**Chapter 13**

**What is a tamper-evident seal? Can you give a real-world example?**

Allows you to determine if the package has been opened(contaminated). Money bags, bottle of water, medicine.

There are two basic categories of sterility packaging: reusable and disposable.

**What are the three primary objectives for both categories of packing materials?**

1.must be able to maintain the sterility of the package until opened.

2.must allow penetration of the chosen sterilant, and be compatible with other requirements fo the sterilization process.

3. Package must be able to be opened aseptically and the contents must be sterile at moment of use.

The FDA classifies sterilization packages as a Class II Medical Device. The consequences of using non-sterile items during a surgical procedure can life-threatening.

The first step in the packaging process is to select the appropriate type of packaging material and method.

Packaging used for steam sterilization must be capable of withstanding temps. 250 degrees F – 275 degrees F. The packaging must allow air removal and steam penetration to the contents to be sterilized and must permit drying of the contents and packaging material.

Packaging in ethylene oxide sterilization should allow adequate penetration of the gas sterilant andremoval of the gas residue (aeration).

In dry heat sterilization, packages must be able to tolerate 2-3 hours exposure time and temperature of 320 degrees F – 400 degrees F without melting, burning, or being destroyed.

Packaging for gas plasma sterilization must be able to tolerate a deep vacuum draw without absorbing the sterilant, interrupting the cycle, or damaging the contents.

CS Techs must also understand how to use (apply) sterilization packaging appropriately to achieve the desired results: sterilant penetration , barrier effectiveness, and aseptic opening.

**What is a benefit to using textile (reusable) packaging?**

Low-cost, and good for the environment because the packaging is reused, which also decreses combustible load of the department.

**What is a disadvantage?**

More labor, risk of holes and tears, must be patched if damaged, which is not ideal for sterilization.

Linen packaging materials should be held at a roomtemperature ( 64 degrees F to 72 degrees F) and at a relative humidity of ranging from35% to 70 % for a minimum of 2 hours prior to sterilization.

What is superheating?

Dry steam – steam at a temp that exceeds the temp of saturated steam at the same pressure.

The maximum density of linen packs must not exceed7.2 pounds per cubic foot because higher density may reduce sterilant access to all contents.

Rigid container have lids and filters that allow sterilants to penetrate while providing a microbial barrier.

**Advantages of Rigid Container Systems:**

1.excellent barrier to microorganisms

2.easy-to-use

3. eliminates torn wrappers

4. protect instruments from damage during processing, storage, and transport.

**Disadvantages:**

Safety concerns linked to ergonomics. A large empty container weighs approximately \_\_\_\_\_\_\_\_\_\_ to \_\_\_\_\_\_\_\_\_pounds. CS Techs must use proper body mechanics when \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ and \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_containers.

Additional \_\_\_\_\_\_\_\_\_\_\_\_\_ may be required to thoroughly dry the container. The \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Syndrome is a risk also.

**Peel-Pouch Combinations:**

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| --- | --- | --- |
| Material | Details | Uses |
|  | Plastic side allows visibility of package contents, and the paper side allows sterilant penetration. | Typically for use with steam and ethylene oxide sterilization, and not compatible with dry heat or gas plasma sterilization. |
|  | Sometimes referred to as Tyvek, it has a plastic side and a polyolefin side that contains no cellulosic materials. | Used for Gas Plasma Sterilization. Will melt at high temperature processes, such as steam. |
|  |  | Used for dry heat sterilization only. |

This is tape changes color after being exposed to the sterilization process: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. It does not \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ that adequate sterilization of package contents has occurred.

**Seals**

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| --- | --- |
| Type | Details |
|  | Used for paper-plastic or plastic-to-plastic seals. The two sides are fused together with heat. Care must be taken to avoid gaps, wrinkles, or creases which compromise seal integrity. |
|  | Paper Plastic and Polyolefin-Plastic packages contain self-adhesive seals that do not require heat. Care must be taken to avoid gaps, wrinkles, or creases which compromise seal integrity. |
|  | Seals are designed to break when the seal on the container has been broken. The most common types are plastic components that lock in place and must be broken to open the container. |

Why should gauze squares never be used as additional packaging (wicking) material in trays or packs? \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_.

What is wicking material? It is an absorbent material that \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, and \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_.

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| Wrapping Techniques | Details |
|  | The package is wrapped twice, and is a package within a package—the contents have been wrapped in sequence. |
|  | The Package is only wrapped once, but requires special double-layered synthetic non-woven material bound on two or four sides. |
|  | Also called the in-line or parallel fold, most frequently used for larger packs and instrument trays. |
|  | Most commonly used for small packs and most instrument sets and individual items. |

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| Sterility Maintenance | What is it? |
| Time-Related |  |
| Event-Related |  |

Storage temperature should be between \_\_\_\_\_\_\_\_\_\_degrees F and \_\_\_\_\_\_\_\_\_\_degrees F, with less than \_\_\_\_\_\_\_\_% relative humidity.

Packs should be kept \_\_\_\_\_\_\_\_to \_\_\_\_\_\_\_\_\_ inches above the floor to prevent contamination from \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, and \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. There should be at least \_\_\_\_\_\_\_\_to \_\_\_\_\_\_\_\_\_ inches between the highest package and the ceiling to allow for proper circulation.

What is FIFO? What does it mean?