BARRIER ISOLATION TECHNOLOGY FOR STERILITY TESTING, ASEPTIC FILLING & CONTAINMENT PROCESSING
IsoTech Sterility Testing, Aseptic Filling & Containment Isolators

Provide barrier isolation technology for contamination control, sterility assurance and containment management.

STERILITY TESTING:
Eliminate the risk of a false positive sterility test

Up until recently, most pharmaceutical, biotech & medical devices companies were using laminar airflow hoods in cleanrooms to perform sterility testing of their products. In such settings, the average false positive rate is typically higher than 0.25% per year. This results in high costs associated with investigating possible causes and could require that the batch be quarantined and/or sometimes rejected.

ASEPTIC FILLING:
Eliminate the risk of high start-up costs, extended deadlines and possible contamination in small volume and pilot scale aseptic fillings

Costs associated with constructing, validating and operating a cleanroom can be a considerable investment. In a cleanroom setting using laminar airflows, there are human and environmental contacts which greatly increase the risk of contamination, which could result in higher production costs and delays.

CONTAINMENT:
Eliminate the risk of the operator's safety when handling toxic powder and compounds

In most pharmaceutical and biotech companies, handling powder and toxic compounds represents a hazardous environment for the operator. Process operations such as weighing, transferring and handling such compounds must be contained to provide a safe environment for the operator while maintaining an aseptic environment.
Barrier isolation technology offers cost savings over traditional cleanroom technology, better sterility assurance, contamination control & safety

Barrier isolation technology can offer up to 50% cost savings when compared to constructing, validating and operating a cleanroom. IsoTech isolators do not require a controlled background environment and are compact. Consequently, only low cost laboratory space for sterility testing is required for siting the isolators. Gowning is reduced, which can save up to 70% of the operational, maintenance, energy and labor costs, and greatly increases employee comfort. The successful performance history of the isolators enables ease in validation while being widely accepted by the FDA and EC GMP.

In recent years, barrier isolation technology has been introduced for sterility testing, aseptic filling and containment processing, and by the end of 1998, over 100 systems have been installed and approved by the FDA and EC GMP. Because barrier isolation technology eliminates human and environmental contact with the product, the risk of contamination is greatly reduced. The success with barrier isolation technology systems can be substantiated by the fact that many sterility testing systems have been in use for over 5 years without a single false positive test. In aseptic filling process, isolators on both continents have been in operation and validated with high level of sterility assurance. As for containment, operator safety is assured within an aseptic environment.
HemiSphere™

- Standard design for interfacing with Kuhlman GMP Sterilizers
- Softwall or hardwall half-suit workstation with gloveport product handling for operator comfort
- Cabinet-enclosed piping and control systems
- Rigid wall isoTransfer™ isolator for material surface decontamination and rapid product transfer
- Standard half-suit position design allows for greater mobility
- Custom integrations and connections for specific applications
- Applications with laminar airflow hood for aseptic filling with or without environmental control
- Class 10 (M2,5) at rest

Kuhlman Pharma Pro Vertical Sliding Door Autoclaves are engineered and designed to fully interface with the IsoTech HemiSphere isolator.

The Millipore Sterile™ Integral 3 to 11 for sterility testing is easily integrated into the work surface of the isolator. Only the components for conducting sterility tests are exposed to the clean environment.
The HemiSphere isolator systems are designed to meet the stringent demands of the Pharmaceutical and Biotech industries for large volume size lot sterility testing applications (HemiSphere-ST™) and small volume aseptic filling applications (HemiSphere-AF™). The workstation is a turbulent airflow system for sterility testing or laminar airflow system for aseptic filling with a side-mounted half-suit and four glove ports. The ventilated half-suit allows for easy management of material transfer. The glove ports are used for actual product manipulation. IsoTech’s unique ergonomic design allows the operators to accomplish the majority of the work in the human friendly environment of the laboratory rather than in the half-suit.

All piping and controls are located in the lower portion of each isolator to provide a clear pathway for ceiling lights and to eliminate dust-collecting areas. The flexibility of our systems allows an interfacing with other possible equipment such as autoclaves, lyophilizers or dry heat ovens. Optional items such as sterility testing pumps or aseptic filling equipment can be flush mounted into the work surface of the isolator.
**IsoSphere™**

The *IsoSphere-ST™* is designed to meet the demands of small to medium size lot sterility tests. The *IsoSphere-AF™* with laminar airflow hood is designed for small or pilot scale aseptic filling applications. The true isolation design eliminates the need for a controlled room or a very highly classified room by providing two totally enclosed, self-contained environments with a semi-permanent connection. This makes it possible to lower investment costs and reduce the amount of floor space needed. The IsoSphere workstation isolator is equipped with four or more glove ports and is ergonomically designed for operator comfort. Independant ULPA or HEPA filtered, single pass or recirculated turbulent or laminar air is maintained throughout the system to ensure air quality and an aseptic working environment. The flexibility of our system allows for integration of optional items such as sterility testing pumps, aseptic filling equipment and other equipment.

**IsoSphere™**

- Softwall or harwall workstation
- Stainless steel rigid wall *IsoTransfer™*
- Rigid airtight transfer doors
- Independent ULPA filtration systems
- Compact space-saving design
- Low capital, operating and maintenance costs
- Standard design for sterility testing applications
- Applications with laminar airflow hood for aseptic filling with or without environmental control
- Custom integration for specific applications
- Class 10 at rest
IsoTransfer™

- Stainless steel hard wall isolator
- Equipped with large standard airtight rectangular transfer doors to enable easy loading & unloading of large container
- Connected to a hydrogen peroxide generator for surface decontamination of materials
- Independant ULPA filtration systems
- Standard design to connect with any of the IsoTech working isolators
- Transfer mechanism, trolley, mobile storage to improve ergonomics, reduce direct operator handling and facilitate procedural steps
- Custom design racking systems for specific sample sizes to improve process
- Inclined front panel and clear PVC top panel for better visibility
- Class 10 (M2.5) at rest

The all-stainless-steel construction of the IsoTransfer™ allows rigorous surface decontamination with aggressive sterillants and enables faster decontamination cycles with the hydrogen peroxide vapor generator because of quicker aeration phases. The IsoTransfer™ can be equipped with Alpha/Beta ports for moving and transferring materials with a high level of sterility assurance. A loading cart and transfer trolley make it possible to load and unload materials quickly and efficiently.
IsoTransfer™
Powder

Two, four glove or custom design isolator, class 10 (M2.5), turbulent flow in negative pressure for handling, weighing and transferring powder.

IsoProtect™

Two, four glove or custom design, class 10 (M2.5) isolator, turbulent or laminar flow, negative pressure with or without environmental control for all types of toxic compound manipulations: Biological, chemical, nuclear and radiopharmaceutical.
HemiSphere™ Powder Transfer

HemiSphere™ Powder Transfer
Half-suit isolator, class 10 (M2.5), turbulent flow in negative pressure for large volume powder handling, transferring and/or weighing.
## Technical Data

<table>
<thead>
<tr>
<th></th>
<th>HemiSphere-ST™</th>
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<th>IsoSphere-ST™</th>
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<tbody>
<tr>
<td><strong>External Dimensions</strong></td>
<td>76&quot; W x 76&quot; D x 85&quot; H 1930 mm W x 1930 mm D x 2159 mm H</td>
<td>76&quot; W x 76&quot; D x 94&quot; H 1930 mm W x 1930 mm D x 2388 mm H</td>
<td>74&quot; W x 32&quot; D x 66&quot; H 1880 mm W x 813 mm D x 1676 mm D</td>
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<td><strong>Internal Dimensions</strong></td>
<td>72&quot; W x 72&quot; D x 48&quot; H 1829 mm W x 1829 mm D x 1219 mm H</td>
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<td>72&quot; W x 31.5&quot; D x 31.5&quot; H 1829 mm W x 600 mm D x 800 mm H</td>
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</tr>
<tr>
<td><strong>Materials of Construction</strong></td>
<td>Stainless 316L / PVC</td>
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<tr>
<td><strong>Inlet Air Filtration</strong></td>
<td>ULPA</td>
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<tr>
<td><strong>Airflow</strong></td>
<td>Turbulent</td>
<td>Laminar</td>
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<tr>
<td><strong>Air Classification</strong></td>
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<td><strong>Internal Pressure</strong></td>
<td>± 0.15&quot; WC ± 37 Pa</td>
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<td>± 0.15&quot; WC to ± 0.40&quot; WC ± 37 Pa to ± 100 Pa</td>
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<td><strong>Pressure Controller</strong></td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
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<tr>
<td><strong>Process Connections</strong></td>
<td>IsoTransfer™ Alpha/Beta Door VHP Generator Autoclave Sterility Testing Pump</td>
<td>IsoTransfer™ Alpha/Beta Door VHP Generator Autoclave Lyophilizer Dry Heat Oven Aseptic Filling Equipment Environmental Control</td>
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<td><strong>Electrical Supply</strong></td>
<td>115-120V, 60 Hz, 6A 210-220V, 50 Hz, 3A</td>
<td>115-120V, 60 Hz, 10A 210-220V, 50 Hz, 10A</td>
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### Testing, Start-up and Training

Full factory testing is your assurance of reliability once the equipment reaches your facility. Each IsoTech product is thoroughly inspected in our factory prior to shipment.

Our qualified service engineers will do the start-up of the IsoTech equipment along with the training and installation qualification. All electrical components meet international standards.

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### Warranty

We believe our customers deserve the best equipment available in terms of performance, safety and service.

We offer our customers a solid, effective one-year warranty. We want you to know that your confidence in the IsoTech product is justified.

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<td>87.2&quot; W x 33&quot; D x 99&quot; H 2215 mm W x 838 mm D x 2514.6 mm H</td>
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<td>37.5&quot; W x 31.5&quot; D x 31.5&quot; H 952.5 mm W x 800 mm D x 800 mm H</td>
<td>47.2&quot; W x 19.7&quot; D x 27.5&quot; H 1199 mm W x 500 mm D x 699 mm H</td>
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**Customer Service**

Our customers stand by our products. We develop strong relationships with our customers.

We fully support and service our equipment.
Protecting life with barrier isolation technology and clean air environments for contamination control, sterility assurance and containment management.

5778, Thimens
Saint-Laurent (Quebec)
Canada H4R 2K9
Tel.: 514.956.1602
Direct: 1.800.ISO.2010
Fax: 514.956.1032
E-Mail: info@isotechdesign.com
Web: isotechdesign.com

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