



14" (355.6mm) Diameter Continuous Liner Systems



SYSTEM DESCRIPTION

This easy-to-use system has been proven effective in containing active pharmaceutical ingredients API's and other hazardous compounds. This system uses a five-liner canister, which will allow up to five contained changes of the 30' packs before cleaning or canister recovery is required. This system also provides the 30' liner packs pre-bundled, which reduces operator time. Its use assures a safe and effective transfer of powders, tablets, vials, tools, and trash.

BENEFITS

- $<1\mu\text{g}/\text{m}^3$ contained processing to protect the operators (with results in the 250 nanogram/ m^3 range)
- cGMP processing in a completely closed operation to protect the product
- Single person operation
- Significant reduction in cleaning time, waste, and validation expenses

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Attach neck of continuous liner to canister
Install a band clamp
Slide the pack onto the canister
Install the outer shroud
Unsnap the retaining snaps on the pack



Pull down liner material to start processing

Materials

ArmorFlex® is ILC Dover's proprietary family of films

These films pass incendivity testing and are designed and manufactured using FDA & EU compliant materials.

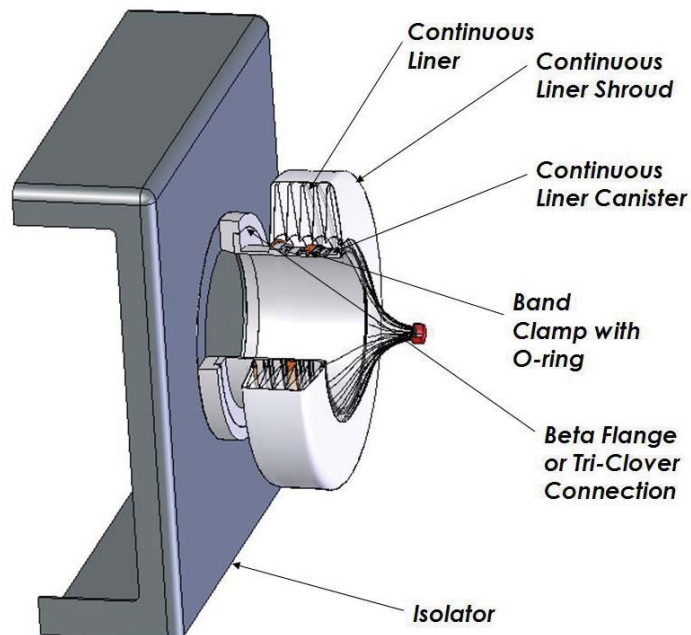
System Components

The system components for contained discharging as pictured here consist of:

- 8" Sanitary Flange Five Liner SS Canister (
- 30' Continuous Liner Pack
- Fabric Outer Shroud
- Pack Protector
- 8" Stainless Steel Band
- 8" Sanitary Clamp
- 8" Sanitary Gasket
- 14" Crimp Kit
- 8" FlexLoc™ Clamp

This system can be supplied with an alpha/beta port interface to allow attachment to an isolator as depicted in the drawing. This allows the contained removal of product containers, samples, or waste from the isolator.

Continuous Bag-in/Bag-out System



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Crimp Separation Kit

The 14" crimp kit is used to separate the filled drum from the unused pack.

The 14" Crimp Separation (start-up) Kit includes:

- 200 Crimps
- 1 CrimpLoc™ Hand tool
- 1 Cutter
- 100 Cable Ties (7" Nylon)
- 1 User's Manual

Additional spare items can be ordered separately by their individual model/part numbers.

The crimps have been designed and tested to compress the standard 14" diameter liners made with ArmorFlex® film. Use on any other system will preclude the crimps from closing correctly, which could result in operator and product exposures.

The hand tool applies two crimps at once. The cutter is then used to cut between the two crimps, and the cap is slid onto the closed crimp body.

This system has been proven effective in containing active pharmaceutical ingredients and other hazardous compounds to assure a safe and effective transfer of powders, tablets, vials, tools, and trash—an operational requirement that cannot be achieved with a standard drum liner.

Containment Levels

While specific powders react differently due to their particle size, customer testing has shown that these systems are capable of providing containment levels to below 1 µg/m³ on a task basis in applications around the world.

ILC crimps have been designed and tested to compress standard diameter liners and sleeves made with ArmorFlex® film



Load crimp into installation tool



Position crimp



Squeeze tool until crimps are engaged—then release tool



Cut and separate



Install crimp cap on crimp body

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FlexLoc™ Clamp

The FlexLoc clamp is used to secure the neck of the liner to the canister. Construction of the molded clamp is of FDA compliant elastomer with integrated stainless steel band clamp.

The clamp has a molded ridge along one surface to help install it in the correct orientation.

It functions to prevent powder from going between the inside of the liner and the outside of the canister to minimize cleaning operations. The FlexLoc clamp is designed to operate in the off-loading and the charging operations.

Other System Components and Accessories

Other system components and accessories developed by ILC Dover to support contained pharmaceutical ingredient processing include:

- Wash In Place Enclosure
- Clean In Place System
- In Line Filter Kit

Applications

- Product offloading
- Tablet offloading
- Bag-in/Bag-out



FlexLoc Clamp

Beyond Boundaries™.

Innovators at our core, we develop engineered solutions for our customers' complex problems. Recognized globally for our flexible containment solutions, ILC Dover serves customers in a diverse range of industries, including pharmaceutical and biopharmaceutical manufacturing, personal care, food and beverage, chemical, aerospace, healthcare and government agencies. At ILC Dover, quality is a culture, not a measurement. Our customers will tell you that we cater to their every need and that we're highly innovative, responsive, dedicated and competitive. We have been innovating since 1947. ILC Dover's visionary solutions improve efficiency, safeguard workers and product, and prevent disasters – proof that we are on the front line of business excellence.

Engineering evolution beyond boundaries.



One Moonwalker Road
Frederica, DE 19946 USA
+1.302.335.3911
+1.800.631.9567

customer_service@ilcdover.com

www.ilcdover.com

