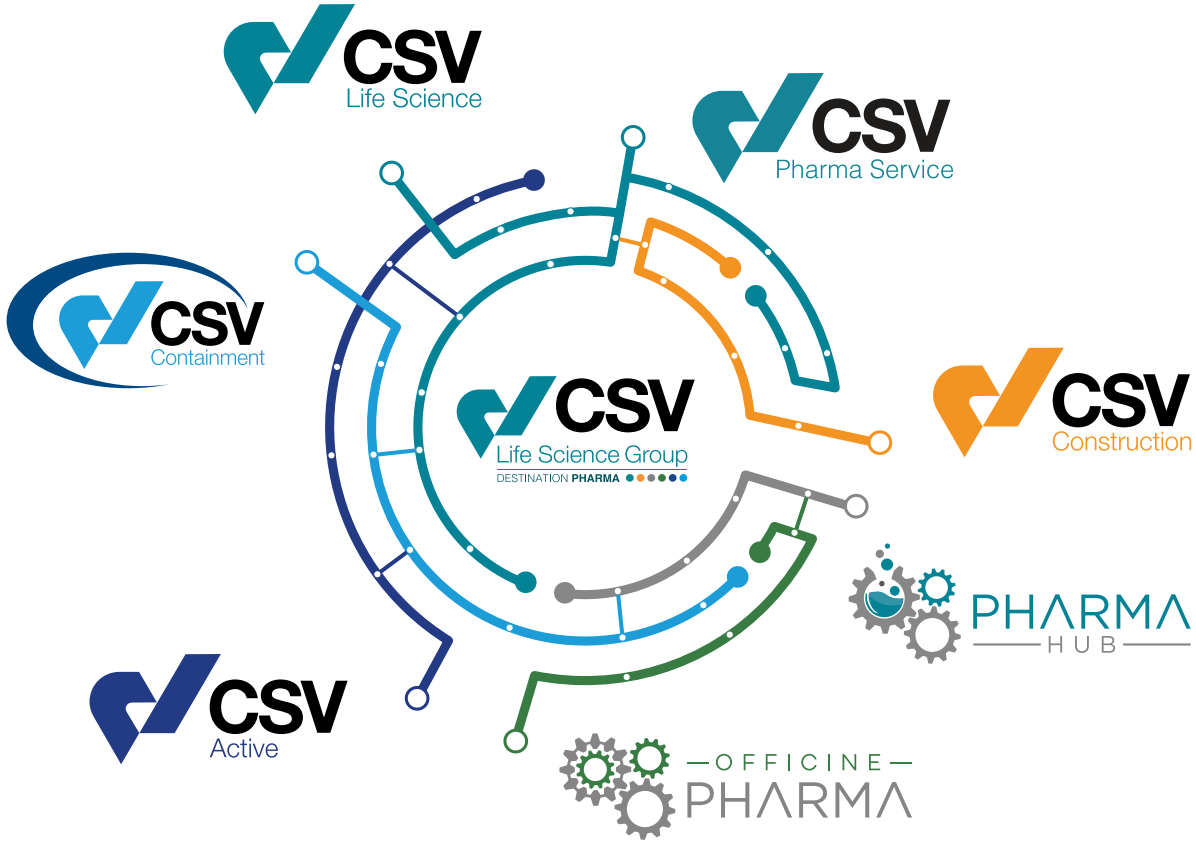
CSV Containment



Engineering CQV Services
Construction
Process Equipment Supply
Equipment Manufacturing
Api Trading
Containment Solutions

CSV Life Science Group since its foundation in 1998 has put the passion for work and the care for people at the core of its growing values.

Today the Group has become a multidisciplinary company with highly skilled team that can support you for comprehensive project approach with focus on strategic services and supply for the **international pharmaceutical market.**

Our Vision

We bring our passionate approach to humanity into the pharmaceutical market.
We face the industry's challenges by placing quality of life at the center.

Our Mission

We want to grow with our clients realizing custom-made solutions for the pharmaceutical world.
We focus on the human factor and on the value of its uniqueness.

CSV Life Science Group
DESTINATION PHARMA

ITALIAN OFFICES

MILAN
Registered office
and technical office

PARMA
GMP services
technical office

FIRENZE
GMP services
technical office

FORMIA
Technical office

ANAGNI
Mechanical workshop

LATINA
Engineering and GMP services

ALESSANDRIA
Clean rooms, Isolator assembling

CSV Life Science Ibérica

CSV Ελλάς

INTERNATIONAL OFFICES

SPAIN

GREECE

LOCAL REPRESENTATIVES

- Austria
- Brazil
- Canada
- Czech Republic
- Egypt
- France
- Germany
- Greece
- Ireland
- Poland
- Saudi Arabia
- Scandinavia
- Slovakia
- South Africa
- Switzerland
- Turkey
- United Kingdom
- United States

PRODUCT FAMILIES

Isolation Technology

Drum Iris Technology

D I T®

iris Mousehole Cleanroom Solution

Big Bag Solutions

iris BIBO™ Bag in / Bag out Automatic Drum Operations

Flexible Isolators

Disposable Bags

T-ONEBAG™ Single Use Transfer

T-ONEBAGbio™ Single Use Transfer

MIX-ONEBAG™ Single Use Fluid Mixer

Continuous Liners & Twin Tie® Systems

TWIN TIE®

API MANUFACTURING

Twenty-five years of experience in process engineering for **HPAPI** synthesis have led us to better understand the needs of production operators.
Such know-how drives the design of our isolators, enhancing integration with reactors and general production equipment by facilitating related loading and unloading steps.

KEY BENEFITS:

- Isolators suitable for ATEX processes and environments (up to OEB 5).
- Chambers in AISI 316L and C-22 Hastelloy when aggressive solvents shall be handled.

FINISHED PHARMACEUTICAL FORMS

CSV Containment presents its state-of-the-art **multiple chambers isolators**, to allow the safe management of up to OEB 6 contained processes.

KEY BENEFITS:

- Full pharma grade custom design to fit client and application requirements/ needs, with a special focus to meet the most demanding requirements.
- Comfortable docking of both small containers and large BINs through High Containment Transfer Valves.
- Easy integration with production equipment like ovens, micronizers, mills, and reactors.

POLYCARBONATE ISOLATORS

An ideal solution for **laboratories.**

KEY BENEFITS:

- Optimum visibility for operators thanks to **complete transparency** of all its parts
- Improved ergonomics with the main rounded corners walls
- Fast track delivery
- Easy to clean

Available in different materials, **both antistatic and non-antistatic**:

- Polycarbonate
- PMMA
- PEG
- PVDF

DIT ® GLOVE BOXES

- Full CFR 21 Part 11 control system, with premium brand SCADA platform, for isolator control and interfacing with company systems.
- Portable WIP system for decontamination of internal surfaces and effluent recovery.
- Masterclass patented **DIT®** for automatic docking of multiple-diameter drums when a high volume of product needs to be quickly handled.
- The **DIT®** can dock drums with diameters from 50 to 550 mm.
- Customized shapes and sizes are possible to fit existing reactors and their constraints.
- Fully automated system for contained drum handling.

D I T®

- Patented **DIT®** (Drum Iris Technology) technology for automatic docking of multi-diameter drums.

DIT ® GLOVE BAGS

Flexible isolators are cost-effective and quick to implement solutions for your **OEB 4 and OEB 5** containment needs. In passive configuration or integrated with a device to maintain internal volumes under negative pressure, they allow existing equipment to be quickly upgraded to meet production requirements of High Potent Products, even when special or inert atmospheres are necessary.

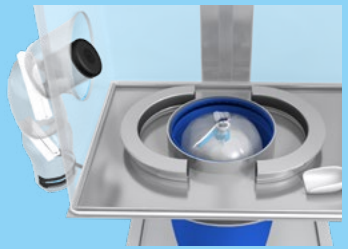
The custom design perfectly meets customers' specific needs and allows safe, effective, and operator-friendly use through improved ergonomics. All supplies are codified for easy supply of spare parts and disposable parts over the years. Every dissipative film used has documentation certifying its **compliance with EU and US pharmacopoeia.**

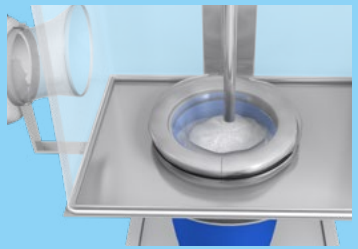
Automatic Iris Bag In Bag Out Drum Transfer Containment

CSV Containment has developed the **Iris BIBO** Automatic Drum Transfer Containment System, an advanced solution for the safe and efficient pneumatic transfer of powders from drums using the **Bag-In/Bag-Out** (BIBO) system.

It is compatible with **multiple drum sizes** and system configurations, ensuring flexibility across applications. A pneumatic lifting system enhances ergonomics and simplifies handling, while integrated features support clean, controlled workflows.

This system automates critical steps, improving containment and reducing risk. It combines **DIT®** Iris Diaphragm technology with an **automatic bag locking mechanism to create a double containment barrier** that is maintained during drum insertion and removal to prevent contamination of the drum.





Automatic Iris Bag In Bag Out Drum Sampling Containment

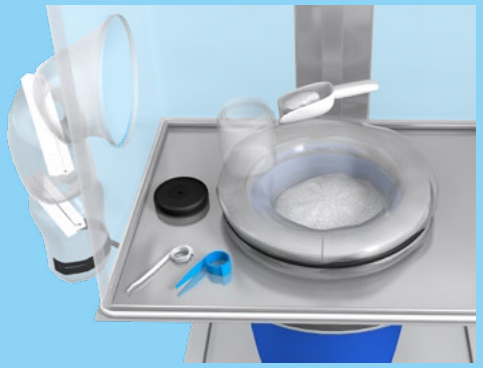
The CSV Containment Iris **BIBO Automatic Drum Sampler** is designed to ensure safe, reliable and compliant drum sampling in high-containment pharmaceutical environments. Drum sampling is a critical quality control step which often involves potent or hazardous materials.

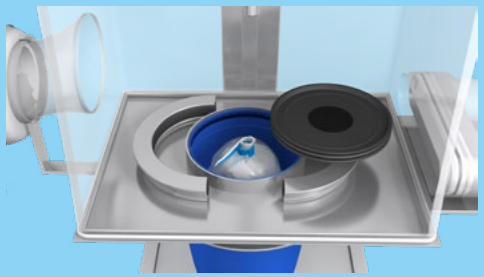
iris BIBO™
Bag in / Bag out Automatic Drum Operations

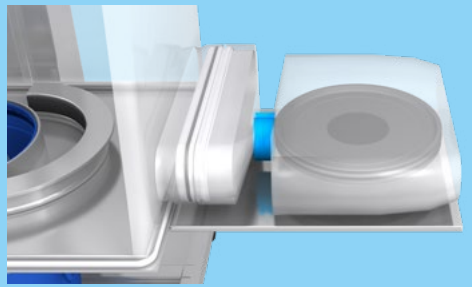
KEY BENEFITS:

- Double containment barrier for maximum operator protection
- High flexibility for different drum sizes and systems
- Reliable sampling of potent and hazardous materials
- Clean, contamination-free transfer process
- Continuous liner system for safe waste management
- Integration with bag-in/bag-out sleeves and canisters

This system enhances safety by integrating an automatic **BIBO interface with DIT®** Iris Diaphragm technology to create a double containment barrier during sampling operations.
The Iris Diaphragm technology provides a tight seal around drums of different diameters, while the automatic bag locking system protects the operator and maintains containment. Continuous liner technology supports the safe handling of waste and ensures containment continuity, even during critical phases such as lid removal.





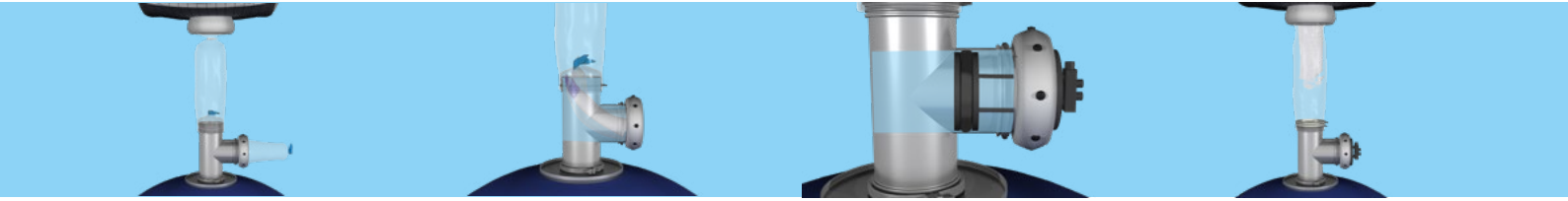


FIBC BIBO HARDWARE INTERFACE

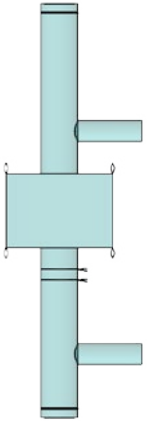
This Bag-in/Bag-out solution for big bags—**FIBC liners**—is designed for the safe transfer of powders in a high-containment environment, using a **dedicated stainless steel docking system**. When installed directly on receiving or discharging equipment, the system enables a safe, dust-tight connection between the liner and the process.

The hardware interface provides a secure seal via clamping or an **inflatable system**, ensuring containment is maintained during material transfer and preventing product release or contamination.

Compared to fully flexible solutions, this configuration offers greater robustness and consistency, making it ideal for more demanding applications. The result is a reliable, scalable containment approach that combines operator safety, process control and integration with existing equipment.



BIBO Pac T-SHAPE FIBC



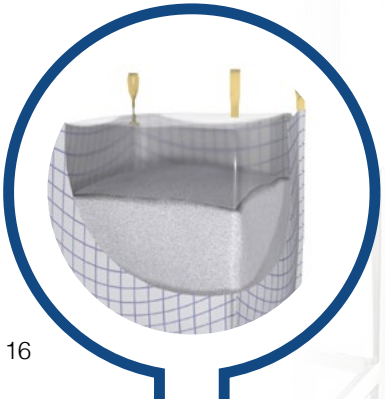
This innovative bag-in/bag-out solution for big bags—**FIBC liners**—enables the safe handling of powders without the need for dedicated hardware. The system features a **T-shaped design** that is welded directly to the liner to create an integrated interface for contained operations.

FIBC liners are widely used to protect products and ensure contamination control during handling and transfer. Building on this concept, the T-shaped configuration enables operators to connect and discharge materials while maintaining containment, thereby simplifying operations and reducing equipment requirements.
The result is a flexible solution for handling big bags safely, easily and efficiently.

BIG BAG IRIS DOCKING STATION

We produce special and innovative big bags—**FIBC liners**—which represent an alternative to drums for moving materials in the pharmaceutical world.
Packages can be equipped to have in-line routes during loading and unloading.

- Available custom shapes and films.
- **Hardware to load and unload** equipment from both high-containment big bags and dust-free, GMP applications.



GMP MANUFACTURING

Clean production is a must for us. Whether or not your process is developed in a **classified environment**, we want to keep you safe from any potential risk. This approach has led to a radical development of our manufacturing facility towards ISO 7 and 8 clean rooms and to qualifying and inspecting suppliers of critical raw materials.

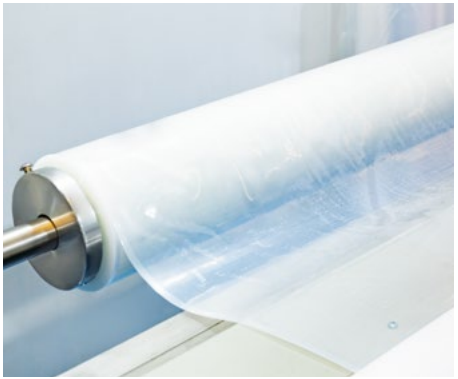
The **FlexiLab** is the consequence of our commitments and the place where, from the very beginning, **we produce all flexible isolators and disposable parts**. All of our environments and processes are qualified. Our clients, pharmaceutical manufacturers, periodically perform audits at our production sites to verify their compliance.

GMP COMPLIANT FILMS

Our **flexible isolators, liners and bags are manufactured using GMP-compliant films**, which are developed by qualified suppliers according to our specifications and the highest pharmaceutical standards. Materials are selected based on the needs of the application, combining transparency, mechanical resistance and electrostatic control.
We offer a wide range of options, **from LDPE to PU**, including customer-qualified materials, to ensure **fully tailored solutions** for safe product handling, high containment performance, and reliable operation across multiple pharmaceutical processes.

KEY FEATURES:

- Transparent, lightweight, and highly strong materials
- Suitable for API discharge, sampling, and product transfer
- Available in a range of diameters, lengths, and thicknesses



FLEXIBLE ISOLATORS

CSV Containment's **flexible sampling and dispensing isolators** are designed to enhance the efficiency, safety and ergonomics of contained powder handling operations.
These systems provide a practical, adaptable solution for pharmaceutical environments where flexibility and high containment are required.
Thanks to their **telescopic design**, for example, flexible isolators can be easily adjusted in height to allow operators to work in optimal ergonomic conditions.
A **Venturi system** ensures negative pressure inside the enclosure, enhancing operator protection and preventing the release of airborne particles.
High containment performance enables operations up to OEB5 level to be carried out safely.

Each isolator is fully customizable, from the gloves and internal accessories to the decontamination systems, enabling configurations to be tailored to specific processes.
Manufactured in ISO8-certified environments, these systems are supplied with disposable flexible enclosures, ensuring a quick changeover between campaigns and eliminating the need for complex cleaning validation.
Flexible isolators are quick to install and remove, making them ideal for operations such as sampling, weighing and dispensing where adaptability and speed are essential.
Glove Bag solutions offer a cost-effective, scalable approach to modern dispensing operations, combining containment performance with operational flexibility.

KEY BENEFITS:

- High containment performance
- Improved ergonomics thanks to the through telescopic structure
- Negative pressure via Venturi system for enhanced safety
- Fully customizable design for specific applications
- Disposable solution for fast changeover and reduced downtime
- Quick installation and easy handling

INSTANT BENCHTOP ISOLATORS

Instant Benchtop Isolators – the ultimate single-use solution for fast, reliable containment in **laboratory environments, ready to use in just 5 minutes**.
The Instant Benchtop Isolator offers an innovative, **disposable glove bag system** mounted on a sturdy acrylic frame.
deal for quality control, laboratory testing, and in-process control, it combines ease of use with full compliance and safety.





CORE STRUCTURE

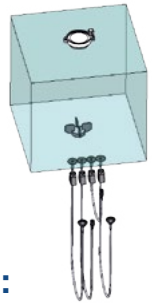
- Lightweight 20 mm acrylic tubes
- Soft plastic quick-release couplings
- Compact travel kit in shoulder bag
- Fits any desk or workbench
- Standard size: **H 800 x W 900 x D 600 mm**
- Custom sizes available on request

KEY BENEFITS:

- Transparent, dissipative polyurethane film, high visibility and strength
- Compliant with USP and PE standards for pharma contact
- Two butyl gloves with white (matt) PU sleeves
- Large gas-tight zip on the back for easy pre-loading
- Snap fasteners for quick, secure mounting
- Top-mounted particulate filter
- Includes bag-in/out (matt) sleeves (270 mm standard, other sizes available)
- Full batch traceability and material certification

MIX-ONEBAG™

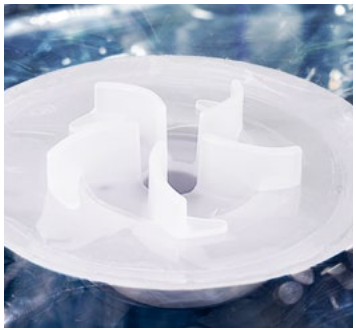
Single Use Fluid Mixer



Mix-OneBag is the ideal solution for **single-use mixing of water-like fluids** of various types, where the goal is to avoid cleaning validation procedures and all issues related to cross-contamination.
Fully customizable and compliant with the most stringent FDA requirements, it is compatible with bags from all major suppliers on the market.

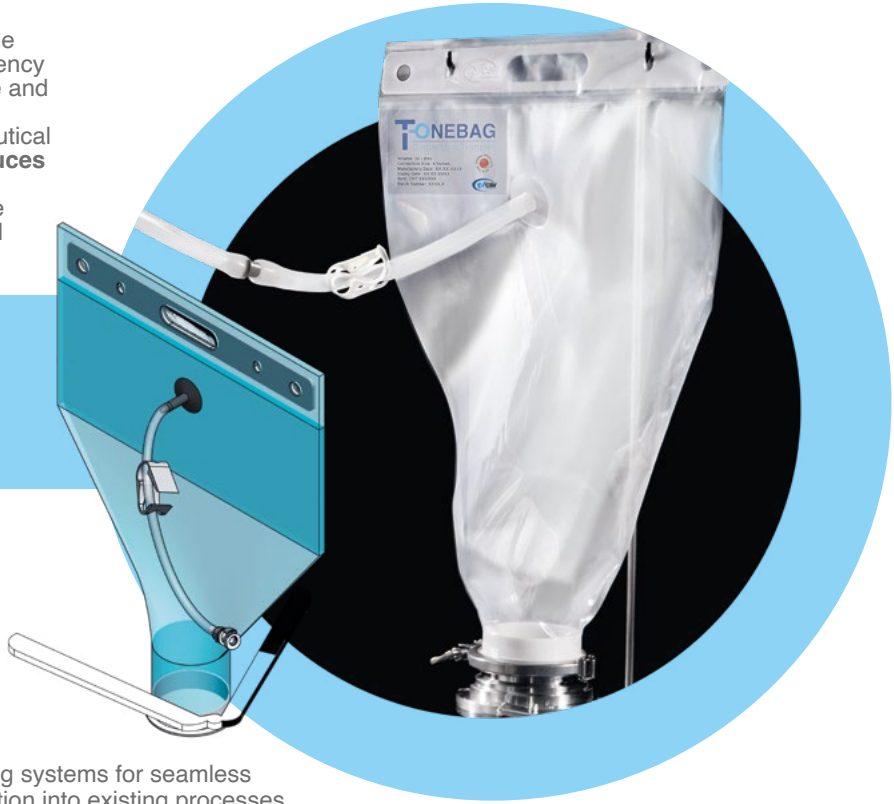
KEY BENEFITS:

- Fully customizable dimensions and volumes
- Impeller customizable according to customer requirements
- Connections, nozzles, and accessories tailored to customer needs
- Possibility to use customer-supplied plastic materials
- Fully FDA compliant



The **T-One Bag** is CSV Containment's single-use flexible solution, designed to ensure maximum safety and efficiency during **powder transfer operations**, either for dust free and high potent applications.
Developed to meet the strict requirements of pharmaceutical GMP manufacturing environments, the **T-One Bag reduces cross-contamination risks**, simplifying workflows and cutting operational costs. **Special configurations** make **T-One Bag** ready for containing High Potent Compound transfers.

T-ONEBAG™
Single Use Transfer



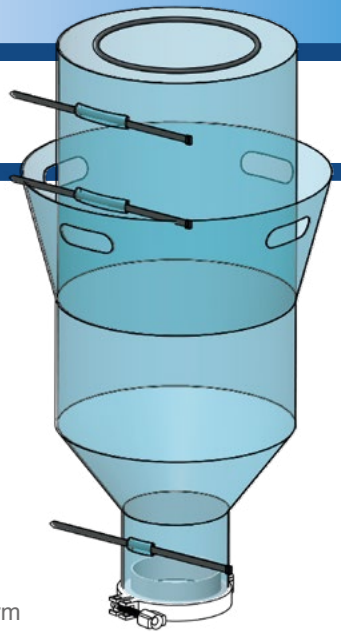
KEY BENEFITS:

- **Reduced cleaning effort**
  Single-use design eliminates the need for cleaning and validation, saving time and resources.
- **Transparent, lightweight, and easy to handle**. Supplied with all necessary light, telescopic, and movable accessories to support filling and emptying operations
- **Ease of integration**. Compatible with standard clamp connections and can be equipped with a wide range of commercially available valves, high-containment devices, and handling systems for seamless integration into existing processes.
- **Optimised powder recovery**
  Funnel-shaped design and anti-static film support complete product transfer with minimal residue.
- **Aseptic ready**
  Manufactured under controlled cleanroom conditions, available gamma sterilised for direct use.
- **Safety assured** High-integrity multilayer film provides robustness, purity, and operator protection.

T-ONEBAG bio™
Single Use Transfer

The bag for Biotechnology Manufacturing

A specialized product line, the **T-One Bag Bio**, has been developed for **Biotechnology manufacturing,** covering buffer and media preparation transfers.



Each **T-One Bag** is pressure tested and supplied with individual traceability information, guaranteeing the highest compliance standards. To suit a wide range of powder transfer applications, **T-One Bags** are available in various formats with different features.

KEY BENEFITS:

- **Material:** Dissipative LDPE film available as CSV Containment's materials or, upon request, the customer's own material.
- **Film thickness:** 200 µm
- **Tri-clamp connection options:** 2"–4"
- **Standard Capacity:** 5l, 10l, 20l (custom sizes available upon request).
- **Cleanroom Manufacturing:** ISO 7 and ISO 8
- Available **Gamma Irradiation** upon request
- **Batch Traceability**
- **Neck Configurations:** Clamp–S-Folded–Integrated O-ring

Accessories available:

Clamp caps	Support platform
Reversible Zippers	Funnel
Flushing/rinsing	Gaskets
Quick process connection	Weloc

CONDUCTIVE T-ONEBAG SUITABLE FOR EXPLOSION-PROOF AREAS

The T-One Bag Dissipative Powder Transfer Bag is a single-use solution designed for safely handling and **transferring powders in controlled environments where electrostatic risk must be carefully managed**.
Manufactured using dissipative film, this bag is part of the T-One Bag family and reduces the accumulation of electrostatic charges during powder handling operations. This feature enhances operator safety and minimizes the risk of ignition when working with potentially sensitive or explosive powders.
The system is equipped with dissipative clamps to ensure continuity of electrostatic discharge across the assembly. Disposable valves featuring the same dissipative properties can also be integrated, providing a fully compatible and consistent containment solution.
Designed for flexibility and ease of use, the T-OneBag Dissipative Powder Transfer Bag enables safe and efficient transfer of materials while maintaining high containment standards.

KEY FEATURES:

- Dissipative film for controlling electrostatic charge
- Dissipative clamps for enhanced safety
- Single-use solution for reduced cleaning and downtime
- Suitable for high-containment powder handling applications

CONTINUOUS LINERS

In our manufacturing facility, we produce compressed and **pre-packaged folded or donut** wound plastic packs. They can be connected to the isolator and equipment for material transfer and ensure containment during unloading.

- Several solutions with different films, shapes, colours, and dimensions
- Antistatic EU and US compliant LDPE or LLDPE
- Available also with customer films

TWIN TIE®

Twin-tie is a contained separation tool for continuous liners safe closure.
It does not require film twisting.

- Fit all continuous liner diameters.
- Containment performance up to OEB 5
- Available in different colours
- Delivered in a case containing a pneumatic/manual gun for tightening the clamps and a cutter for cutting the continuous liner.

TWIN TIE®: THE SPECIAL CLAMPS OF CSV CONTAINMENT

TWIN TIE® is a contained separation kit for continuous liners safe closure. They are the quickest and most effective way to ensure safe operation when separating liners and are always supplied in pairs. The **TWIN TIE®**, once tightened with the most suitable tightening tool, are separated with a simple cutter.
They do not require film twisting.

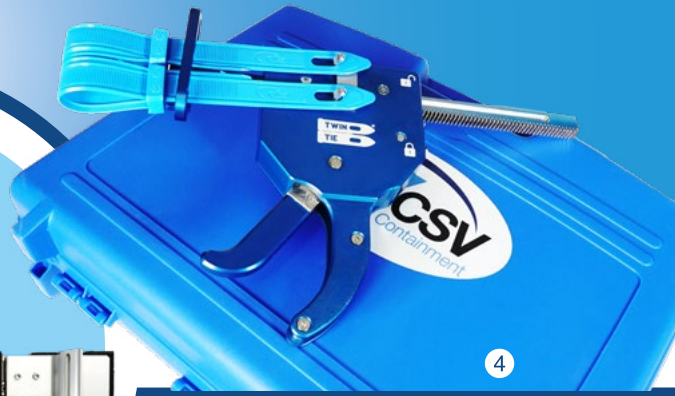
Main features of **TWIN TIE®** :

- Adapting to all continuous liner diameters.
- No slipping after tightening.
- Containment Level OEB 5, validated through. SMEPAC tests in our laboratories.
- User friendly and extremely simple procedures.

Packaging options:

- Standard: 100 **TWIN TIE®** per pack.
- In clean room: 100 **TWIN TIE®** in a double pack.
- Gamma irradiation sterilization: 100 **TWIN TIE®** in a triple pack
- Raw material control and batch traceability.
- Custom logo of the client.
- Fast delivery and priority delivery option.

COMPONENTS



TWIN TIE® KIT: MANUAL OR PNEUMATIC TIGHTENING TOOL AND CUTTER

CSV Containment offers **TWIN TIE®** in a practical kit. The case contains, in addition to a supply of **TWIN TIE®** a tightening tool and a simple cutter. The customer can choose between a manual or pneumatic tightening tool, depending on the type and on the frequency of the crimping operations.

1. **Manual tightening tool**
2. **Pneumatic tightening tool closed**
3. **Pneumatic tightening tool extended**
4. **TWIN TIE® manual kit**

Pneumatic tightening tool

It is recommended when there are numerous crimping operations and when continuous liners are involved.

Main features:
- Maximum torque: 6-8 bar
- Compressed air
- Clamp opening min - max: 120 mm - 210 mm
- Ergonomic handle
- Push button activation
- Weight: 1.9 kg

Manual tightening tool

It is the best solution for large bags and very large packages.

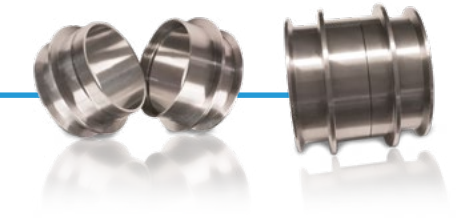
Main features:
- Easy to use
- No compressed air required
- Adaptable to any size of sleeve and continuous liner
- No need to roll up plastic film
- Material: anticorodal aluminium
- Weight: 1.7 kg

Mousehole
Cleanroom Solution

CSV Containment has developed the **Iris Mousehole System** to allow the passage of cables and small objects between two isolated rooms of different classifications. It provides flexibility and a high degree of tightness and is an ideal solution for interfacing and **wall pass-through systems.**

The **Iris Mousehole System** is the non-contact transfer solution for passing round devices (pipes, bottles, cans, containers) between two clean rooms (Pass-Through or Iris). This makes it possible to move large volumes of liquids without the risk of breakage or spillage during container transfer.

The **elastomer Iris Valve** (available in EPDM or SILICONE) is designed to eliminate problems, allowing increased production while reducing labour and equipment costs.Compared to traditional steel solutions, this valve is manufactured with a reduced weight (material and geometry) that facilitates its application.



KEY BENEFITS:

- Standard sizes: 4”, 6”, 8” BS 4825
- Tri-clamp connections
- Iris made of EPDM/ FKM/ silicone
- Wall pass-through made of AISI 304 Stainless Steel or Polyoxymethylene (POM)
- FDA compliant
- Valve made of Polyoxymethylene (POM-C) or Stainless Steel
- Easy Installation and Maintenance
- No product contact transfer
- Complete clamp version
- Other sizes and materials available on request

SMEPAC MONITORING

SMEPAC testing is essential for **objectively verifying the actual containment performance** of pharmaceutical equipment under defined operating conditions. Based on a standardized methodology, it provides measurable and reproducible data on airborne particle emissions, which supports risk assessment and regulatory compliance.

SMEPAC is not only a qualification tool, but also a key means of **ensuring operator safety**, preventing cross-contamination and demonstrating that containment solutions perform as intended in real process scenarios.

We offer SMEPAC monitoring, to demonstrate that a high-containment isolator reduces the presence of potentially hazardous particles in the air.
It is based on monitoring the background environment to evaluate direct/cross contamination or containment performance.

The SMEPAC monitoring consists of replicating critical operations as they are executed during standard production processes but using a safe product, usually lactose.

CSV Containment

DESTINATION **PHARMA**

csvcontainmentnews.com

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