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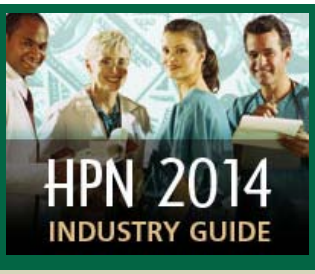

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Names and hospital identification will be withheld upon request.

Sterilization failures and packaging

by Ray Taurasi

From time to time we have encountered sterilization failures such as CI and BI failures, wet loads and the like. Our Bio med engineer insists that the sterilizer is performing properly and he has not been able to replicate these failures in any of his test runs. He believes it must be due to some human errors. He also claims that the manufacturer's consultant said it's most likely related to some packaging issues. I don't understand how that could be since we use all name brand packaging supplies. What am I missing here?

Use of inappropriate packaging materials or packaging techniques can often be the culprit in failed sterilization loads. Often times it can be very easy to identify the problem and source and take the necessary corrective actions. Other times it's more complicated and like peeling the layers of an onion until we zero in on the cause. Herewith are some of the most common sources related to packaging which can contribute to sterilization failures. You can follow the check list below as you investigate your problem. HPN

✓ **Incorrect packaging or containment device for the cycle parameters**

Careful attention must be given to the selection and use of sterilization containment devices. Refer to the manufacturer's IFU, 510K, and technical data to confirm what type of sterilization process (e.g. steam, EO, gas plasma) and what cycle parameters are appropriate for the containment device. You might find that some are appropriate for only one method e.g. gravity, prevac or gas plasma, while a select few may be classified as universal meaning they may be used in all methods.

✓ **Incorrect preparation of containment device for use**

Containment devices must be thoroughly cleaned following each use in accordance with the manufacturer's IFU. A tight closure and seal is important to the container's performance thus the following measures are critical:

- The containers must be carefully inspected to be certain there are no dents or damage around the edges of the lid or base.

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The lid gasket should also be inspected to be certain it is securely seated and free of any debris or defects such as breaks and cracks.

- The container latches and locking mechanisms must be inspected for completeness and proper functioning.

Where applicable pressure valves should be inspected for cleanliness, completeness and proper functioning. Filter retention plates must be removed to be properly cleaned. Post cleaning, prior to use, the retention plates should be inspected for cleanliness. When applicable, the filter retention plate's gasket should be inspected to ensure it is free of any defects and that it is securely in place. The retention plate fastener latch or locking device should also be tested for proper functioning. The proper filtering material must be selected and used for the sterilization method to be used. Reusable or disposable filters should be inspected for cleanliness and any defects such as tears, breaks or holes.

✓ **Use of a tray that does not allow air removal and steam penetration**

Be certain that any instrument, containment device, tray or their parts are compatible with the sterilization method to be used and that they are used appropriately. These devices must allow for sterilant permeation and air removal.

✓ **Use of a wrapper that is too large for the application**

Proper wrapping and packaging techniques are critical to sterilization efficacy. Inappropriate use of packaging materials and/or excessive layering could affect the sterilant permeability resulting in a sterilization failure.

✓ **Placement of a folded paper–plastic pouch inside another paper–plastic pouch**

Paper plastic peel pouches must never be folded as this would create a situation of plastic to plastic contact which would impede the sterilant's (steam's) ability to permeate the various layers. Double pouching should only be done if the manufacturer has validated their peel pouch for this application. (It should be noted that most peel pouches used have not been validated for double pouching.) Manufacturer's IFU for double pouching must be followed and the sizing for the inside and outside pouch should be specified.

✓ **Placement of a paper–plastic pouch inside a wrapped set or containment**

In accordance with AAMI and AORN recommendations paper/plastic peel pouches should not be placed inside of a wrapped set or a sterilization container. The peel pouches cannot be properly positioned (standing on edge) inside of a container or wrapped package thus an improperly positioned peel pouch may impede the sterilant penetration and contact with items to be sterilized. Further, peel pouches lying flat inside of these packages would be more prone to moisture retention. There is also concern that when placed inside of a container the pressure and vacuum could draw the peel pouch into the filtering system obstructing the sterilant permeability and air removal. Currently there is no peel pouch that has been validated for such use.

✓ **Incorrect placement of basins and concave items in an instrument set**

Basins and other concave items should be aligned in the same direction and positioned in a manner presenting the least degree of challenge for sterilant contact and circulation.

✓ **Failure to use non linting absorbent material between nested basins**

The placement of non linting absorbent material (compatible with the sterilant) between nested basins or other concave objects will prevent the items from contact with one another and will allow for moisture wicking and the sterilant contact to all surfaces. Non linting material will prevent the deposit of foreign matter on to package contents as well as prevent lint from causing mechanical blockages and interfering with the sterilizer's performance.

✓ **Preparation of textile packs that are too dense to sterilize with the chosen cycle parameters.**

Density in textile packs relates to how items are folded, arranged and how tightly they are wrapped and compacted. Textile packs should be carefully assembled in a manner which will present the least degree of resistance to proper flow and penetration of the sterilant within the establish load parameters.

✓ **Inadequate preconditioning of packaging materials**

Most packaging materials have specific storage condition requirements, temperature, humidity and the like. Many packaging materials have pre-conditioning requirements such as,

holding the package materials at 68°F to 73°F for 2 hours before use. It is imperative that the manufacturer's IFU are consulted and followed relative to any required pre-conditioning. Failure to do so could prevent the packaging materials from performing appropriately resulting in sterilization failures.

Ray Taurasi is Eastern Regional Director of Clinical Sales and Services for Healthmark Industries. His healthcare career spans over three decades as an Administrator, Educator, Technologist and Consultant. He is a member of AORN, AHA, SGNA, AAMI and a past president of IAHCSMM and has served on and contributed to many national committees with a myriad of professional organizations, manufacturers, corporations and prestigious healthcare networks. Taurasi has been a faculty member of numerous colleges teaching in the divisions of business administration and health sciences. In addition to this column he has authored several articles and has been a featured speaker on the international scene.