

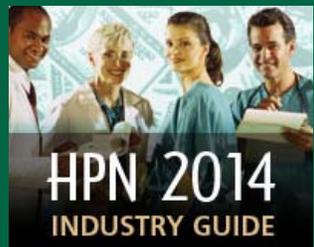
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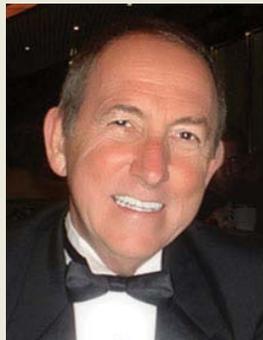
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CS Solutions

Questions can be sent to:jakridge@hponline.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.



Packaging semi-critical devices; What is TASS and why is it a concern?

by Ray Taurasi

Q

I am the nurse manager of the sterile processing department in a large academic teaching hospital. While I provide technical guidance to hospital affiliated clinics and medical offices, I have no authority over their practices. Recently I conducted quarterly rounds of some of the clinics with our Infection Control officer. I observed that many of the clinics were utilizing high level disinfection on certain semi-critical instruments such as nasal and ear speculums. Although this practice does follow Spaulding recommendations, after HLD these devices are being stored, unpackaged, in drawers and cabinets in the various exam rooms. This concerns me. I believe The Joint Commission has made the recommendation that laryngoscope blades be packaged following HLD or sterilization. Do you know if this recommendation is being expanded to cover other devices such as those previously mentioned? Personally I would rather see these items packaged and sterilized. The clinic managers are challenging the need to package these items and will not change their practice unless I can provide some written documentation from AAMI, CDC or TJC requiring these items be packaged. Can you offer any assistance or references?

A Let us start by reviewing the Spaulding Classification System:

The Spaulding Classification System divides medical devices into categories based on the risk of infection involved with their use. This classification system is widely accepted and is used by the Food and Drug Administration (FDA), the Centers for Disease Control and Prevention (CDC), epidemiologists, microbiologists, and professional medical organizations to help determine the degree of disinfection or sterilization required for various medical devices. Three categories of medical devices and their associated level of disinfection are recognized.

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- **Critical:**

A device that enters normally sterile tissue or the vascular system or through which blood flows should be sterile. Such devices should be sterilized, which is defined as the destruction of all microbial life.

- **Semicritical:**

A device that comes into contact with intact mucous membranes and does not ordinarily penetrate sterile tissue. These devices should receive at least high-level disinfection, which is defined as the destruction of all vegetative microorganisms, mycobacterium, small or nonlipid viruses, medium or lipid viruses, fungal spores, and some bacterial spores.

- **Noncritical:**

Devices that do not ordinarily touch the patient or touch only intact skin. These devices should be cleaned by low-level disinfection.

The speculums you describe certainly do fall within the classification of semi-critical. If you review the definition of semi-critical, you will note it says, "*These devices should receive at least high-level disinfection*". In other words at minimum these device should be high leveled disinfected. This does not preclude that sterilization might be the best practice. So there is value to your preference to package and sterilize these items.

While according to the Spaulding Classification, High level Disinfection of semi critical devices might be acceptable, following cleaning and High level disinfection these devices do need to be stored in a manner that will prevent any cross contamination by environmental or airborne substances which could fall on them during storage in drawers or cabinets. A clean plastic zipper lock or closed bag may be used to store the clean disinfected instruments. I have often found that many clinics lack the trained personnel, facilities and equipment to properly clean and reprocess medical devices. As you know, reprocessing, cleaning, disinfection and sterilization are precise operations to which there are no short cuts.

It is not typical to find any specific recommendations relative to packaging from TJC for HLD devices. They leave it to you, the expert, to use your knowledge and judgment to develop and implement policies and procedures with sound rationale. In this case, that would include providing protocols and conditions that would protect all clean, disinfected and/or sterilized medical devices for the potential risk of cross contamination which could compromise patient care and safety.

The accrediting bodies do expect that all affiliated entities within an organization do follow the same protocols, practices, and standards of reprocessing and sterilization. This means that the policies and procedures established by the Sterile Processing department and IC, relative to reprocessing need to be enforced throughout the healthcare facility regardless of where the items are being reprocessed.

Q

What exactly is TASS and what is its significance to sterile processing?

A

TASS is an abbreviation for Toxic Anterior Segment Syndrome. TASS is an acute inflammatory response (infection) of the eye resulting from the exposure to foreign matter. Improperly cleaned ophthalmic instrumentation can be the source of transmission of contaminants into the eye. Ocular tissue is very delicate, porous and highly sensitive to foreign matter. TASS may lead to severe visual impairment if it is not recognized and treated in a timely manner. Intraocular instruments are very delicate and complex and as a result many of them must be cleaned manually as opposed to being processed by automated means. Manual cleaning processes are often more difficult to control than automated cleaning methods therefore additional attention and care must be taken during reprocessing to ensure cleaning effectiveness and consistency in the application of protocols. Outbreaks of TASS within healthcare facilities have often been linked to the failure to follow manufacturers' instructions for the cleaning, decontamination and sterilization of ocular devices. Water quality, residuals from chemical solutions used during surgery, detergents, sterilants and endotoxins have all been identified as sources attributing to TASS. It is critical that Sterile Processing Managers develop, implement and service protocols and procedures to ensure the proper processing of all ophthalmic instrumentation in accordance with manufacturers' IFUs and professional practice guidelines published by organizations such as AORN, AAMI, CDC and IAHCMM.



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 IAHCSSM 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.

