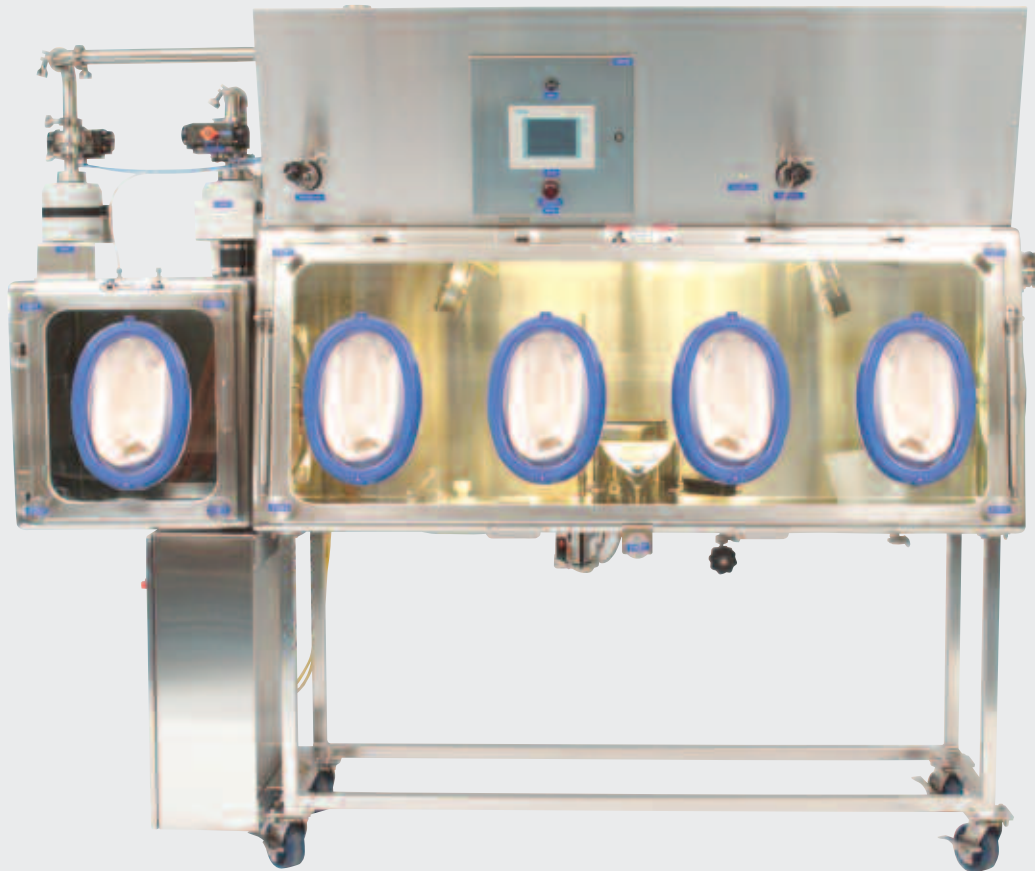


# ISOLATORS

OPERATOR, PRODUCT AND ENVIRONMENTAL PROTECTION



# Aseptic Isolators



**Extract Technology** is a leading supplier of containment and aseptic systems for the pharmaceutical and biotech markets. We have been designing and manufacturing Isolators for over 15 years and have installations worldwide.

## Aseptic Isolators

The Extract Technology Aseptic Isolator is used for the protection of product during processing, achieving high levels of product sterility which cannot be achieved/guaranteed in a traditional cleanroom with standard aseptic gowning. Furthermore the Aseptic Isolator provides a significant cost saving against the consumable costs of running a cleanroom installation.

The Isolator is designed to provide both a physical barrier between the product and operator/surrounding environment as well as added protection with the creation of a positive pressure within the chamber(s).

Extract's Aseptic Isolator range includes sterility testing systems, vessel charging and filling Isolators as well as interface Isolators for autoclaves, depyrogenation ovens and lyophilisers with controlled transfers being provided by Aseptic Transfer Isolators.



**Sterile Process Isolator**

# Containment Isolators

The Extract Technology Containment Isolator is used extensively in the pharmaceutical industry to safeguard both operators and local environments against harmful dust generated during the handling of pharmaceutically active powder materials/compounds across a wide range of applications.

The Isolator is designed to not only provide a physical barrier between the operator and the product but to also provide a controlled environment, negatively pressurised with an atmospheric condition or a reduced oxygen content using an inert gas.

To maximize both operator and equipment interfaces 3D modelling and full scale mock-ups are used extensively to facilitate the best understanding possible of the pharmaceutical process and the operators involvement whilst ensuring high levels of containment are achieved.

Extract's Isolator range includes, single chamber enclosures mounted directly to a process device inlet/outlet through to multiple chamber systems incorporating a wide range of process devices, operator aids and safety interlocks.



Dispensing/Mixing Isolator



Laboratory Processing Isolator

# Design Advantages

**Twin Chamber Dispensing Isolator**



- Ergonomic design generated by the use of sloping operator interface panels, large oval gloveports (safe change), and drum/product manipulation devices, all proven with the aid of full scale mock-ups
- Multiple chamber arrangements providing defined barriers between process steps, enhancing containment performance whilst reducing the necessary cleaning zones
- Fully welded fabrications of 316L stainless steel, providing crevice free construction with internally radiused corners and sloping bases (where required for the removal of cleaning fluids)
- New gloveport design eradicating contamination normally found around the operator access glove/gauntlet and the viewing panel
- On-board safe change filter systems, ranging from push-push cartridge to high volume bag-in/ bag-out types matched to suit the application
- Closed loop fan control systems maintaining operational settings and providing breach protection in the event of a port failure



**ChargeCube 100**



# Optional Features

For those applications where a standard solution is not suitable, then a comprehensive list of options are available to customise the Isolator to your requirements, examples of which are:

- Multiple types of control systems (single loop, PLC and Ethernet connection for CFR 21 part 11 data collection) providing full integration of process devices and sequencing process steps
- Fully integrated WIP/CIP cleaning facilities based upon water, water and detergent or solvent based systems, incorporating hand wash lance, rotary sprayball and solvent atomising devices
- Contained transfer ports including bag-in/bag-out, airlocks, rapid transfer ports (alpha/beta), and Split Butterfly Valves (SBVs) for material, equipment and waste transfer. Raise/lower systems available to aid operator during connection/disconnection of vessels
- Hinge/slide open access doors incorporating inflatable seals and full interlock capabilities
- Connection interfaces for liquid, gas and power utilities
- Dispense equipment interface including electronic weigh scales, displays, label printers and dispensary management computer systems



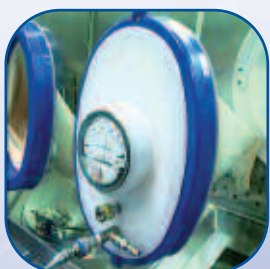
**Vessel Charging Isolator**



**QC Analytical Isolator**



**Milling Isolator**



**Glove Test Kit**



**Scale Integration**



**Incorporated Process Vessel**



**PharmaPort**



**Drum Manipulation Device**

# Flexible Isolators



Extract Technology Flexible Isolators are a rapidly growing product range in the field of operator protection. They provide containment standards better than can be achieved with Downflow Booth technology, and compare favourably with a rigid Isolator system. As well as providing high levels of operator safety, Flexible Isolators benefit from relatively short lead times and lower costs than Booths or rigid Isolator systems.

Due to their light duty construction, Flexible Isolators are often applied to experimental or R&D applications where speed of deployment and operator safety are a priority. Process applications can be met by the Flexible Isolator range through the addition of features such as RTPs and rigid work platforms.

## Design Advantages

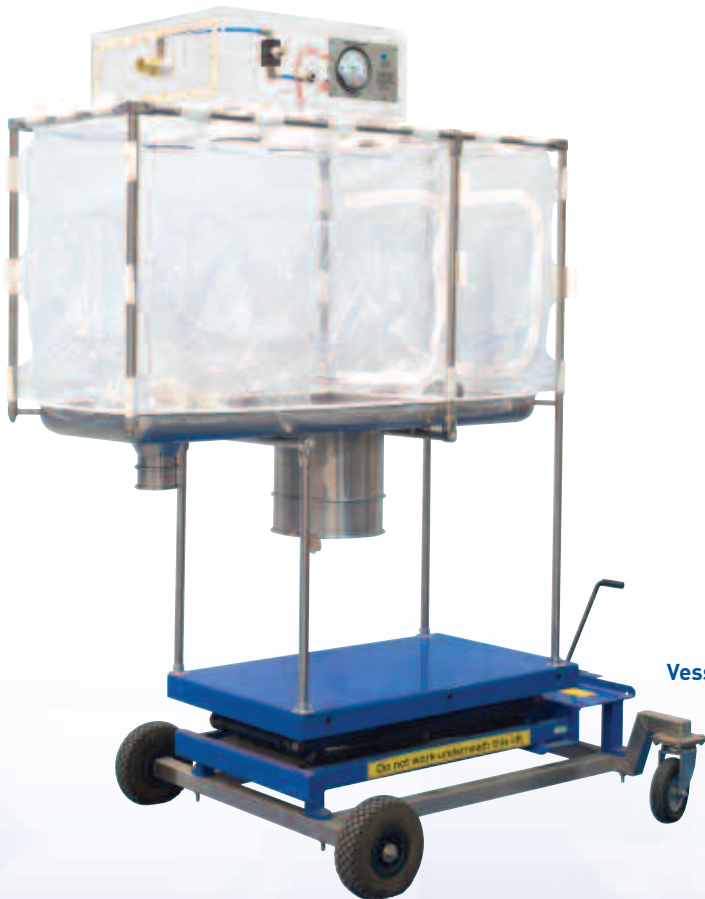
- Guaranteed containment performance down to  $1\mu\text{g}/\text{m}^3$  dependent upon the design and SOPs
- Rapid installation and start up
- Self contained air movement and negative pressure filtration system
- Ergonomic design to maximize operator comfort
- Low cost of replacement at product changeover or campaign end



# Optional Features

As the Flexible Isolators are designed to suit the process, many standard options are available to ensure customer needs are met in a cost effective manner.

- Rigid base for electronic balance or process vessel
- Rigid airlock for improved entry/exit flow of materials
- Alpha/Beta port (RTP) entry/exit for contained transfer
- Onboard HEPA inlet and exhaust filters
- Envelope and filter condition gauges
- Floor junction sealing frame for walk in enclosures
- Material/personnel airlocks
- Personnel decontamination showers
- Services/gas line pipe interface
- WIP/CIP decontamination lance and drain facilities



Vessel Charging Isolator



Dispensing Isolator



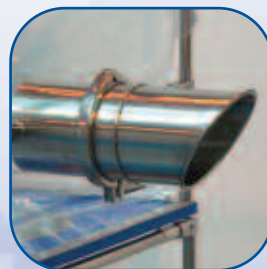
Enclosure Support Frame



Safe Change Filter System



Zipped Access Door



Bag-out Port



Product Transfer Port

# Design and Build

## Design

We generate conceptual designs based upon proven solutions, before finally compiling product specifications, standard operating procedures (SOPs) and working schematics (P&IDs).

## Mock Up

We can create full scale, fully-operating mock-ups which take into account ancillary equipment, manipulation devices and airflow/pressure regimes. The client review follows, at which stage any necessary modifications can be made.

## Manufacturing

Manufactured in high quality stainless or exotic alloy steels the Isolator fabrications are formed, welded and polished to exacting standards and client requirements within ISO 9001 operating procedures.

## Factory Acceptance Testing

Only when the equipment is fully built and pre-commissioned to design parameters is it exposed to a range of tests and standard operating procedures (SOPs). These can include high volume dust in air monitoring, internal/external surface swabbing, standard dust in air monitoring, and full scale operational tests of performance, all being performed within our controlled test environment.

## Installation/Commissioning

Every installation is conducted under full supervision by fully qualified, highly experienced Extract Technology engineers. Commissioning/validation services are undertaken, along with comprehensive operator training packages. Full test reports and IQ/OQ documentation can also be provided.

## Optional Design Study Facility

Extract Technology offer a full design study service which allows the client to fully investigate all possible containment solutions with a minimum outlay. A typical design study involves a detailed site survey and process discussion to establish the full extent of the project. Next the engineering designs, specifications and costings are generated before a full on site presentation is undertaken.

An additional option involves the construction of full working Isolator mock-ups for review by the client.



Isolators in Test Area

**Extract Technology are also able to offer other Engineered Solutions such as Containment Booths, Contained Powder Discharge Systems, Sampling and Dispensing Facilities.**