



CSP Flexible Isolators

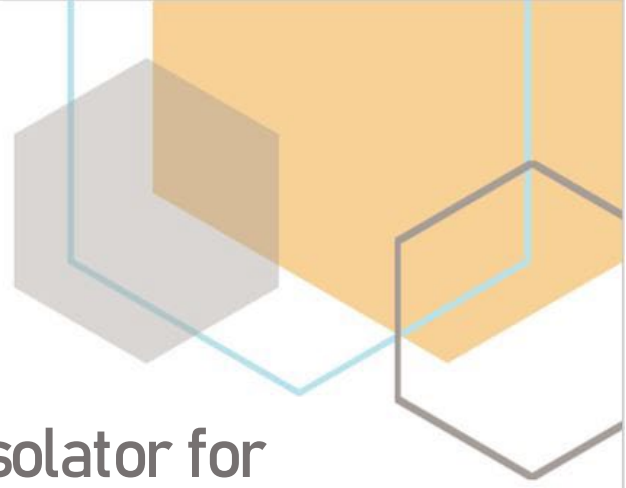
Overview

Containment Service Providers (CSP) is a design engineering company specialising in flexible containment. We design and develop custom-made flexible isolators (FI's) to suit our customer's requirements. Flexible isolators can also be referred to as "glove bags" (GB's). These isolators, the majority of which are passively operated, are ideally suited for the handling of Active Pharmaceutical Ingredients (API's). Our FI's mainly utilise the barrier containment method. We are also specialists in retrofitting and upgrading existing equipment. This improves the containment performance of the equipment enabling it to be operated under much higher containment conditions.

Specification

Our flagship material used in the manufacturing of these isolators is the CSP PharmaFlex™ Polyurethane (PU). We can also manufacture from PharmaFlex™ Polyethylene (PE). This material is antistatic and food grade. It is highly transparent with very good clarity. The type of material used (PU or PE) will depend on the customer's compatibility requirements. All of the PharmaFlex™ range is suitable for product contact. For passive operations, a particulate filter can be fitted to the isolator to allow it to breathe. A feed in/passive airlock can comprise of a series of clamps or zips on a sleeve, or a combination of both. A product out/waste sleeve can be fixed to the isolator or it can be interchangeable depending on customer requirements. A continuous liner product out sleeve can also be attached to the isolator. The Isolator can be suspended from local pipework or CSP can supply a light stainless frame to support the isolator in position. To date we have over 4000 different designs on our system. These flexible systems have endless applications and the examples provided on the following pages are just some of the many applications they can be used on. For further information please contact CSP at info@containment.ie or visit our website www.containment.ie.





Using a CSP Flexible Isolator for Filter Changeout

Product Design

This flexible isolator allows the operator to change out a used or blocked filter in a contained and safe manner. The used filter is removed from the process line within the flexible isolator and disconnected from the flexible isolator in the trash out sleeve. A new clean filter is passed into the flexible isolator through the feed-in sleeve and is connected using the gloves provided. This isolator can be used also to recover product from the filter if necessary. This system has been validated to less than 1µg occupational exposure limit (OEL) during passive use. Therefore, it's an inexpensive way to deal with highly valuable and sometimes highly problematic filters. This isolator can also be a completely sealed unit and pre-loaded with the necessary filters so that there is no break in containment until the operation is completed.

Benefits & Key Features

Eliminates Contamination The high containment levels of this isolator have been proven to support an occupational exposure band (OEB) of 5 on a passive system.

Cost effective system This simple design is easy to install and ensures zero cleaning validation when one is finished. This reduces time and cost associated with cleaning when compared with solid-state isolators.

Maximise Product Yield The ergonomic designed allows the recovery of product from the filters in a safe and efficient manner.

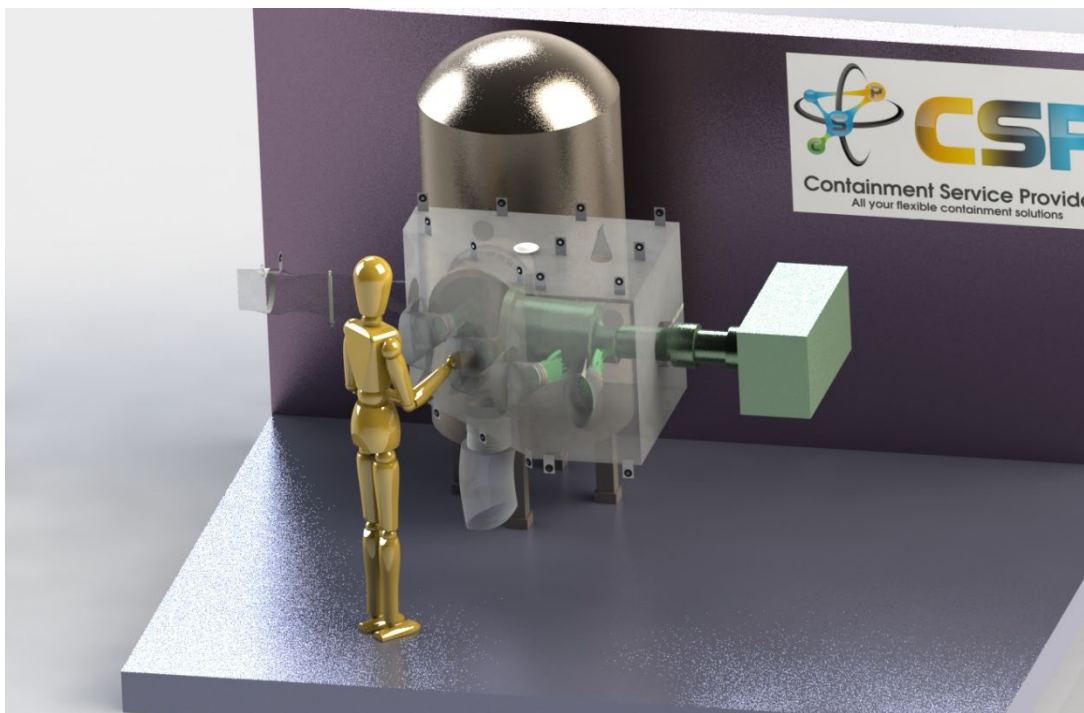




Using a CSP Flexible Isolator for Heel Removal

Product Design

The heel removal flexible isolator enables the operator to remove heel from a filter dryer in a contained and safe manner. It allows the operator to feed the required tools into the enclosure and they can then be used to scrape the product out of the filter and into the required product holding devices. A CSP continuous liner (CCL) can also be used with this system in conjunction with the isolator for contained continuous packaging of the heel. The heel removal isolator can be retrofitted onto existing filter dryers. CSP can also work with filter dryer manufactures in the event that a customer buys a new filter dryer and needs to attach an ergonomic system for removing heel from the new dryer



Benefits & Key Features

Convenient Design

This FI is extremely adaptable when compared with solid-state isolators, accommodating for retrofitting and new fitting.

Customisable

The high containment nature of this system reduces the overall risk of contamination, therefore, improving one's overall manufacturing practice.

Enhances GMP

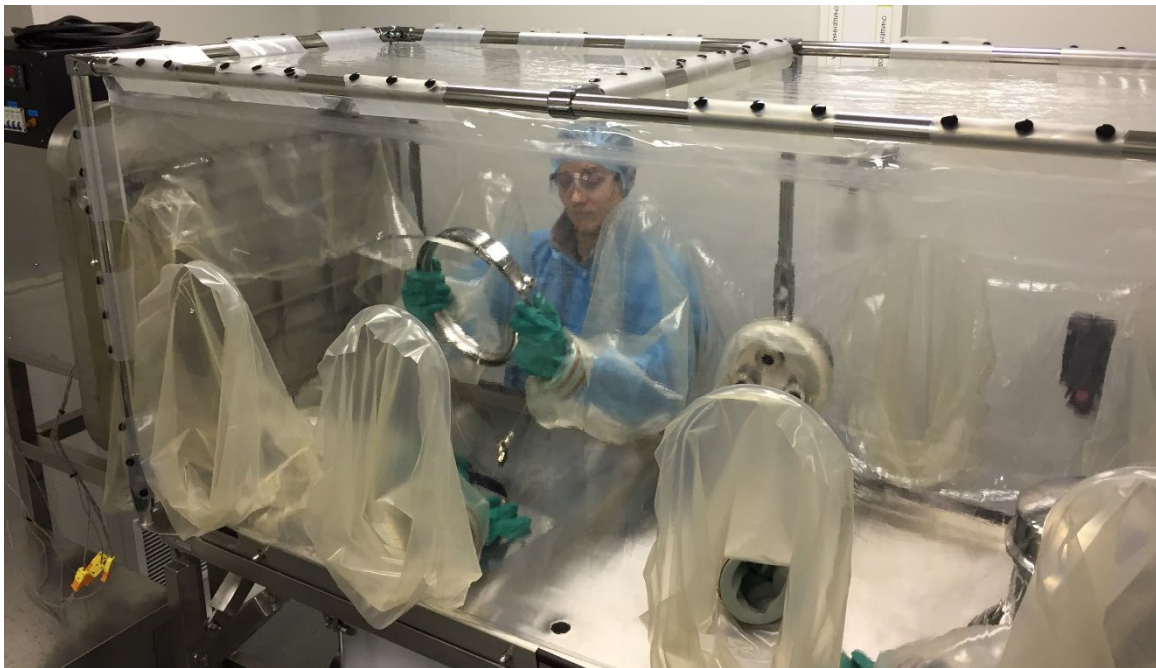
CSP can provide other ergonomic devices with this FI such as the CCL and/or the CSP bottle bag to further improve the efficiency of the overall system.



Using a CSP Flexible Isolator for Inspection

Product Design

This flexible isolator (FI) can be used for the inspection of the internal areas of equipment or a module in a contained and safe manner. The FI allows access to within the module without any risk of outside contamination, or products of the module contaminating the general area. The isolator is used as a barrier to separate the outside environment from the inside of the module, therefore, keeping all areas safe and clean. These isolators are normally custom designed to suit a particular operation. If you need to break containment in your existing process equipment but run the risk of introducing contamination to the inside of the process equipment; these isolators can be custom designed to negate that risk. Furthermore, if you are breaking into a high containment piece of equipment, these isolators will help to do so in a safe manner keeping the rest of your production facility and personnel clean and safe. This system satisfies good manufacturing practice and also high containment preventing egress and ingress, therefore, keeping the internal equipment contaminant free and external area safe.



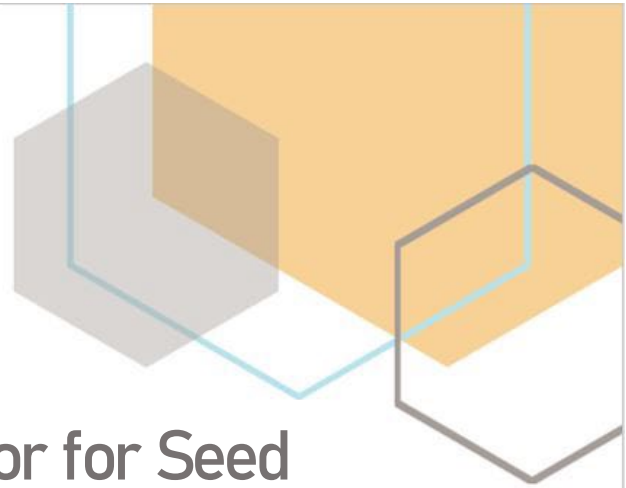
Benefits & Key Features

Eliminates Contamination Risk

The high containment levels of this isolator have been proven to support an occupational exposure band (OEB) of 5 on a passive system.

Custom Design

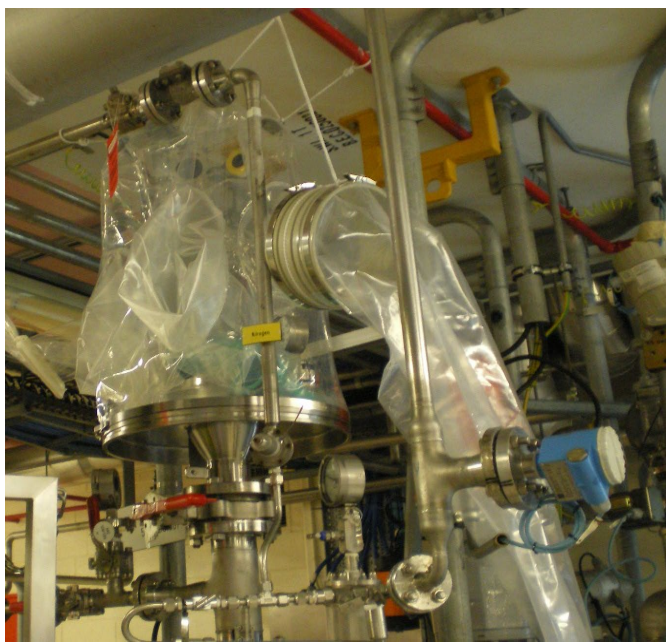
Each flexible isolator is tailored to the exact needs of the customer. Maximising the efficiency of the isolator and ensuring timely and seamless progression of the customer's project.



Using a CSP Flexible Isolator for Seed Charging

Product Design

The seeding flexible isolator allows the operator to add seed (product) into a vessel in a contained and safe manner. The operator can pass packages (quantities) of seed material into the flexible isolator using a feed in sleeve or passive airlock. This enables the operator to safely open the seed package/container and charge or unload the contents into the vessel through the charge port. The empty container can now be trashed out using the trash out sleeve attached to the flexible isolator.



Benefits & Key Features

Eliminates Contamination Risk

The high containment levels of this isolator have been proven to support an occupational exposure band (OEB) of 5 on a passive system.

Cost effective system

This simple design is easy to install and ensures zero cleaning validation when one is finished. This reduces time and cost associated with overall operation.

Enhances GMP

The high containment nature of this system reduces the overall risk of contamination, therefore, improving one's overall manufacturing practice.