Device Reprocessing Recommendations

Patient safety is the number one goal of every hospital.This goal is achieved by keeping patients and employees safe by reducing the risk of cross-contamination created by the surgical instruments. Safe instruments can only be provided by a safe sterilization process. A safe sterilization process can only be provided by monitoring every step.

Every patient undergoing a medical procedure has a basic expectation that the environment and instruments of care will be clean and safe. In recent years, that expectation has been shaken by reports of patients put at risk of serious infection from reusable medical devices that were inadequately cleaned, sterilized, or disinfected—the domain known as reprocessing. (1)

Disinfection and sterilization are essential for ensuring that medical and surgical instruments do not transmit infectious pathogens to patients. Health care policies must identify, primarily on the basis of the items intended use, whether cleaning, disinfection, or sterilization is indicated. Sterilization describes a process that destroys or eliminates all forms of microbial life and is carried out in health care facilities by physical or chemical methods. Steam under pressure, ethylene oxide and hydrogen peroxide are the principal sterilizing agents used in healthcare facilities. Disinfection describes a process that eliminates many or all pathogenic microorganisms, except bacterial spores, on inanimate objects. Cleaning is the removal of organic and inorganic material from objects and surfaces. It is essential before high-level disinfection and sterilization because inorganic and organic materials that remain on the surfaces of instruments interfere with the effectiveness of these processes. (2)

It is recommended that health care personnel should perform verification testing on all mechanical cleaning equipment (washer–disinfectors, automated endoscope reprocessors, ultrasonic cleaners) as part of the overall quality assurance program. Methods of verification include directly testing individual instruments for residual soils e.g., adenosine triphosphate [ATP]. (3)

ATP is the molecule that provides energy for cellular metabolism and is present in all living cells. Consequently it is present in any organic residue e.g. body fluids, skin cells and microorganisms making ATP an excellent marker for organic contamination or contamination from a biological source. ATP test provides a real-time result that indicates the cleanliness of the instrument tested. This provides an opportunity to take any corrective action required such as re-cleaning and reprocessing.

Saturated steam under pressure is one of the oldest and safest methods used in health care facilities to sterilize medical devices. The efficacy of any sterilization process, including saturated steam, depends on a consistent system for lowering and limiting bioburden before sterilization, preparing items for sterilization, selecting the sterilization parameters, and establishing and implementing controls to maintain the sterility of sterilized items until they are used. (3)

Monitoring of each sterilizer and every cycle is essential to ensure sterility of the reprocessed medical devices. Biological indicators (BIs) are the only sterilization process monitoring devices that provide a direct measure of the lethality of the process. BIs provides evidence of efficacy by challenging the sterilizer with a large number of highly resistant bacterial spores. Self-contained BIs (SCBIs) include incubation media with the spore carrier in a single vial. (2)

In a sterilizer every cycle is a unique event. (4) Routine monitoring and control shall be performed on each operating cycle. (5) Every load monitoring with BI allows earlier discovery of equipment malfunctions and process errors. Each implant load should be monitored with BI and should not be released until the results of spore tests are known to be negative. (2) Rapid readout biological systems provide faster results that can increase set turnaround and utilization.

For heat and moisture sensitive materials low temperature sterilization methods are being used (Ethylene Oxide, hydrogen peroxide). Every load monitoring should be a part of sterilization monitoring steps in low temperature sterilizes.

Chemical indicators should be used at every pack to assist in the detection of potential sterilization failures that could result from incorrect packaging, incorrect loading of the sterilizer, or malfunctions of the sterilizer. In WHO "Surgical Safety Check List" (6) there is a nursing team review about the result of the chemical indicator.

References:

1 Reprocessing Summit publication Priority Issues from the AAMI/FDA Medical Device Reprocessing Summit, 2011. http://s3.amazonaws.com/rdcms-aami/files/production/public/FileDownloads/Summits/2011_Reprocessing_Summit_publication.pdf

2 Guideline for Disinfection and Sterilization in Healthcare Facilities (2008) https://www.cdc.gov/infectioncontrol/pdf/guidelines/disinfection-guidelines-H.pdf

3 ANSI/AAMI ST79:2017 Comprehensive guide to steam sterilization and sterility assurance in health care facilities

4 Dr. Brian Kirk, Colin Hunt, "With Changing Sterilization Challenges is it time to think again?", White Paper

5 EN ISO 17665-1:2006 Sterilization of health care products – Moist heat – Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices.

6 https://www.who.int/patientsafety/safesurgery/checklist/en/

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