CONTAINMENT EXPERTS.

High containment valves and disposable containment solutions for the pharmaceutical industry.

GEA Engineering for a better world.

GEA.com

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High containment valves and disposable containment solutions for the pharmaceutical industry.

GEA has a long history of expertise in the field of containment. The company not only offers a comprehensive range of robust and compliant containment products, it also boasts unrivaled experience in identifying the most appropriate solution and a thorough understanding of containment risk analysis.

Our distinctive specialization lies in the integration of BUCK® containment technology into complete solutions for pharmaceutical solid dosage form facilities.

Having developed the original pharmaceutical split butterfly valve, the company supplies stateof-the-art BUCK® high containment technology and Hicoflex® disposable containment bags and equipment that improve and enhance the safety, efficiency and performance of powder transfers in solid dosage form facilities.

With thousands of global implementations and 20 years of experience, GEA has been actively involved in many powder containment Communities of Practice, including the development of ISPE's SMEPAC guidelines to evaluate containment equipment and the latest risk-based approach to the selection of containment equipment.

BUCK® VALVE TECHNOLOGY.

An important feature of the GEA IBC is the high containment split butterfly valve.

The BUCK® MC Lite is the lightest split butterfly valve for the contained transfer of highly potent solid dosage products.

The BUCK® MC containment valve offers improved containment levels for a variety of applications. The valves can be fitted to the IBC inlet for contained charging or an invertible design allows charging through the outlet valve.

BUCK® MC split butterfly valves offer a modular, off-the-shelf solution for a variety of powder handling needs. As a successor to the BUCK® HC valve, this second-generation split butterfly valve's unique design facilitates fast product changeovers through make-and-break connections.

For rapid implementation and a low initial investment, or when a single-use method is required, GEA offers the Hicoflex® disposable bag system as an alternative or additional interface (featuring a manually operated transfer interface and bag volumes of up to 50 L).

Also available, the BUCK® MC Lite DN100/150 is the lightest split butterfly valve for the contained transfer of highly potent solid dosage products and is compatible with existing BUCK® MC half valves. GEA has succeeded in making the actuator ring even more compact and lightweight (just 3.3 kg), which makes the entire unit easier to handle and implement.

Offering free orientation during docking and fast product changeovers, the MC Lite is designed to be portable and can be effortlessly moved from station to station. It is also simple to operate, disassemble and maintain.

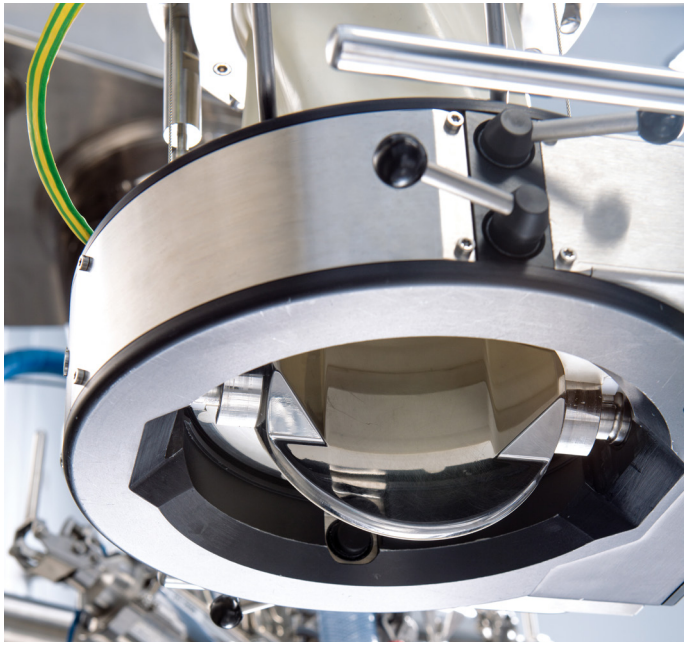
Competitively priced, BUCK® valves are fully GMP-compliant, offer robust, free-oriented docking, a dust- and contamination-free interface, and quick and easy maintenance. The portfolio includes a wide range of smart standard products, ranging from manually operated mobile systems up to fully automatic pneumatic assemblies, all of which can be configured by the company's engineers to meet specific requirements.

Smaller sizes can be ready for dispatch in 4 weeks, whereas larger standard sizes require slightly longer lead times (10 weeks), depending on configuration and number of valves.

BUCK® Valve Technology.

Features of the BUCK® MC Split Butterfly Valve.

- Unique passive-to-passive valve design with a centralized actuation ring; the passive valves freely orientate through 180°, making docking an easy process
- Both passive halves are driven simultaneously, improving the seal between the two valve faces
- 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: the passive-to-passive design means fewer component parts and more identical parts, reducing spare part inventory
- WIP, CIP and COP as standard
- With working parts remaining on the station, rapid removal of the contaminated valve core enables quick and contained product changeovers
- Robust docking: the new central actuation ring design and compensator device overcomes potential misalignment of the container and docking station.

Unlike many single-component providers, GEA is the only company that can supply entire contained material handling solutions that can be used to dock several vessels within the same facility.

This cost-effective and flexible system enables off-line cleaning without interrupting production, ensuring high productivity and reduced downtime.

HICOFLEX® DISPOSABLE CONTAINMENT SOLUTIONS.

Disposable, low-cost high containment materials handling.

The Hicoflex® disposable containment system has been designed to provide a high containment docking solution between the product handling bag and the process. The system is simple, effective and provides a safe working environment for a minimal investment.

Flexible and transparent disposable bags provide a number of benefits compared with solid containers for handling small quantities of material in a production or R&D facility.

Hicoflex® Disposable Containment Solutions.

Benefits include the following:

- visual product transfer
- lightweight and easy for a single operator to handle
- disposable, so no cleaning or validation
- low cost compared with solid transfer systems
- bags can be manipulated to ensure high yield discharge, even with poorly flowing materials
- no cross-contamination
- instant protection for operator and product
- very fast installation
- simple/fast materials handling.

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

The Hicoflex® is attached to both a disposable containment bag (from 1–50 L) to transport material and to a disposable containment adapter that fits the inlet or outlet chute of the process to allow product transfer.

With containment performance from 1–10 µg/m³ (STTWA) as standard, and an optional extraction shroud to further improve containment levels down to <1 µg/m³ (STTWA), the system is more than suitable for both active pharmaceutical ingredient (API) and biotech manufacture, as well as secondary solid dosage production.

Whatever your application, from charging a reactor or tablet press to discharging an isolator or process unit, to the fully contained transfer of hazardous materials, we have a solution that fits your needs.

Hicoflex® Hicobox

The Hicobox unit has been designed for applications in which the process environment operates at a lower working pressure than the surrounding area. In such situations, without a Hicobox in place, the flexible bags can collapse as a result of the negative differential pressure. This, in turn, prevents material (tablets) from flowing 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 the process area. This eliminates the pressure differential and guarantees material flow.

The Hicobox unit comprises a mobile cabinet with one or two chambers, each of which can accommodate a 25 L Hicoflex® Bag.

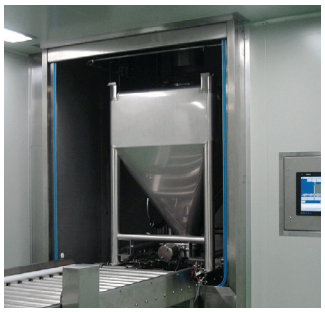
The dual chamber Hicobox means that when the first Hicoflex® Bag is full, production can be switched to the second one without halting the process, making it ideal for use with continuous processes. And, as the unit is mobile, it can easily be moved around the room to provide access to other areas.

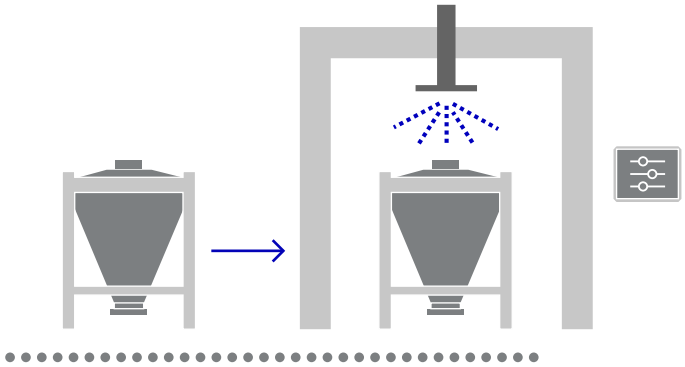
Hicoflex® disposable containment bag and the Hicoflex® Pneumatic Opening Tool.

Hicoflex® Hicobox.

WASHING.

As cleanliness is paramount in pharmaceutical manufacturing, an important feature of any IBC system is the ability to wash containers to a consistent, repeatable standard, both externally and internally.





IBC Washing

GEA supplies simple-yet-contained wash systems that ensure operator safety during cleaning. We also provide wash solution preparation systems and process control solutions to allow full validation of the washing system.

Your Washing Solution

It is critical to establish an appropriate cleaning philosophy for any new facility. Depending on the products, processes and production demands, cleaning should be thought of as an integrated part of the materials handling system and not looked at in isolation.

A multi-product plant may require quick changeovers, whereas product-dedicated facilities might adopt a clean-in-place (CIP) approach. When handling hazardous or toxic materials, CIP may be the preferred option, particularly if it can be combined with a contained rapid changeover solution.

Washing.

Our range includes

- mobile CIP/WIP units
- clean-off-line designs
- internal wash systems
- Moduwash container washing systems
- automated container washing systems
- IBC Halo washing technology.

GEA supplies simple-yet-contained wash systems that ensure operator safety during cleaning. We also provide wash solution preparation systems and process control solutions to allow full validation of the washing system.

Clean-in-Place (CIP)

An important feature of any containment system is preventing operator intervention. All GEA IBCs are designed to be CIP-compatible with our range of wash stations. The passive valves are mounted on the inlet and outlet of the IBC in a manner that allows full CIP without removal. For truly contained processing, however, rectangular IBCs are recommended. Round IBCs fitted with blending baffles cannot be cleaned-in-place. Naturally, both the Prism and the Vibroflow have also been designed to accommodate full CIP solutions.

IBC Wash Systems.

An extensive selection of IBC wash systems has been created to suit the diverse needs of the market — and to minimize production downtime — ranging from simple manual wash systems to fully automatic washing, drying and cooling booths.

GEA provides a range of IBC wash systems, from simple cleaning devices — for filling and discharge stations, containers and charge vessels — to mobile washing units, and from modular container wash systems to completely contained and automated wash stations, ensuring that water usage is minimized and systems are environmentally friendly.

Washing.

BUCK® Containment Valve Washing
Although it is important to handle and transfer powders in a contained way to prevent operator exposure, it is equally important to be able to wash the IBC and the containment valves in place without the need for operator intervention to strip and clean the half valve.

Any system that relies on the operator to remove a contaminated half valve for cleaning will directly expose the operator to the product. All IBCs and their half valves are designed to be fully cleaned-in-place within the wash station. CIP of the BUCK® half valve is achieved using the BUCK Wash System.

Further information
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