Housekeeping Issue

- Same rules as this morning

Objectives of the program

- Focus mainly on peel pouches
- Review the “10 truths” about packaging
- Know the differences between the Two Primary types of Peel Pouches
  - Tyvek
  - Plastic-paper
- Demonstrate and Understand the difference between Heat and Self Seal Pouches
- Understand the failures in peel pouching
- Talk briefly about other packaging types
  - Wrap
  - Reusable
  - Disposable
- Review the Guidelines and Standards
- Close with a workshop on peel pouches

CSSD has its own circle of life. All steps have to be performed well. We will be talking packaging its role in the CSSD circle of life and its impact on reducing infections.
FDA Class II Medical Device

FDA classifies sterilization wrap and peel pouches 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."

Purpose of Sterilization Packaging

"The 10 Truths"

1. Allow effective penetration of the sterilization agent
2. Ensure that sterility of contents is maintained
3. Afford easy removal of contents / easy open
4. Provide a reliable microbiological barrier
5. Be suitable for the methods used
6. Have required strength and durability
7. Be effective to use
8. Be free of toxic ingredients and non-fast dyes
9. Maintain positive sealant integrity
10. Permit complete removal/evacuation of the sterilant from the package

Types of Packaging

- Briefly talk about Sterilization containers
- Briefly talk Sterilization wrap
- Main focus is on Peel Pouches

Types of Packaging

- Sterilization Containers
  - Full instrument sets
  - Heavy instrument trays
  - Instrument sets that are frequently used - cost effective

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
### Types of Wrap Packaging

**Sterilization Wrap**
- Two types
  - Reusable
  - Disposable
- Instrument sets
- Single items
- Bed pans/basins other odd shaped items

### Wraps
- **Reusable - Textile**
  - Barrier qualities diminish with repeated use
  - Clean and launder before each use
  - Delint impact over an illuminated table for defects, tears, holes, worn spots, and stains
  - Minor holes may be mended with appropriate thermal seal patches (no stitching)
  - Wicking and permeability considerations (density and liquid shield of material)
- **Disposable**
  - One time use
  - Some linting
  - Pinholes can be an issue
  - Many different manufactures
  - Many different grades and types
  - SMS – spun bond-melt blown – spun bond (polyolefin plastic)

### Types of packaging materials used for wrapping
- **Woven (usually reusable)**
  - Muslin
  - Treated barrier cloth
  - Others
- **Nonwoven material (usually disposable)**
  - Kraft type papers
  - Spundbond-meltblown-spundbond (SMS)
  - Others
- **Two layers**

### Types of Packaging

**Peel Pouches**
- Single instruments
- Small items
- Light-weight
- Low-profile
- Various types
  - Heat sealable
  - Self seal
  - Roll stock
  - Gusseted

### Many choices but not all the same choose wisely?
Why use Pouches?

- You can easily identify what is inside

Types of Peel Pouches

- Poly/Paper(Paper/Plastic)
  - Steam and EO Sterilization

- Tyvek®
  - EO, Plasma Sterilization, Low Temperature Sterilization
Plastic Film (Peel-Pouches)

- Thermoplastic polymers of various formulations and individual trade names are distributed by numerous companies.
- Not all types of plastic and/or plastic–paper combinations can be used for all sterilization methods. That is why we have two primary types of peel pouches.

Two Primary Types of Peel Pouches

- Tyvek (which is porous and non-woven) on one side and of BOPET/PE laminate (polyester/polyethylene, which is non-breathable) on the other side. This is used with EtO and Gas Plasma/Low Temperature sterilization systems.
- Plastic-Paper, a medical grade paper on one side and laminate (film) on the other side. This is used for Steam an EtO sterilization.

General Information

- Not all plastic or plastic-paper combinations can be used with all methods
- Some plastics should only be used for low-temperature sterilization
- Most commonly used for small instruments, lightweight devices and porous items

General Information continued

- Manufactured with three sides closed (pouch style)
- Roll style is cut to fit
- Must be pinhole free and non-toxic
  - Must be resistant to tears and punctures

General Information Continued

- Should not delaminate/shred on opening
- Must be properly secured
- Must be sized and applied properly and not be overfilled
- Peel Pouches can not be put inside trays/sets/container (use “paper bags”)
- Pouches should be traceable by lot #
  - You should not have to save the box

Types of Pouches

Steam

Low Temperature Plasma
Each pouch should have these features

- Proper direction to open pouch
- Each Pouch has a Lot #

Packaging Selection

- Determine the medical device or devices being packaged
- Determine the sterilization modality to use: Steam, ETO, other low-temp
- What type and style of pouch to use

Styles of Heat Seal Peel Pouches

- Pre-cut
- Heat seal
- Self seal
- Roll Stock
- Gusseted

Heat Seal a mechanical bond

- Air-tight closure
- Fast and easy closing process can be validated
- Safe and tight barrier against contamination
- Visual check facilitated by the Green Seal feature
- No deterioration upon time
- Seal strength is affected by autoclaving process, not by storing conditions & time
- Low unit price: choice of tubing or ready made pouch
- Sealer investment pays back on safety and fastness

Gusseted Pouch

- Use for bulkier items
- If bursting occurs try using a flat pouch without gussets may eliminate the problem.
Example Gusseted Pouch

Self Seal – Adhesive Bond

Self Seal ↔ Heat Seal

How Pouches Work

In the Sterilizer

Tips for Peel Pouch Use

- Consider the Sterilization Method
- Use tip protectors
- Select the proper pouch size—allow 1'-1 ¼” around all sides
Tip for Peel Pouch Use

- Chemical Indicators (class 3,4,5,6) should be placed inside every pouch
- Quality of the seal should be carefully checked each and ever time you handle the pouch
- Use the right size of pouch

Proper size pouch is important

General Guidelines for Peel Pouching

General Guidelines for Peel Pouching

A sealed pouch

Too tight

Too loose
General Rules of Sealing the Pouch

- Before sealing, remove as much air as possible from the pouch. This will help prevent rupturing in sterilization.
- Ensure that pouch contents and the internal indicator are away from the seal area, and will not get caught in the seal.
- Seal the pouch securely, according to the pouch manufacturer’s instructions.

Heat Sealing the Pouch continued

- Leave enough material beyond the seal for the opener to easily grasp (usually 1 - 1 ¼ inches).
- Rubber bands, non-approved tape, safety pins, paper clips, staples or other sharp objects should not be used to secure packages or to organize the contents.

Heat Seal Pouches

How to seal a Heat Seal & Roll Type Pouch

- Follow general Guidelines for all pouches.
- Ensure that the proper sealer conditions are used. (temperature each peel pouch has a temperature range to provide maximum sealing, if a heat seal type pouch)
- To prevent injury keep fingers away from sealer bars/rollers.

Heat Sealing the Pouch continued

- Hold the pouch taut in the sealer, to prevent wrinkles or air bubbles from forming in the seal. If using a rolling type sealer let the peel pouch move along the guide on its own.
- When heat sealing "tubing/roll" type pouches, always leave enough material beyond the seal for the opener to easily grasp (usually 1 - 2 inches).
General Information
- Pouches and roll stock are commonly used for small instruments, light weight devices and porous items
- Roll stock is cut to fit
- Scallop cut opening end.
- Make sure scallop cut recognizes the correct opening direction.
- Must be pinhole free and non-toxic
- Must be resistant to tears and punctures

Sealing the Pouch Continued
- Hold the pouch taut in the sealer, to prevent wrinkles or air bubbles from forming in the seal. If using a rolling type sealer let the peel pouch move along the guide on it’s own.
- Always leave enough material beyond the seal for the opener to easily grasp (usually 1 – 2 inches) critical to allow for aseptic presentation

Opening Roll Stock
- Open at scalloped end
- (Verify your opening in the correct direction)

Peel Down Top-Side Seams (Thumb Tabs)

Grab & Roll Down Top Seam (4th side user created) - pulling film away from paper

Once Top Seam is released open the package using proper aseptic technique
Self Seal Pouches

How to seal a Self Seal

Self Sealing the Pouch

- Follow General Guidelines for all peel pouches
- Remove protective strip
- Fold flap
- Press down from the center with both thumbs and move outward. Apply even press while moving thumbs.

How do I know I have a good seal on my peel pouch?
Heat Sealers

- Information
  - AAMI ST 79
  - AAMI TIR 22
  - ISO Standards 11607
  - JCAHO
  - IAHCSMM 7th Edition

- Two major types
  - Bar sealer-impulse sealers
  - Continuous feed-rotosealers

- Critical parameters for both types of sealers to achieve a proper seal are:
  - Temperature
  - Pressure
  - Dwell time

Bar Type Sealer

- Different pressure points for sealing
- Pressure bar

Temperature Control is an issue with push bar type sealers

Continuous feed type sealers

- Feed product into system
- Adjustable depth of seal
- Equal pressure
- Equal temperature
- More productive
In 2006 ISO 11607 was updated. This is a two part document concerning packaging. To complement the release of this new standard, the AAMI guidance document, Technical Information Report – TIR 22:2007 was updated.

Under the new ISO Standard 11607-2: 2006 a process validation program is required to validate the efficacy and reproducibility of all sterilization and packaging processes, and this validation must be documented.

- Commercial products available
- The Steriking® Seal Control Sheet SC250 is made of ESPP film and medical grade paper. It simulates the sealing process very effectively and is suitable for the rotosealers and impulse units in widespread use.

Heat Sealing the Pouch

- Ensure that the proper sealer conditions are used.
- Use a sealer designed for medical packaging
- Each brand may have a slightly different melt point.
- Be sure to test your brand.
- Review Steriking® temperatures
  - Example
To allow for Safe Transport

TRANSPORTATION

- The handling and moving of sterile items from point A to point B
- Watch closely for any holes, tears or breaks in the wrappers, peel pouch or outer barrier
- Discard / return any item with a defective wrapper or peel pouch. Follow hospital policy on return supplies
- Close system to transport

In a hospital there is no 5 second rule for dropped items.

- Carol Chenoweth, M.D., a clinical associate professor at U of M Hospital, Ann Arbor, MI. “bacteria can transfer immediately onto a dropped item,” she says but adds that her kids still follow the 5 second rule. Detroit News; 5/23/06
- AAMI ST 79-8.8.6

In Sterilizer

- Peel Pouches should be arranged in the sterilization rack so that the pouches stand vertically on their edges.
- Not too tight
- All plastics face the same direction
- All Paper face the same direction

Loading of the Peel Pouch in the Sterilizer

- Use a basket or other container to hold pouches upright in the chamber.
- Load pouches loosely in the basket to ensure that air can be removed from the package and to allow sterilant to reach all surfaces.
- Never fold pouches, as folded areas can trap air, and prevent sterilant penetration.
- Paper side of one pouch facing the film side on the next pouch.
Do not let poor work practices hamper your hard work.

Tips for Peel Pouch Use
- Consider the Sterilization Method
- Use tip protectors
- Select the proper pouch size—allow 1”-1 ¼” around all sides

Always write on the film side of pouch using an approved marker, do not write on paper or Tyvek®

Peel pouches are not appropriate for use within wrapped sets or containment devices that are going to be steam sterilized. ANSI/AAMI ST 79

Tips for Peel Pouch Use

NO to Pouches inside Trays
- “…Paper–plastic pouches are not appropriate for use within wrapped sets or containment devices, small perforated mesh-bottom baskets with lids can be used instead of paper-plastic pouches to contain small items in sets. Small items or instruments can also be placed in an all-paper bag, an absorbent, single-layer, …. A CI should be placed inside these inner packages….” AAMI ST 79 – 8.3.4

What can I put in the trays
- 100% medical grade paper, which is porous to sterilant
- The moisture absorbent paper helps to disperse condensate—helping to fight wet packs
- Paper bags, multi-pouch instrument organizer

Paper bags can prevent Ink transfer
Tip for Double Pouching

- Check with pouch manufacture for Instructions for Use when choosing to double pouch
- The inner and outer pouch must be arranged by film to film. (Paper to Paper – Plastic to Plastic)
- The inner pack shall not be folded
- Seal the inner pack as well as the outer

Double Peel Pouching

- For Sterile Presentation in the O.R.
- Maintain integrity of the product
  - If sterilization pouch is routinely tearing or ripping and that is the reason for double pouching, you may want to select a different type of packaging. i.e.: Sterilization Wrap
- Manufacturers Instructions for Use
  - Have studies been done to support use

Storage and Handling of Peel Pouches

- When pouches have cooled after sterilization, inspect them for material and seal integrity, the presence of moisture, or any indication that sterility could be compromised. Always check the indicator and reprocess any questionable items.
- Store pouches in your sterile storage area. Stock sterilized pouches loosely, to prevent damage to either the package or its contents

Storing Pouches Continued

- Rotate pouches with FIFO method (first in first out)
- As with any sterile supply item the “events” such as handling and transportation, that can cause contaminations, should be minimized.

Box labels

- [Image of box labels]
Stacking of Wrapped Instrument Trays

- Stacking of instruments is against the new AAMI 79 standards.
- AAMI 8.92 of AAMI 79
- The wrapped instruments can not be stacked, containers can be stacked

Stacking of Instruments

- Stacking cause compress of the wrappers
- This causes contamination by pushing contaminates through the wrapper
- The debris comes in contact with instruments
- This would be a patient safety issue
- Check with the manufacture of your wrap to see if stacking is allowed

How much can a wrapped tray container weight?

AAMI ST 77:2006
The combined weight of container, tray and wrapper shall not exceed 25 pounds
**Typical Questions & Answers**

<table>
<thead>
<tr>
<th>Question/Description</th>
<th>Answer/Recommendation</th>
</tr>
</thead>
</table>
| The package does not seal properly? | • Check the sealing temperature and pressure settings  
• Recommended temperature 165-180°C |
| Double packaging? | • Paper to paper, film to film  
• Folding of package edges not recommended |
| The package burst open during sterilization? | • Check the loading of tray and/or chamber  
• Pack up to ¾ of the theoretical packaging area  
• Manufacture variations/fluctuations in seal strength and paper porosity |
| Wet packages after sterilization; water droplets on the film? | • Let the load cool down sufficiently  
• Check the cooling process and vacuum pulses |
| Package tears when opening? | • Use the correct direction, check the peel symbol  
• Correct opening technique |

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**Quiz Time!**

- A Tyvek Pouch will melt inside the sterilizer if used in a high heat sterilizer. **T** or **F**
- You can place any style peel pouch inside a tray to hold items if it is going to be sterilized by steam. **T** or **F**
- When sterilizing a mixed load, it is best to place pouches in racks on the top shelf. **T** or **F**
- A chemical indicator should be placed inside each peel pouch. **T** or **F**

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**Quiz Time!**

- Double pouching is recommended when pouch material routinely rips. **T** or **F**
- You can write anywhere on the pouch just so it is legible. **T** or **F**

**For more educational programs go to www.Crazy4Clean.com**

Courtesy of Healthmark Industries

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**Educational Opportunities**

**Decontaminator of the Year Award**

- Healthmark has been a continued sponsor of the Decontaminator of the Year Award, named in Honor of Anne Cofiell. The Decontaminator of the Year Award, sponsored by Healthmark, recognizes the author (a CSSD technician) of an outstanding paper focusing on understanding the importance of decontamination in their workplace environment. The recipient of this award is recognized annually at the IAHCSMM meeting and receives an engraved plaque plus $1000 and free registration to the IAHCSMM annual.
If you do not follow the standards. You can always; Pray if you want.

The first step in the acquisition of wisdom is silence, the second listening, the third memory, the forth practice, the fifth teaching others.

Solomon Ibn Gabriol

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Remember to Share your Knowledge with others
Check out Sterile Processing Dollars for Education from Healthmark

THANK YOU

What did you think?

The Sun has Set on this Program…….thank you and safe journey where ever you are going