

THE BASICS OF PACKAGING

Objectives:

- Review the regulatory requirements for packaging
- Present the purpose, function and essential characteristics of packaging
- Describe packaging options, their use, and the pros and cons of each
- Review sterility maintenance
- Examine the selection and evaluation process for packaging

Introduction

Selecting and using the most appropriate sterilization packing for use in the healthcare setting today is a challenging responsibility for healthcare professionals and has an impact on surgical instruments and medical devices, infection control and patient safety, and the healthcare facility's bottom line.

A variety of sterilization packaging materials and types including wraps, pouches, and rigid container systems are available in varying sizes and configurations to package and sterilize surgical instruments, medical devices, and other reusable supplies and equipment. The proper selection, use, and performance of sterilization packaging systems is crucial to achieve sterilization of the package contents, maintain sterility of the contents until the package is opened for use, and permit removal of the contents without contamination.

Items classified as critical devices by Spaulding, such as surgical instruments and implants that enter vascular systems or sterile body tissue, pose the highest risk of infection transmission and must be sterile at the moment of use. Sterilization packaging reduces the risk of healthcare-acquired infections by protecting the sterile contents from contamination until they are used.

Sterilization packaging systems that are of high quality and performance optimize the ultimate goal of infection control and patient safety. Products that have been validated for effective sterilization performance and provide a reliable barrier to microbial penetration and protection against contamination during handling and storage should be selected for use.

Regulatory Requirements

The Food and Drug Administration (FDA) regulate all sterilization packaging systems used by healthcare facilities to package and sterilize surgical instruments, medical devices, and equipment. These include wrap, pouches, rigid containers, trays, and cassettes.

Sterilization packaging systems are classified as Class II medical devices and require a 510(k) for their intended use to be legally marketed. Manufacturers of sterilization packaging systems must submit a Premarket Notification 510(k) Submission to the FDA prior to marketing their product. The submission includes a completed application, extensive data, documentation of testing and validation studies, special labeling, intended use, and instructions for use.

Key Factors

The purpose of sterilization packaging systems is to provide a safe and effective method to package and protect instruments and other medical supplies and equipment for sterilization, transportation, storage, and aseptic presentation.

The prime functions for effective packaging systems are to:

- Permit sterilization of the package contents
- Maintain sterility of the contents until the package is opened
- Permit aseptic presentation of the package contents

Several essential performance characteristics of packaging include:

- Ability to withstand physical conditions of the specific sterilization process
- Adequate air removal; sterilant penetration and contact with the contents; and evacuation of the sterilant
- Free of toxic materials or dyes; and be low-linting
- Adequate barrier to microorganisms and environmental contaminants
- Durability to resist tears and punctures
- Removal of the contents without contamination

Additionally, packaging systems should be easy to use and cost-effective.

Packaging Options

Packaging systems must be appropriate for the items being sterilized and compatible with the specific method of sterilization to be used, i.e. steam, ethylene oxide, hydrogen peroxide gas plasma, or ozone. However, all packaging types and materials are not appropriate for all devices or compatible with all sterilization methods. Each packaging system should be used in accordance with the manufacturers' written instructions.

The correct choice and use of sterilization packaging is critical to achieve sterilization of the contents and maintain the sterility of the contents until used. Several materials and combinations of materials most commonly used for in-house sterilization packaging include woven textiles, non-woven materials, and rigid sterilization containers.

Reusable woven textile fabrics

Reusable woven textile fabrics used as sterilization packaging are a flat wrapper, made of cotton, linen and blends of cotton and synthetic materials such as polyester. The woven materials generally provide the least effective bacterial barrier of all the various wrapping materials available and are not compatible for all sterilization methods.

The original reusable woven textile wraps were made of 140-thread count muslin cloth. Based on the findings of shelf life studies conducted in the early 1970's by the Centers for Disease Control using 140-thread count muslin cloth, a time limit or expiration date was required on wrapped items. A 30-day shelf life was recommended.

Reusable wrap must be laundered, inspected, and delinted, after each use. Holes must be patched, and the fabric wears thin with use and gradually loses its barrier properties. Reusable wrap requires purchasing wrappers for replacement as needed.

Disposable non-woven materials

Disposable non-woven materials used as sterilization packaging are a flat wrapper made by methods other than weaving. The pressure-bonded sheets of material provide effective barrier properties and moisture resistance. Validation data of shelf life studies for specific wraps can be obtained from the individual manufacturer for their specific sterilization packaging products.

Specific materials, such as paper or synthetics, i.e., as polypropylene/spun-bond materials are available in a variety of wrapper sizes for various methods of sterilization. Paper has extensive memory and is not compatible for all sterilization methods. Packaging which contains cellulose cannot be used in hydrogen peroxide gas plasma sterilization.

The appropriate size and strength of wrapping material should be selected and it is essential to wrap the items securely to prevent gapping and air pockets from forming which could compromise sterility. Double wrapping should be done using either of two methods, i.e., sequentially, with one wrapper and then with the second wrapper applied; or simultaneously, in a single step with two wrappers that have been fused or bonded on the edges by the manufacturer. The square fold and the envelope fold are the two techniques used for wrapping packs. After the pack is wrapped the closure must be secured. Sterilization tape is generally used. The pack should be labeled, with information documented on the tape, using a felt-tip, indelible, non-toxic ink marker.

Disposable wrap can tear or puncture and require that the items be reprocessed before they can be used, resulting in increased use of labor, material, time and money. Application of a plastic sterility maintenance cover after sterilization can

add protection to the sterilized package during storage and handling, but will increase the supply budget.

Disposable wrap requires cost for continual purchase, stock of a variety of sizes and strengths, inventory control, and costs for disposal.

Disposable peel pouches

Disposable peel pouches, composed of paper/plastic combinations or Tyvek/plastic combinations are available for the various methods of sterilization. However, not all types are suitable for all methods of sterilization. Tyvek, for example, is intended for use in low temperature sterilization methods only, such as ethylene oxide and gas plasma.

Peel pouches were designed to contain lightweight items or for containment of a group of small items. Pouches must be sealed by heat-sealing the open end or by using a self-sealing pouch with an adhesive strip that is folded over the opening of the pouch. Peel pouches should not be used for heavy or bulky items because the seals can become stressed and rupture.

Peel pouches are advantageous when visibility of the contents is important. When packaging items in pouches, care must be taken to leave a minimum of 1 inch of space between the item and the seal of the pouch. Double peel packaging is not routinely required, but if items are double pouched, they must be packaged paper against paper, plastic against plastic. The inner packages should not be folded as this may entrap air and inhibit the sterilization process. A felt-tip, indelible, non-toxic ink marker should be used to label the clear plastic side of the pouch.

Pouches can retain moisture if they are not positioned appropriately for sterilization and the items will require reprocessing. Specially designed racks are available so pouches can be placed on edge and properly spaced for sterilization. The Association for the Advancement of Medical Instrumentation (AAMI) document ST46:2002 states that peel pouches are not appropriate for use within wrapped sets or containers because they cannot be positioned to ensure adequate air removal, steam contact, and drying. Small, perforated insert boxes or cases can be used instead of the pouches to contain small items in wrapped sets or containers.

Disposable peel pouches require cost for continual purchase, stock of a variety of sizes, inventory control, and costs for disposal.

Reusable rigid container systems

Reusable rigid container systems are the most durable sterilization packaging system as they are constructed of a rigid material such as metal, plastic or a composite material. Containers have a box-like structure comprised of a lid and base, carrying handles and a latch or locking mechanism that secures the lid to

the base. They are designed with either a perforated or solid base, and include a filter or valve system to allow the sterilant to enter and exit the container.

Container systems are easy-to-use and very versatile. A variety of sizes can accommodate a wide range of instrument sets, from simple delicate sets to full complex sets that can be standardized and customized. Inner baskets, trays, and various inserts organize and protect the instruments within the container. Nameplates or tags identify the sets and disposable items such as filters, tamper evident seals/locks, and load cards/external chemical indicators complete the system.

A container's material composition, rigid construction, and design features combine to provide a sterilization packaging method that offers a high degree of sterility assurance and provides an optimum barrier to protect the sterilized contents until they are used. However, containers do differ in design, material and intended use. Scientific data indicates that metal containers, especially aluminum, have the highest heat transfer ratio for sterilization and drying of the contents. Containers eliminate torn wrappers, and are impossible to puncture during normal use, however, plastic can become brittle and crack.

The FDA has cleared some container systems for multiple methods of sterilization and there is one universal container system that is cleared for all methods of sterilization commonly used in the healthcare setting. Some systems are also cleared for event related sterility maintenance.

A newly developed design and performance standard for containment devices, AAMI ST77:2005, "Containment devices for reusable medical device sterilization," addresses the weight issue of a containment device, the instruments, and any accessories or wrappers, and recommends that the combined maximum weight should not exceed 25 pounds. It is important to note that the document further states that if a healthcare facility chooses to use a set above the 25-pound limit, the facility is responsible for verifying that the set can be sterilized and dried using hospital sterilizer settings.

Containers must be disassembled and require cleaning after each use. There are cleaning product considerations, i.e., neutral pH detergents are required for aluminum and plastic containers. And, containers need to be rinsed thoroughly. Container systems usually require a capital purchase, however some companies have leasing programs and other innovative programs available. The containers will usually pay for themselves within one to two years depending on how often they are used.

Monitoring the Load

Healthcare facilities are required to utilize ongoing sterility assurance programs. A chemical indicator or integrator should be placed within the package to

demonstrate whether conditions were adequate to achieve sterilization. In sealed containers, chemical indicators or integrators should be placed in opposing corners of the tray or trays. In wrapped packs, the most challenging location is in the center of the wrapped pack, because of the difficulty of sterilant penetration to the center.

Sterility Maintenance

Sterility is the state of being free of viable microorganisms. According to AAMI, in practice, there is no absolute statement regarding the absence of microorganisms. Shelf life that is time dated has a defined term for storage before a sterile package must be reprocessed. Event related shelf life is based on the principle that specific events, not time, are responsible for sterile products becoming compromised. Events that can compromise a sterile package include tears or holes in the wrapper, rupture of seals or closures, wetness and compression of packs.

The quality and bacterial barrier property of the sterilization packaging used to package and sterilize medical devices is the critical first factor that contributes to maintaining sterility of the contents until the item is used. Several packaging products have undergone event related shelf-life studies in recent years. The manufacturers of specific sterilization packaging products can be contacted to obtain documentation of the shelf life studies that were performed for their specific sterilization packaging systems. The validation data will support the effectiveness of the system as a microbial barrier and demonstrate whether or not the packaging material held up during handling and storage.

In the healthcare setting, the integrity of the package is the determining factor in establishing sterility of the contents in an event related shelf life system. Ultimately, the user bears the responsibility to assure the integrity of the package before it is opened for use.

Selection and Evaluation Process

There are nationally recognized documents currently available that contain essential information for the selection and evaluation of packaging systems that can be used as guidelines to assist healthcare staff in the selection and evaluation process including:

The Association of periOperative Registered Nurses (AORN) Standards, Recommended Practices and Guidelines, which contain recommended practices for selection and use of packaging systems. The recommended practice provides guidelines for evaluation, selection and use of packaging systems for items to be sterilized.

The Association for the Advancement of Medical Instrumentation (AAMI) ST33:1996 which provide "Guidelines for the selection and use of reusable rigid sterilization containers systems for ethylene oxide sterilization and steam sterilization in healthcare facilities" and ST46:2002 which provide guidelines for "Steam sterilization and sterility assurance in health care facilities." AAMI ST46 is among the documents being incorporated in the new AAMI ST79 document, "Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities," which is scheduled for release in 2006.

New sterilization packaging systems offering technological improvements are continually being developed and introduced in the marketplace. It is important to be aware and informed of the newest state-of-the-art products and innovative technology. Manufacturers of sterilization packaging demonstrate by scientific evidence the effectiveness for the sterilization method, penetration of the sterilant, and barrier efficacy to contamination. Packaging products that have been validated to be of high quality and performance to be effective for the sterilization of medical devices and provide a reliable barrier to microbial penetration and protection against environmental contamination and contact contamination during handling should be selected for use.

Selecting the appropriate sterilization packaging system for the items to be processed and the type of sterilization that will be used in the healthcare facility can be a challenge. The staff involved in the product selection must be knowledgeable regarding packaging principles and the suitability and reliability of various sterilization packaging systems, to help ensure the selection of a safe, efficient, and cost-effective system for the healthcare facility.

Healthcare staff should carefully review the current standards and recommended practices for sterilization packaging systems and the manufacturer's labeling, validation test results, and instructions for use, care and handling, for the sterilization packaging systems being considered for purchase. Manufacturers' representatives serve as resource people for information as well. They should be able to provide clinical and technical data related to the products.

Evaluating the performance of packaging products being considered for purchase can provide important feedback on the effectiveness of the product for the process. A value analysis may be performed as part of the evaluation and selection process.

AORN recommends that each facility should evaluate and test the performance of each packaging system before selection and implementation to ensure conditions for sterilization, storage, and handling can be met. AAMI recommends that users should conduct a prepurchase product evaluation of any container system being considered for use so as to determine whether or not the healthcare facility can verify the manufacturer's test results. AAMI ST33 describes the recommended test protocols for prepurchase evaluation of

container systems intended for use in pre-vacuum and gravity displacement steam processes and ethylene oxide.

All evaluations should be based on pre-established objective criteria pertinent to the product to ensure the reliability and validity of the trial evaluation results. A written evaluation tool will facilitate objective review and results, and recommendation of a product that best meets the facility's needs.

Summary

The proper selection, use, and performance of sterilization packaging systems can enhance sterility assurance of in-house sterilized items, contribute to safe patient care, and save the healthcare facility money.

Knowing the basic essentials of packaging and understanding the selection and evaluation process can help healthcare professionals ensure that the appropriate sterilization packaging is being used for the medical device being packaged for sterilization and for the method of sterilization being used.

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