



## 23" (584 mm) Diameter Continuous Liner Systems

- ▶▶ Contained processing to protect the operators
- ▶▶ cGMP processing in a completely closed operation to protect the product
- ▶▶ One person operation
- ▶▶ Pre-loaded liner material minimizes processing time
- ▶▶ 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 to assure a safe and effective transfer of powders – an operational requirement that cannot be achieved with a standard drum liner. The 23" (584 mm) diameter continuous liner system is designed to allow continuous offloading of powders into drums. This contained powder transfer system consists primarily of a set of hardware that fits the flange of a vessel and a factory packed kit of liners that are delivered in a pack ready to install on the canister. Standard systems are supplied in continuous sleeves. Sample sleeves are often added as custom applications.

The system is available in the following sizes:

Pack Length	Number of Drums per Pack*
50'	10
100'	20
150'	30

\* assumes 5' of liner per drum to accommodate drum height and crimping. Actual usage will depend on the drum height



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creating what's next▶▶

The basic steps for operating this easy to use system are shown in these continuous liner process steps



Versatile hardware easily mounts to vessel discharge port



Continuous liner pack is installed



Sleeve is pulled into drum and filled



Unique DoverPac® crimping system is used to separate filled drum



Next sleeve is pulled into drum

## 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.

## Continuous Liner Kit

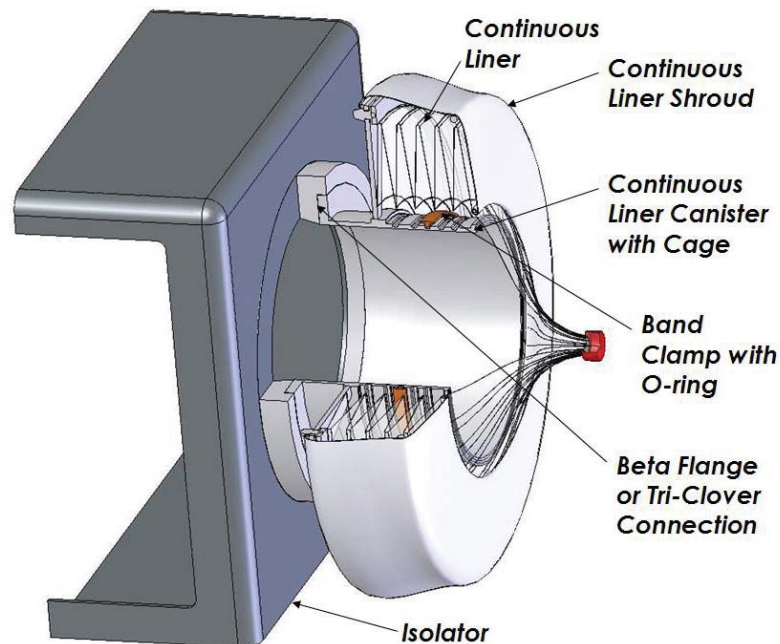
The Continuous Liner Kit includes:

- Canister
- Cage
- Shroud
- Pack Protector
- 12" Band Clamp
- Sanitary Clamp and Gasket
- FlexLoc Clamp
- 23" Crimp Kit
- Turn Table
- Continuous Liner Pack

The canister will attach to the vessel using a transition adapter. The transition adapter has a nitrogen purge/vent to discharge into an inert atmosphere (if required).

## Continuous Bag-in/Bag-out System

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.



### ▶▶ Crimp Separation Kit

The 23" crimp separation kit is used to separate the filled drum from the unused pack. The 23" 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 23" 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.

### ▶▶ 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.



*FlexLoc Clamp*

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

### ▶▶ 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/m<sup>3</sup> in applications around the world.

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



*Load crimp into installation tool*



*Position crimp*



*Squeeze tool until crimps are engaged -- then release tool*

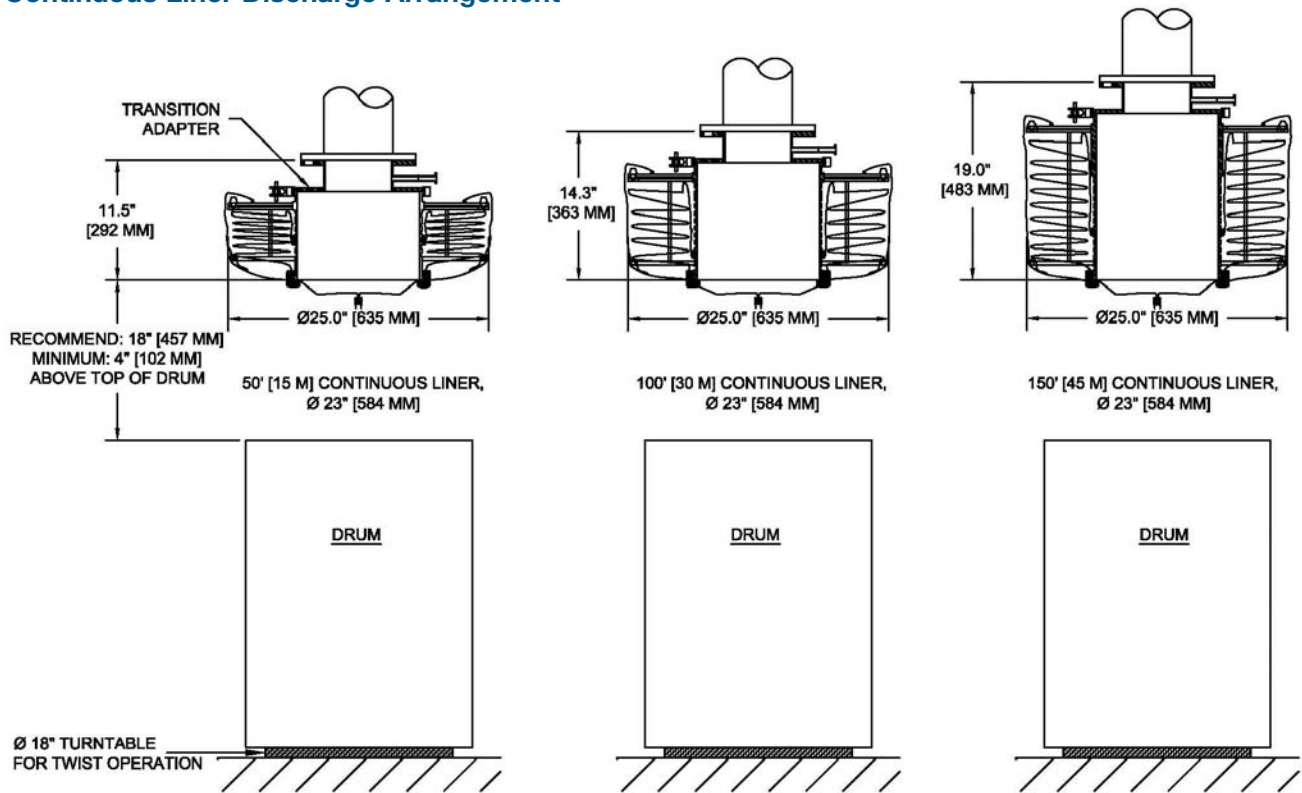


*Cut and separate*



*Install crimp cap on crimp body*

▶▶ **Continuous Liner Discharge Arrangement**



▶▶ **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 from sifters, mills, blenders, centrifuges, dryers and other process equipment.
- Bag-in/Bag-out

