



*Protecting Life
Protéger La Vie
Protegiendo La Vida*



BARRIER ISOLATION TECHNOLOGY FOR STERILITY TESTING & ASEPTIC FILLING

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

	MicroSphere™ RABS	ChemoSphere™ CRABS Isolator	IsoSphere™	
Applications	Small & medium volume sterility testing & aseptic filling	Small & medium volume sterility testing & aseptic filling	Medium & large volume sterility testing & aseptic filling	
Size	4', 6', 8' or custom			
Materials of Construction	Anodized Aluminum & 316L stainless steel	316L stainless steel, No. 4 finish	316L stainless steel, No. 4 finish	
Air Filtration	HEPA filters (99.99% DOP at .3 u) on the inlet	HEPA filters (99.99% DOP at .3 u) on the inlet and outlet		
Airflow	Unidirectional			
Air Classification	Iso Class 4 (Class 10)			
Internal Pressure	+ 0.15 WC + 37 Pa	- 0.15 WC - 37 Pa	+/- 0.15 WC +/- 37 Pa	
Process Connections	Sterility Testing Pump Aseptic filling equipment	Sterility Testing Pump Aseptic filling equipment	PLC Integration & decontamination with H2O2 Generator Sterility testing pump	Aseptic filling equipment Alpha/Beta Door
Electrical Supply	115-120V, 60 Hz, 210-230V, 50 Hz, 3A			
Noise Level	< 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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ISOLATOR ADVANTAGES :

- Lower Contamination: Increased SAL
- Aseptic: Exceeding the cGMP requirements of ISO class 4 with unidirectional airflow
- Complete Product / Operator Protection
- Smaller critical area increases test efficiency: No false positives for sterility testing
- Minimal energy requirements
- Turnkey solution: Barrier Isolation Technology solution, equipment integration, H2O2 decontamination, IQ/OQ, cycle development, HMI and validation documentation & execution

FOR SMALL & MEDIUM VOLUME



MICROSPHERE™ - RABS

Iso class 4, unidirectional positive pressure RABS CAI with one or two unidirectional antechambers with an open lid window. Manual decontamination with a cold sterilant.



CHEMOSPHERE™ - CRABS

Iso Class 4, negative pressure, hardwall, unidirectional airflow CRABS CACI, with one or two unidirectional antechambers & open lid window. Manual decontamination with cold sterilant. Can be connected to an H2O2 generator for decontamination

FOR LARGE VOLUME



ISOSPHERE™ - ISOLATOR

Iso Class 4, positive, unidirectional airflow hardwall isolator, filter in + filter out, with one or two unidirectional antechambers, PLC, integration & decontamination with H2O2 generator. For hazardous compounds, can be connected to a secondary HEPA filtration system. Can be connected to an IsoTransfer or a process equipment.

ACCESSORIES AND SERVICES:

- Integration with pumps, filling & process equipment
- Casters
- Ball valve drain
- Lifting system
- Service plate for sanitary connections
- Installation, start-up and training
- FAT, SAT & IQ / OQ, documentation and execution
- Cycle development



**BELLOWS
INTERFACE**



PLC



**ALPHA-BETA
DOOR**



The Millipore™ or Sartorius® Pumps can easily be integrated into the work surface