



*Protecting Life
Protéger La Vie
Protegiendo La Vida*

BARRIER ISOLATION TECHNOLOGY FOR ASEPTIC FILLING



T E C H N I C A L D A T A

	IsoSphere™ - AF	IsoTransfer™ - AF 2 or 3-glove														
Applications	Small to Medium Volume Aseptic Filling	Decontamination Process and Aseptic transfer														
External Dimensions	96" W x 32" D x 85" H Custom sizes available	38" - 48" W x 32" D x 67" H														
Materials of Construction	316L stainless steel, No. 4 finish base with coved corner	316L stainless steel, No. 4 finish base with coved corner														
Air Filtration	HEPA filters (99.99% DOP at .3 u) on the inlet and outlet	HEPA filters (99.99% DOP at .3 u) on the inlet and outlet														
Airflow	Unidirectional	Unidirectional														
Air Classification	ISO class 4 (Class 10)	ISO class 4 (Class 10)														
Internal Pressure	+ 0.15 WC + 37 Pa	+ 0.15 WC + 37 Pa														
Process Connections	<table border="0"> <tr> <td>Filling Equipment</td> <td>Process Equipment</td> </tr> <tr> <td>Peristaltic Pump</td> <td>Lyophilizer</td> </tr> <tr> <td>Semi-Automatic Filler</td> <td>Dry Heat Sterilizer</td> </tr> <tr> <td>Monobloc Filler</td> <td>Autoclave</td> </tr> <tr> <td></td> <td>IsoTransfer™</td> </tr> <tr> <td></td> <td>Alpha-Beta Door</td> </tr> <tr> <td></td> <td>VHP Generator</td> </tr> </table>	Filling Equipment	Process Equipment	Peristaltic Pump	Lyophilizer	Semi-Automatic Filler	Dry Heat Sterilizer	Monobloc Filler	Autoclave		IsoTransfer™		Alpha-Beta Door		VHP Generator	<p>IsoSphere-AF™ Alpha/Beta Door VHP Generator</p>
Filling Equipment	Process Equipment															
Peristaltic Pump	Lyophilizer															
Semi-Automatic Filler	Dry Heat Sterilizer															
Monobloc Filler	Autoclave															
	IsoTransfer™															
	Alpha-Beta Door															
	VHP Generator															
Electrical Supply	115-120V, 60 Hz, 6A 210-230V, 50 Hz, 3A	115-120V, 60 Hz, 6A 210-230V, 50 Hz, 3A														
Noise Level	< 65 dB	< 65 dB														

Installation, Start-up and Training:

Full factory testing is your assurance of reliability once the equipment reaches your facility. Each IsoTech Design 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 qualifications. All electrical components meet international standards.

Delivery Delays:

16-20 weeks from drawing approval.

Warranty:

We believe our customers deserve the best equipment available in terms of performance, safety and service. We offer our customers a solid 18-month warranty.

We want you to know that your confidence in the IsoTech product is justified.



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New York, 12919 USA
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ISOLATOR ADVANTAGES:

- Lower Contamination: Increased SAL.
- Aseptic: ISO class 4 (10) unidirectional airflow isolator, exceeding the cGMP requirements of ISO class 5 (100)
- Complete Product / Operator Protection
- Operator physically separated from aseptic area
- Smaller Critical Area
- Minimal energy requirements
- Turnkey solution: Integrated design, Barrier Isolation Technology solution, Filling Equipment & Process Equipment integration, H2O2 decontamination, HMI and validation



ISOSPHERE™-AF & ISOTRANSFER™

- IsoClass 4 positive pressure unidirectional airflow isolator.
- Monobloc filler integration.
- Decontamination with an H2O2 Generator.



2 GLOVE ISOTRANSFER™

- Positive Pressure IsoClass 4 Transfer Isolator
- Unidirectional Airflow
- For material & product transfer and decontamination with VHP
- Fixed or mobile
- Available in with 3 glove ports for more space



**HMI
TOUCH SCREEN**



**BELLOWS
INTERFACE**

ACCESSORIES AND OPTIONS:

- Casters
- Flush bottom ball valve drain
- Service plate for sanitary connections
- Recirculation fans for better air distribution
- Integration of Aseptic Filling & Process Equipments
- Interface with Lyophilizers, Autoclaves and DHS
- Installation, start-up and training
- Design integration
- IQ, OQ, PQ documentation and execution
- FAT and SAT Validation



ALPHA-BETA DOOR



FLEXICON PERISTALTIC PUMP AND SANITARY CONNECTIONS INTEGRATED IN WORK SURFACE OF ISOSPHERE™-AF

HEMISPHERE-AF™ INTERFACE ISOLATOR

- IsoClass 4, Unidirectional Airflow Isolator.
- Interface with Lyophilizers, Autoclaves and DHS.
- Decontamination with H2O2 Generator.