Sterile Packaging & The End User

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Sterility Maintenance

• The goal of sterile processing is to ensure that the sterility of critical patient care equipment and medical devices is achieved and maintained until used.
• There are many conditions, behaviors and events that can challenge the sterilization process and compromise the integrity of sterile goods and packaging.
• It has been several years since most institutions have instituted an ERSM program and eliminated expiration dating. This program will revisit the concept of ERSM and assess how technological dynamics, packaging methods, staff complacency and other factors can affect sterility maintenance.
Sterility Maintenance

Objective:

• Demonstrate how personal behavior, handling, environmental conditions and packaging affects sterility maintenance and the shelf life of sterile goods
FDA Class II Medical Device

FDA classifies sterilization wrap as a Class II Medical Device
(Federal register, vol.45, No.205)

“It is intended to allow sterilization of the enclosed material and also maintain sterility of the enclosed device until used”
Expiration Dating

• Time related shelf life

Expiration date was assigned to a sterile package indicating a specific point in time beyond which the sterilized contents would no longer be considered sterile or safe to use.

**Question:**

*when did they become unsafe?*

7:00 AM? Noon? Midnight?
Event-Related Shelf Life

• Recognizes that contamination is event related rather than time related

A sterile product will remain sterile until contaminated
Small Basin
5 East
Exp. 5/4/66
ERSM

- Events vs. Time
- Based on sound principles
- Makes sense
- Economical
- Potential for improved processes
Dangers of ERSM program

- Lack of understanding and knowledge
- False security
- Inferior products
- Lack of QA / QC
- Poor work practices
- Staff complacency
- Inappropriate environments
Packaging challenges

- Devices to be packaged
- Sterilization process
- Storage
- Distribution
- Materials Handling
Guidance for ANSI/AAMI/ISO 11607, packaging for terminally sterilized medical devices
Much of manufacturer’s assessment & validation is supposed to be based on worse case scenario

What’s that mean??????
a picture is worth a 1,000 words

Welcome to Candid Camera
A day in the life of a sterile package
Folded packages
The Pits!
Hold that door!
Hospital folks are sooo creative!
Splish Splash!
Oh where oh where have my instruments been??

OOOh Those infamous Loaners Trays!
Running between buildings
Oooops !!
The Doctor’s Locker Room
Sterility Maintenance

Achieving Sterilization is worthless unless we can ensure the *sterile integrity* of all packages and maintain the sterility of the packaged medical devices until used !!
User Responsibility

• Knowledge of sterilization technology and its affect on packaging materials
• Knowledge of medical devices and supplies and their compatibility with sterilization technology and packaging materials or devices
• How packaging materials affect sterilization parameters
• Knowledge of manufacturers technical data, instructions for use, and care and handling
• Develop, implement, and enforce policies and procedures based on manufacturers instructions
Selection of Packaging Materials
Recommendations & Guidelines

- AAMI
- AORN
- IAHCSMM
- JCAHO
Joint Commission (AKA JCAHO)

Since 1990 – written policies for addressing the shelf life of all stored sterile items

- Recognizes “user’s” expertise in monitoring and delivering sterile products
- Expertise is therefore expected to be applied in practice
- QA focused
QA & QC
What’s involved?

- Policies and procedures re: sterile processing, cleaning, inspection, assembly, packaging, sterilization, handling, storage, and distribution
- Staff training and competency re: all policies and procedures
- Product knowledge
- Proper selection and use of validated quality packaging products
- Supervision and continuous surveillance
user’s expectations

selection of packaging materials

• allow adequate air removal and sterilant permeation from package contents
• provide an adequate barrier to microorganisms or their vehicles
• resist tearing and puncturing
• allow method of sealing that results in complete seal that is tamper evident and provides seal integrity
• allows for ease of sterile presentation
• be free of toxic ingredients (including inks, dyes, and adhesives)
• color fast dyes will not bleed or fad post sterilization
• be non linting
user’s expectations

- Long / indefinite shelf life (pre / post sterilization)
- Compatible with all hospital sterilization methods
- Memory free
- Conforms to device
- Varied sizes, grades to accommodate broad range of applications
- Heat seal, type, pressure, temps, time
- Environmentally friendly
- Be economical and cost effective
user needs

- Detailed IFU
- Technical data / documentation
- Product validation for intended uses
- Evaluation product
- Customer service / support
- In-service / Training
- Real time shelf life documentation
trends

- Offsite clinical areas, ASC, GI, clinics, physician offices
- Varied sterilization parameters (extended cycles)
- Loaner instrumentation
- Diminishing material, human, financial resources
- Emerging scientific technology (robotics, lasers, endoscopy, etc)
- Weights / metal mass & density
- Going Green
- Cleaning challenges
- Competitive market conditions
sterilization methods

- Steam
- EO
- VHP
- Gas Plasma
- Ozone
review environmental / storage conditions expected of user’s

• 8 – 10 inches from floor
• 18 inches from ceiling
• 2 inches from outside walls
• 64 – 72 degrees
• 35 – 70 % humidity
• dry clean environment
• controlled secure environment
general considerations

• Conditioning of materials- should be held at room temperature 68°F - 73°F and relative humidity (RH) from 30% - 60% for minimum of 2 hours
• Must inspect all materials for any defects, foreign matter, holes, cleanliness
• Ensure packaging techniques are consistent with manufacturers instructions and acceptable techniques
• Conduct routine process audits to ensure compliance
Wet Packs

- Zero wetness acceptable
- Totally broken down, all CIs replaced, reprocessed
- Replace packaging materials
- Freshly laundered textiles (un ironed)
- Discard any disposable components e.g. cotton balls, gauze, packaging accessories etc.
examples of wetness
Improper loading

overloading
Moisture Management
labeling
selection and evaluation -

- Compatible with process
- Process indicators and labels capable to adhering to packaging material throughout process until opened
- Use of acceptable marking pens – permanent non leaching, non toxic inks suitable for sterilization process
- Write only on plastic side of peel pouches
- Write on tape or other suitable label and affix to wrapped packages
- Inappropriate labeling could damage packaging materials affecting sterile integrity
- legible
- differentiation, colors, prints etc
Labeling

Users must understand symbols, codes, methodology.
package closure

• Acceptable material and technique compatible with sterilization process
• Use only appropriate sterilization tape
• Use of straps, ties, or elastomer bands are acceptable for outside closures provided they are medical grade, validated, compatible with sterilant & used in accordance with manufacturers instructions (appropriate sizing is essential)
• Double pouching when absolutely necessary needs to be done appropriately

• product validated for double pouching
• IFU how to double pouch / sizing
Punctures
Packaging aids for protection and tear management
Peel Pouch Options
Dust Covers
containment devices

- Validated for selected sterilization process, parameters and cycles
- Obtain technical data and instructions for care handling and use
- Follow manufacturers instructions
- Appropriate and validated for use with specific medical devices
- Use only components and accessories approved and validated by manufacturer, filters, locks, baskets, inserts, labels and the like
- Disposable labels inspected prior to use in CPD and OR
Sterilization Containers
use of proper filter for containment device and sterilization process
Filter Inspection
containment devices
cases, cassettes, baskets
Mysterious Cuts
TEAR MANAGEMENT
storage
No outer shipping cartons in clean or sterile storage areas
Shipping Boxes / Corrugated Boxes
distribution

- Transport in covered or enclosed vehicle with solid bottom shelf
- Avoid any potential for compression
- Carts and reusable covers should be cleaned after each use
- Cart covers should have re closable openings
- Appropriate sized vehicle items should not protrude or extend beyond shelf area
- Proper placement on vehicle flat and secure
- Caution and proper handling when via hand transport
- Contain sterile goods when using dedicated lifts and other vessels
A wise man once said it is good idea to leave your audience before they leave you!!

Thank You!!