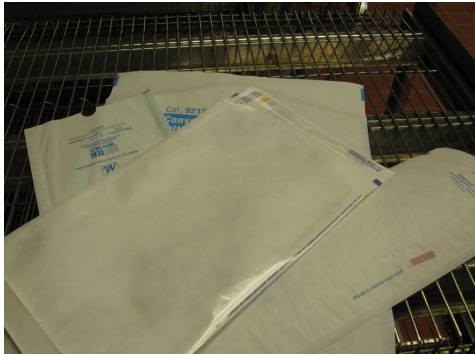


PACKAGING AND POUCHING 101
STEPHEN M KOVACH
DIRECTOR OF EDUCATION

Healthmark Industries, Fraser MI

Lots of Choices



CONFLICT OF INTEREST

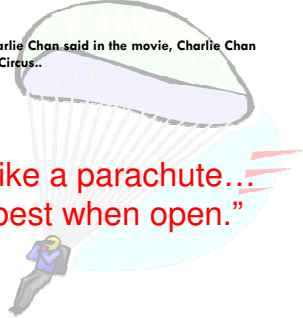
✓ The following individuals are industry employees and report.

"I, or a member of my family, or partner, have a significant financial interest of other significant relationship with one or more companies who manufacture products used in the treatment of perioperative patients."

Stephen Kovach, Healthmark

As Charlie Chan said in the movie, Charlie Chan at the Circus...

**"Mind like a parachute...
 Work best when open."**



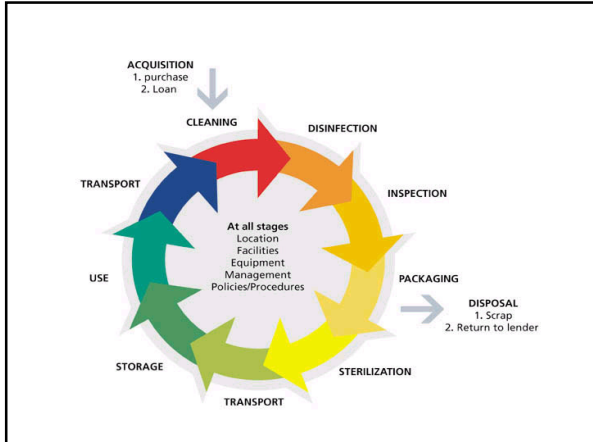
Objectives of the program

- 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 about other packaging types
 - Wrap
 - Reusable
 - Disposable
- Review the Guidelines and Standards
- We are not talking about containers today

Housekeeping Issue

- Who is here today ?
- Questions during the presentations ?
- Pictures help tell a story, you will see a lot of them today
- Cell phones off
- Ready lets go

CSSD has its own circle of life. All steps have to be performed well. We will be talking packaging it's role in the CSSD circle of life and it's impact on reducing infections.



Background Information

- FDA in the US classifies packaging used for sterilization as a Class II medical device.
- FDA defines the function of packaging as follows:
 - “ The prime purpose and function of a packaging material (pack, sterilization wrapper, bag or accessories) is to enclose a medical device that is to be sterilized by a healthcare provider. It is intended to allow sterilization of the enclosed device and also to maintain sterility of the device until it is used.”
- A peel pouch falls into this classification

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

- Sterilization containers
- Sterilization wrap
- Peel Pouches

Types of Packaging


Sterilization Wrap

- Instrument sets
- Single items
- Bed pans/basins other odd shaped items
- Linen packs / gowns

Types of packaging materials used for wrapping

- Woven (usually reusable)
 - Muslin
 - Treated barrier cloth
 - others
- Nonwoven material (usually disposable)
 - Kraft type papers
 - Spunbond-meltblown-spunbond (SMS)
 - Others
- Two layers

Work station for Wrap



Why use Pouches?

- You can easily identify what is inside



Types of Packaging

Peel Pouches


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



Allows for effective sterilization



Provides safe handling and storage



Provides for Aseptic Presentation

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, light weight 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

DO NOT USE IF PACK IS DAMAGED
KEINE BESCHÄDIGT VERWENDEN

Proper direction to open pouch

LOT 001 Multi-X

Each Pouch has a Lot #

Steam

Plasma

Types of Pouches

DO NOT USE IF PACK IS DAMAGED
KEINE BESCHÄDIGT VERWENDEN

Proper direction to open pouch

LOT 001 Multi-X

Each Pouch has a Lot #

How can you trace this peel pouch



Packaging Selection

- Determine the medical device or devices being packaged
- Determine the sterilization modality to use: Steam, ETO, other low-temp

How Pouches Work



In the Sterilizer

- The paper or Tyvek side allow the sterilant penetration in and out of the pouch.
- In a mixed load the pouches should be placed on the top shelf in the sterilizer and arranged such that they allow for free flow of the sterilant.

Proper size pouch is important



Too tight



Too loose



Too loose



A sealed pouch



General Information Continued

- Two Types of Seals are used for Peel Pouches
 - Heat Seal
 - Self Seal

Types of Peel Pouches

Heat Seal


Self Seal



Types 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

<p>Self Seal is a chemical bond</p> <ul style="list-style-type: none"> □ High risk of air channels □ Sealing process cannot be validated or verified □ Seal integrity dependent on end-user's handling □ Quality impossible to control □ Tapes provide a limited shelf life (glue dries out) □ Shelf life affected by sterilization & storing conditions □ High unit price □ No investment in sealer 	<p>Heat Seal a mechanical bond</p> <ul style="list-style-type: none"> □ Air-tight closure □ Fast and easy closing process can be validated and verified <ul style="list-style-type: none"> □ Industrial standard □ Safe and tight barrier against contamination □ Visual check can be facilitated by some pouches like STERIKING® 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
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General Guidelines for Peel Pouching

General Guidelines for Peel Pouching

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

Heat Sealing the 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 it's 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)



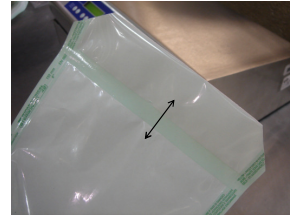
General Information

- 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

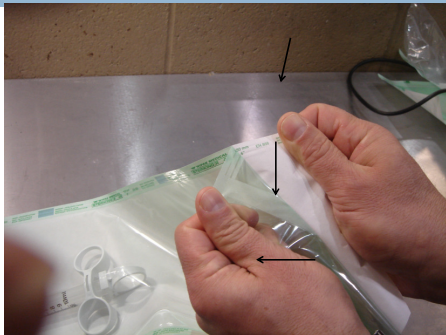
- Open at scalloped end
- (Verify your opening in the correct direction)



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



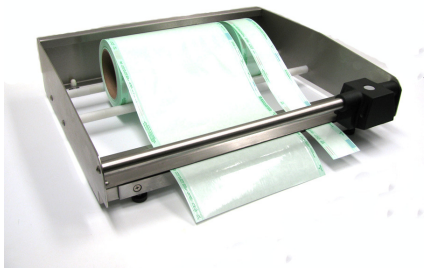
Peeling the film from the paper side of package for Sterile Presentation



Stay awake now !!!!



Roll Stock Cutter



Self Seal Pouches

**How to seal
a
Self Seal**

Self Seal – Adhesive Bond



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 ?



Tip for Peel Pouch Use

- Chemical Indicators should be placed inside every pouch
- Quality of the seal should be carefully checked each and ever time you handle the pouch

Heat Sealers

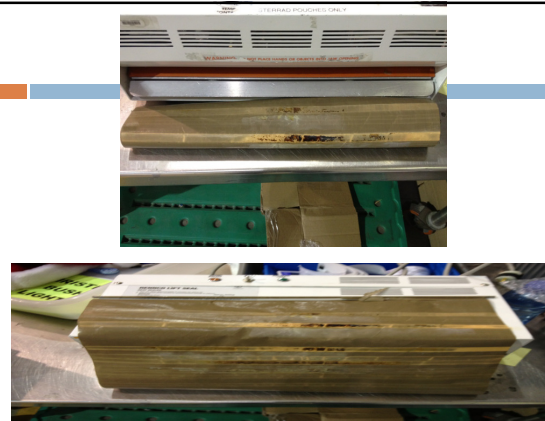
- Information
 - AAMI ST 79
 - AAMI TIR 22
 - ISO Standards 11607
 - JCAHO
 - IAHCMM 7th Edition

Heat Sealers

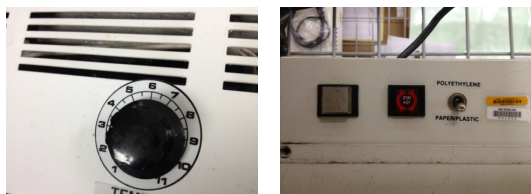
- Two major types
 - Bar sealer-impulse sealers
 - Continuous feed-rotosealers
- *Critical parameters for both types of sealers to achieve a proper seal are :*
 - Temperature
 - Pressure
 - Dwell time

Bar Type Sealer

- Different pressure points for sealing
- Pressure bar



Temperature Control is an issue with push bar type sealers

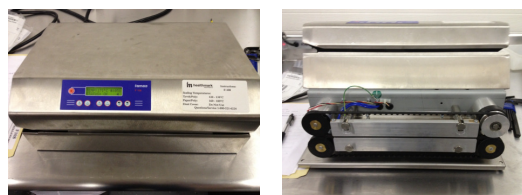


Continuous feed type sealers

- Feed product into system
- Adjustable depth of seal
- Equal pressure
- Equal temperature
- More productive



Roll type sealer



Seals do fail, you need to verify your process.



Verifying the seal

- 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



Check the Seal



To allow for Safe Transport



Half way point in the program



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
- Closed 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




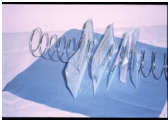
In Sterilizer

- 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.

The sterilization pouch racks keep pouches on edge, prevent over stacking and facilitate sterilant contact and reduce drying time, all in accordance with AAMI ST79. Styles include full loop, peg and multi-height racks. All models of manufactured of stainless steel.




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 1/4" around all sides



Tips for Peel Pouch Use

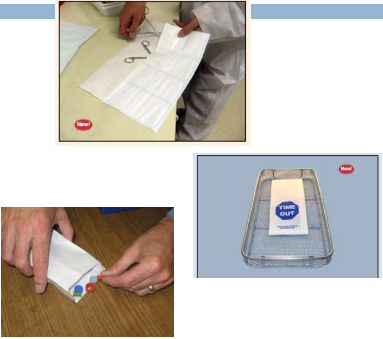
- Always write on the film side of pouch using an approved marker, **do not** write on paper or Tyvek®
- Peel pouches are not appropriate for use within wrapped sets or containment devices that are going to be steam sterilized. ANSI/AAMI ST 79

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 dissipate condensate- helping to fight vent 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



Work Station – an important part of productivity

Handling and Storage

General Guidelines for handling and Storage of Peel Pouches

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.

Time Related Sterility

- refers to an item considered sterile for a predetermined length of time
- 30 days, 6 months, 1 year,..
- or if the package integrity is in question

Event Related Sterility

- an item is considered sterile as long as there are no tears, holes or breaks in the peel pouch seal
- item is considered sterile until the package is opened or damaged
- this may be anywhere from minutes to years depending on your specific policy

BEFORE PLACING AN IN-HOUSE
STERILIZED ARTICLE IN THE
STERILE STORAGE AREA IT IS
IMPORTANT TO:

In-house Sterilized items

- check the condition of the closure of the peel pouch to make sure that it adequate
- make sure that the package is completely cool
- make sure that the package is dry
- make sure that the shelf is clean and dry where the item is to be stored
- check that the or breaks in the peel pouch seal color has changed
- It is properly labeled...name of contents on package...
- initials on the person who prepared the pouch
- lot control label

Storage and handling of Peel Pouches

- Store pouches in your sterile storage area.
- Stock sterilized pouches loosely, to prevent damage to either the package or its contents

Box labels



Stacking of Wrapped Instrument Trays

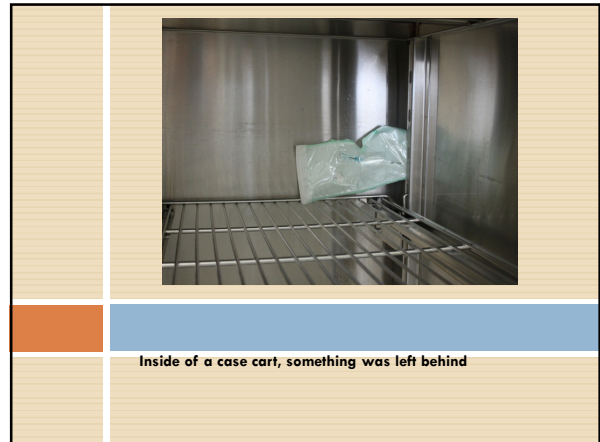
- Stacking of instruments is against the new AAMI 79 standards.
- AAMI 8.92 of AAMI 79
- The wrapped instruments can not be stacked, containers can be stacked



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






Inside of a case cart, something was left behind

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

Question / Description	Answer / Recommendation
The package does not seal properly?	<ul style="list-style-type: none"> • Check the sealing temperature and pressure settings • Recommended temperature 165-180 °C
Double packaging?	<ul style="list-style-type: none"> • Paper to paper, film to film • Folding of package edges not recommended
The package burst open during sterilization?	<ul style="list-style-type: none"> • Check the loading of tray and/or chamber • Pack upto ¾ of the theoretical packaging area • Manufacture variations/fluctuations in seal strength and paper porosity
Wet packages after sterilization; water droplets on the film?	<ul style="list-style-type: none"> • Let the load cool down sufficiently • Check the cooling process and vacuum pulses
Package tears when opening?	<ul style="list-style-type: none"> • Use the correct direction, check the peel symbol • Correct opening technique

10
03/2003 Wpack Medical / AL

STERIKING®

Review How to Seal Heat Sealable Pouch

Heat seal cont.

- Seal must extend completely across the pouch
- Hold the pouch taut in the sealer
- If using a roller type – let the peel pouch move along the guide on it's own.
- **Heat Seal Rolls**
 - Cut length with enough material beyond the seal to allow for ease of opening - usually 1 to 2 inches

Review on How to Seal Heat Sealable Pouch

- Heat Seal Rolls cont.
 - Scallop cut the opening end
 - Make sure scallop cut recognizes the correct opening direction

Review on How to Seal a self seal pouch

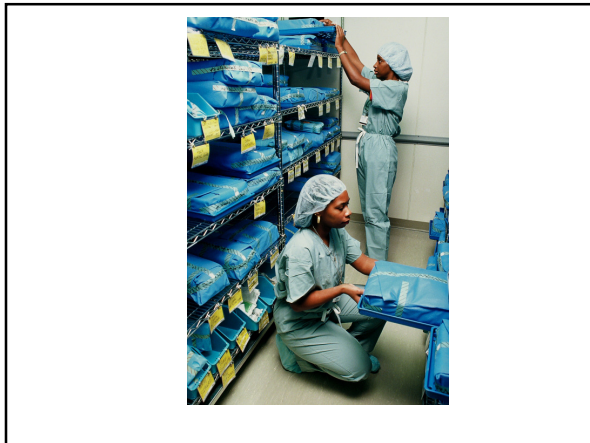
Self Seal –

- Use manufactured fold or perforation
- Press from center outward – pressing firmly



Packaging & Pouching review

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



Just Bad Practice



Really is this the right way ?

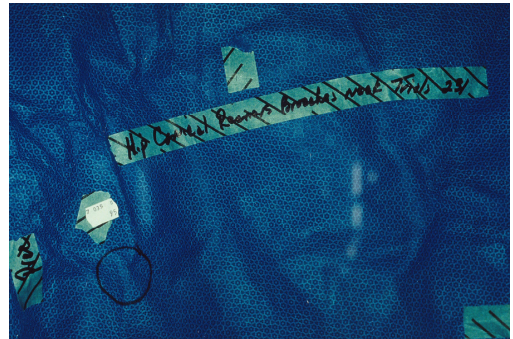
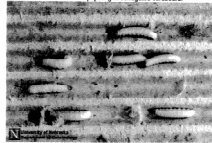


Why no cardboard in department ?



2. Corrugated cardboard boxes are not appropriate because they are an excellent habitat for insects and pests as pictured below (courtesy University of Nebraska);

Material Inside Without seeing possibility to congregate outdoors;



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

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

I just had to show you all this picture.



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 Cofiehl. 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 IAHCSSM meeting and receives an engraved plaque plus \$1000 and free registration to the IAHCSSM annual.



WIKI's Pouching Paradise

Play Now!

WIKI's Pouching Paradise! A new Flash-based game that takes you on an adventure of proper peel pouching.

Work with WIKI to learn about proper packaging techniques using peel pouches. WIKI will show you how to choose the correct type of packaging for different instruments, how to load a sterilizer cart, and more! Join WIKI in his Pouching Paradise to learn all about the packaging process.

Check out Sterile Processing Dollars for Education from Healthmark

Healthmark

My Family

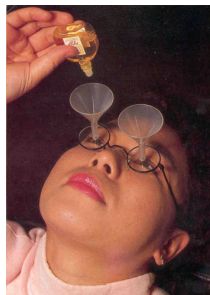
All of You for attending and wanting to share information

Fill out the evaluation form

THANK YOU



Remember Be Creative



Contact Information Stephen M. Kovach

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www.cpdguy.net

www.hmark.com

Famous Quotes

"Always do what is right when people are looking"
Mark Twain

"Quality is doing the work right when nobody is
looking" Henry Ford

"What gets measured is improved"
Peter Drucker

Sharing is Caring

Some say that Knowledge is
Power but I say The real Power
is when you share your
Knowledge with other. Please
share your knowledge.

S.M.Kovach