



14" (355.6mm) Diameter Continuous Liner Systems

- ▶ $1\mu\text{g}/\text{m}^3$ 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
- ▶ One person operation
- ▶ Inert atmosphere offloading of products
- ▶ Significant reduction in cleaning time, waste, and validation expenses

▶ System Description

This easy-to-use system has been proven effective in containing active pharmaceutical ingredients 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.

Uses ILC Dover's Patented Technology



ILC DOVER
creating what's next ▶▶



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 used exclusively in the DoverPac® family of high potency flexible containment products.

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

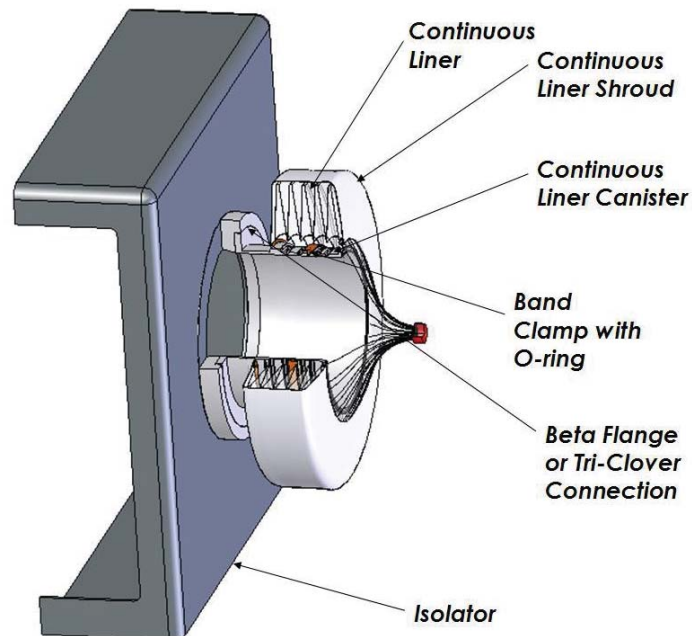
» **System Components**

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

- 8" Sanitary Flange Five Liner SS Canister (used to make contained connection of DoverPacs®)
- 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**



▶▶ 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 Crimp 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



FlexLoc Clamp

» 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 offloading 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