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Sterile Barrier Systems: Key Information for Sterile Processing Professionals

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LEARNING OBJECTIVES

1. Describe the important role sterile barrier systems play in sterility assurance
2. Discuss how to maintain the integrity of the sterile barrier system
3. Apply key concepts in sterile barrier system sterility assurance

Medical devices cannot be transported unprotected. They require some type of case to protect them during transportation and storage to ensure that their technical performance characteristics are preserved at all times. At the Aesculap Museum in Tuttlingen, Germany, many instruments used in the 18th century are displayed in their original transportation cases. (See **Figure 1**)

Figure 1: Example of a medical device transportation case used in the 18th century

As evidence for rigorous sterilization techniques was being discovered, dry heat sterilization became a worldwide method to reduce the microbiological load on instruments to a level where medical devices were considered sterilized. To maintain the sterilized condition of the devices, a metal case was used (the lid was left semi-open during sterilization and at the end of the cycle), the dry heat sterilizer door was opened, and the lid was manually pushed closed.[1] This metal case began having two purposes—transportation and sterile barrier—a situation still seen today.

The discovery of the efficiency of saturated steam in the inactivation of bacterial spores by Charles Chamberland in 1880 introduced a new method of sterilization. The method was relatively simple because it only required water to be heated in a pressure chamber to achieve the saturated condition and then maintained for a short period of time until the sterility assurance level was reached.[1]

Changing the sterilization method from dry heat to saturated steam required some changes in the sterilization process, specifically in relation to the protective metal case. In dry heat sterilization, the medical devices needed to be heated entirely in order to inactivate the spores, whereas in saturated steam sterilization, steam must contact all surfaces of the medical devices, which wasn't possible with a fully closed metal case.

The metal cases that were used to transport, sterilize and maintain the sterilized condition of medical instruments now needed to have holes drilled in their surfaces to allow steam to enter and contact the medical device surface area. Because a container with holes is not a microbial barrier, the single metal case lost its multipurpose functionality.

Objective 1: Describe the important role sterile barrier systems play in sterility assurance

Disposable non-woven wraps or reusable woven wraps are the most common sterile barriers used to allow steam to penetrate during the sterilization cycle and maintain sterility after the cycle and during storage and transportation to the surgical suite. They are wrapped around trays and perforated boxes that contain medical devices, providing a microbial barrier after the sterilization process until the point of use. Reusable woven wraps are sent to the laundry to be washed and dried, so they are ready to be reused for a determined period of time.[1]

Today, there are many options of sterile barrier systems. All need to allow air removal and sterilant penetration during sterilization, be resistant to tearing, serve as an effective microorganism barrier during storage and transportation to the point of use, and facilitate aseptic presentation. All sterile barrier system options must be non-linting, free of toxins and compatible with the chosen sterilization method.[2]

The selection and use of a sterile barrier system should be based on the medical device and sterilization equipment manufacturers' instructions for use (IFU), and Sterile Processing (SP) professionals need to understand the important role these barriers play in sterility assurance. Inadequate selection, assembly, use or maintenance will either prevent the sterilization of medical devices or compromise the maintenance of the sterilized condition. Because of the critical role sterile barrier systems play, they should undergo a rigorous verification process. To implement and execute a verification process, standards and guidelines are available for all types of sterile barriers currently used in Sterile Processing departments (SPDs).[3]

Objective 2: Discuss how to maintain the integrity of the sterile barrier system

Many factors can affect the performance of a sterile barrier system, and if those factors are not addressed correctly, the integrity of the system could be compromised, without SP professionals being aware of a problem. SP professionals require comprehensive knowledge surrounding three main areas to maintain the integrity of the sterile barrier system: package assembly, package handling and monitoring the sterilization cycle. The first two areas are well addressed in articles, guidelines and manufacturers' IFU.[2,4]

Knowing the pressure variation of sterilization cycle phases is important when preparing and placing a sterile barrier for a sterilization cycle. (See **Figure 2**, green curve) A saturated steam sterilization cycle is typically seen as a temperature-controlled cycle (just like dry heat cycles), but to reach the sterilization temperature, a pressure two times atmospheric pressure is required. For air removal during a pre-vacuum cycle, a vacuum 70% to 80% below atmospheric pressure is also needed.

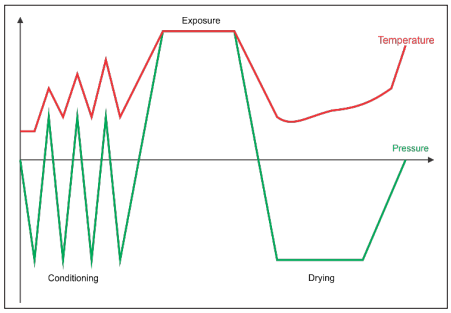

Figure 2: Saturated steam sterilization cycle phases

These pressure variations are applied on the sterile barrier system and, if not taken into consideration, will interfere with the integrity of the system, especially where it is sealed. During the conditioning phase, vacuum and pressure are interchanged and sterile barriers are exposed to continuous pressure variations—with the temperature rising and in the presence of saturated steam—for a period of 25 to 40 minutes. During the exposure phase, sterile barriers are exposed to the highest pressures and temperatures but for a brief period of three to four minutes. At the final phase (drying) where the pressure drops from two times the ambient pressure to a very low vacuum, sterile barriers are exposed to a rapid pressure variation and are maintained in vacuum for 15 to 30 minutes.

Condensate, a known phenomenon, is significantly present in the conditioning and drying phases and responsible for placing more stress on the sterile barrier system during these phases. This is because when water changes

to a gaseous phase due to exposure to temperature and pressure variations, it occupies a volume up to 700 times larger than in the liquid phase. This volume expansion challenges the seals of the sterile barrier system, especially containers and pouches, even though they are air- and sterilant-permeable, because of the rapid increase in volume inside the barriers due to the transition from liquid water to vapor.

Objective 3: Apply key concepts in sterile barrier system sterility assurance

Pouches are commonly used as a sterile barrier system for single medical devices, but they can be generally used in the SPD for larger instruments and items like bowls and trays. The integrity of the pouch relies on adequate sealing performed in the SPD, the weight of the enclosed device(s), and puncture prevention.

Two additional factors must be addressed when using pouches. During the steam sterilization cycle, the volume of each pouch increases significantly when the vacuum is present in the conditioning and drying cycle phases. (See **Figure 3**) The placement of the pouches on the sterilization rack, therefore, must take into consideration this volume variation to prevent the pouch from rupturing or becoming perforated.

Also, excessive condensation might cause pouches to rupture at the seal due to the subsequent re-vaporization of the condensate. Because the conditioning and drying phases have vacuum and pressure ratios that cannot be altered by the SP professional, preventive actions include having steam with the correct saturation and allowing more internal area in pouches containing heavier devices, which cause more condensation.

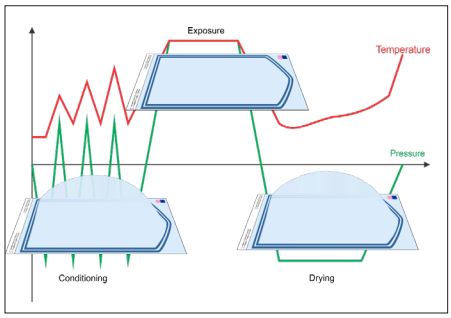

Figure 3: Pouch condition at each steam sterilization phase

Trays and cases containing medical devices are commonly wrapped with sterilization wrap, non-woven or woven. Wrapping techniques are described in guidelines,[2] and the barrier integrity is maintained by the sterilization indicator tape used to secure the wrapped pack. The tape used on these wraps is exposed to pressure and temperature variations during the cycle, and its ability to secure the package during the entire cycle depends on its quality and correct usage.

Rigid containers are a sterile barrier system that allow fast and reproducible assembly of medical devices within a sterile barrier. Many sizes are available on the market to accommodate a great majority of devices, with variations on lid material, filter fixture and color. Sterilization cycle pressure, temperature variation and condensate formation will challenge the sealing capacity of the gasket and filter holders during the entire cycle. (See **Figure 4**) In order for a rigid container to maintain the integrity of the sterilized medical device after the cycle, its lid must be in perfect condition (without dents) and aligned with the bottom portion. The latches must maintain adequate pressure on the gasket to ensure the sealed condition. The filter and its holder will have the same sealing requirement.

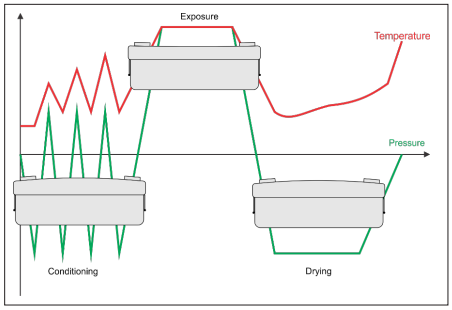

Figure 4: Container condition at each steam sterilization phase

Due to their robust presentation, rigid containers are sometimes not handled with the critical care that a sterile barrier system demands, which can result in undetected failures in the sterile barrier.[5] Adequate procedures based on guidelines and a validated process will help ensure that rigid containers can be safely used.[2,3]

Loading and unloading

All sterile barrier systems should be placed and removed from the sterilizer rack (avoiding pushing and pulling) to prevent tears and punctures of the sterile barrier. This also applies to rigid containers, which should only be transported using both handles. Holding a container by its lid will damage the latches in the long term and might also bend the lid. Weight limits are recommended in guidelines due to ergonomic concerns and sterilizer performance,[2] but such limits also benefit the handling of medical devices, which further helps preserve the integrity of the sterile barrier.

Unloading of the sterile barrier system after the sterilization cycle is completed can only be done when the packages' temperatures are below 75°F.[2] This practice also helps maintain the sealing integrity of all sterile barrier systems (each is tested and validated by its manufacturer to demonstrate its sealing efficiency at ambient temperatures). Handling sterile barriers at higher

temperatures might impact the sealing efficiency, allowing microorganisms to pass into the packages.

Metallic and non-metallic

Trays and containers, in part or totally, can be constructed with metallic and non-metallic materials. Metallic materials have excellent heat conductivity, which helps evaporate condensate formed during the sterilization cycle. Non-metallic materials do not have the same heat conductivity and, in contrast to metallic ones, will cause condensate formation.[6,7] Since condensate might impact the integrity of the sterile barrier systems and is typically the reason for wet packs, replacing non-metallic trays and containers with metallic ones will help reduce the occurrence of wet loads.

Many medical devices have transportation cases designed to hold all items in place, with easy-to-locate sizes and types. These transportations cases, commonly seen with loaner sets, are typically comprised of non-metallic materials. Again, the manufacturer's IFU should always be followed.

Quality indicators

Sterile barrier systems, if incorrectly assembled or inappropriately placed on the sterilizer rack, may interfere with the performance of quality indicators used to monitor the sterilization cycle. If a quality indicator is placed in an area where greater condensation occurs (e.g., at the bottom of the container), its performance will be impacted and a false result could occur.

Quality indicators are intended to monitor whether sterilization conditions have been achieved[2] but cannot determine whether a sterile barrier system was compromised; therefore, SP and Operating Room staff can only consider an item to be sterile by having satisfactory results from the quality indicators and observing that the integrity of the sterile barrier system was maintained after sterilization, in storage and during transportation to the point of use.

Conclusion

Sterile barrier systems help maintain sterile device integrity from sterilization to the point of use. Ensuring SP professionals understand how the sterilization cycle affects the different barrier systems is important for having a successfully sterilized item and a device that can be safely transported and used on the next patient.

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