



DELIVERING  
INNOVATION  
TO PROTECT

 [extract-technology.com](http://extract-technology.com)

# ASEPTIC SOLUTIONS

## FILLING LINE ISOLATOR

FULL PROCESS EQUIPMENT  
INTEGRATION WITHIN A  
GRADE A ISO 5  
ENVIRONMENT



FILLING LINE



## STERILITY TEST ISOLATOR

DESIGNED TO  
PERFORM STERILITY  
TESTING IN AN ASEPTIC  
ENVIRONMENT  
PROVIDING  
ASSURANCE OF  
PROCESS INTEGRITY

STERILITY TEST



## CELL THERAPY ISOLATOR

ERGONOMIC AND  
PRACTICAL ALTERNATIVE  
TO TRADITIONAL CLEAN  
ROOMS FOR THE  
PRODUCTION OF CELLS  
FOR CLINICAL USE

CELL THERAPY

## C-RABS AND O-RABS

DEVELOPED TO ENHANCE  
ASEPTIC PROCESSES  
CARRIED OUT IN  
CONVENTIONAL CLEAN  
ROOMS



CRABS & ORABS



Process Systems



**Complete Aseptic Solutions** based around an innovative range of **Isolators** and **RABS** bringing different features and benefits to your application, but all have one thing in common: they provide **Guaranteed Product Protection**.

### EXTRACT TECHNOLOGY

ASEPTIC ISOLATORS ARE DESIGNED TO ALLOW OPERATORS TO PERFORM ASEPTIC PROCESSES IN A STERILE ENVIRONMENT PROVIDING ASSURANCE OF PROCESS INTEGRITY. EXAMPLE BELOW:



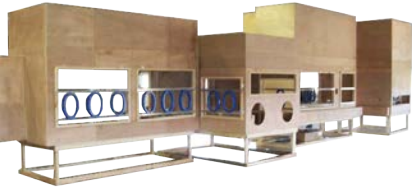
### DESIGN FEATURES

- Fully welded 316L stainless steel construction < .
- Positive pressure regime < .
- Turbulent or unidirectional airflow systems available < .
- Air recirculation within glass panels available < .
- Hydrogen Peroxide decontamination < .
- Full process equipment integration < .
- Controlled environment available ( $N_2$ , RH & temperature) < .

### Example process description:

The above **Filling Line isolator** allows for the entry of pre-sterilized stoppers and caps through a Rapid Transfer Port (RTP). Product can also be introduced into the Isolator via the RTP. Glassware is transferred to the isolator in separate transfer isolators. The Transfer Isolator "docks" to the filling isolator via a RTP and the trays of glassware are manually positioned on the accumulator of the filling machine. The vials are automatically moved by the filling machine through the filling, stoppering and capping stations and exit through a "mouse hole" in the end wall of the isolator. A conveyor carries the vials from the Isolator under an external unidirectional airflow module and into the adjoining packaging room.





## 2. Design

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

## 4. Factory Acceptance Testing

Only when the equipment is fully built and fully tested to the design parameters it is exposed to a range of tests and standard operating procedures (SOPs). These can include H<sub>2</sub>O<sub>2</sub> chemical indicator testing, particle monitoring tests, smoke studies and full scale operational tests of performance all being performed within our separate test environment.

## 1. Mock up

We can create full scale mock-ups which take into account ancillary equipment and manipulation devices. The client review follows, at which stage any necessary modifications are made.

## 3. Manufacturing

Manufactured in high quality stainless or other alloy steels the Isolator fabrications are formed, welded and polished to exacting standards and client requirements.

ISO 5/

**Grade A** within unidirectional airflow system



## FILLING MACHINE

ISOLATORS ARE DESIGNED TO ENCLOSE THE FILLING, STOPPERING AND CAPPING OPERATIONS OF A POWDER OR LIQUID FILLING MACHINE WHILE PROVIDING AN ASEPTIC ENVIRONMENT FOR THE PROCESS, ACHIEVING ISO 5 GRADE A CLASSIFICATION.

<30 mins

**decontamination** possible within fast gassing airlock



## INTERFACE

ISOLATORS ARE USED TO PROVIDE AN ASEPTIC ENVIRONMENT AROUND THE LOADING/ UNLOADING OPERATIONS IN AN AUTOCLAVE, LYOPHILISER AND DEPYROGENATION OVEN.

UL/CE

**certified**

Inhouse control panel build



## CELL THERAPY

ISOLATORS ARE DESIGNED TO PROVIDE AN ERGONOMIC AND PRACTICAL ALTERNATIVE TO TRADITIONAL CLEAN ROOMS FOR STRINGENT CGMP AND INTERNATIONAL REGULATIONS FOR THE PRODUCTION OF CELLS FOR CLINICAL USE.



## CUSTOM DESIGN

We know that not all customers' requirements will fall into our standard Steripharm Isolator design. For that reason we offer **custom designed isolators** to suit individual customer requirements including **Half suits, 6 glove ports, Multiple chamber construction and custom sizes.**



## AVAILABLE OPTIONS

- > Continuous particle monitoring system
- > Hydrogen peroxide vapour generator integration
- > Automated multiple glove port tester
- > Rapid Transfer Ports
- > Airlocks

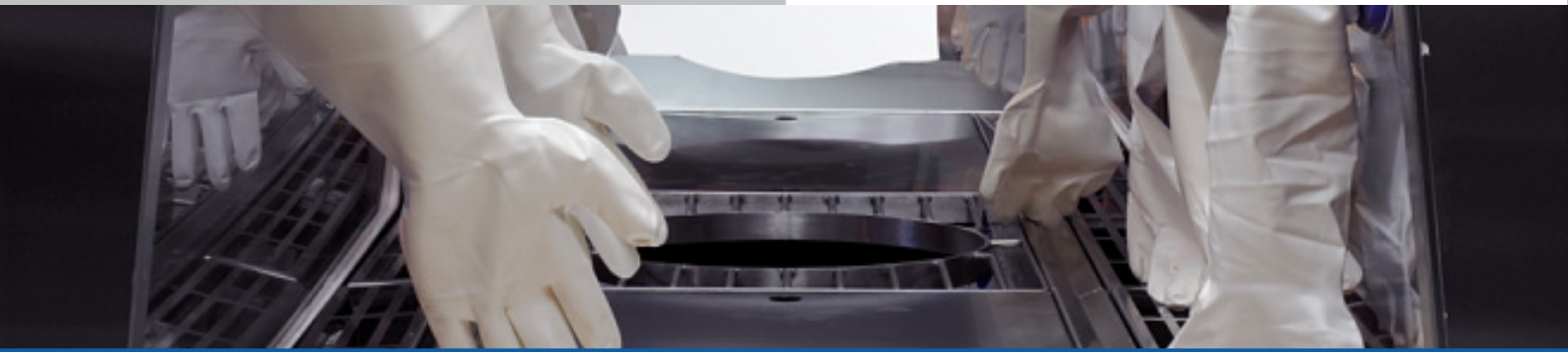
## STERILITY TESTING

CUSTOM STERILITY TEST ISOLATORS ARE DESIGNED TO ALLOW OPERATORS TO PERFORM STERILITY TESTING IN AN ASEPTIC ENVIRONMENT PROVIDING ASSURANCE OF PROCESS INTEGRITY. THEY ALSO PROVIDE A CONTROLLED MEANS OF LOADING AND REMOVING THE PROCESSED PRODUCT AND WASTE MATERIALS FROM THE ISOLATOR ENCLOSURE.

## DESIGN FEATURES

- Multiple chambers available  
6 glove main chamber or half suit < . .
- 316L stainless steel construction < . .
- PLC with password protection < . .
- Ergonomic design < . .
- Full process equipment integration of Millipore Steritest Unit or Sartorius Sterisart NF < . .
- Hydrogen Peroxide Decontamination ready < . .
- Custom racking and storage to suit the application < . .
- Recirculation laminar flow airflow system or turbulent airflow systems available ISO 5 / Grade A classification (unidirectional only) < . .





Restricted Access Barriers (RABs) were developed to enhance aseptic processes carried out in conventional clean rooms. Extract Technology custom RABs are designed to fully comply with our customers' requirements for aseptic processing.

RABS ARE AVAILABLE IN **OPEN** OR **CLOSED** DESIGNS.

## OPEN RABS

- > **OPEN PASSIVE RABS** utilise existing clean room overhead air supply systems to deliver HEPA filtered air over a critical process before returning air back into the clean room without the need for additional fans or filters. The RABs enclosure is not sealed to the filling machine.
- > **OPEN ACTIVE RABS** have an onboard fan/filtration units to supply HEPA Filtered air over a critical process before returning air back into the clean room. The RABs enclosure is not sealed to the filling machine.



### DESIGN FEATURES

Restricted Access Barriers (RABS) were developed to enhance aseptic processes carried out in conventional clean rooms.

- > Rigid wall enclosure
- > ISO 5 UDAF environment
- > Gloves for set up and interventions
- > Access door for rare interventions

## CLOSED RABS

**CLOSED RABS** is a positive pressure system with onboard fan/filtration units to supply HEPA Filtered air over a critical process which then passes through exhaust filters before being recirculated.

Airflow recirculates with the RABs enclosure. RABs typically are not decontaminated, unless the filling machine and all other openings can be sealed.

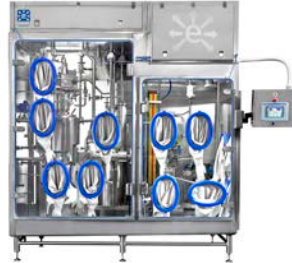
All RABs can include glove ports, RTP systems, access doors with interlocks and EM systems as required.

# EXTRACT TECHNOLOGY

also offers containment and mobile cleanroom solutions:



DOWNFLOW BOOTHS



CONTAINMENT ISOLATORS



SAMPLING FACILITIES



PACK OFF AND PROCESS



MOBILE CLEANROOMS



STANDARD PRODUCT RANGE



## WHERE WE WORK

- Europe
- Asia
- Australasia
- Russia
- Middle East
- Africa
- South America
- Central America
- North America

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