ASEPTIC SOLUTIONS

FILLING LINE ISOLATOR
FULL PROCESS EQUIPMENT INTEGRATION WITHIN A GRADE A ISO 5 ENVIRONMENT

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

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

C-RABS AND O-RABS
DEVELOPED TO ENHANCE ASEPTIC PROCESSES CARRIED OUT IN CONVENTIONAL CLEAN ROOMS
Example process description:
The above Filling Line isolator allows for the entry of pre-sterilized stoppers and glassware through a separate transfer port (RTP). Product can also be introduced into the isolator via the RTP. Glassware is transferred to the isolator in separate transfer chambers or wrapped in a disposable tray. Modulation devices are introduced into the pre-sterilized glassware. The client review follows, at which stage any necessary modifications are made.

Interface
Isolators are used to provide an aseptic environment around the loading/unloading operations in an autoclave, depyrogenation oven.

Cell Therapy
Isolators are designed to provide an ergonomic and practical alternative to traditional clean rooms for STRIGHT COMP AND INTERNATIONAL REGULATIONS FOR THE PRODUCTION OF CELLS FOR CLINICAL USE.

Sterility Testing
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.

Extract Technology
Aseptic Isolators are designed to allow operators to perform aseptic processes in a sterile environment providing assurance of process integrity. Example below:

1. Mock up
We can create full scale mock-ups which take into account operational requirements, manipulation devices. The client review follows, at which stage any necessary modifications are made.

2. Design
The complete design is based upon proven solutions, current technology, specification, standard components, excludes (GMP) civil engineering schematics (plgs)

3. Manufacturing
Manufacturing in high quality stainless steel or other alloys which meet the required specifications, is performed and adhering to existing standards and client requirements.

4. Factory Acceptance Testing
Only when the equipment is fully tested and fully tested to the design parameters it is exposed to a range of tests and signed operating guidelines. Tests include: H2O2 chemical indicator testing, particle monitoring tests, smoke studies, visual and ultrasound checks carried out inside the complete suite in an independent test environment.

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.

Design Features
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)

Available Options
> Continuous particle monitoring system
> PLC with password protection
> Sterile苋t Unit or Surformal Disinfection
> Custom racking and storage to suit the application

Sterile Isolator Design
Aseptic Isolators are designed to allow operators to perform aseptic testing in an aseptic environment providing assurance of process integrity. They also provide a controlled means of loading and removing the product and waste materials from the isolator enclosure.

Aseptic Isolators
Complete Aseptic Solutions based around an innovative range of isolators and RABS offering different features and benefits to your application, all at a piece of kit in common: they provide Guaranteed Product Protection.
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.

**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

For more information on our products please visit our website or contact us directly:

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