ChargePoint TECHNOLOGY

Technical Overview

ChargePoint Containment Valves Solutions for Clean Processing

INTRODUCTION

Split Butterfly valve technology is a widely adopted method of containing the transfer of powder, granular or semi solid materials from process to process. Typically this method is undertaken as a solution to protect the operator from exposure to toxic powders that can become airborne when using other 'non-contained' methods of powder transfer.

However, in aseptic processing the primary concern is of product purity and the need for the processing equipment to conform to the required level of cleanliness or sterility during processing.

Common methods of achieving aseptic conditions in powder handling have been met with unique positive pressure, HEPA filtered gloveboxes. The ability to handle sterile processes outside of these aseptic environments has been a greater challenge.

Applying the method of aseptic powder transfer to the ChargePoint range has been met by continuous development of our valve technology. A range of unique processes have been applied to the ChargePoint valve providing two levels of cleanliness to the product contact and sealing faces of the valve.

In addition to these systems providing the basic level of containment performance for operator protection at <10mcg/m³ the utilisation of a further integral cleaning step after the product charge takes place ensure an increased level of containment to <1mcg/m³.

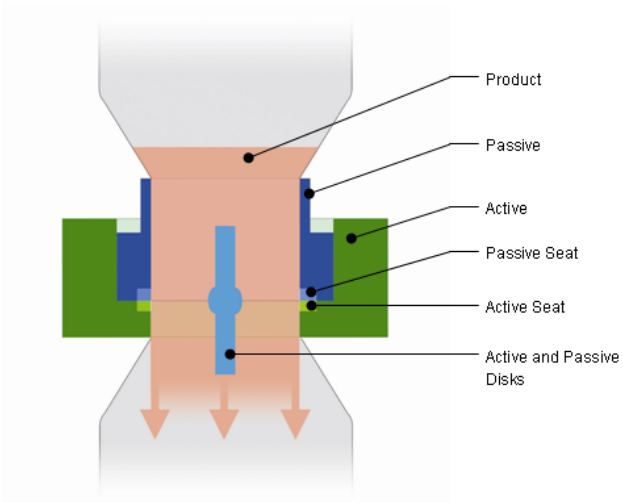


Illustration of how the ChargePoint Active and Passive Units integrate during operation

SOLUTION OVERVIEW

LEVEL	SOLUTION METHOD	CONTAINMENT PERFORMANCE	CHARGEPOINT® VALVE	PAGE
1A	Sterilisation of ChargePoint valve pre-charge	<10 mcg/m³	ChargePoint (Pressure Rated)	Page 5
1B	Sterilisation of ChargePoint valve pre-charge + EXCEL clean post-charge	<1 mcg/m³	ChargePoint EXCEL (Pressure Rated)	Page 8
2A	Sterilisation of ChargePoint valve pre-charge + Bio-decontamination pre-charge	<10 mcg/m³	ChargePoint BIO (Pressure Rated)	Page 10
2B	Sterilisation of ChargePoint valve pre-charge + Bio-decontamination pre-charge + EXCEL clean post-charge	<1 mcg/m³	ChargePoint BIO EXCEL (Pressure Rated)	Page 12

CHARGEPOINT HARDWARE OVERVIEW

ChargePoint Active Unit (Pressure Rated)

Product contact materials:
316L / C22
Seals FKM / FFKM

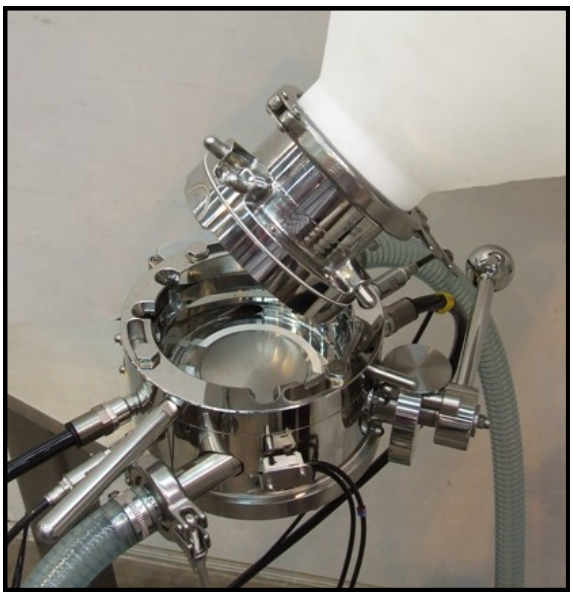
Pressure Rating:
6Bar (when connected to a pressure rated accessory—e.g. Passive

ChargePoint Passive Unit (Pressure Rated)

Product contact materials:
316L / C22
Seals FKM / FFKM

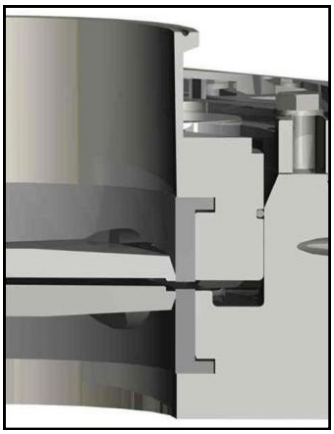
The Pressure Rated Passive features a perimeter o-ring to effect a seal with the Active Unit

ChargePoint EXCEL Active & Passive Units (Pressure Rated)



Product contact materials:
316L / C22
Seals FKM / FFKM

The EXCEL Passive features a perimeter o-ring effect seal with the Active Unit



Cross section showing the void between the Active and Passive mating faces whilst in the EXCEL cleaning position

ChargePoint Active GMP Plug

Materials:
HDPE
Seals EPDM

ChargePoint Passive GMP Cover

Materials:
HDPE
Seals EPDM

ChargePoint SIP Passive (Pressure Rated

Materials:
316L / C22
Seals FKM / FFKM

PROCESS DESCRIPTIONS

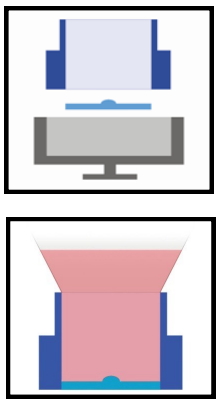
LEVEL 1A: Sterilisation of ChargePoint valve Pre-Charge

Overview:
This method involves sterilising the ChargePoint Active and Passive product contact and sealing surfaces prior to carrying out the charging or discharge of product through the valve.

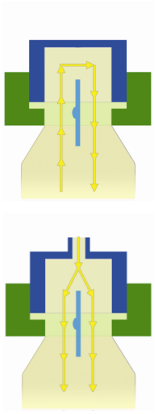
Hardware:
ChargePoint Pressure Rated Active and Passive
Pressure rated SIP (Steam In Place) Passive
(Product contact materials: 316L, FKM or FFKM depending on process)
GMP Passive Cover
GMP Active Plug

Applications:
Single batch charging
Discharge applications

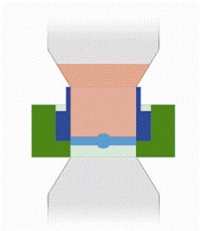
Operation Procedure: Single Batch Charging



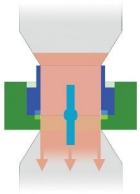
Sterilise Passive in Autoclave. Attach container to Passive and seal in bag within isolator.



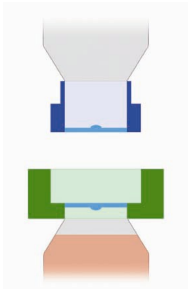
Sterilise Active in place with steam.



Remove bag and GMP Cover from Passive. Dock Passive into Active.



Open valve to charge product.



Close valve and undock Passive.

Passive Unit Preparation

A. The Disc is manually removed from the Passive and together with the body and a corresponding GMP Cover, the 3 items are placed into a suitable autoclave bag.

B. The sealed bag of component parts is placed into an autoclave and sterilised at the required temperature and tim duration.

C. Having autoclaved the Passive and sub parts, the bag is removed and carefully transferred to either a sterile isolator or classified environment.

D. When safely located in this area the bag is opened and the Passive disc is fitted and secured to the Passive body. It is assumed at this stage that the Pharmaceutical product has already been dispensed into a suitable bag/

E. The Passive is docked onto the container and the tri-clamp secured in place.

F. A GMP cover is attached to the Passive and the container, Passive and cover complete is transferred into a bag and sealed, ideally by twisting, tie wrapping, goose necking and further tie wrapping. This bagging procedure offers a secondary barrier and although not essential offers a second level barrier protection from exposure to the

Active Unit Preparation

A. The mating Active unit would typically locate upon the receiving process equipment. In order to sterilise this part, the use of steam at a nominal 2bar pressure at 120degC.

B. **Option 1:** Where steam is to be introduced through the ChargePoint Active, an SIP Passive is docked into the Active valve, with the source of process steam being connected to the inlet connection of this part.
Option 2: If steam is to be fed through the process equipment upon which the Active is connected , the Active will this time be fitted with an SIP Passive without an inlet connection. In either case, both components when docked and locked into the Active will render the assembly a pressure rated valve.

C. At the stage before introducing the steam, the Active valve is opened. As the Chargepoint offers a unique design which enables the Active to be opened under pressure rated conditions (only when a suitable pressure rated module is fitted to the Active). The common difficulty experienced when attempting to sterilise butterfly valves disc edges (otherwise known as the 'ring of concern') is overcome by this feature.

D. With the Active valve open, steam is introduced of the required pressure and temperature, for the set time period. During this time the valve bore, disc faces and edges will be exposed to he steam and thus sterilised in the

E. During the sterilisation stage of the Active, precautions must be taken not to touch the surface of the valve, as this will be at elevated temperatures. Once the process is complete, the valve must be allowed to return to ambient temperature before further operations are carried out.

Charging Operation

A. The packaged container is transferred to the location where it is to be charged into the process. Additional measures can now be introduced towards manufacturing higher levels of local area classification. If the room environment is not already manufactured to a class 100 or 10 thousand category, it is advisable to have some form of VLAF (vertical laminar air flow) or cross flow HEPA filtered air flow, passing across the Active valve locality. This should be in place prior to carrying out any ongoing steps.

B. The out bag sealing the container can now be removed followed by the removal of the GMP Passive Cover. If appropriate, this should be carried out within the vicinity of the HEPA filtered airflow. Immediately after the Passive cover is removed, the Active valve is closed and the SIP cover is detached.

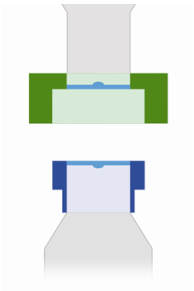
C. At this stage, both faces of the Active and Passive discs are exposed to the room environment. Although these surfaces are not direct product contact, it is essential to minimise the duration of exposure as there will be a variable level of disc to seat interface exposure. The time required to dock the passive and container into the active must be limited to several seconds.

D. Once docked and locked into place the Active valve is opened and the product transferred through into the process.

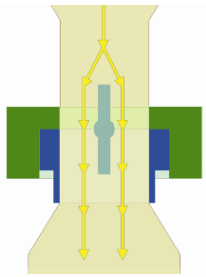
E. Having completed the transfer, the Active is closed and the Passive undocked. A suitable wetted wipe is used to wipe and remove the compressed product residue from the disc/seal interface.

F. The autoclaved GMP Active Plug is then inserted and docked into the Active, offering a sealed GMP unit.

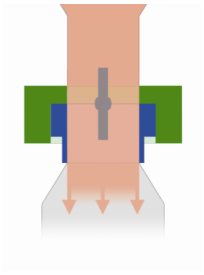
Operation Procedure: Discharge applications



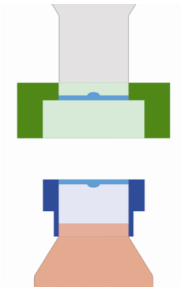
Dock Passive into the Active.



Open the valve and steam through to sterilise.



Open valve to charge product.



Close valve and undock Passive.

Discharge Operation

A. Isolate the ChargePoint valve from the process. For example this could be a discharge plug on a filter dryer, or an isolation valve between the valve and a centrifuge.

B. Dock the Passive to the Active and lock in place.

C. The valve can then be opened at which point steam can be introduced through the valve to sterilise the product contact surfaces of the valve. This is only possible with a ChargePoint valve thanks to the unique method of pressure sealing.

D. The SIP (Steam in Place) process is carried out for the required amount of time at the appropriate temperature.

E. Once the SIP process is complete the isolation valve can be opened to allow product to be charged through the valve into the connected vessel or container.

F. The ChargePoint valve is then closed, unlocked and undocked.

G. A suitable wetted wipe is used to wipe and remove the compressed product residue from the disc/seal interface.

H. The autoclaved GMP Active Plug is the inserted and docked into the Active, offering a sealed GMP unit.

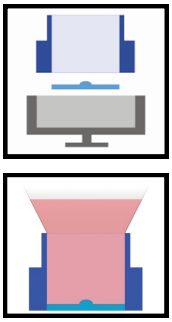
LEVEL 1B: Sterilisation of ChargePoint valve Pre-Charge + EXCEL Cleaning Post-Charge

Overview:
This method involves pre-sterilising the ChargePoint EXCEL Active and Passive product contact surfaces prior to carrying out the charging or discharge or product through the valve. Once the product transfer has taken place, an 'EXCEL' cleaning cycle takes place to ensure a higher nanogram level of contained transfer.

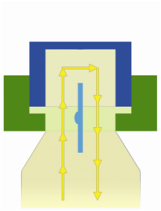
Hardware:
ChargePoint EXCEL Pressure Rated Active and Passive
Pressure Rated SIP (Steam in Place) Passive
(Product contact materials: 316L, FKM or FFKM depending on process)

Applications:
Single batch charging
Discharge applications

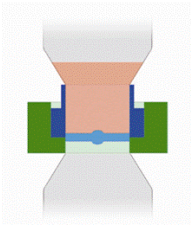
Operation Procedure: Single Batch Charging



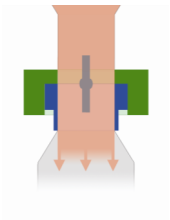
Sterilise Passive in Autoclave. Attach container to Passive and seal in bag within isolator.



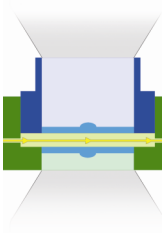
Sterilise Active in place with steam.



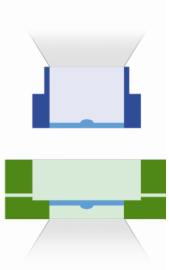
Dock Passive into Active.



Open valve to transfer product.



Undock the Passive to the 'EXCEL cleaning' position. Purge with air and extract to clean the mating faces for High Containment.



Undock the Passive from the Active.

Passive Unit Preparation

A. Completed as per 1A (page 6)

Active Unit Preparation

A. Completed as per 1A (page 6)

Charging Operation

A-D. Completed as per 1A (page 6)

E. Having completed the transfer, the Active is closed and the Passive undocked to an intermediate position for 'EXCEL' cleaning. An interlock mechanism prevents the Passive from being fully removed to a point where a chamber is achieved between the Active and Passive disc faces. At this point a purge and extraction process is carried out, removing traces of any particles that coul potentially become airborne once the Active and Passive units are disengaged.

F. Once the EXCEL cleaning cycle has run for its allotted time, the interlock will be released so that the Passive can be disengaged from the Active.

G. A suitable wetted wipe is used to wipe and remove any remaining compressed product residue from the disc/seal interface.

H. The autoclaved GMP Active Plug is then inserted and docked into the Active, offering a sealed GMP unit.

Operation Procedure: Discharge Operation

A-E. Completed as per 1A (page 7)

F. Having completed the transfer, the Active is closed and the Passive undocked to an intermediate position for 'EXCEL' cleaning. An interlock mechanism prevents the Passive from being fully removed to a point where a chamber is achieved between the Active and Passive disc faces. A this point a purge and extraction process is carried out, removing any traces of any particles that could potentially become airborne once the Active and Passive units are disengaged.

G. Once the EXCEL cleaning cycle has run for its allotted time, the interlock will be released so that the Passive can be disengaged from the Active

H. A suitable wetted wipe is used to wipe and remove any remaining compressed product residue from the disc/seal interface.

I. The autoclaved GMP Active Plug is then inserted and docked into the Active, offering a sealed GMP unit.

LEVEL 2A: Sterilisation of ChargePoint valve Pre-Charge + Bio-decontamination Pre-charge

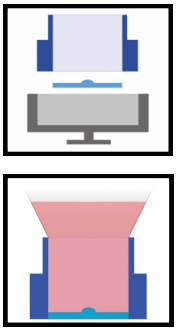
Overview:
This method involves pre-sterilising the ChargePoint Active and Passive product contact surfaces prior to docking the units together. To ensure a satisfactory level of bio-decontamination of the Active and Passive mating surfaces that are momentarily exposed to the environment prior to docking, a further step is introduced which involves exposing these surfaces to VHP (Vaporised Hydrogen Peroxide) within a sealed chamber prior to fully docking together.

Hardware:
ChargePoint BIO Pressure Rated Active and Passive
Pressure Rated SIP (Steam in Place) Passive
(Product contact materials: 316L, FKM or FFKM depending on process)
GMP Passive Cover
GMP Active Plug

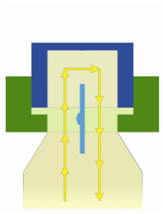
Applications:
Multiple batch charges

Note:
If product is sensitive to VHP, a pressure hold test must be performed on seals prior to VHP purge.

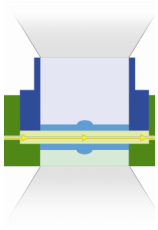
Operation Procedure



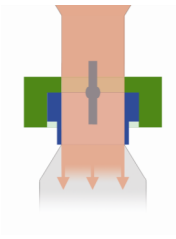
Sterilise Passive in Autoclave. Attach container to Passive and seal in bag within isolator.



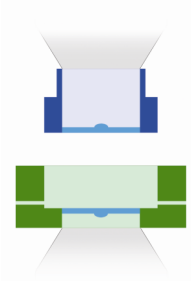
Sterilise Active in place with steam.



Dock Passive into the Active. Unlock the Passive to the 'BIO' position. Purge with VHP to BIO— decontaminate the previously exposed faces of the Active and Passive.



Open valve to transfer product.



Undock the Passive from the Active.

Passive Unit Preparation

A. Completed as per 1A (page 6)

Active Unit Preparation

A. Completed as per 1A (page 6)

Charging Operation

A The packaged container is transferred to the location where is to be charged into the process. Additional measures can now be introduced towards manufacturing higher levels of local area classification. If the room environment is not already manufactured to a class 100 or 10 thousand category, it is advisable to have some form of VLAF (vertical laminar air flow) or cross flow HEPA filtered air flow, passing across the Active valve locality. This should be in place prior to carrying out any ongoing steps.

B. The out bag sealing the container can now be removed followed by the removal of the GMP Passive Cover. If appropriate, t his should be carried out within the facility of the HEPA filtered airflow. Immediately after the Passive cover is removed, the Active valve is closed and the SIP cover is detached.

C. At this stage, both faces of the Active and Passive discs are exposed to the room environment. Although these surfaces do not have direct product contact , it is essential to minimalize the duration of exposure as there will be a variable level of disc to seat interface exposure.

D. The Passive is docked to the Active and locked fully in place. However the valve is not opened.

E. In order to remove any contaminate that potentially found the exposed surfaces in step C, these surfaces are now decontaminated. This is done by unlocking the Passive to an intermediate 'BIO' position for Bio-decontamination. An interlock mechanism prevents the Passive from being fully removed to a point where a chamber is achieved between the Active and Passive disc faces. The isolation valves on the BIO Active inlet and outlet connections are opened. At this point the void can now be purged with VHP for a pre-validated time period.

F. The VHP is removed from the void and the isolation points are closed.

G. The Passive is then fully locked to the Active once again.

H. Once docked and locked into place the Active valve is opened and the product transferred through into the process.

I. Having completed the transfer, the Active is closed and the Passive undocked. A suitable sterile wipe is used to wipe and remove the compressed product residue from the disc/deal interface.

J. Before the next charge a new pre-sterilised Passive should be used to dock to the Active and the VHP bio-decontamination carried out prior to product transfer.

LEVEL 2B: Sterilisation of ChargePoint valve Pre-Charge + Bio-decontamination Pre-charge + EXCEL cleaning Post-charge

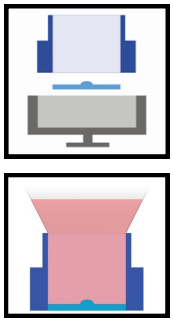
Overview:
This method involves pre-sterilising the ChargePoint Active and Passive product contact surfaces prior to docking the units together. To ensure a satisfactory level of bio-decontamination of the Active and Passive mating surfaces that are momentarily exposed to the environment prior to docking, a further step is introduced which involves exposing these surfaces to VHP (Vaporised Hydrogen Peroxide) within a sealed chamber prior to fully docking together. Once the product transfer has taken place, an 'EXCEL' cleaning cycle takes place to ensure a higher nanogram level of contained transfer.

Hardware:
ChargePoint BIO EXCEL Pressure Rated Active and Passive
Pressure Rated SIP (Steam in Place) Passive
(Product contact materials: 316L, FKM or FFKM depending on process)
GMP Passive Cover
GMP Active Plug

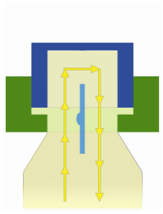
Applications:
Multiple batch charges

Note:
If product is sensitive to VHP, a pressure hold test must be performed on seals prior to VHP purge.

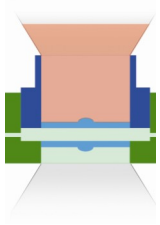
Operation Procedure



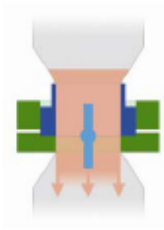
Sterilise Passive in Autoclave. Attach container to Passive and seal in bag within isolator.



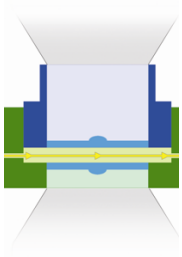
Sterilise Active in place with steam.



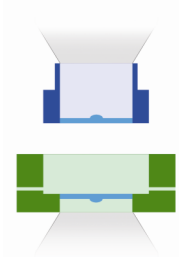
Dock Passive into the Active. Unlock the Passive to the 'BIO' position. Purge with VHP to BIO—decontaminate the previously exposed faces of the Active and Passive.



Open valve to transfer product.



Undock the Passive to the 'EXCEL' position. Purge with air and extract to clean the mating faces for High Containment.



Undock the Passive from the Active.

Passive Unit Preparation

A. Completed as per 1A (page 6)

Active Unit Preparation

A. Completed as per 1A (page 6)

Charging Operation

A-D. Completed as per 2A (page 11

E. Having completed the transfer, the Active is closed and the Passive undocked to an intermediate position for 'EXCEL' cleaning. An interlock mechanism prevents the Passive from being fully removed to a point where a chamber is achieved between the Active and Passive disc faces. At this point a purge and extraction process is carried out, removing traces of any particles that could potentially become airborne once the Active and Passive units are disengaged.

F. Once the EXCEL cleaning cycle has run for its allotted time, the interlock will be released so that the Passive can be disengaged from the Active.

G. A suitable sterile wipe is used to wipe and remove the compressed product residue from the disc/seal interface.

H. Before the next charge a new pre-sterilised Passive should be used to dock to the Active and the VHP bio-decontamination carried out prior to product transfer.

ABOUT CHARGEPOINT TECHNOLOGY

ChargePoint Technology are market leaders in the supply of containment valves and integrated material handling equipment for the Pharmaceutical, Chemical, Food and other process based industries.

Our most important goals are to create lasting partnerships by providing high quality and reliable products, coupled with outstanding customer service.

As a pioneer of split valve technology our consultative approach will provide the right technological solution, as well as delivering the lowest cost of ownership benefits by maximising yield, reliability, productivity and flexibility.

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