



Offloading Using the Individual DoverPac® System

- » Contained processing to protect the operators
- » cGMP processing in a completely closed operation to protect the product
- » Available in sizes ranging from 20L to 2000L
- » 100% inflation tested
- » CE Marked
- » Significant capital cost savings over rigid isolation systems
- » Significant reduction in cleaning time, waste, and validation expenses
- » Integral sampling sleeve
- » Static dissipative film with groundable restraint (type c)

» System Description

This easy-to-use system has been proven effective in containing active pharmaceutical ingredients and other hazardous compounds. Its use assures a safe and effective transfer of powders, an operational requirement that cannot be achieved with a standard FIBC or big bag. The DoverPac® contained powder transfer system includes a flexible ArmorFlex® liner with restraint for containing powders and a set of hardware that fits the flange of a vessel.

While specific powders react differently due to their particle size, OEB 5 (<math><1.0 \mu\text{g}/\text{m}^3</math>) levels have been demonstrated on a task basis with results in the nanogram range. This is based on proven applications, third party testing to the "SMEPAC" protocols on similar designs, and the 100% inflation tests performed on the delivered systems.

Uses ILC Dover's Patented Technology



ILC DOVER
creating what's next»

Basic Offloading Process Steps



Attach



Bag out stub



To sample, extend sleeve and fill



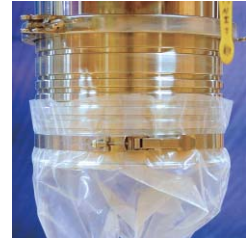
Place crimp cap on crimp body

▶ **Materials**

ArmorFlex® is ILC Dover's proprietary family of films used exclusively in the DoverPac® family of high potency flexible containment products. Details are available in a databook upon request.

▶ **Offloading Canister and Transition Adapter**

The canister pictured at the right shows the set up on a straight transition adapter at ILC's test facility. While canisters typically are 316L stainless steel, Hastelloy® canisters also are available. This unit has an initial groove for the canister end cap, additional grooves for liner attachment (typically 5 or 10 grooves depending on process requirements and available height), and 1 groove for the cleaning sleeve or clean-in-place (CIP) sleeve attachment.



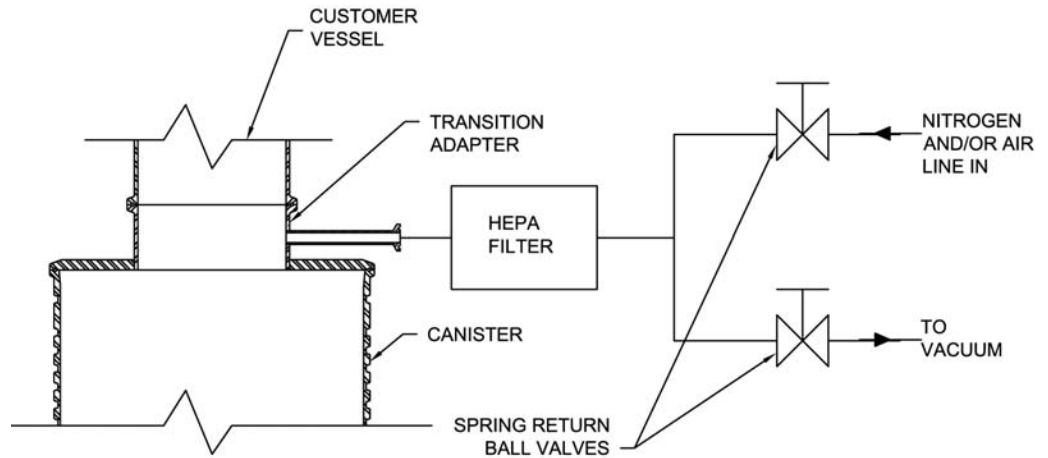
Canister and Transition Adapter Attached to ILC Dover Test Rig.

The canister is supplied with a 12" sanitary flange on each end. This allows for a common design for attachment to vessel specific transition adapters and our CIP tundish.

This hardware is supplied with a 240 grit (15RA) internal finish and a 180 grit (32 RA) external finish. Other materials and finishes can be quoted separately.

The custom transition adapter is fitted with a flange on one end that interfaces with the vessel flange (or valve that is in-line on the vessel flange). The opposite end is a 12" sanitary flange that interfaces with the canister. For flanges smaller than 12", a conical transition adapter is used to allow powder flow directly into the vessel without accumulation on the hardware. The adapter also is fitted with a vacuum flange port with a 1/2" sanitary flange for attachment to the vacuum and nitrogen sources to allow inert processing.

▶ **Purge/Vacuum Arrangement**



Note: Common vacuum/purge supply connection to HEPA filter provides backwash function to extend filter life.

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.

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.



FlexLoc Clamp

Crimp Separation Kit

Contained separation between vessels and DoverPacs® is achieved through a Crimp Separation Kit, using ILC's uniquely designed crimp system.

Crimps are color coded to assure that the right crimp is selected for the right product. Red crimps are used for the 14" necks, blue crimps are for the 23" diameter continuous liners, and yellow crimps are for the 4" diameter sample sleeve on the DoverPacs®.

A Crimp Separation 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 diameters 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 used to cut between the two crimps, and then the cap is slid onto the closed crimp body.

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

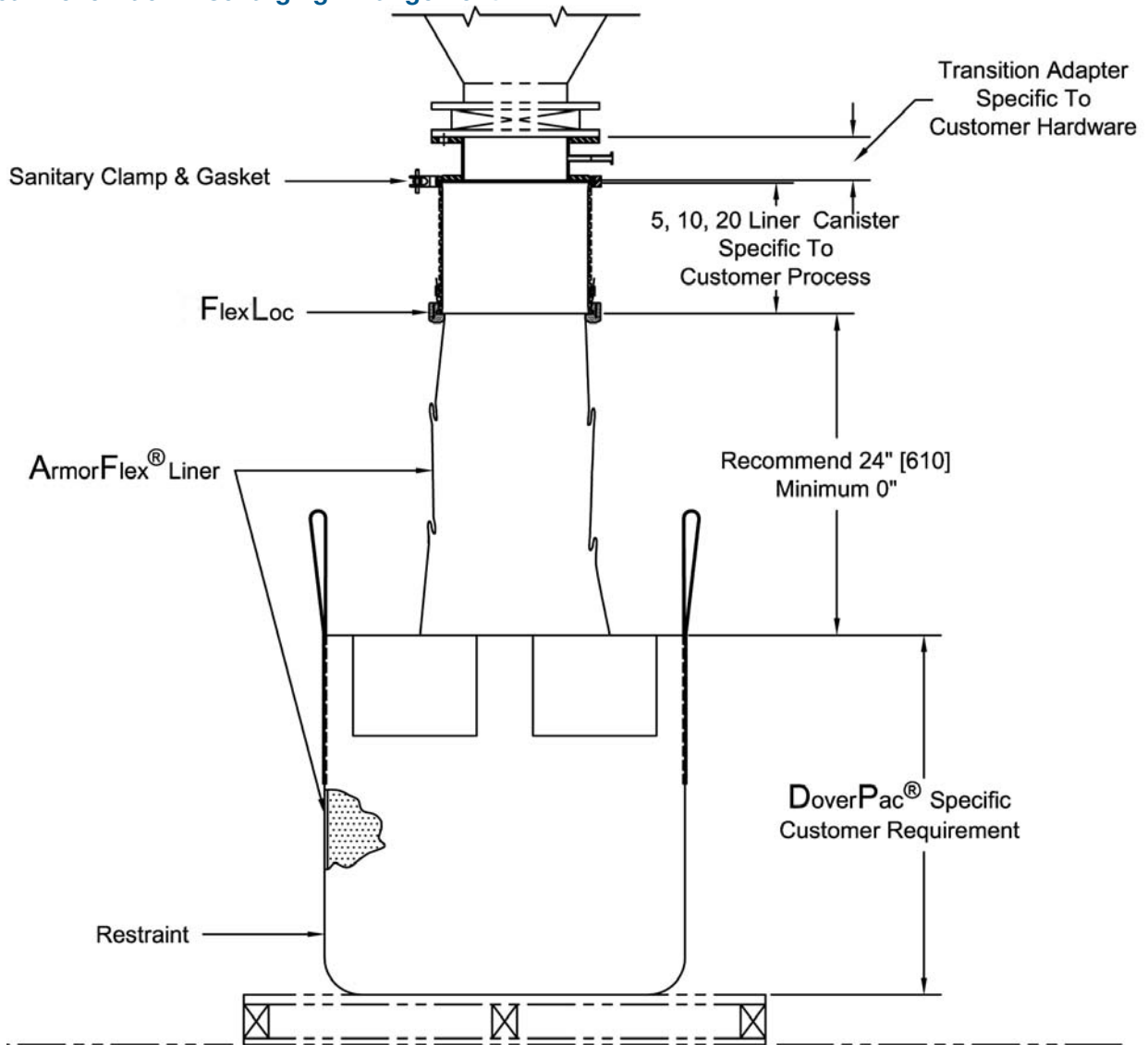


Cut and separate



Install crimp cap on crimp body

► **Typical DoverPac® Discharging 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

Patented



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