

## BASICS OF PEEL-POUCH PACKAGING

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### Objectives

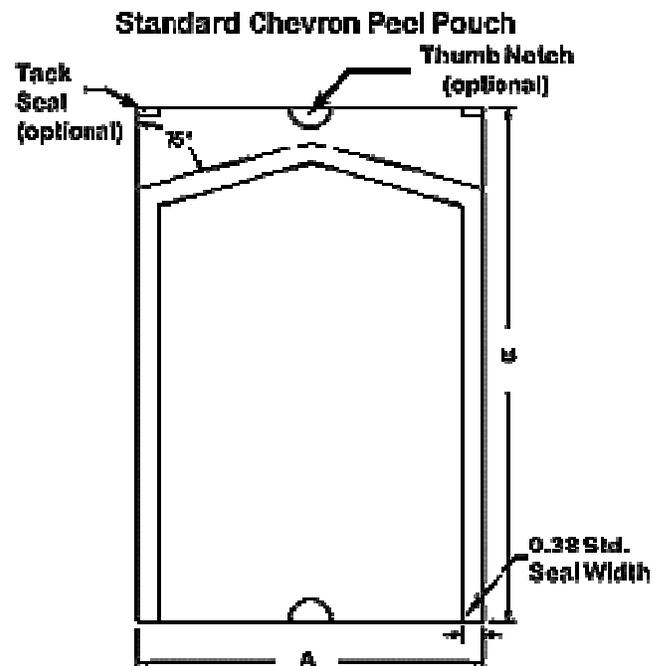
- Discuss the function, purpose and characteristics of packaging
- Describe the regulatory requirements for packaging
- Review sterility maintenance

All of us know you can't sterilize something unless it is in a package of some sort. What is questionable is the type of package one needs to use to meet criteria set up for packaging use. Packaging is generally divided into three basic types: peel-pouches, woven and/or non-woven material wrappers and rigid containers. The selection of any or all of these types of packaging depends on the needs of the facility, how many areas they service, the amount of storage available to them, the method of sterilization and the weight of the contents. I don't believe we would want to put a ball ping hammer into a single peel-pack and expect it to hold up to sterilization and storage.

Peel-pouches are made from plastic/paper combinations or Tyvek/plastic combinations. But remember, not all peel pouches go with every type of sterilization. For example, Tyvek/plastic combinations are considered flammable and will melt in a steam sterilization process. If you are still using an ethylene oxide (EtO) sterilizer either type of peel pouch can be used with EtO. Occasionally because of the number of items or the weight of an item, the peel-pouch will need to be doubled. In other words, a pouch will be inside another pouch. When that happens, the inside pouch must be flat with no folds and the paper side must be against the paper side. Also, no peel pouch should be used inside a container as there is no way to adequately ensure appropriate air removal or that the steam will penetrate inside the

pouch or that the pouch will dry completely along with the items packaged inside.

Peel-pouches are designed to be used as a container for light weight items. They also are used when we need to see the item inside the pouch. When packaging the item, it is expedient for the user to be able to grasp the item quickly and without contamination. For this reason, we generally package the item with the handle closest to the peel area of the pouch. It is also imperative to make sure the seal of the pouch is as smooth as is possible. If you are using a self seal pouch, there is an adhesive portion with a removable strip. The strip is removed and the adhesive is carefully sealed to the pouch creating a barrier on the pouch. If you are using a sealer, make sure the pouch is big enough to seal without causing any creases or gaps or wrinkles which would let bacteria into the pouch. With any method of sealing including using tape, it is essential to make sure the ends are closed securely without gaps or creases to prevent any contamination.



Almost any item can be placed in a peel-pack provided it meets the criteria.

1. Packaging systems should be appropriate for items being sterilized. The package system should

- \* provide an adequate barrier to microorganisms, particulates, and fluids;
- \* maintain sterility of package contents until opened;
- \* allow sterilant penetration and direct contact with the item and surfaces, and removal of the sterilant;
- \* be free of toxic ingredients and nonfast dyes;
- \* permit aseptic delivery of contents to the sterile field (e.g., minimal wrap memory, removal of lids from containers);
- \* permit complete and secure enclosure of item(s);
- \* protect package contents from physical damage (e.g., compression, stacking);
- \* provide adequate seal integrity;
- \* resist tears, punctures, abrasions, and prevent the transfer of microorganisms;
- \* be tamper-proof and able to seal only once;
- \* permit adequate air removal;
- \* be low-linting;
- \* permit identification of contents;
- \* be large enough to evenly distribute the mass;
- allow ease of use by personnel preparing and/or opening the package or container (AORN).

### Types and Use of Sterilization Packaging Materials

Sterilization Method	Packaging Material Requirements	Acceptable Materials
Steam autoclave	Should allow steam to penetrate.	Paper Plastic Cloth Paper peel packages Wrapped perforated cassettes
Dry heat	Should not insulate items from heat. Should not be destroyed by temperature used.	Paper bags Aluminum foil Polyfilm plastic tubing Wrapped perforated cassettes
Unsaturated chemical vapor	Vapors should be allowed to precipitate on contents. Vapors should not react with packaging material. Plastics should not contact sides of sterilizer.	Wrapped perforated cassettes Paper Paper peel pouches

When looking at packaging systems, the FDA classifies them as a Class II medical device and requires a 510 (k) for their intended use in order to be legally marketed. In other words, in order for those peel-pouches to be used in your facility, the manufacturer must first submit a Premarket Notification 510(k) to the FDA including the application, documentation of testing and validation studies, all data collected during the testing phase, both good and bad, what it's going to be used for, any special labeling needed and what the manufacturer's instructions for use are. After all that, once the FDA gives their approval, any time the manufacturer makes a change, they must let the FDA know what the changes are, how it is going to affect the product, does it change the use of the item, and any data collected during the change process. If the FDA deems there have been too many changes, they may require a new 510(k) for the product before it can be sold as an upgraded product.

When preparing peel-pouches for sterilization there are several things to remember.

1. Ensure the item/items in the peel-pouch are not so small as to create a potential blow out from the sterilization process nor so large as to have the items sliding around and possibly puncturing the pouch.

2. If using double pouches, make sure the paper side is touching the paper side and the plastic side is touching the plastic side. This ensures the sterilant can get to the packaged item. Also remember to not fold any portion of the inner package as this will prevent proper sterilization.

3. When labeling the pouch with the contents, use a felt tip marker only on the plastic side or the folded over sealing flap. Never use an ink pen as the ink tends to run when wet and may contaminate the contents.

4. When placing the pouches on the sterilizer rack, they should be positioned standing on edge in a loading rack or basket and properly spaced. They should never be placed flatly on the shelf or stacked on top of each other. This will cause condensation to form inside the package.

5. Remember to position the pouches paper-to-plastic, paper-to-plastic in order to ensure the sterilant gets inside the packages. Remember the sterilant gets to the inside of the pack by going in thru the paper side.

6. After sterilization, please check the pouches for moisture and check again before placing the pouches into storage.

Post-sterilization, the sterilized product is considered sterile until opened. This is called "event-related sterility". In other words, until something happens to contaminate the pouch, like dropping the pouch in the floor or having water dripped on it, it is considered sterile.



The CS Tech must also be aware of handling processes as well as the storage of sterilized items in order

to prevent over-handling as well as being stored too tightly in bins. By controlling the environment and the events to which the sterilized product is exposed, contamination can be greatly minimized. It is up to each of us to be knowledgeable of sterilization processes and to continue to monitor the complete process of packaging, sterilization, storage and handling in order to have a product that is safe to be used on any patient.

#### Bibliography

AORN: Recommended Practices for Selection and Use of Packaging Systems for Sterilization. Denver, Colorado, 2007

Peel-Pouches: Information for Your Use  
Spring-2014

1. Every peel-pouch goes with every type of sterilization.  

True	False
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2. When putting a pouch inside another pouch, the first pouch must have no folded parts.  

True	False
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3. Pouches are used for light weight items and when it is necessary to see what is inside.  

True	False
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4. Peel pouches need to be able to protect the items inside from physical damage, i.e., stacking.  

True	False
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5. The FDA does not require a 510 K in order to make peel packs.  

True	False
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6. When sterilizing peel packs, the paper side can be placed next to the paper side.  

True	False
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7. Peel pouch should be used inside a container as there is no way to adequately ensure appropriate air removal or that the steam will penetrate inside the peel –pack.  

True	False
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8. Post-sterilization, the sterilized product is considered sterile for one month.  

True	False
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9. Peel packs do not need to be checked for moisture before being put into storage.  

True	False
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10. When sterilizing packages, they can be placed on top of each other.  

True	False
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