



Compounding Aseptic Isolators

The marketplace offers a variety of compounding aseptic isolators (CAIs) for pharmacy applications. On this page, PP&P highlights some of the CAIs available for the compounding of hazardous and non-hazardous sterile preparations. To obtain more information on any of these products, circle their corresponding reader service numbers on the reader service card bound in this issue of PP&P. For a list of purchasing considerations, see the opposite page.

The Baker Company

For non-hazardous drug preparation, the Baker Company offers the **SteriSHIELD**, a positive-pressure CAI, and for hazardous drug preparation, a negative-pressure CACI (compounding aseptic containment isolator), the **ChemoSHIELD**. Baker CAIs are height-adjustable via an optional electric-over-hydraulic lift system, allowing users to sit or stand. The oval glove ports are built into the ergonomically slanted (10 degrees) view screen and, hence, are easily accessible. Baker CAIs' unidirectional airflow, in both work chambers and pass-throughs, aids in the immediate removal of generated aerosols and particles. Baker also offers an optional cleaning tool, designed specifically to assist personnel in accessing all internal areas when cleaning and disinfecting.



For more information, circle reader service number 99.

Comecer

The Comecer **PH-S** is a negative-pressure isolator, designed for the compounding of cytotoxic pharmaceuticals. Users can sit or stand while working, and the glove flanges are oval to improve reach and manipulation. Gloves are also available in different sizes to accommodate the operator. With two transfer chambers (one for bringing materials into the isolator, and one for extracting them), the PH-S features HEPA-filtered unidirectional airflow in the main work chamber.



For more information, circle reader service number 81.

Germfree

Germfree's **LFGI** isolator is available in either a positive or negative pressure configuration. The standard hydraulic or optional electric height-adjusting stands offer a 10-inch range variance, allowing operators to sit or stand. Extra large oval glove ports are angled to accommodate a wide range of body types and to increase range of movement. Glove ports have a 3-inch armrest to reduce operator fatigue, and the viewing panel is angled to reduce glare and strain. HEPA-filtered unidirectional air bathes the work area, and a sealed two-door airlock, with a timed HEPA-filtration purge system, separates the work area from ambient conditions. A four-inch trash tube is provided with a removable cover, along with a 2.5-inch sharps tube with a removable cover that facilitates sharps disposal.



The all-stainless-steel **Versaflow** provides HEPA-filtered, unidirectional airflow in its positive-pressure work chamber. An optional height-adjusting stand offers a 10-inch range variance. The extra large oval glove ports have a 3-inch armrest to reduce operator fatigue, and the viewing panel is angled to reduce glare and strain. The laminar airflow pass-through has sliding ingress/egress doors. Users may choose a bag-in/bag-out waste disposal method or a container disposal system.

For more information, circle reader service number 82.

IsoTech Design

The **ChemoSphere** CACI has a negative-pressure work chamber, with a 45-second recovery rate, and a mechanical or electrical lifting system to suit operators of different heights. The isolator features a unidirectional-airflow, negative-pressure pass-through with a one-minute recovery rate. A 10-inch shoulder port ring facilitates operator movement, reach, and comfort. The isolator's gloves are chemo-tested and come in various sizes. A disposal port can be used for both waste and sharps. Each unit comes with ancillary supplies including sleeves, gloves, and cleaning products, such as a mini-adjustable mop for hard-to-reach areas.



The positive-pressure, unidirectional airflow **MicroSphere** CAI features a mechanical or electrical lifting system, an adjustable ergonomic chair, a 12-inch shoulder port ring, and a variety of glove sizes, to increase operator comfort. To facilitate efficient pharmacy workflow, the MicroSphere's work chamber and antechambers have recovery rates of less than one minute. The isolator comes with a waste and a sharp port integrated into the work surface, and ancillary supplies such as sleeves, gloves, and cleaning products, including a mini-adjustable mop.

For more information, circle reader service number 62.

NuAire

NuAire offers both positive- and negative-pressure **PharmaGard** CAIs with HEPA-filtered unidirectional airflow and optional height-adjustable base stands and large oval glove ports. The interchange chamber of both models maintains 20 air changes per minute. NuAire's PharmaGard CAIs feature an integral waste disposal system accessible from the work area. Contaminated waste or used sharps can be dropped through a stainless steel chute into standard containers. HEPA filters can be replaced from the front of the unit. Scientific Visions, NuAire's online store (www.scientificvisions.com), offers a wide variety of cleaning products and accessories to aid in the cleaning of all of our products.



For more information, circle reader service number 83.

Terra Universal

Terra Universal's **BioSafe Compounding Aseptic Isolator** provides unidirectional, HEPA-filtered airflow through the work chamber and features a large, ergonomically sloped, transparent-polycarbonate viewing window. A separate antechamber features a swing-out access door for the introduction and removal of compounding materials. Terra offers a Chamber Cleaning Kit, including a cleaning tool and prewetted 70% IPA wipers. A variety of stands are available, including Terra's ErgoHeight Auto-Adjusting Bench. Terra also manufactures negative-pressure ventilation chambers for the containment of hazardous materials.



For more information, circle reader service number 71.



Compounding Aseptic Isolators: Purchasing Considerations

Pharmacies seeking to use compounding aseptic isolators (CAIs) as part of their sterile compounding operations need to consider several key factors while making a CAI purchase or evaluating the CAIs currently in use at their facilities. Among these factors are:

- air pressure
- ergonomics
- airflow
- trash disposal
- pass through technology
- cleaning/disinfecting

And, of course, per USP <797> standards, any isolator you purchase must maintain ISO Class 5 air quality conditions during compounding activities.

Air Pressure:

CAIs can provide positive or negative air pressure relative to the rooms in which they operate. A CAI that provides positive air pressure in its main work chamber is suitable for the compounding of non-hazardous drugs. For the compounding of hazardous agents, the air pressure inside the CAI work chamber must be negative to the air pressure outside of the isolator.

Airflow:

An isolator that employs unidirectional airflow sweeps HEPA-filtered air over and away from exposed sterile materials, washing particles generated by compounding activities from the sterile materials, avoiding turbulent or stagnant airflow, and systematically exhausting air from the work chamber. This process can aid in maintaining the asepsis of your compounded sterile preparations (CSPs).

Pass Through Technology:

Material transfer is recognized as the stage most vulnerable to contamination in the compounding process. Understanding the importance of eliminating contamination, most CAI manufacturers have engineered material transfer protection, through the use of HEPA filtration and airflow, into their isolator's pass through chambers. HEPA-purged pass throughs are able to eliminate virtually all particle transfer into the isolator work chamber, and pass throughs that are purged with unidirectional airflow allow the almost immediate transfer of materials into the work chamber.

Ergonomics:

User comfort is critical to your compounding personnel's productivity and aseptic technique. Therefore, choose a CAI that enables height adjustment to accommodate different users. You should also ensure that the isolator's gloves will be easy for your employees to reach and work with.

Trash Disposal:

Select an isolator that enables your compounding personnel to easily dispose of sharps and pharmaceutical waste while preparing CSPs.

Cleaning/Disinfecting:

In selecting a compounding aseptic isolator for your pharmacy, consider how you will clean and disinfect it to promote CSP sterility and/or prevent worker exposure to hazardous drug agents. ■

One Stop Shopping for your USP <797> needs



- ✓ Economical Media Fill Aseptic Technique Kits & Components
- ✓ Sterility Test Kits for High-Risk CSPs
- ✓ Air, Surface, & Glove Fingertip Sampling Paddles
- ✓ 1 Hour Endotoxin Test
- ✓ Hazardous Drug Handling Test Kit
- ✓ Totally Pharmacy Based, Reduce Your Lab Costs

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For more information, circle #70 on the Reader Service Card