performance LDPE
- Each ChargeBag® is packed within a sealed sleeve and gamma irradiated to ensure integrity until use.
- The anti-static property of the film assists poorly flowing materials to maximize the recovery of product from each transfer.

## Specifications

		AP50	AP100	AP150	AP200
<b>ChargePoint® AseptiSafe™</b>	SIP (Steam In Place)	•	•	•	•
<b>ChargePoint® AseptiSafe™ bio</b>	SIP & H <sub>2</sub> O <sub>2</sub> Biodecontamination		•	•	
<b>Size</b>		DN50 (2")	DN100 (4")	DN150 (6")	DN200 (8")
<b>Containment Performance</b>		Available from < 10 ug/m3			
<b>Autoclavable</b>		•	•	•	•
<b>SIP (Steam In place)*</b>		Up to 2.5 Bar (36 psi)			
<b>Pressure Rating*</b>		Up to 6 Bar (87psi)			Up to 3.5 Bar (50 psi)
<b>Vacuum Rating*</b>		Full vacuum			
<b>Operation</b>	<b>Manual</b>	•	•	•	•
	<b>Semi Automatic</b>		•	•	•
	<b>Fully Automatic</b>		•	•	•
<b>Product Contact Material</b>	<b>Body</b>	<b>316L</b>	•	•	•
		<b>Alloy 22</b>	•	•	•
	<b>Seals</b>	<b>FKM</b>	•	•	•
		<b>FFKM</b>	•	•	•
<b>Passivation (product contact parts)</b>		•	•	•	•
<b>Connection Interface</b>	<b>Tri-Clamp (BS/ISO/DIN/JIS)</b>	•	•	•	•
	<b>Aseptic Tri-Clamp / ASME BPE</b>	•	•	•	•
	<b>Other</b>	Available to suite process / container			

\*Pressure/vacuum Rated only when fitted with a suitable pressure/vacuum rated component or accessory

## Compliance & Quality Assurance

- ✓ Designed to GMP standards
- ✓ FDA compliant materials
- ✓ Conforms to European Hazardous Area directive (ATEX)
- ✓ Conforms to European Pressure Equipment Directive (PED)
- ✓ European Machinery Directive
- ✓ Manufactured in ISO9001 accredited facilities
- ✓ Full material certification and batch traceability
- ✓ Independently validated according to ISPE containment performance measurement (SMEPAC) guidelines

## Handling & Automation

Systems to ensure safe operation in hazardous or inaccessible areas or where the production scale does not permit manual handling:

- Manual or automated valve operation and docking.
- Proximity sensors
- Control systems
- Repeatable and safe alignment of equipment in conjunction with lifting hoists and docking systems.
- Reduced weight versions.
- GMP covers to protect the valve while not in use.



Also available - our range of high integrity single use transfer bags and robust containers.

ChargeBag® & ChargeBottle®



Assisting you throughout the warranty period and continuing to offer our responsive support to ensure continuity of production with Onsite Service Packages, Spare Parts, Consumables and Training delivered via our dedicated support centres in Europe, North America and Asia.

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