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CS Solutions

Questions can be sent to: jakridge@hpnonline.com
called in to Jeannie Akridge at HPN: (941) 927-9345 ext.202 or mailed to:
HPN CS Questions, 2477 Stickney Point Road, Suite 315B, Sarasota, FL 34231
Names and hospital identification will be withheld upon request.

Sharpies for labeling; returning explants to patients; disposable wrap

by Ray Taurasi

Q Our staff used to label all of our cardiovascular sets and supplies with a red Sharpie brand permanent marker and we would use a black Sharpie for all other items. This provided a quick and easy method to visually identify these special critical items. The labeling was restricted to the autoclave tape on the outside of wrapped packages and the film side of peel pouches. We have a new OR educator who claims we cannot use the red colored markers, because it violates AAMI standards. I have looked through the AAMI documents and could not find any such statement. Before I discontinue the use of the red markers for labeling I thought I would consult with you, is the red Sharpie okay to use for labeling packages to be sterilized?

A To my knowledge there is no such AAMI document. Regardless of the ink color, it is important that you only use marking pens that have been validated for use in sterilization conditions and the sterilization process you are utilizing. Most Sharpies have not been validated for industrial usage or for use in the sterilization conditions. There are a couple of Sharpie markers that do conform to the ASTM standard D4236 which means the product has been evaluated by a toxicologist for acute and chronic toxicity and the Safety Data Sheet (SDS) identifies ingredients as presenting any chronic health hazard, along with safe use instructions. The pens that bear the AP seal with the

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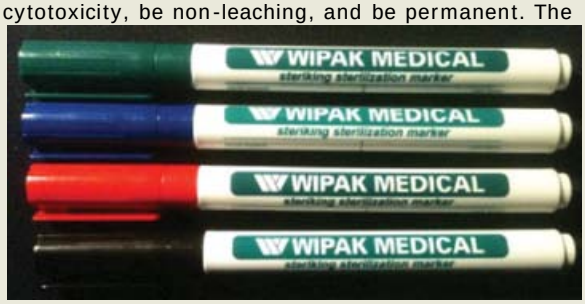
notation "conforms to ASTM D4236" (see right) are the markers that may be used for labeling your packages. The onus however remains with the user to check the manufacturer's documentation to determine under what temperatures and conditions the inks can be used and to be mindful to consult the SDS. The user must also ascertain the compatibility with the intended sterilization process and the potential for any chemical reactivity. In my opinion it would make more sense to utilize medical grade markers that have been designed and validated for the use of labeling medical packages for sterilization. The inks should be of a medical grade, present no cytotoxicity, be non-leaching, and be permanent. The manufacturer should provide instructions for use and validation documentation for the conditions and methods of sterilization that the markers are compatible with. I only know of one medical packaging manufacturer and source for such marking pens which are available in four colors: red, black, blue and green (see above).



Q I am an OR nurse and recently started a new job in a prestigious orthopedic hospital. At the request of a surgeon or patient when implants are removed we have been cleaning and flashing them and returning them to the patient in a plastic bag. At my previous hospital we never would do this as it was considered unsafe and a possible infection hazard. I questioned the peri-operative educator about this practice and she stated there was nothing wrong with doing this and there was no regulation against returning explants to patients. Frankly, I am appalled at this practice. Can you tell me if there is any professional standard on this or if this is an acceptable practice?

A There is no universal standard or regulation on this practice. In my experience the decision and process is left to each hospital to decide and to develop a hospital policy.

In developing a policy on the return of explants to patients there are many concerns and issues that need to be considered and addressed. It is suggested that a task force or committee be established, bringing together the required expertise to develop a sound and rational policy. Representation on the committee may include surgeons, peri-operative staff, infection control, epidemiology, risk management, legal affairs, manufacturer, sterile processing, pathology and materials management. Each committee representative or grouping of representatives will investigate issues related to their area expertise. The following is a list of some of the concerns and issues to address.

- Reprocessing of implants
- Method of cleaning, decontamination and sterilization for each type of explants
- Personal safety, injury risk assessment associated with explants to be processed and returned to patient
- Identify which explants can and cannot be returned to patients
- QA of reprocessing efficacy
- Packaging and labeling of device for sterilization and return to patient
- Adherence to any biohazard handling or labeling in accordance with federal, state and local regulations
- Who rightfully has ownership rights to the explant

Issues involving past, current or future implant recalls — and compliance to FDA regulations — e.g. tracking, ownership, reporting, return to manufacturer

- Compliance with FDA and/or other regulatory mandates relating to disbursement and distribution of such devices
- Maintenance of required documents and manifestoes for tracing purposes
- What other records will hospital create and maintain
- Who, when, where and how will explants be returned to patient

Reference: February 2012+AORN Journal Vol. 95, Issue 2, Pages 288-296

Q When unused sterile instrument sets are returned from the OR or patient floors our policy is to re-sterilize the sets. Since these were unopened we inspect the wrap to be sure there are no holes, replace the tapes and labeling and re-sterilize the item. One of the OR nurses was helping us the other day and she said that we should not do this and claims the set should be completely reprocessed and new wraps applied. I think it would be a waste of money and time to throw away perfectly good wrap, etc.

A It is not an acceptable practice to do what you are doing. Your OR nurse is correct. Unused sets that require re-sterilization must be completely broken down and run through the full reprocessing cycle. The disposable wraps you are using are single-use devices, which means they cannot be reused, reprocessed or re-sterilized. Doing so would be in violation of FDA regulations. HPN

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.