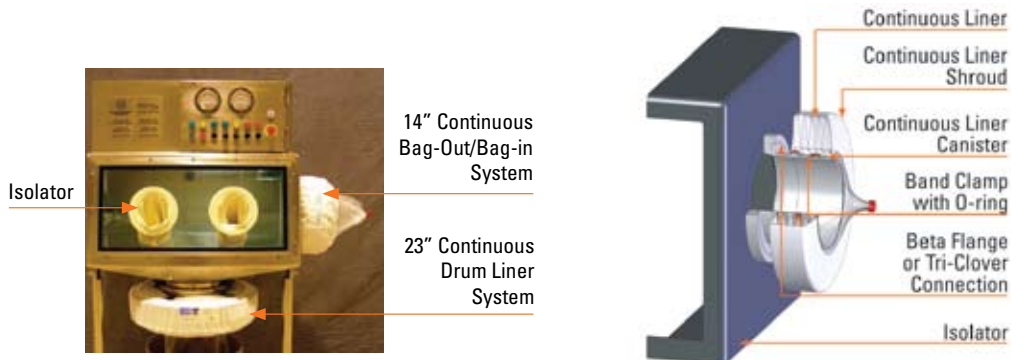


Bag In/Bag Out System

OVERVIEW

The **DoverPac® Bag In/Bag Out (BIBO) system** is a family of contained transfer designs for multiple processes. The primary components for this validated operation consist of multiple groove canisters, docking interface hardware, and softgoods in either continuous liner form or discreet liners as illustrated below in the continuous liner application.



This system can be applied to any rigid isolator. The use of multiple size canisters allows a broad range of needs to be met, systems can be retrofit to existing assets, and the BIBO system requires a low capital outlay.

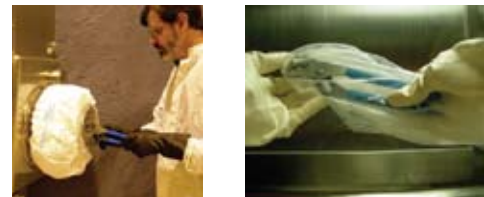
OPERATION

By utilizing the patented multi o-ring and flexible containment techniques developed by ILC Dover, this system builds on proven DoverPac® designs. The hardware is docked to the containment enclosure either by using the existing alpha/beta port hardware or bolting directly to the wall of the rigid isolator. The liner is then extended over the item to be introduced or removed from the enclosure and then crimped off to complete the contained transfer.



« Continuous Liner being attached to isolator

Operator shown “bagging in” a tool »



« Operator shown “bagging out” a sample

Uses ILC Dover’s Patented Technology

Accessories and support equipment include a lifting stand to help support the larger canister size, crimps and the FlexLoc™.



▲ Crimping tool/crimps



▲ FlexLoc™



◀ Lifting Stand

APPLICATIONS CURRENT AND POTENTIAL

Current applications: tool pass through on 22 rigid isolators at one international Pharma manufacturer’s site, trash bag out, sample bottle transfer, tablet transfer for testing/analysis, pre-packaged seed/API processing after tare weight process

Other potential applications: document transfer, gamma irradiated for sterile transfer operation, wall mounted in process suite for contained pass thrus.

CONTAINMENT LEVEL

Nanogram containment levels demonstrated during task based operations – see data below.

Sample*	Location	Duration of Operation (mins.)	Measured Airborne Concentration (µg/m3)
Source Sample (AS-0BH)	At Bagout Port	31	<0.017
Operator #1 (PSBZ)	On Shoulder	31	0.017
Operator # 1 (PSBZ)	On Shoulder	30	<0.017
Operator # 2 (PSBZ)	On Shoulder	30	<0.018
Source Sample (AS-0BZ)	At Bagout Port	30	<0.017

* Finished Product, raw materials, cleaning materials, waste materials

FEATURES

- Validated system
- Proven and tested softgoods
- Disposable
- Bolt on or RTP Interfaces available

BENEFITS

- Minimizes risk during operation
- ArmorFlex films are regulatory compliant
- Eliminates concern of cross contamination due to “pneumatic” effect of low end films leaking
- Reduced cleaning and cleaning validation costs
- Reduced process time and cost by eliminating multiple RTP canisters
- Eliminates RTP seal maintenance

