GEA engineering for a better world

2017 Portable Containment Equipment
BUCK® & Hicoflex®



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2 INTRODUCTION

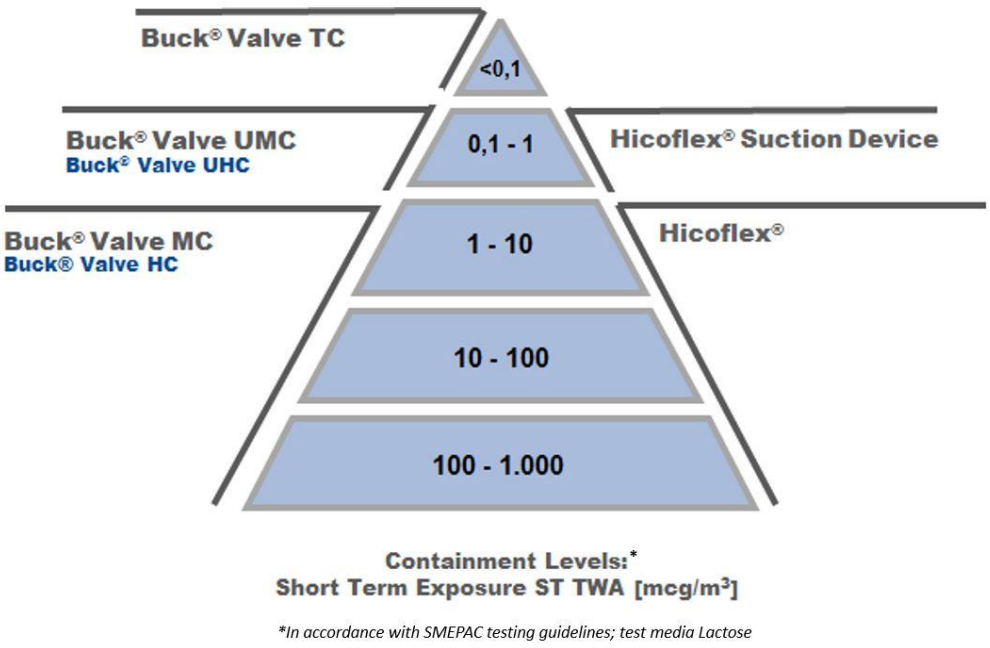
2.1 Containment

Containment issues are a vitally important aspect of solid dosage form production. Active Pharmaceutical ingredients (APIs) are becoming increasingly hazardous, with more than 50% of all new chemical entities (NCEs) being classified as potent (OEL <10 µg/m³). It is essential and often Law to protect operators from exposure to the product as well as prevent cross-contamination of other products manufactured in the same facility.

GEA has a long history of expertise and an unparalleled depth of experience in the field of containment and offer a wide range of technologies and equipment that improve and enhance the efficiency and performance of solid dosage form plants for the safe transfer of powders.

GEA does not only offer a comprehensive range of robust and compliant containment products, it also boasts unrivalled experience in identifying the most appropriate solution for your specific needs and a thorough understanding of containment risk analysis.

BUCK® is the market leading supplier of split butterfly valves and contained docking systems for the transfer of powders. The BUCK® range of containment products includes the Buck MC Valve utilising two identical passive halves and the unique Hicoflex® disposable containment system.



Attention:
The containment performance values (STTWA) of the valves are not directly comparable to the product OEL.

2.2 BUCK® MC valve

The BUCK® MC (modular containment) split butterfly valve builds on the proven design principles of the first generation of Buck split butterfly valves and offers a number of key additional features and benefits:

- Unique passive-to-passive valve design with a centralised actuation ring; the passive valves freely orientate, reducing operator docking error.
- Modular design to allow flexible and customized solutions for every requirement, built from standard components.
- Modular containment: with a 1–10 µg/m3 (STTWA) containment level offered as standard, the system is also available with an advanced air cleaning actuator to further improve containment levels down to <1 µg/m3 (STTWA).
- Simple maintenance: fewer component parts and more identical parts owing to the passive-to-passive design, reducing spare part inventory
- WIP, CIP and COP as standard
- Contained quick changeover of the contaminated valve core with working parts remaining on the station, allowing for extremely fast product changeover – fully complementing the Courtoy™ MODUL™ tablet press ECM containment concept.
- Robust docking: the new central actuation ring design and compensator device overcomes potential misalignment of the container and docking station.



Manual docking for discharging from a mill to an IBC with a BUCK® **MC** valve.



Automated docking for discharging into an IBC with a BUCK® **UMC** valve (with suction).

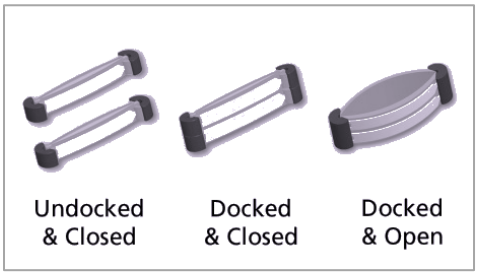
2.3 Hicoflex®

Hicoflex® (**Hi**gh **Co**ntainment **Flex**ible) was the first disposable high containment interface for dust free and safe transfer of solid dosage materials in the market. Since 2006 Hicoflex® has offered our worldwide client base the following advantages:

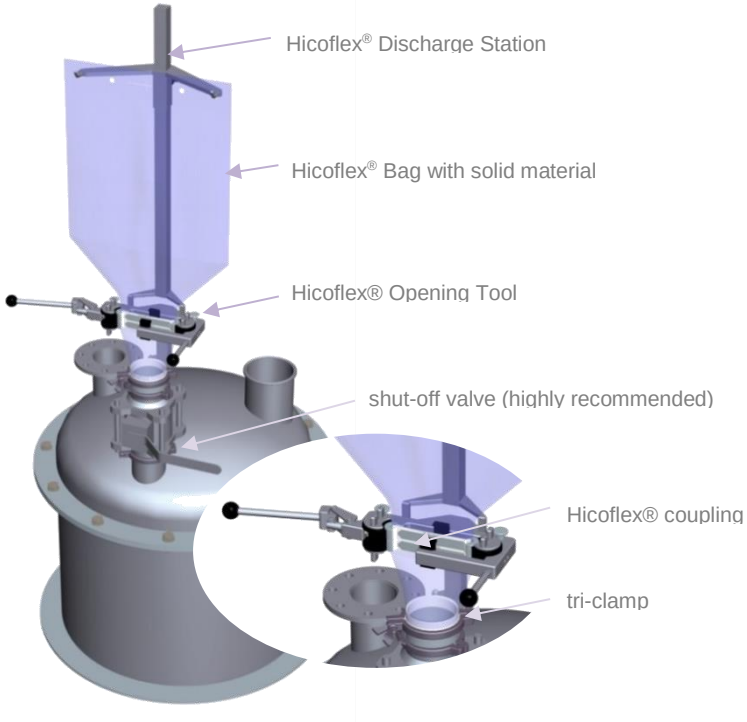
- Lightweight and easy for a single operator to handle
- Flexibility to allow poor-flowing materials to be manipulated out of the bag
- Disposable, so no cleaning or validation
- Low cost compared with solid transfer systems
- Full yield discharge
- No cross-contamination
- Instant high protection for operator and product
- Very fast installation
- Simple/fast materials handling
- Visual product transfer.

Functionality

The Hicoflex® disposable containment technology consists of two identical couplings that are joined together to seal the external faces, thus enabling closed transfer. The Hicoflex® disposable containment system is opened by applying a compression force to both ends to create an opening through which product transfers.



Each Hicoflex® coupling is either attached to both a disposable containment bag to transport material or to a disposable containment adapter that fits the inlet or outlet chute of the process to allow product transfer.



3 EQUIPMENT SPECIFICATION

3.1 BUCK® MC Valves

MC Lite Actuator Ring

The MC Lite Actuator Ring is a lightweight manually operated portable drive unit for the opening and closing of two Buck passive MC half valves together as one valve enabling contained material transfer. The actuator ring contains a manual locking mechanism to keep the two MC half valves locked together during operation. The opening and closing of the valve is done via the manual handle which is connected to the discs drive shaft. Alignment of the two passive valves during docking is achieved by the unique chamfer around the MC Lite Actuator Ring allowing self-centering of the two halves.

- Materials
  - non-product contact: Aluminium, Polyamide
- Release: Two sided



MC Half Valve



The MC Half Valve forms the basis for the Buck® MC docking system. It is the only part of the docking system which is in contact with the product. It consists of a steel housing, main body seal, disc seal and a butterfly disc fixed by bearings.

The MC Half Valve can be integrated in the Actuator Ring or directly mounted to the process unit or a container, bin or drum.

- Materials:
  - product contact metal parts: SS 1.4404 / 316L
  - non product contact metal parts: SS 1.4301 / 304
  - seal material: White EPDM
- Disc: Polished
- Tightness: vacuum - 0.2 bar (g), in closed position

Tri-Clamp Flange

This adapter piece has a mating flange according Buck Valve foot-print on one side and a Tri-Clamp flange on the other side. Once bolted to the MC Half Valve, the Half Valve can be easily connected to a number of process units or IBCs via the Tri-Clamp connection.

- Materials:
  - - product contact metal parts: SS 1.4404 / 316L
  - - fastener: SS 1.4301 / 304
  - - gasket: PTFE
- Type: O.D. (standard)

Note: The Tri-Clamp fastener and gasket are not included in the scope of supply, but can be quoted on request.

Manual Raise/Lower Assembly



The Manual Raise/Lower Assembly allows manual docking of two valve halves without the need for a mechanical lift. While one valve remains static, the second valve is manually raised or lowered to dock with the static valve. A good example is from an isolator outlet to a static IBC inlet valve. A flexible bellow allows for any required compensation for valve misalignment during the docking process.

The manual/ raise lower assembly is to be fixed to the process equipment and consists of a stainless steel support with handles on both sides for a comfortable handling, a flexible bellow and a connection Tri-Clamp flange.

An MC Actuator Ring or MC Lite Actuator Ring will be required to open and close the two valve halves.

- Materials:
  - product contact metal parts: SS 1.4404 / 316L
  - non product contact metal parts: SS 1.4301 / 304
  - bellow: White EPDM
  - gasket: PTFE
- Approx. Stroke: 110mm
- Working condition Bellow: ±50 mbar (g)
- Connection to the process unit: Tri-Clamp Flange

Note: The Tri-Clamp fastener and gasket are not included in the scope of supply, but can be quoted on request.

Wash-Hood with CIP Spray Balls & Wash Valve

The Wash Hood is directly mounted onto the MC half valve, typically an inlet valve. It includes an integrated wash valve and two CIP spray balls, for wetting down and cleaning of the docked valve and also comes with a drain in case it is mounted upside down.



The non-rotating CIP spray balls with a spray angle of approximately 360° will distribute the wash detergent in the product contact area. The lance provides effective cleaning of the contaminated surfaces of MC half valve and additional extended product contact areas such as bellows.

The cleaning can be started after locking and opening of the valve.

- Materials:
  - product contact parts: SS 1.4404 / 316L
- Connection:
  - for Detergent Supply Fix: ½" Tri-Clamp
  - for Drainage: 1" Tri-Clamp (DN100/150)
- Pressure: optimal: 2,5 bar
- Temperature Range: 5°C - 95°C

Wash MC half valve

The Wash Valve is constructed in a steel housing, with a special main body seal with chamfer, disc seal and a special "wash" disc with further chamfer fixed by bearings. This chamfer allows cleaning of the opposed docked MC half valve. The housing has mounting holes to allow mounting on different attachments

- Materials:
  - product contact metal parts: SS 1.4404 / 316L
  - non product contact metal parts: SS 1.4301 / 304
  - seal material: White EPDM
- Disc: polished, with chamfer
- Body seal: with chamfer
- Tightness: dust tight

Wash-Hood with adjustable Lance & Wash Valve

The Wash Hood is directly mounted onto the MC half valve, typically an inlet valve. It includes an integrated wash valve, CIP spray ball, extractable wash lance with rotary spray nozzle for wetting down and cleaning of the docked valve and process equipment internals and also comes with a drain in case it is mounted upside down.



The non-rotating CIP spray ball with a spray angle of approximately 360° will distribute the wash detergent in the product contact area. The lance provides effective cleaning of the contaminated surfaces of MC half valve and additional extended product contact areas such as bellows.
The cleaning can be started after locking and opening of the valve.

- Materials:
  - product contact parts: SS 1.4404 / 316L
- Connection:
  - for Detergent Supply Fix: ½” Tri-Clamp
  - for Detergent Supply Lance: ¾” Tri-Clamp
  - for Drainage: 1" Tri-Clamp (DN100/150)
- Pressure: Optimal: 2,5 bar
- Temperature Range: 5°C - 95°C

Wash MC half valve

The Wash Valve is constructed in a steel housing, with a special main body seal with chamfer, disc seal and a special “wash” disc with further chamfer fixed by bearings. This chamfer allows cleaning of the opposed docked MC half valve. The housing has mounting holes to allow mounting on different attachments

- Materials:
  - product contact metal parts: SS 1.4404 / 316L
  - non product contact metal parts: SS 1.4301 / 304
  - seal material: White EPDM
- Disc: polished, with chamfer
- Body seal: with chamfer
- Tightness: dust tight

Drain Pot with Wash Valve

The Wash Pot with Drain only is typically connected to the outlet valve of a process unit during CIP/WIP procedure. It is integrated with a wash valve to ensure proper wetting down of all possible product contact parts of the MC half valve. The Wash Pot is supplied with handles for easy handling.

The cleaning can be started after locking and opening of the valve.



The Wash Pot will be supplied with a Tri-Clamp connection to use as a drainage for wash water.

- Materials:
  - product contact parts: SS 1.4404 / 316L
- Connection:
  - for Drainage: 1" Tri-Clamp (DN100/150)
- Temperature Range: 5°C - 95°C

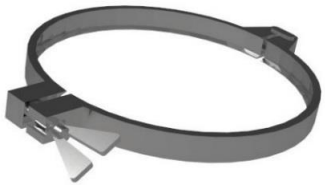
Wash MC half valve

The Wash Valve is constructed in a steel housing, with a special main body seal with chamfer, disc seal and a special “wash” disc with further chamfer fixed by bearings. This chamfer allows cleaning of the opposed docked MC half valve. The housing has mounting holes to allow mounting on different attachments

- Materials:
  - product contact metal parts: SS 1.4404 / 316L
  - non product contact metal parts: SS 1.4301 / 304
  - seal material: White EPDM
- Disc: polished, with chamfer
- Body seal: with chamfer
- Tightness: dust tight

3.2 Buck Valve Accessories

Tri-Clamp Fastener & Gasket



The Tri-Clamp fastener is to connect the MC half valves Tri-Clamp flange to the process interface.

- Materials:
  - non product contact metal parts: SS 1.4301 / 304
  - seal Material PTFE
- Seal type: O.D. (standard)

Opening Tool



The opening tool is used to manually open the MC half valve without the use of the actuator ring. It is also used for mounting and removing of the disc during maintenance work.

- Material: SS 1.4301 / 304
- Knob: Duroplastic

Removal Tool



The Removal Tool affixes itself to the MC half valve and can easily lift the MC half valve from its location to be taken away for cleaning and servicing.

- Material: SS 1.4301 / 304

Vacuum Removal Tool



The Vacuum Removal Tool is used to remove and insert the MC half valve from a one sided release fixed actuator collar.

Protective Cover

The Protective Cover protects the MC half valve when undocked from limited, external influences. The protection cover can be easily fitted and removed from the MC half valve by hand.

- Material: Silicon 60 Shore A
- Colour: red RAL 3000

Maintenance Tool Box

This Tool-Box includes special keys and tools to maintain the MC Buck® Valves according to the Buck MC Manual.

It includes following items:

- Socket wrench (7mm)
  to screw and unscrew the locking device to/from the actuator ring
- socket wrench (13mm)
  to adjust/ fix the sensors on the pneumatic valves
- Disc seal installer
  to lips the disc seal into the disc
- Lubricant seal
  to grease the body seal and bearing shell



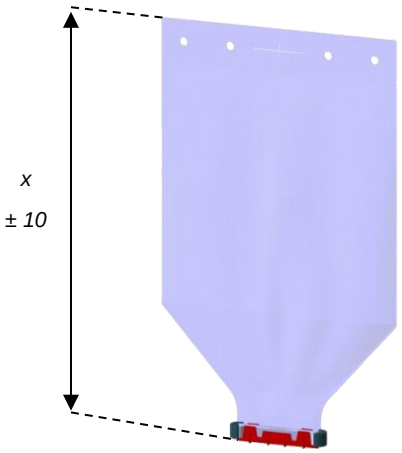
3.3 Hicoflex® Consumables

Hicoflex® Charge Bag

The Hicoflex® Charge Bag comprises a coupling and a PE bag. A handle is incorporated for easy transportation to hang the bag up during discharge.

Following sizes are available:

Part No.	Description	x (approx.)
203155	Hicoflex® Charge Bag 1L	400 mm height
203156	Hicoflex® Charge Bag 5L	480 mm height
203157	Hicoflex® Charge Bag 10L	565 mm height
203158	Hicoflex® Charge Bag 15L	635 mm height
203159	Hicoflex® Charge Bag 25L	775 mm height
203160	Hicoflex® Charge Bag 50L	930 mm height

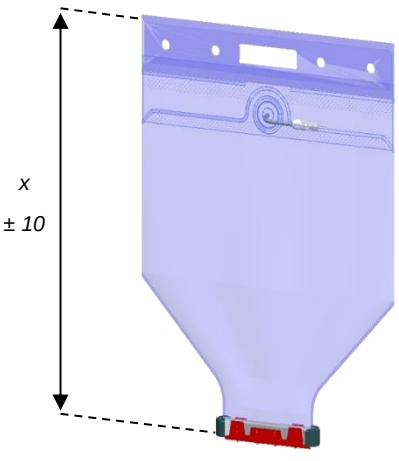


Hicoflex® Charge Bag with flush connector

The Hicoflex® Charge Bag with flush connector ensures a full yield discharge because of an internal rinsing device.

Following sizes are available:

Part No.	Description	x (approx.)
203161	Hicoflex® Charge Bag 5L with flush connector	540 mm height
203162	Hicoflex® Charge Bag 10L with flush connector	625 mm height
203163	Hicoflex® Charge Bag 15L with flush connector	695 mm height
203164	Hicoflex® Charge Bag 25L with flush connector	835 mm height
203165	Hicoflex® Charge Bag 50L with flush connector	990 mm height



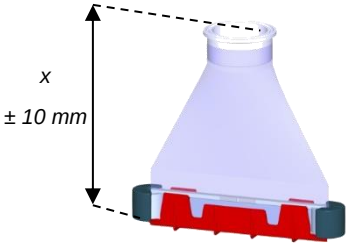
Hicoflex® Adaptor

The Hicoflex® Adaptor is used to connect Hicoflex® Bags to the processor. This adaptor is made from a Hicoflex® coupling and a standard tri-clamp connector.

Hicoflex® Adaptors are available with tri-clamp 2”, 4” and 6” according O.D. (BS 4825).

The following sizes are available:

Part No.	Description	x (approx.)
203166	Hicoflex® Adaptor 2” (DN 50)	185 mm height
203167	Hicoflex® Adaptor 4” (DN 100)	175 mm height
203168	Hicoflex® Adaptor 6” (DN 150)	170 mm height

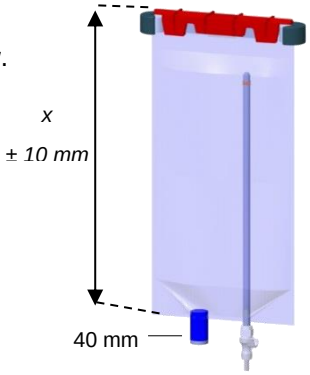


Hicoflex® Spray Bag with drain

The Hicoflex® Spray Bag with drain is delivered with a spray nozzle that's suitable for rinsing the adaptors and connectors inside the charging point. Wetting the contaminated surfaces prevents the escape of potent or toxic dust before removal.

Additionally a drain enables the rinsing/wetting of the connectors from below.

Part No.	Description	x (approx.)
203169	Hicoflex® Spray Bag with drain	400 mm height

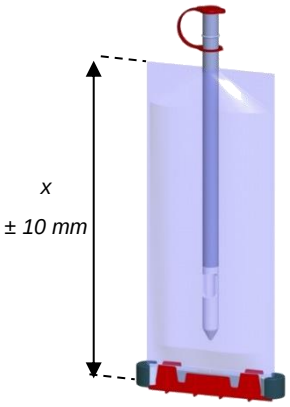


Hicoflex® Sample Bag 400

The Hicoflex® Sample Bag 400 is a hose-shaped bag with a sampling device. After docking the bag, a sample can be taken in a fully contained way. We highly recommend the use of a Hicoflex® Opening Tool Pistol to take product samples.

The approx. volume of sample that can be taken is 5ml.

Part No.	Description	x (approx.)
203170	Hicoflex® Sample Bag 400	400 mm height

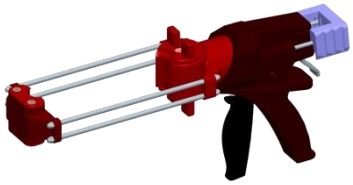


3.4 Hicoflex® System Components

Hicoflex® Opening Tool Pistol

The Opening Tool Pistol is suitable for manual use, such as taking samples from a Hicoflex® Charge Bag and a Hicoflex® Sample Bag 400.

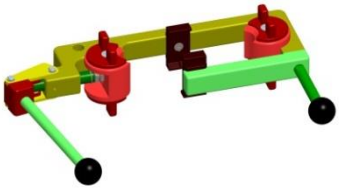
Part No.	Description
7.200.1001	Hicoflex® Opening Tool Pistol



Hicoflex® Opening Tool with mechanical stop

The manually operated Hicoflex® Opening Tool, which is attached to our Hicoflex® Stations and Trolleys, can also be supplied and installed separately.

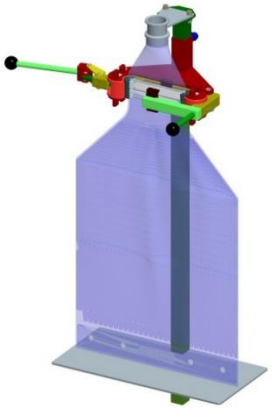
Part No.	Description
159033	Hicoflex® Opening Tool with mech. stop



Hicoflex® Charge Station

To charge product into a Hicoflex® Bag, we recommend the use of our stainless steel Hicoflex® Charge Station, which comes supplied with an adjustable support platform for the bags.

Part No.	Description
209883	Hicoflex® Charge Station 2“ (DN 50)
209884	Hicoflex® Charge Station 4“ (DN 100)
209885	Hicoflex® Charge Station 6“ (DN 150)



Hicoflex® Discharge Station

The stainless steel Hicoflex® Discharge Station features a height adjustable bag support, facilitating product transfer from the Hicoflex® Bags.

Part No.	Description
209880	Hicoflex® Discharge Station 2“ (DN 50)
209881	Hicoflex® Discharge Station 4“ (DN 100)
209882	Hicoflex® Discharge Station 6“ (DN 150)



Hicoflex® Trolley 4”

The Hicoflex® Trolley is a mobile stainless steel frame with a 4” tri-clamp for the manual charging of Hicoflex® Bags.

Part No.	Description
0157541	Hicoflex® Trolley 4” (DN 100)



Hicoflex® Suction Device 4”

To reduce surface contamination, the Hicoflex® Suction Device can be used to extract airborne particles and dust, down to a level of <1 µg/m³, during dedocking.

Part No.	Description
193550	Hicoflex® Suction Device 4“ (DN 100)



Hicoflex® Hicobox

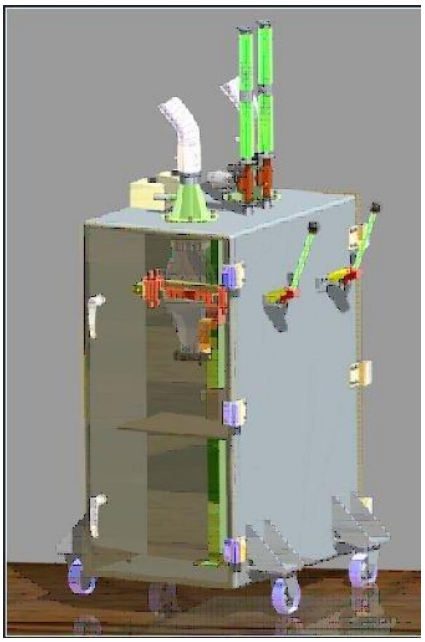
The Hicobox is a unit for use with the Hicoflex® technology in applications where the process area is working under a lower pressure than the surrounding area. Without using the Hicobox system, the flexible bags can collapse due to the negative differential pressure, which in turn stops the material (tablet) flow into the Hicoflex® Bag.

The Hicobox completely encapsulates the Hicoflex® Adapter, Hicoflex® Bag and the Hicoflex® Pneumatic Opening Tool and is put under the same pressure as that in the process area. This ensures that a differential pressure is fully prevented and a material flow (tablets) is guaranteed.

The Hicobox unit comprises a mobile cabinet with single or dual chambers, each suitable for housing a 25 litre Hicoflex® Bag. The dual chamber Hicobox means that when the first Hicoflex® Bag is full, the production can be switched to the second Hicoflex® Bag without halting production.

As the unit is mobile, it can easily be moved around the room to provide access to other areas.

Part No.	Description
TBC	Hicoflex® Hicobox Single Chamber
TBC	Hicoflex® Hicobox Dual Chamber



4 TECHNICAL DATA

4.1 Buck Valve Materials

- Product contact metal parts are available in:
  - Stainless Steel 1.4404 / 316L
- Non product contact metal parts are made of:
  - Stainless Steel 1.4301 / 304 (or higher)
- Surface roughness for metal parts (none coated) is:
  - Product contact parts: Ra < 0.5µm
  - Non product contact parts: Ra < 1.6µm
- Surface qualities:
  - mechanically polished, welds ground and polished to parent metal
- Elastomers are available in:
  - EPDM white

All product contacted elastomers used for the BUCK® MC valve fulfil the FDA requirement

4.2 Hicoflex® Materials

The standard material used for Hicoflex® Consumables are:

Description	Material	Hicoflex® Consumables
Film (product contact part)	LDPE and LLDPE (Low Density Polyethylene and Linear Low Density Polyethylene)	Hicoflex® Charge Bag Hicoflex® Adaptor Hicoflex® Spray Bag Hicoflex® Sample Bag
Coupling (non product contact parts)	Hard components POM white (Polyoxymethylene)	
Coupling (product contact parts)	Soft components TPE white (Thermoplastic elastomer)	
Joint caps (non product contact parts)	PEEK (Polyetheretherketone)	
Safety cap (non product contact parts)	PS (Polystyrene)	
Handle (non product contact parts)	PE (Polyethylene) or HDPE (High Density Polyethylene)	
Tri-clamp / tube (product contact parts)	PE (Polyethylene) or HDPE (High Density Polyethylene)	

All Hicoflex® parts in contact with the product are FDA-compliant.

The standard material used for the Hicoflex® System Components are:

Description	Material	Hicoflex® System Components
Metal part (non product contact parts)	Stainless steel (min. 1.4301 / ANSI 304)	Hicoflex® Opening Tool Hicoflex® Charge Station Hicoflex® Discharge Station Hicoflex® Trolley
Metal parts (product contact parts)	1.4401/ANSI 316 L	
Plastic parts (non product contact parts)	POM black (Polyoxymethylene)	
Plastic parts (non product contact parts)	PUR (Polyurethan), coated (FDA)	Hicoflex® Suction Device

4.3 Heights and Weights

Height in mm	DN100	DN150
BUCK® MC half valve	45	45
BUCK® MC half valve, tri-clamp flange	80	80
BUCK® MC Lite actuator ring	90	90

Weight in kg	DN100	DN150
BUCK® MC MC half valve	3.0	4.8
BUCK® MC MC half valve, tri-clamp flange	4.6	6.9
BUCK® MC Lite actuator ring	3.2	3.9

4.4 Temperature and Pressure Range

- Temperature range for the actuator ring: 0°C to 60°C
- Temperature range for the MC half valve in operation: 0°C to 60°C
- Temperature range for the MC half valve during storage: 0°C to 90°C
- Discharge and storage of powder at atmospheric pressure
- Tightness MC half valve in closed position with seals in new and clean condition: vacuum - 0.2 bar(g)

Hicoflex® Consumables are made solely from plastics like POM, thermoplastic elastomers and LDPE film for which reason the temperature range in which it can be operated is limited.

Hicoflex® Consumables shall not be held in environments or handle solids materials below temperatures of -20°C or exceed temperature of to +50°C.

Neither positive nor negative pressure can be applied to Hicoflex® Consumables. A special device developed by us to equalise the different pressure levels is available on request.

For storage of empty bags the following is recommended:

- Maintain storage in dry conditions and keep storage temperature between 15°C and 35°C at a humidity of 45% RH – 75% RH
- Protect the Hicoflex® Consumables from UV radiation
- Prior to usage of the Hicoflex® Consumables, keep it for 48 hours under processing conditions in order to acclimatize

4.5 BUCK MC Valve ATEX 94/9/EG

MC portable actuator rings are manually operated with no electrical device. Therefore MC portable actuator rings are not subject of ATEX.

Explosion protection "Avoidance of effective ignition sources"

BUCK® valves with white EPDM seals can be safely used in Category D (Zone 21/22) areas as long as there is no pneumatic conveying and the product drops from a height less than 5 meters.

The interaction of solids (dust / granulate) and non-conductive elastomers can generate electrostatic "brush discharges". According to TRBS 2153 and CLC/TR50404 and IEC/TS 60079-32-1 these "brush discharges" cannot ignite solids (dust / granulate).

Electrostatic "propagation brush discharges" can ignite solids (dust / granulate). However, "propagation brush discharges" can be excluded in this context, when there is no pneumatically conveying and when the product drops from a height less than 5 meters (TRBS 2153 and CLC/TR50404 and IEC/TS 60079-32-1; "GPS Code of Practice: Ignition source due to static electricity, Dr. M. Glor SWISSI" (15.10.2008)).

The characteristics of the handled active solids material (powder) is based on the following:

Minimum ignition energy with/without additional inductivity (MIE)	≥ 1 mJ
Specific powder flow resistance	arbitrary (Ωm)
Ability of spontaneous degradation	none
Reaction with water or flammable solvents	none

For Category G (Zone 1 or 2 inside and/or outside) the valve can be equipped with antistatic, dissipative seals, black. In addition for Zone 0 “inertisation (e.g.N2) is necessary.

All Buck Valve components and accessories meet the appropriate European standards

Maintenance
Damaged or worn elastomeric parts have to be replaced according to maintenance instructions.

Various
The valve system may not to be exposed to flames or hot gases.
Possibly effects of exothermic reaction including self-ignition of processed material has to be a part of user’s risk assessment.

4.6 Hicoflex® ATEX 94/9/EG

Explosion protection "Avoidance of effective ignition sources"

Non-conductive / dissipative plastic bags can generate by interaction with solids / (dust / granular) electrostatic "brush discharges".

According to TRBS 2153 and CLC/TR50404 these "brush discharges" cannot ignite solids (dust / granular); however, this is not significant for hybrid mixtures.

Electrostatic "propagation brush discharges" can ignite solids (dust / granular); however, "propagation brush discharges" can be excluded in this context, as long as there is no pneumatically conveying and as far as the product drops from a height less than 5 meters (TRBS 2153 and CLC/TR50404; "GPS Code of Practice: Ignition source due to static electricity, Dr. M. Glor SWISSI" (15.10.2008)).

The characteristics of the handled active solids material (powder) is based on the following:

Minimum ignition energy with/without additional inductivity (MIE)	≥ 1 mJ
Specific powder flow resistance	arbitrary (Ωm)
Ability of spontaneous degradation	none
Reaction with water or flammable solvents	none

4.7 Documentation

We supply one hard copy of the BUCK® valve documentation data book and one electronic version on CD of following documents:

- Operating and maintenance instructions
- Part list
- Dimension drawings
- Certificate of compliance with the order (EN 10204 2.2) for all product contacted metal parts
- FDA certificate of conformity for all product contacted seal materials

4.8 Marking

The valve will have acid etched marking with following information:

- CE Marking (where necessary)
- Name and address of manufacturer
- ID number for each valve