General Information concerning Peel Pouches

In general, peel pouches should be used for small, lightweight, low-profile items.

A well-designed and correctly used sterilization pack provides effective sterilization, safe handling and storage of all items until the moment they are used. A pack must remain sealed against bacteria and facilitate aseptic presentation of the packaged product. The sterile state of a medical device is maintained with the help of an appropriate packaging. The design, materials and manufacture of the packaging materials have to be compatible with the medical device to be packed, the handling processes of the medical device, the sterilization method to be used, the labeling systems, and the distribution and storage conditions as well.

Sterility maintenance is event-related rather than time-related and as such the definition of the “best before” dates lies in control of the packager. Users need to follow manufacturers’ IFU (instructions for use) concerning expiration dates of the peel pouch.

In the following sections we will examine some key aspects connected with packaging and autoclave loading.

Selecting a correct packaging

When choosing appropriate packaging material, careful attention should be paid to the following aspects:

- The product to be packaged, its size, shape and nature.
- The method of packaging; ease and speed of the packaging process.
- The closing method of the package; sealing and folding processes.
- The sterilization method to be used; stability when exposed to high temperatures and high pressure variations.
- Freedom from airborne particle.
- Resistance to moisture and dirt.
- Porosity needs depending on sterilization method.
- Protection against bacteria and mechanical wear.
- Storage conditions and storage-time related issues.
- Ease of opening the package and facilitating aseptic presentation of the sterile item.

Packing guidance: See-through Peel Pouches & Rolls

The see-through peel packaging is a time-saving concept. It is fast and easy to pack an item into a pouch and to close it with a heat sealer (or self seal). Recommended sealing temperatures and pressures and other technical advice should be followed carefully. When using a self seal pouch, the attached adhesive strip provides for a tight closure. The identification of packed instrument(s) is easy because of the transparent plastic film.

The WIPAK / STERIKING® brand (is one brand of pouch) has a green color film which facilitates visual control of the sealed lines and their integrity. WIPAK / STERIKING pouches use BOPET/PE laminate (polyester/polyethylene) in their Tyvek pouches. They also use medical grade paper in their poly-paper pouches. These are just some of the reasons the WIPAK/STERIKING pouches are stronger and more reliable than other pouches. This was the brand of pouch used in the videos and games.

Peel packs are available in a wide range of sizes and shapes. They come as ready-made pouches or tubing (roll type stock), fit for the large variety of items in hospitals. The regular ranges of products are manufactured of medical grade paper and plastic film and are suitable for sterilization in steam and EO processes. A dedicated range of products featuring Tyvek® (Du Pont´s registered trade name) is developed for low temperature sterilization, for example by EO, gas-plasma, H2O2, or Ozone.

The less air left inside the final pack when packaged, the easier it will be to evacuate the air by means of a vacuum process from the pack and especially from the products to be sterilized and thus to enable the sterilant to penetrate into the products. Porous loads shall be packed loosely.

Some practical tips:

Tip 1

The peel pouches shall be arranged in the sterilization rack so that pouches stand vertically on their edges and should not be tightly packed. You want to allow free circulation of the sterilant for facilitating air removal and sterilant penetration. The pouches should be positioned so that plastic faces plastic and paper faces paper. Pouches should never lay flat. If double pouching is used, the inner and the outer pouch must be arranged by film-to-film. The inner pack shall not be folded, and it is recommended to close it by sealing.

Tip 2

Plastic films are, in practice, fully airtight, and as such they form an excellent protection against bacteria for the packaged product. They withstand moisture and wetness extremely well. The steam permeability of plastics is minimal – practically nil. The packages are to be placed on their edges in the direction of the steam flow when possible.

Tip 3

The sterilization peel pouch racks must not be packed tightly or too full in the chamber. You need to allow sufficient free space for the sterilant to circulate and to replace any air pockets in the products. The peel packs must not be folded in a way that the plastic side is turned on top of the paper side. On the other hand, the products are not to be packed too loosely so that they could move around during processing, causing folding effects by themselves, wrinkled corners, "turn-ups" and depressions, as those would negatively impact the processing result.

Tip 4

The peel pouches should be arranged in the sterilizer chamber in such a way that they do not touch the walls or other interior surfaces. If they do, then quality-weakening factors may appear in the products and the wet pack risk grows because the free passage of steam is hindered.

Tip 5
Always write on the film side of the peel pouch with an approved marker. Pouches should have at least the name of the item along with an initial of the person who assembled the item and the load identifying sticker in case of recall.

Tip 6
Peel pouches of any type are not appropriate for use within wrapped sets or containment devices that are going to be steam sterilized, according to ANSI/AAMI ST 79.

Tip 7
If using a heat sealer to seal pouches, users need to verify that their heat sealer is performing properly according to ISO Standard 11607-2; 2006/(R)2010 and AAMI TIR 22:2007.

TIP 8
Regardless of the type of seal (self sealed or heat sealed), the quality of the seal should be carefully checked. If there are any signs of defects in the seal (like a gap) the item should be reprocessed.

Tip 9
Paper clips, pins, staples or any similar items should never be used for closure of a peel pouch.

Tip 10
When packaged in peel pouches, a tip protector should be used to prevent damage to delicate items (like the tips of scissors) and to help prevent puncture of the pouch.

Tip 11
When storing peel pouch items, follow the manufacturer's IFU for temperature and humidity control of the area where the products are being stored before and after sterilization. Incorrect temperature and humidity can contribute to the failure of a peel pouch.

Tip 12
In general you can save money by using a heat seal pouch instead of a self seal pouch.

Some typical packaging failures:
Packaging failures are usually the results of:

1) bursting during sterilization processing or
2) film tear and/or paper shear when opening a package.

The packaging can fail during sterilization and burst open if the pack is too full, wrapped too tightly (see Tips 2, 3 and 5 for support), or the sterilization tray is too fully loaded. Thus, the packs cannot breathe during the vacuum process; the pre-vacuum or the post-vacuum process is too radical for the packed products and their packaging.

As a general guideline, it is recommended to fill a pouch to a maximum of ¾ of its packing volume in order to allow the package to conform to air evacuation processing during sterilization. It is also recommended that you keep 1 to 1 ½ inches of space around the item being sealed from all sides of the pouch.

Peel pouches are permeable only through the paper side (or alternatively through Tyvek®) and it takes time to evacuate the air from the package during the pre- or drying vacuum process.

If bursting occurs when packing in pouches with gussets, using an ordinary flat pouch without gussets may eliminate the problem. A flat pouch without gussets presents more paper surface permeable to air and steam.

A peel pouch must remain sealed against bacteria and facilitate aseptic presentation of the packaged sterile product. If the package is damaged during sterilization, warehousing or transport, the packed item shall be sent for re-packing and reprocessing.

A well designed and correctly used sterilization peel pouch provides for effective sterilization, safe handling and storage of all items until the moment they are used.

NOTE: Because practices in pouching differ around the world, this in-service is generic in nature with a focus on practices in the United States of America.

Helpful links:

Double Pouching Guide Heat Sealable Pouches
http://www.healthmark.info/SterilizationProducts/Pouches/PaperLaminate/Double_Pouching_Reference_Guide_Heat_Seal.pdf

Double Pouching Guide for Self Seal Pouches
http://www.healthmark.info/SterilizationProducts/Pouches/PaperLaminate/Double_Pouching_Reference_Guide_Self_Seal.pdf

How to Video on using a Heat Sealer
http://www.healthmark.info/videos/f108video/index.html

How to seal a Heat Seal and Roll Type Pouch
http://www.healthmark.info/SterilizationProducts/Pouches/PaperLaminate/Heat_sealing_roll_stock.pdf

References:

ANSI/AAMI ST 79
AORN 2011 Recommended Practices
The Basics of Sterile Processing;2nd Edition; Sterile Processing University, LLC
IAHCSMM Central Service Technical Manual 7th Edition

http://www.healthmark.info/sterilizationproducts.php