



**CONSOLIDATED
STERILIZER SYSTEMS**

A COMPREHENSIVE GUIDE TO
**BSL-3 Biocontainment
Lab Autoclaves**



BSL-3 autoclaves, also commonly known as biocontainment sterilizers, are essential in handling microbes that can lead to serious or potentially lethal disease through inhalation.

State-of-the-art BSL-3 autoclaves are utilized every day at leading universities, hospitals, biotechnology facilities and other laboratories around the world to help sterilize an extraordinary range of items and substances under conditions that ensure optimal safety.

Most standard steam sterilizers (autoclaves) are suitable for use in BSL-1 and BSL-2 labs. BSL-3 and BSL-4 facilities, however, require autoclaves that possess additional features. Here we will focus on BSL-3 facilities only, as BSL-4 is far less common and adds a lot more complexity to the discussion.

This eBook will also explore several key factors to think about when researching or purchasing a BSL-3 autoclave – the bio-seal, autoclave door safety and effluent decontamination systems.



LABORATORY BIOSAFETY LEVELS

Laboratories that work with microorganisms are assigned a “Biosafety Level” (BSL) designation by the Centers for Disease Control and Prevention.

This is to protect laboratory personnel, as well as the surrounding environment and community. Biosafety levels range from BSL-1 (least hazardous) to BSL-4 (most hazardous/dangerous). This graphic gives an easy-to-read breakdown of the criteria that go into determining a lab’s BSL level.

Biosafety Level	BSL-1	BSL-2	BSL-3	BSL-4
Description	<ul style="list-style-type: none"> - No Containment - Defined organisms - Unlikely to cause disease 	<ul style="list-style-type: none"> - Containment - Moderate Risk - Disease of varying severity 	<ul style="list-style-type: none"> - High Containment - Aerosol Transmission - Serious/Potentially lethal disease 	<ul style="list-style-type: none"> - Max Containment - “Exotic,” High-Risk Agents - Life-threatening disease
Sample Organisms	E.Coli	Influenza, HIV, Lyme Disease	Tuberculosis West Nile Yellow Fever	Ebola Virus
Pathogen Type	Agents that present minimal potential hazard to personnel & the environment.	Agents associated with human disease & pose moderate hazards to personnel & the environment.	Indigenous or exotic agents, agents that present a potential for aerosol transmission, & agents causing serious or potentially lethal disease.	Dangerous & exotic agents that pose a high risk of aerosol transmitted laboratory infections & life-threatening disease.
Autoclave Requirements	None	None	Pass-thru autoclave with Bioseal required in laboratory room.	Pass-thru autoclave with Bioseal required in laboratory room.

For more info on biosafety lab design, please see the [BMBL](#).

THE BIOSAFETY LEVEL 3 LAB

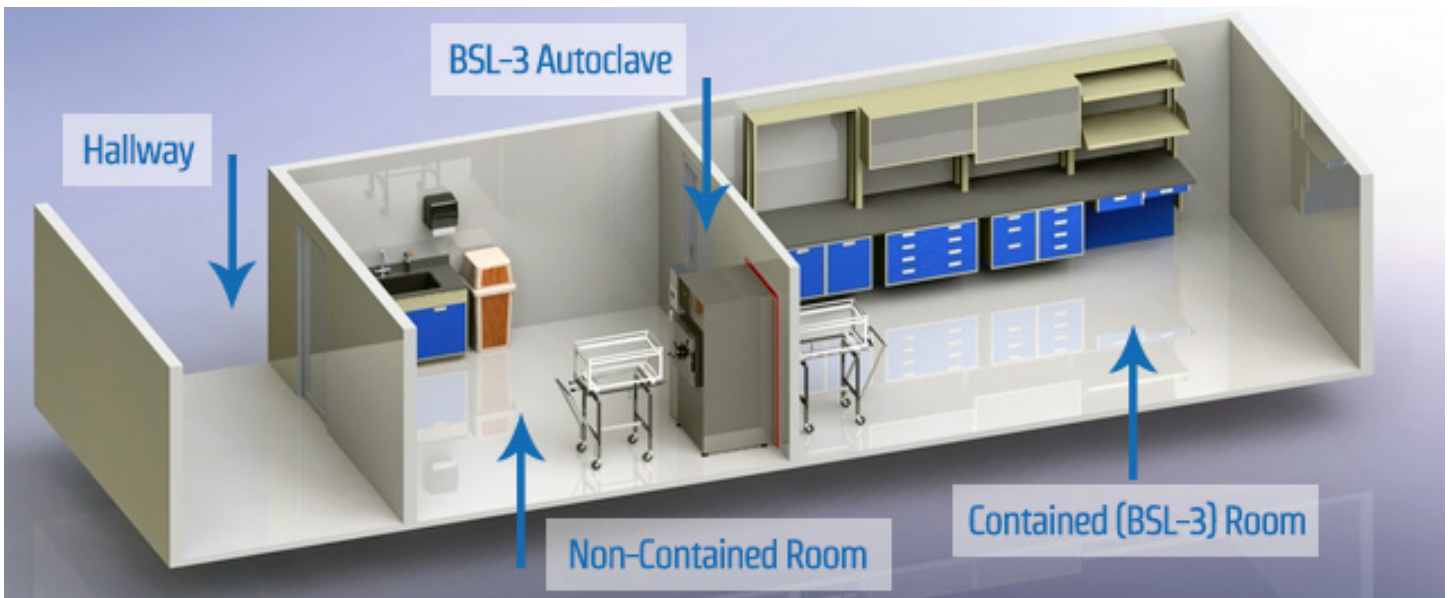
Perhaps the most important characteristic of a BSL-3 laboratory is that all bacteria and pathogens must be contained within the lab; hence, the name biocontainment lab. In other words, microbes must not escape from the room.

This is accomplished by incorporating the following design features into the space and surrounding areas:

- **Separation**
 - Physical separation from access corridors
 - Self-closing, double-door access
- **Containment**
 - Exhausted air, not recirculated
 - Negative airflow into laboratory
- **Decontamination**

These same design features for a BSL-3 room are applied to an autoclave utilized within that space.

For example, most BSL-3 autoclaves have two doors where the flow of goods “pass through” the autoclave – from the contained room out to the non-contained room. The autoclave is installed in the wall opening that separates the two rooms and must be sealed appropriately in the wall to prevent microbes from passing between the contained and non-contained side.



THE BSL-3 AUTOCLAVE

PART ONE

Autoclave Door Safety

Biocontainment autoclaves are typically configured with two doors, referred to as “pass-through” or “double door” autoclaves. One end of the autoclave is in the contained room and the other end extends through a wall to the non-contained side. The flow of goods usually goes from the contained side, where hazardous waste is loaded, to the non-contained side, where sterilized waste is ready for disposal.

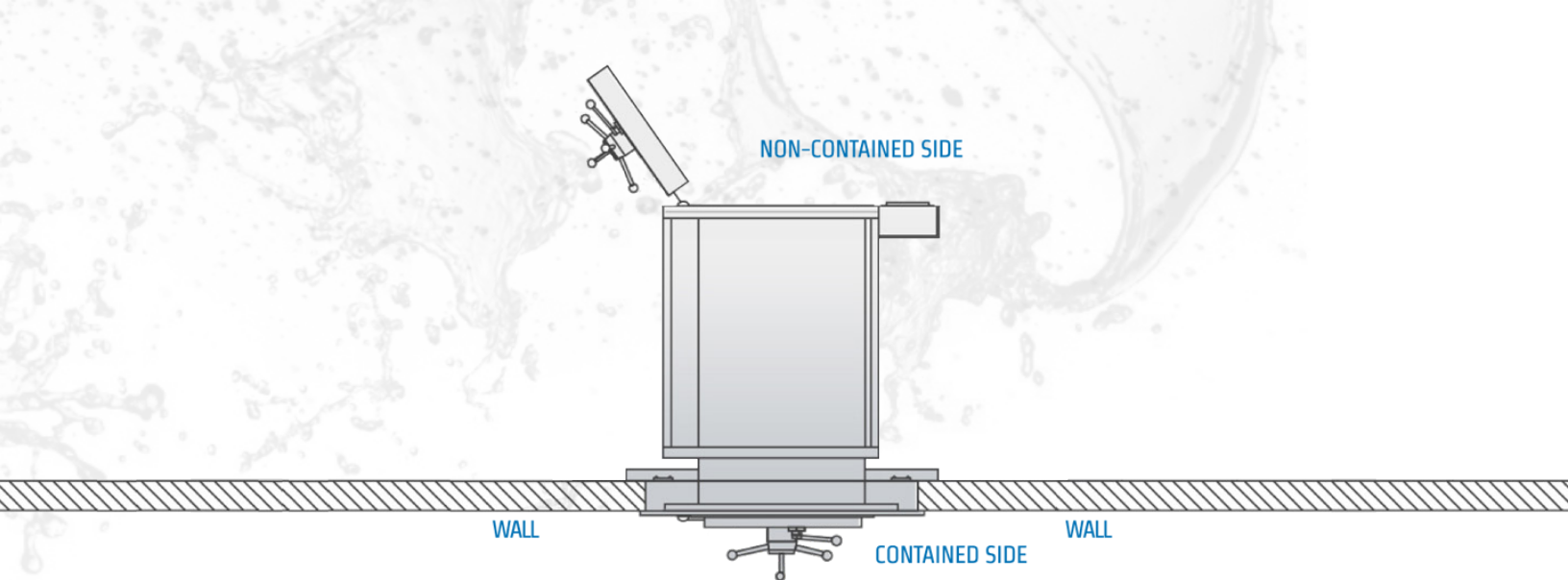
When using a BSL-3 autoclave, it is imperative that pathogens do not escape through these autoclave doors – either via poorly designed gaskets or by inadvertently opening both doors simultaneously. BSL-3 autoclaves must be equipped with proper door gaskets and door safety mechanisms.

Door Operation

All autoclaves are equipped with a safety feature that prohibits the door from opening until ambient pressure within the chamber is reached. Pass-through BSL-3 sterilizers are equipped with an additional interlock that does not allow both doors to open simultaneously.

This mechanical safety feature helps to prevent the passing of microbes from the contained (BSL-3) side to the non-contained side. In other words, when one door is open the other cannot open. The door interlock system is electro-mechanical in nature, therefore, it is fail safe even in the event of power or utility loss. Preventing both doors from opening also helps to maintain a consistent air differential by preventing the bulk passage of air through the chamber.

The control system will not initiate a cycle until both doors are confirmed closed. Furthermore, the door on the non-contained end is locked, preventing the door from opening in the case of an aborted or incomplete sterilization cycle.



In this diagram, the door on the contained end (typically the BSL-3 end) is locked shut because the door on the non-contained end is open. When selecting a BSL-3 autoclave be aware of subtle differences in terminology. For example, an “air differential seal” and a “vermin seal” are not considered the same as a bio-seal as neither option provides the appropriate level of containment for a BSL-3 lab.

Door Gaskets

Door gaskets are typically constructed with solid silicone rubber – a minimum of ¼-inch thickness. As a safety feature, they should not depend on air or steam pressure for their sealing but rather on the pressure of the door as it closes against the gasket. This is referred to as a “passive” gasket design. The benefits include:

- Will not deflate if punctured.
- Does not require air or steam for inflation.
- Will not deflate if compressed air or steam is lost.
- Creates a purely mechanical seal and is therefore fail safe.
- The gaskets can be changed without tools or adhesives when replacement is needed, which reduces maintenance time.

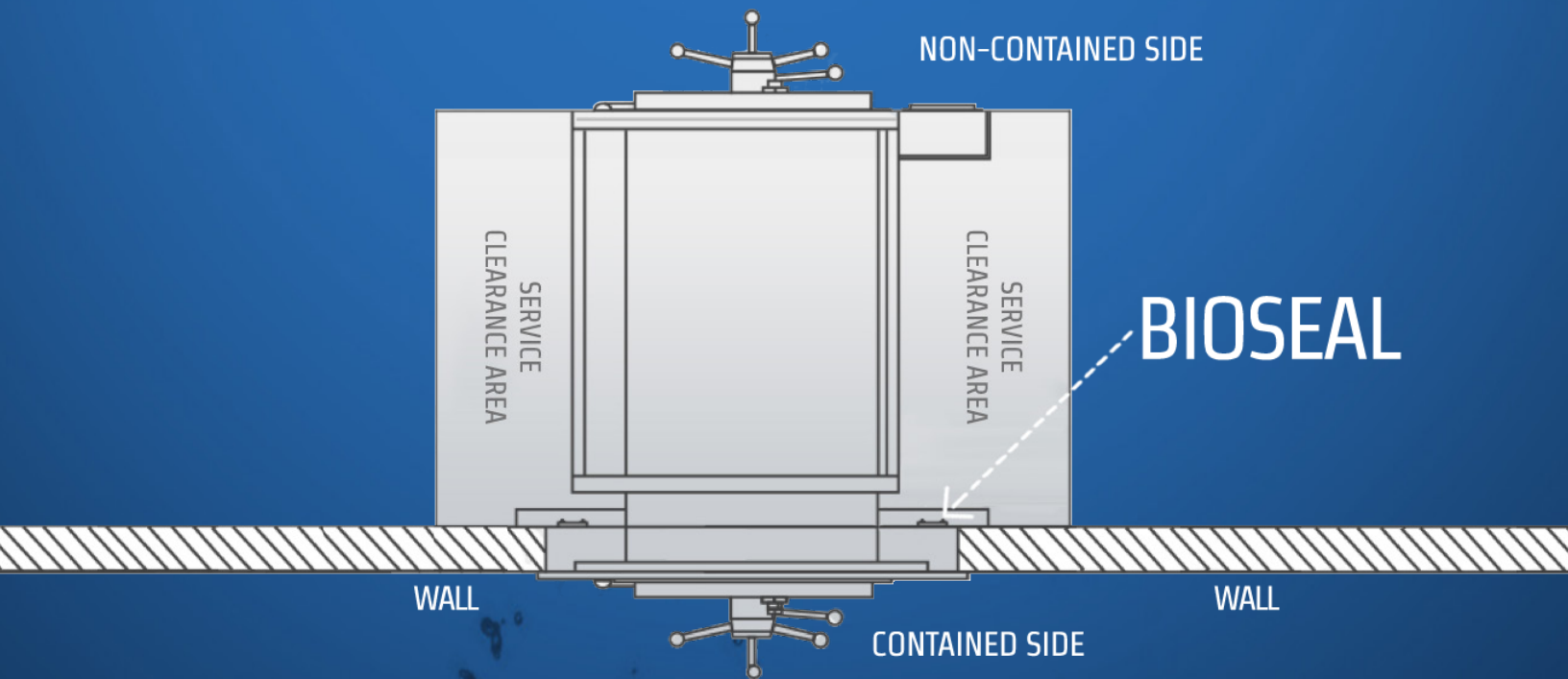
If an “active” gasket (i.e. one that requires air or steam to activate) is incorporated into the autoclave door design then users should verify its operation in the event of either power failure or mechanical fault. If power (steam or air) is lost, will the door unseal on its own? Will microbes be released? If a mechanical failure occurs, will the door be locked in its current position and not be moved until fixed? If so, what happens to the items inside the sterilizer? Can microbes escape once the door is opened after the repair?

PART TWO

The Bio-Seal

When evaluating BSL-3 autoclaves, it is vitally important to understand the importance of the biological sealing flange, a feature that must be incorporated to ensure hazardous microbes like Yellow Fever and West Nile virus don't pass between contained and non-contained rooms.

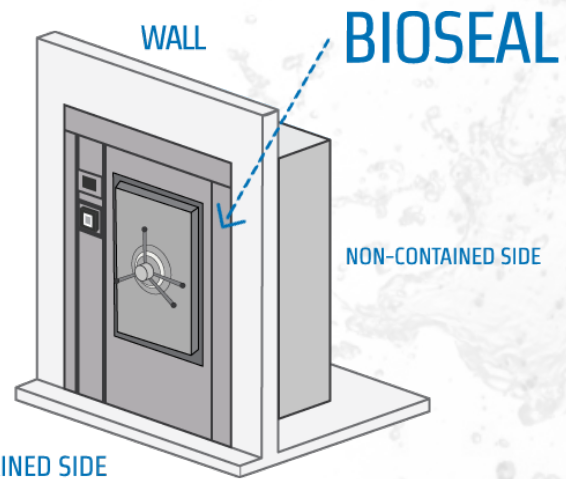
To ensure the BSL-3 lab is contained, BSL-3 autoclaves are equipped with a biological sealing flange or bio-seal. A bio-seal provides separation and a positive seal between the hazardous side and safe side, which is imperative for the safety of personnel. (Remember that these autoclaves are placed within a wall opening and that opening must be sealed properly.)



The graphic above depicts the top view of a BSL-3 autoclave situated into the wall opening.

The bio-seal is comprised of a steel or stainless steel plate (barrier flange) that is continuously welded to all four sides of the sterilizer. It extends out beyond the frame of the sterilizer to which the installer then attaches the barrier – a durable silicone gasket. The gasket extends between the barrier flange and the wall and is secured in place by stiffening bars to ensure a leak-tight fit.

The entire bioseal system must be durable and air tight. Capable of expansion and contraction (due to movement in the building and the equipment). All penetrations through the barrier flange (for either wiring or plumbing) are fully potted to prevent air leaks.



BSL-3 autoclave – 3D view of BSL-3 autoclave recessed into wall.

Testing the Bio-Seal

By design, the biocontainment lab is under lower or negative air pressure relative to the hallway or adjacent lab. Proper testing of the bio-seal assembly is required to ensure the integrity of the seal and prevent biological contamination in the non-contained room. Testing should be performed by trained personnel who are proficient with the equipment and familiar with the appropriate testing standards. Further testing should be performed by an independent third party.

Here are a few testing guidelines:

1. Test the bio-seal using the industry standard bulk smoke leak test. Smoke generated for this test has a particulate size no larger than 0.2 microns.
2. For the duration of the test, the BSL-3 room should be maintained at a negative pressure differential of at least 0.002 PSIG. (Facility safety procedures may require an even deeper negative pressure during testing.)
3. The seal is considered secure upon no visible penetration of smoke through the bio-seal or by leakage standards established by the facility's specifications, whichever is more restrictive.

PART THREE

Effluent Decontamination Systems

Next we examine effluent decontamination systems, methods of ensuring that effluent (air, steam and condensate) leaving the autoclave is free of harmful microbes. While this seems obvious, a study conducted by Tufts University Medical School demonstrated that a variety of laboratory autoclaves expel bacteria through the chamber's drain port during the preconditioning (purge) phase of the sterilizer cycle.

To clarify this phenomenon, consider the following steps of a typical sterilization process:

1. The user loads the sterilizer with contaminated goods.
2. The door is closed and a cycle is initiated through the autoclave's control system.
3. The air is purged from the chamber either by vacuum or by steam pressure.
4. This air/steam effluent is discharged through the chamber's drain port and into the floor drain throughout the entire cycle.

The potential for contamination arises in steps 3 and 4. As air is purged from the chamber, microbes may become aerosolized and discharge into the floor drain and surrounding environment. Effluent that flows through the chamber drain during the initial part of the cycle has not yet been fully exposed to the proper combination of time and temperature required to destroy microbes to the proper lethality of sterilization (i.e. log₆ kill).

BSL-3 facilities work with microbes that may pose serious health risks, therefore it is recommended the sterilizer effluent be contained, filtered or decontaminated prior to exhausting into the environment. Verify with the facility's safety officer to determine the effluent decontamination requirements for your lab.

Examples of Effluent Decontamination Systems

There are three acceptable methods for decontaminating the effluent from an autoclave.

Internal HEPA Filter

This method utilizes a 0.2-micron, ultra-high-efficiency HEPA filter located within the autoclave chamber. The filter retains any bacteria that may become aerosolized from the contaminated goods within the chamber. The key aspect of this design is the placement of the filter (i.e. within the chamber as opposed to outside the chamber). This is significant because the steam that sterilizes the products within the chamber also sterilizes the filter (and the bacteria captured by the filter membrane) thereby making it safe to handle and replace without the need of a service technician.

External HEPA Filter

This technique utilizes a 0.2-micron HEPA filter mounted outside the autoclave chamber to purify the effluent discharging from the autoclave. This system directs the effluent through an orifice typically located in the top of the chamber. It then travels through the external filter before going to the drain. The filter is encased in a housing that is heated by steam during the exposure phase, thereby sterilizing the retained filter. A separate (or additional) temperature control system is used to control the temperature in the filter housing. With this method, it is imperative that condensate within the chamber does not drain until the end of the cycle thus ensuring its sterility. The filter should be monitored and replaced frequently and usually requires a service technician to do so.

External Decontamination Chamber

In this method, effluent is discharged to an external decontamination tank (or “kill tank”) where steam is added to destroy the bacteria. The tank must be large enough to ensure proper mixing and sufficient time for complete kill. It employs a separate (or additional) temperature control system in order to maintain the proper minimum temperature. Although this method is the most complex and costly, it does allow the facility to capture effluent from multiple autoclaves and sources (e.g. washers, sinks, etc.).

PART FOUR

Other Important Considerations

Some additional considerations when planning for a BSL-3 autoclave include:

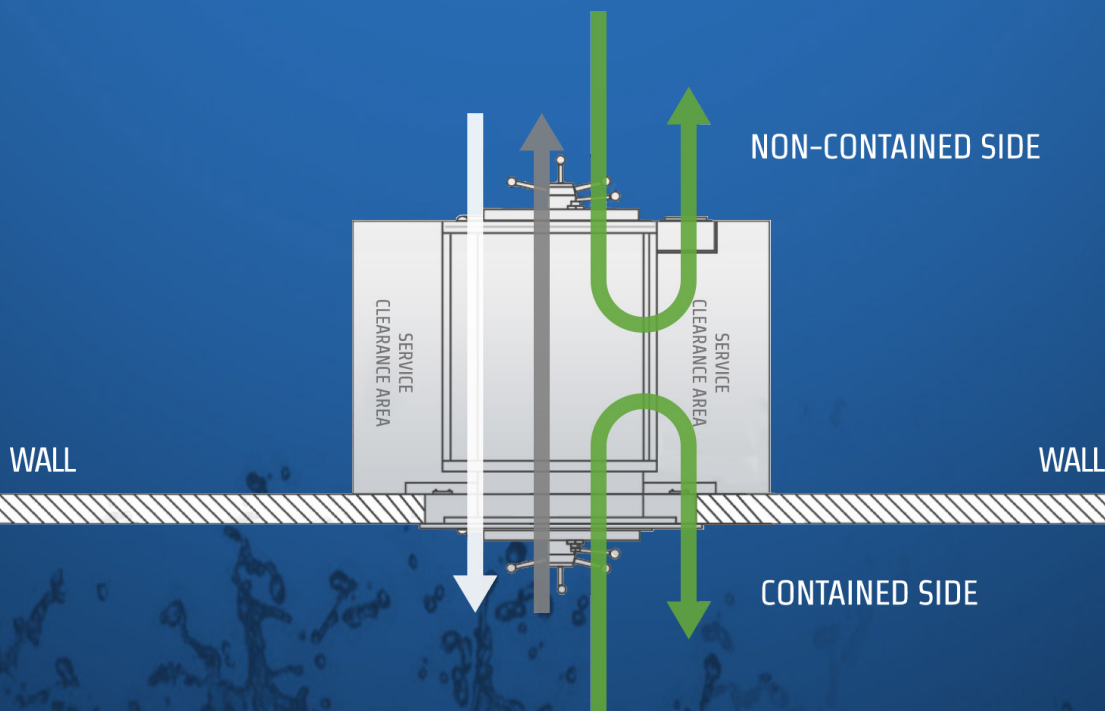
1. Which end of the autoclave will have the plumbing, components, utilities, and drain?

For service reasons stated above, plumbing and utilities should be located on the non-contained end. Placing components on the non-contained end protects them from contamination and makes service easier (see service area in figure below). Should a component require repair or evaluation, uncontaminated parts can be mailed or brought to a work bench whereas contaminated parts require sterilization before repairing.

2. Which end of the autoclave will be the Load End?

BSL-3 autoclaves are used to decontaminate the hazardous waste generated within the lab, therefore, the Load End is typically on the contained side and the Unload End is on the non-contained side. In other words, the flow of goods travels from the BSL-3 lab, through the autoclave, to the hallway. If the lab requires goods to flow in the opposite direction (i.e. into the BSL-3 laboratory) then this should be noted with the autoclave manufacturer.

Also consider this emerging trend: Using a BSL-3 pass-through autoclave as a “single door” unit. In this case, the load never “passes through” the autoclave but is loaded and unloaded from the same side. For example, researchers may desire to sterilize glassware or liquids without entering the BSL-3 lab. Again, if this configuration is desired then it should be noted with the autoclave manufacturer at the time of purchase. (See figure below.)



3. Which end of the autoclave will have the primary control system?

Many BSL-3 autoclaves have a single (primary) control system and printer. These controls are located on the non-contained side. Secondary controls, located on the contained side are available as an option and are highly recommended so that sterilization cycles can be initiated or aborted from within the BSL-3 lab. An advantage to having the primary controls on the non-contained (clean) side is so service technicians don't have to dress in PPE and enter the BSL-3 lab. Additionally, locating the printer on the non-contained side allows the printed record to be used and stored outside of the contained area.

4. What loading equipment is required?

Consider how the load will be configured and loaded into the autoclave. For instance, will red-bag waste, glassware, or animal bedding be sterilized? Will it be placed on a standard oven-style shelf in the autoclave, or will the load require a loading cart and transfer carriage for easier mobility. If a cart and carriage is preferred then it is strongly recommended to have two carriages (one for each end of the autoclave). Two carriages will assure that the carriage in the BSL-3 suite will never have to leave the contained lab.



Conclusion

The BSL-3 autoclave features mentioned throughout this ebook allow researchers to safely handle potentially lethal microbes. These features are necessary for maintaining a barrier between dirty (contained) and clean (non-contained) sides of the laboratory.

With so many factors to consider and laboratory safety a paramount concern, it is imperative to gather as much information about your lab to help identify a biocontainment lab autoclave solution that meets your needs.

Consolidated Sterilizer Systems manufactures top-quality steam sterilizers for leading universities, hospitals and biotechnology facilities worldwide. Our biocontainment lab autoclave specialists are available to answer all of your questions.

Please contact us for more information on BSL-3 autoclaves.

www.consteril.com
617-762-5475



www.consteril.com

617-762-5475

©Consolidated Sterilizer Systems

All Rights Reserved