

# Flexible Containment Solutions Guide



## Contained Offloading of Aurora Filters - Processing from Nutsche Filters

### OVERVIEW

Nutsche Filters are a mainstay in processing in the Pharmaceutical and Chemical industries. They typically function by keeping the slurry contents fluidized until most of the mother liquor is filtered through. When filtration is complete, the cake can be washed by reslurrying the cake. After washing, the mother liquor can be refiltered and the cake can then be discharged.

AURORA FILTERS, a Division of ALL-WELD Company Limited, designs and fabricates a line of Nutsche filters for the pilot scale production of active pharmaceutical ingredients. These designs typically combine a glove box with a single plate vacuum Nutsche under an inert gas blanket to ensure operator safety and product integrity.

- Each filter has seven process connections - Slurry Inlet, Nitrogen Inlet, CIP Wash Inlet, Vent, Nitrogen Inlet for Drying, Final Vacuum Outlet, and Filtrate Vacuum Outlet.
- Each filter has a large viewing window on the Upper Chamber as well as a small sight glass on the Lower Chamber.
- A Heating/Cooling Jacket designed for 50 to 75psi and registered to ASME Code surrounds the cake collection area. This jacket is for use with heat transfer fluids only, such as cooling brine, hot water, Dowtherm, Silthane, Glycol, or similar liquids.
- The remainder of the filters are not considered a registered pressure vessel. The Upper Chamber is designed for atmospheric conditions only and the Lower Chamber is designed for atmospheric to full vacuum conditions.
- The CIP Spray ball assembly is designed such that the entire spray ball assembly can be extracted from the nozzle without disassembly within the filter. The spray ball components are either Teflon or equivalent to the wetted material of choice.

However, the outlet of the filter is not typically contained. This Flexible Containment Solutions Guide outlines several methods of achieving a contained discharge from the Aurora Filter.

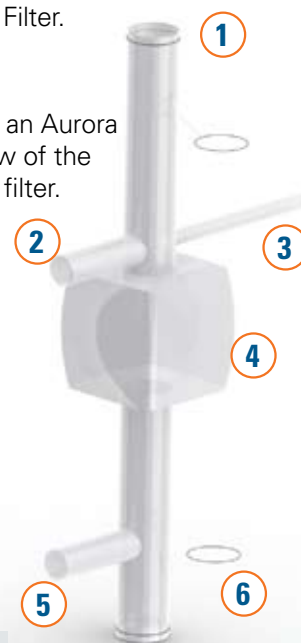
### HOW DOES THE CONTAINED OFFLOADING SYSTEM WORK?

There are a variety of methods that can be used to achieve contained offloading of an Aurora Filter. The designs of the filters are varied so the applications below represent a few of the installed solutions. Some customization may be needed depending on the specific filter.

#### Offloading to DoverPacs®

The key components in The DoverPac® system include:

- Transition adapter between the vessel and the DoverPac® canister
- Multiple o-ring canister (typically separate from the Transition Adapter but these can be combined into one piece of hardware)
- DoverPac® which is a combination of inner liner and outer Type C restraint
- The new FlexLoc clamp (an improvement over the original DoverLoc clamp that replaced the original cir-clip)
- The Crimp Separation System (the replacement for the original twist, tie, tape and cut system for repeatable separation of the liner from the vessel without breaking containment)



- |                          |                               |
|--------------------------|-------------------------------|
| 1 Fill neck with o-rings | 4 Body                        |
| 2 Bag Out Sleeve         | 5 Bag Out Sleeve              |
| 3 Sample Sleeve          | 6 Discharge neck with o-rings |

DoverPac Liner (shown without Restraint)

**The basic operational steps are performed for offloading the filter:**

- 1 Attach the fill neck of the DoverPac® to the ILC Dover supplied multiple o-ring canister and shuffle up some of the neck to create a clean zone for crimp separation
- 2 Bag out the stub from the previous liner
- 3 Open the valve on the vessel and use the sample sleeve to take a sample if required by the process
- 4 Finish filling
- 5 Pull down the clean zone, twist the neck, and apply the crimps.
- 6 Cut between the two crimps and close the caps on the crimps. Note that this leaves the stub that will be bagged out with the next DoverPac®
- 7 Repeat steps 1 – 6.

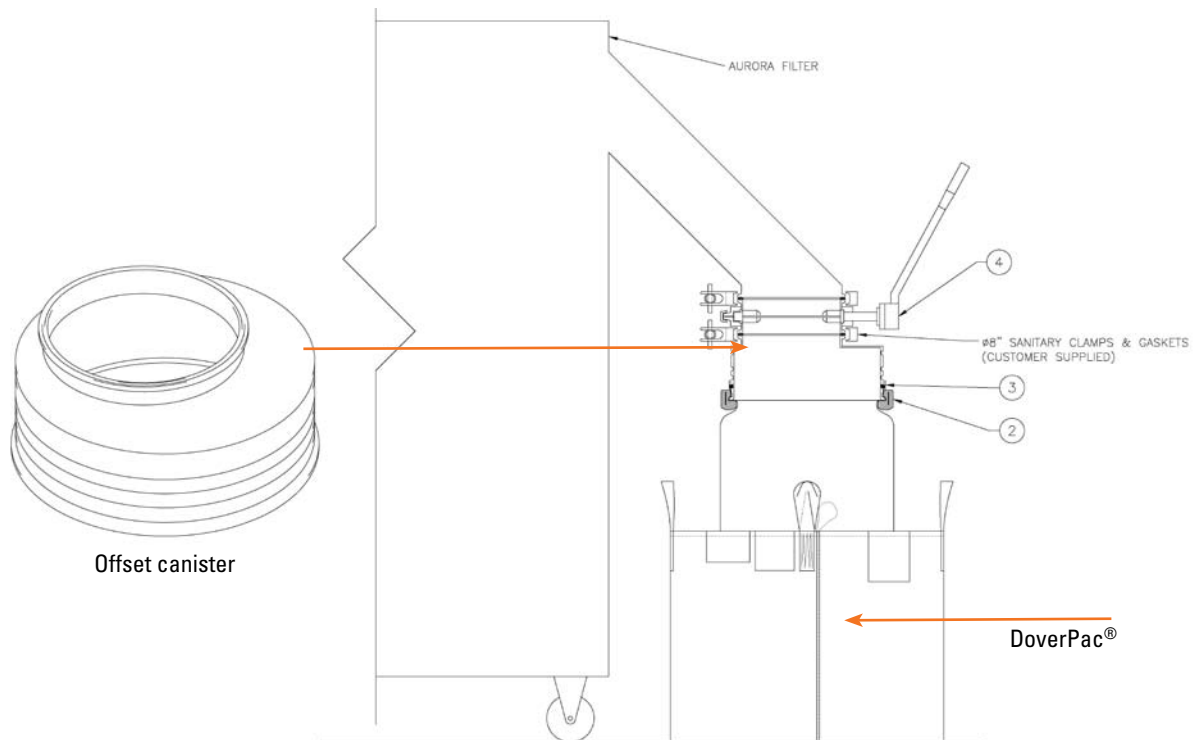
The same process is used to charge the next vessel except there is no sampling sleeve at that point.

In the application below, an offset canister with the capability to offload to three 110L DoverPacs® was installed on the sanitary flange of the 8" (200mm) Cora Valve on the discharge chute of the vessel.

Once the filtration process is complete, the valve is opened and the Operator scoops powder through the chute and into the DoverPac® using the glove ports that are supplied as part of the Aurora Filter.

The DoverPac process outlined above is then followed.

After processing, a Clean In Place (CIP) tundish is attached to the sanitary flange on the canister by bagging it in with the CIP sleeve.





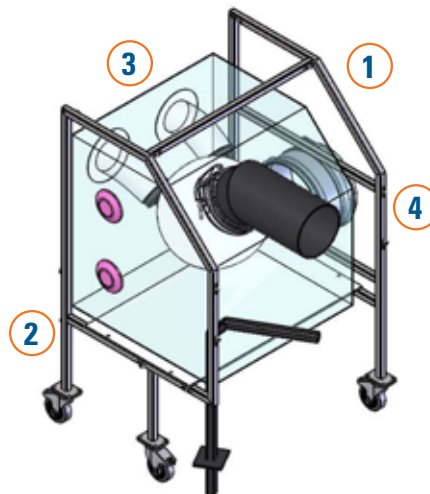
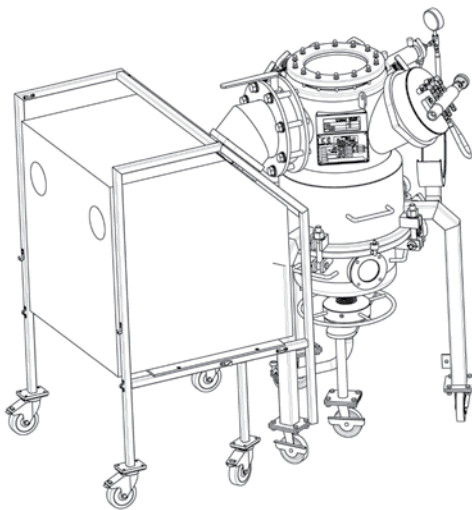
### *Flexible Enclosure Offloading*

Flexible Enclosures are a proven alternative to rigid gloveboxes. These can be provided in either a passive system or with a Ventilation System included.

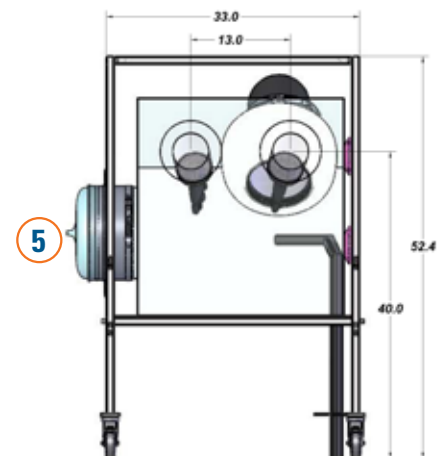
The enclosure is manufactured from clear ArmorFlex® film that will allow room light to illuminate inside the enclosure for easy viewing. It is also equipped with a bag in/bag out sleeve which is used for introducing product and tools to and from the enclosure without breaking containment.

In this application, a standard 8" multiple o-ring canister is attached to the outlet of the filter. The enclosure is then attached to the same canister to provide a contained connection during the transfer of powder.

A 14" Continuous Liner is connected to the canister inside of the enclosure. This is a factory packed, 35' long liner. Once the Continuous liner is filled, it is crimped and the bagged out using the BIBO Sleeve on the side of the Enclosure.



Isometric View



View from the Glove port side

- |                      |                               |
|----------------------|-------------------------------|
| 1 Mobile Frame       | 4 Attachment to Filter Outlet |
| 2 Flexible Enclosure | 5 BIBO Canister               |
| 3 Glove ports        |                               |

**The basic process steps include:**

- 1 pull a length of the Continuous Liner down from the pack
- 2 open the valve on the filter outlet to allow powder transfer to the liner
- 3 when filled, twist and crimp the liner
- 4 place the filled section of the liner into the bag out sleeve and then twist and crimp the BIBO Sleeve. This is then moved to the next step of the process.

**FEATURES**

- Validated containment technology
- Clear film on enclosures
- Passive and ventilated systems available
- Flexible materials
- Disposable components
- Retrofits to existing filters

**BENEFITS**

- nanogram containment levels achieved
- visibility during operation
- Containment to a broad range of requirements
- Ergonomics maximized
- Reduced cleaning and cleaning validation
- Low capital and operating cost
- Speed of implementation

**WHAT CONTAINMENT LEVEL PROVIDED?**

OEB 5 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 deliverable systems.

**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**

AURORA FILTERS are designed primarily for the applied research, development and pilot scale operations within the pharmaceutical and chemical industry. Containment for offloading in addition to the applications outlined above can be applied via:

- Continuous liner system on outlet for contained filling in drums
- Transfer Sleeve on the outlet for direct transfer to IBCs or other vessels



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