AseptiSafe®

CONTAINED ASEPTIC TRANSFER VALVES
• 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.
AseptiSafe aseptic transfer valves can be integrated into the production of both powder and liquid formulations from API production to fill/finish processes, transferring either powder or components.

Components
Stoppers / caps / closures

Powder Product
- Spray Drying
- Filtration / Drying
- Gamma Irradiation of product
- Mixing and Formulation
- GMP Buffer Preparation
- Autoclave of components within ChargeBag®
- Bulk processing vessels
- Bulk rotary drum autoclave
- Batch gamma irradiation of components

Liquid Filling
- API Dispensing
- Mixing and Formulation
- GMP Buffer Preparation

API Dispensing

Powder Filling

GMP Buffer Preparation

Batch gamma irradiation of components

Bulk rotary drum autoclave

Autoclave of components within ChargeBag®

Bulk processing vessels
Solutions to meet critical area set up and required sterility assurance

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.

### Operation Sequence

1. **ChargePoint AseptiSafe®**
   - 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

- The disc faces are exposed to decontamination gases within a sealed chamber prior to the product transfer to ensure decontamination of all critical areas, providing a validated 6 log reduction.

### Accessories

- **Passive Opener**
  - Opening device for sterilization of Passive valve within an autoclave.

- **SIP Passive**
  - Local SIP (Steam In Place) sterilization of the Active unit.

- **GMP Cover / Plug**
  - Protect and maintain containment of the AseptiSafe valve.
High integrity single use transfer bags

ChargeBag® PE
- FDA approved high performance LDPE film packed within a sealed sleeve and gamma irradiated.
- Anti-static film assists poorly flowing materials to maximize product recovery.
- Ideal for powders, TRU (Ready To Use) components and gamma irradiation sterilisation processes.

ChargeBag® RTS
- Tyvek and HDPE materials of construction for sterilisation of RTS (Ready To Sterilise) components within autoclave.
- Double packed within easy to tear sealed liners.

Features & Benefits

Enhanced sterility Assurance
- Mechanical interlocks guarantee safety prior to, during and after material transfer.
- Possible to store product/component container under sterile conditions.
- Microbiologically qualified (MBQ).
- H₂O₂ 6 log reduction.

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 sterilisation 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 H₂O₂ decontamination.
- The system kills organisms effectively and quickly.
- The decontamination phase is optimised.
- The product is protected from the decontamination gases.

Specifications

ChargePoint AseptiSafe®
- Terminal HEPA pleats.
- Integral HEPA filter.
- H₂O₂ Biodecontamination.

Size
- DN50 (2”)
- DN100 (4”)
- DN150 (6”)
- DN200 (8”)

Containment Performance
- Available from <1 µg/m³ / OEB5.

Autoclavable
- Yes.

SIP (Steam In place)*
- Full vacuum.

Pressure Rating*
- Up to 6 Bar (87 psi).

Vacuum Rating*
- Full vacuum.

Operation
- Semi Automatic.
- Fully Automatic.

Product Contact Material
- Body 316L.
- EPDM.
- FKM.

Passivation (product contact parts)
- Available to suite process / container.

Connection Interface
- Aseptic Tri-Clamp / ASME BPE.
- Other.

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.

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Process Applications
Aseptic Handling of Components

Batch gamma irradiation of components with ChargeBag® PE

1. Components loaded into clean ChargeBag® PE and Passive is connected. ChargeBag® assembly is sealed within outer liner packaging.

2. Gamma irradiation of ChargelBag® and valve assembly off site.

3. Outer liner removed within facility cleanroom. Transfer ChargelBag® to filling line.

4. Transfer vessel to filling line. Seal Active/Passive with Pressure Cover for sterilisation process.

Bulk stopper processing vessel

1. Fill vessel with components.

2. Dock vessel/ChargeBag® and transfer components to filling line via RABS / Isolator.

3. Dock vessel/ChargeBag® and transfer components to filling line via RABS / Isolator.

4. Dock vessel/ChargeBag® and transfer components to filling line via RABS / Isolator.

Rotary drum autoclave filling gamma sterilised ChargeBag® PE

1. Fill drum with stoppers and sterilise within autoclave.

2. Dock Passive/ChargeBag® to Active located within RAIS/LAF.

3. Transfer components from drum to ChargeBag®.

4. Transfer ChargelBag® to filling line.

5. Transfer ChargelBag® to filling line.

6. Transfer ChargelBag® to filling line.

7. Remove the ChargelBag® and Passives and connect under RAIS / LAF area.

8. Place ChargelBag® into autoclave with open passives for sterilisation.

9. Fill ChargelBag® with stoppers.
Aseptic Processing of Bulk API/Powders

**Bulk Powder Discharge**

1. Sterile API loaded into Isolator
2. API weigh and dispense through valve into ChargeBottle®/ChargeBag®
3. ChargeBottle®/ChargeBag® transferred to powder filling line
4. Docking and discharge of powder product into container

**Buffer / Media Preparation**

- Powder transfer to formulation and mixing tanks
- Disposable transfer ChargeBag® (gamma irradiated)
- Dust free and aseptic connection

**Dispensing of sterile API**

- Dock vessel/ChargeBag® and transfer powder to filling line via RABS/Isolator
- Open SIP of Active valve/vessel using the SIP Passive device prior to transfer
- Product transfers with docked Passive/ChargeBag

**Transfer to mixing/ formulation vessel**

1. Open SIP of Active valve/vessel using the SIP Passive device prior to transfer
2. Sterile API loaded into vessel
3. Liquid formulation to filling
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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