Flexible Containment Solutions Guide

DoverPac® Containment Systems

Coaxial Neck DoverPac®

OVERVIEW

The Coaxial neck DoverPac® was originally designed to allow secondary containment to be used with a DoverPac® in the late 1990's for charging and offloading vessels through isolators. Given the increase in highly potent API manufacturing, the use of this system with either rigid isolators or flexible enclosures is a complimentary processing option.

The Coaxial Neck DoverPac® serves the dual function of contained transfer and storage system. These are available in standard 45, 185, 400, and 700Liter volumes. Custom sizes can also be accommodated.

HOW DOES IT WORK?

This system is designed to provide containment to the OEB 5 (less than 1 µg/m3 with a goal of below 200 nanograms/m3 on a task basis). To achieve this, the secondary containment (i.e. flexible enclosure and the outer neck) at the primary connection points are applied. Figure 1 shows the offloading set up during exposure monitoring trials.

The installation sequence follows:

- The top of the enclosure is attached to the first canister on the vessel outlet.
- The bottom of the enclosure is attached to the canister on the support frame.
- The external neck on the DoverPac® is then attached to the outlet point of the canister on the frame.
- The internal neck of the DoverPac® is pulled up through the lower canister and is attached to the groove on the vessel canister by using the integral glove sleeves on the flexible enclosure.

1. Vessel Outlet
2. Flexible Enclosure
3. Inner Neck Attachment
4. Support Frame
5. Outer Neck Attachment

Figure 1

Once the vessel is offloaded, the internal neck is crimped off and pushed back down through the canister on the frame by using the enclosure to access the neck area. The operator then extracts his/her arms from the enclosure and crimps off the external neck.

The crimping process, Figure 2, is employed for the contained separation operations. This process consists of installing two injection molded crimps into the hand tool, twisting the liner neck, ratcheting the crimps closed, cutting between the two crimps, and installing the protective cap.

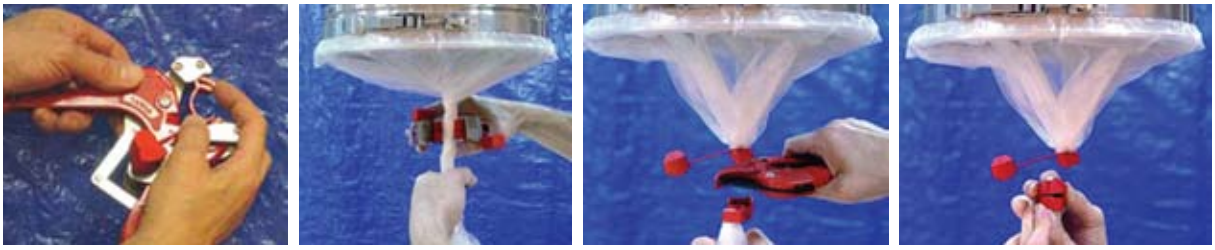
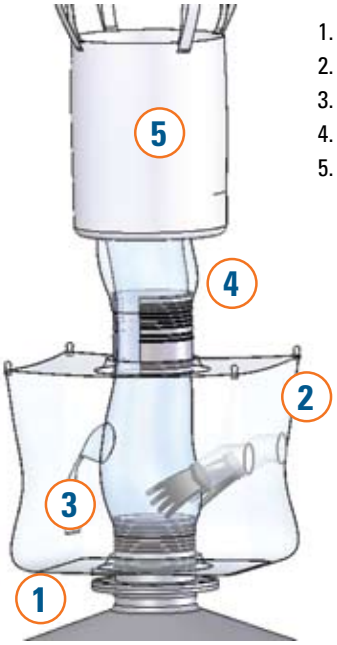


Figure 2



1. Vessel Inlet
2. Flexible Enclosure
3. Inner Neck Attachment
4. Outer Neck Attachment
5. DoverPac®

Figure 3

In addition to offloading vessels, the system can be applied to charging processes as shown in Figure 3. The flexible enclosure design is either supported by a frame or bungee cords.

FEATURES

- Standard DoverPac hardware interfaces
- Standard and custom sizes
- Two barriers for containment
- Product contact with regulatory compliant materials

BENEFITS

- Uses a broad range of solutions depending on containment level needed
- Tailored to specific batch sizes
- Provides nanogram levels of protection without high capital costs
- Eliminates risk to product

WHAT CONTAINMENT LEVEL PROVIDED?

OEB 5 in the nanogram levels. The table below outlines a summary of the results achieved.

Sample Set	N	Mean	Range Lowest	Range Highest	Standard Deviation	Standard Error	Coefficient of Variation	95% Confidence Interval for Population Mean
Personal Sample Breathing Zone PSBZ – with outlier event	12	0.077 µg/m3	0.014 µg/m3	0.50 µg/m3	0.136 µg/m3	0.039	1.8	-0.00980 to 0.163 µg/m3
PSBZ – without outlier event	10	0.032 µg/m3	0.014 µg/m3	0.084 µg/m3	0.023 µg/m3	0.0074	0.72	0.0156 to 0.0490 µg/m3

WHY USE THIS OVER OTHER TECHNOLOGIES?

The cost of ownership, ergonomic advantages, and speed of delivery benefits of this flexible solution far outweigh those of rigid isolation systems

OTHER POTENTIAL APPLICATIONS

This technology is applicable for charging and offloading most vessels. This includes, but is not limited to, reactors (charging only), dryers, blenders and granulators.

Uses ILC Dover's Patented Technology

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