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AST Guidelines for Best Practices in the Reuse of Single-Use Devices in Surgery

Introduction

The following Guidelines for Best Practices were researched and authored by the AST Education and Professional Standards Committee, and are AST approved.

AST developed the Guidelines to support healthcare delivery organizations (HDO) in reinforcing best practices in the *reuse* of *single-use devices* (SUD) as related to the role and duties of the Certified Surgical Technologist (CST®), the credential conferred by the National Board of Surgical Technology and Surgical Assisting (NBSTSA). The purpose of the Guidelines are to provide information that OR supervisors, risk management, and surgical team members can use in the development and implementation of policies and procedures for reuse of SUDs in the surgery department. The Guidelines are presented with the understanding that it is the responsibility of the HDO to develop, approve, and establish policies and procedures for the surgery department regarding the reuse of SUDs in surgery per HDO protocols.

Rationale

It is the responsibility of the HCF to decide if it will reuse SUDs and to what degree it will participate in this practice. The current health care environment is focused upon providing efficient, cost-saving medical/surgical care to the patient that compels facilities to use methods such as the *reprocessing* of SUDs, but this must be balanced with the focus upon patient safety.[3] Therefore, the key points to be considered by the HCF include:

1. If the SUD cannot be properly disinfected, it also cannot be sterilized and reused.
2. If the sterility of the SUD cannot be guaranteed, it must not be reused.
3. If the quality and function of the SUD cannot be shown to be equal to its original level of function after reprocessing and safe for patient care, it must not be reused.

Therefore, the HCF should complete a detailed analysis related to the reuse of SUDs that includes the determination of whether to implement an internal reprocessing system or contract with a third-party reprocessor.[12,4] The HCF must be careful in its choice of a third-party re-processor and ask the right questions of the re-processor, as well as confirming the business has the proper processes in place.

Evidence-based Research and Key Terms

The research of articles, letters, nonrandomized trials, and randomized prospective studies is conducted using the Cochrane Database of Systematic Reviews and MEDLINE®, the U.S. National Library of Medicine® database of indexed citations and abstracts to medical and healthcare journal articles.

The key terms used for the research of the Guidelines include: original equipment manufacturer; reprocessing; reuse; single use devices. Key terms used in the Guidelines are italicized and included in the glossary.

Guideline I

AST recommends HDOs should complete a detailed analysis of the financial, legal, scientific and technical issues related to re-processing SUDs prior to deciding. This includes reviewing the local, state and federal regulations that the HDO will be required to follow or confirm a third-party re-processor is following.

1. HDOs should complete a detailed analysis to aid in the consideration of reusing SUDs. The analysis should ideally be completed prior to the facility reusing any type of SUD. The analysis should include information to aid in the decision whether to invest in development of an efficient and safe internal reprocessing system or if a third-party re-processor should be used. The 12-step process outlined by the International Association of Healthcare Central Service Materiel Management (IAHCSMM) in their publication *Central Service Technical Manual* is recommended for adoption due to its detail, logical order, and description of the initial cost analysis and actual cost assessment.[4,12]
2. HDOs should review economic, ethical, legal, scientific and technical issues, including to what degree the facility will reuse SUDs.[5]
    A. An important note regarding the FDA's regulation of SUDs is the enforcement document does not currently apply to permanent pacemakers, HDOs that are not hospitals or opened, but unused SUDs.[6]
    B. A second important note concerns The Joint Commission standards in that they have not published a standard suggesting that SUDs should not be reprocessed and reused. However, they do require HDOs to have policies and procedures established for disinfecting, packaging and sterilizing reusable items.[7]
    C. When considering the issue, HDOs should take into consideration that U.S. Food and Drug Administration (FDA) regulations established for reprocessing and reusing medical devices must be followed, including pre-market requirements.
        1) As indicated in the U.S. General Accounting Office (GAO) report, *Single-Use Devices: Little Available Evidence of Harm From Reuse but Oversight Warranted*, to reprocess a device that was used on a patient, HDOs must be able to show that the SUD can be disinfected, packaged and sterilized without affecting the ability of the SUD to properly function when reused, thus guaranteeing the safety of healthcare personnel (HCP) and patients.
        2) The following is a list of the FDA regulations that are pertinent to reprocessing SUDs:
            - "Federal Food, Drug, and Cosmetic Act," *Code of Federal Regulations (CFR)Title 21: Food and Drugs, Parts 800 to 1299*. This is what that FDA bases its authority upon for the regulation of SUDs.

- "Medical Device Classification Procedures, Definitions," *Code of Federal Regulations (CFR) 21: Food and Drugs, Part 860.3* The specific FDA requirements for the regulation of devices is based on the assigned class of the device I, II and III. This portion of the CFR provides definitions of class I, II, and III medical devices.
- Registration and Device Listing: "Establishment Regulation and Device Listing for Manufacturers and Initial Importers of Devices," *Code of Federal Regulations (CFR) 21: Food and Drugs, Part 807* (Part 510 of the Act).
- Medical Device Reporting (MDR): *Code of Federal Regulations (CFR) 21: Food and Drugs, Part 803* (Sections 519(a)(b) & (c) of the Act)
- Medical Device Tracking: "Manufacturer Reporting Requirement," *Code of Federal Regulations (CFR) 21: Food and Drugs, Part 821* (Section 519(e) of the Act)
- Medical Device Corrections & Removals: "Medical Devices: Reports of Corrections and Removals, Definitions," *Code of Federal Regulations (CFR) 21: Food and Drugs, Part 806* (Section 519(f) of the Act)
- Quality System Regulation: "Quality System Regulation," *Code of Federal Regulations (CFR) 21: Food and Drugs, Part 820* (Section 520(f) of the Act)
- Labeling Requirements: "Labeling," *Code of Federal Regulations (CFR) 21: Food and Drugs, Part 801*

3) The following is a list of the FDA regulations that are pertinent to pre-market notification and approval requirements. The FDA kept in place its device classifications of class I, class II, and class III as listed in the Code of Federal Regulations to establish its enforcement priorities for the pre-market submission requirements. If a device is not listed as being exempt from the regulations, a 510(k) submission is required for class I and class II devices. Class III devices require either a 510(k) submission or a pre-market approval application (PMA).

   The difference between a 510(k) and PMA is that a 510(k) is a set of information that claims equivalence to one or more marketed predicate devices. A PMA is required for class III devices that have not been previously marketed, or is an existing device but wishing to establish a new intended use for the device.[11] The PMA is the most difficult to submit since validated scientific

data/evidence must be presented to assure the safety and effectiveness of the intended new use.

- "Exemption From Pre-market Notifications," *Code of Federal Regulations (CFR) 21: Food and Drugs, Part 807.85*
- "Content and Format of a 510(k) Summary," *Code of Federal Regulations (CFR) 21: Food and Drugs, Part 807.92*
- "Content and Format for a 510(k) Statement," *Code of Federal Regulations (CFR) 21: Food and Drugs, Part 807.93*
- "Premarket Approval of Medical Devices," *Code of Federal Regulations (CFR) 21: Food and Drugs, Part 814*
- "Premarket Approval Application," *Code of Federal Regulations (CFR) 21: Food and Drugs, Part 814.20*
- "Medical Device User Fee and Modernization Act of 2002," (MDUFMA). This act requires manufacturers of SUDs to submit 510(k) forms to ensure compliance with FDA standards.

3. The reuse of SUDs has legal implications for both the HDO and third-party re-processors that include the following:[10,12]
    A. HDOs that reprocess SUDs or third-party re-processors assume a degree of responsibility for the effectiveness and safety of the SUDs.
    B. HDOs that reprocess SUDs or third-party re-processors that distribute to a separate legal entity for use have the same legal obligations under the Medical Devices Regulations as the *original equipment manufacturer* (OEM).
    C. Because the original intent of SUDs is that they are not to be reused, HDOs which reuse SUDs are fully responsible for their safety and effectiveness.[10] HDOs are responsible for protecting the patient, and providing safe and effective medical devices regardless of who performed the reprocessing of the SUDs and/or where the reprocessing takes place.
4. HDOs should consider the following technical issues when considering reprocessing SUDs:[2,12]
    A. Potential for cross-infection: the risk of cross-contamination can increase due to the inability to properly decontaminate the SUD. Viable microorganisms may go undetected and be transferred to the next patient.
    B. Residues from chemical decontamination agents: some materials may absorb chemicals that could in turn leach out and cause a chemical burn to the patient or user.
    C. Inadequate cleaning and decontamination: cleaning and decontamination processes must allow for thorough cleaning of the medical device. Devices with coils, lumens and odd shapes may not allow for proper reprocessing.
    D. Material alteration: medical devices exposed to chemical and heat disinfection may become damaged during this process. Damaged devices would not be able to function for their intended purposes.

E. Mechanical failure: Devices that are continuously reprocessed may become fatigues and weakened. These devices, such as drill bits and saw blades, could break during use.

Guideline II

HDOs should follow the recommendations provided by the FDA when selecting a third-party re-processor of SUDs to assure that the principles of disinfection, sterilization, and preservation of the device's function are met.

1. When selecting a third-party re-processor, the FDA recommends communicating with other HDOs to request information regarding satisfaction with their services and arrange a visit of the re-processor's facility.
    A. According to the FDA, the HDO must confirm the third-party re-processor:[1,8]
        1) has the proper facilities, equipment, processes and trained personnel to properly perform reprocessing SUDs;
        2) has its own personnel are properly trained to package and label SUDs to ship to the third-party re-processor;
        3) knows the device manufacturer's recommendations and specifications for each SUD.
2. The following are questions that are recommended for HDOs to ask when selecting a third-party re-processor:[8,9]
    - What are the results of your last facility inspection by the FDA?
    - Does the company have a tracking system and how does it work?
    - How does the facility validate the disinfection, packaging and sterilization of SUDs?
    - Do you have documentation of the device manufacturer's recommendations and specifications for each SUD that is re-processed?
    - How are the manufacturing processes monitored and what records are maintained to show compliance with the FDA's Quality System Regulation?
    - Do you have documentation for review that shows the facility has premarket clearance and/or approval by the FDA for each type of SUD that it reprocesses?
    - Has your company set limits on the number of times a SUD can be reprocessed? How was the number determined?

Guideline III

The surgery department should review the policies and procedures (P&P) regarding reprocessing and reuse of SUDs on an annual basis.

1. The surgery department should include members of the surgical team and administration when reviewing the P&Ps, including CSTs, surgeons, RNs, risk management, and infection control officer.
    A. The surgery department should document when the P&Ps were reviewed, revision completed (if necessary), and who participated in the review process.

2. CSTs should be familiar with the P&Ps for reprocessing and reuse of SUDs. The orientation of new employees should include reviewing the P&Ps.

Guideline IV

CSTs should complete continuing education to remain current in their knowledge of reprocessing and reuse of SUDs.[14]

1. The continuing education should be based upon the concepts of adult learning, referred to as andragogy. Adults learn best when the information is relevant to their work experience; the information is practical, rather than academic; and the learner is actively involved in the learning process.[15]
2. It is recommended surgery departments use various methods of instruction to facilitate the learning process of CSTs.
    A. If the education is primarily lecture, methods to engage learners include presentation of case studies for discussion, and audience discussion providing suggestions for reinforcing (subject of Guidelines).
    B. Other proven educational methods include interactive training videos, and computerized training modules and teleconferences.
    C. The continuing education should be delivered over short periods of time such as in modules, and not in a one-time lengthy educational session.
3. Continuing education programs should be periodically evaluated for effectiveness including receiving feedback from surgery department personnel.
4. The surgery department should maintain education records for a minimum of three years that include dates of education; names and job titles of employees that completed the continuing education; synopsis of each continuing education session provided; names, credentials, and experience of instructors.

Competency Statements

Competency Statements	Measurable Criteria
1. CSTs are knowledgeable of the procedures for assessing the function, assembly, use and care of equipment and surgical instruments OR.	1. Educational standards as established by the *Core Curriculum for Surgical Technology*.[20]
2. CSTs are knowledgeable of the correct procedures for processing equipment, supplies, and surgical instruments for use in the OR.	2. The didactic subjects of sterile processing including processing SUDs, prevention of transmission of infectious materials, and hazards of blood-borne pathogens are included in a CAAHEP accredited surgical technology program.
3. CSTs have the knowledge and skills for properly using sterilization equipment as part of the overall processing of equipment, supplies and surgical instruments.	3. Students demonstrate knowledge of processing equipment, supplies and surgical instruments in the lab/mock OR and during clinical rotation.
4. CSTs understand the importance of following OEM recommendations regarding reprocessing SUDs and ensuring the device is safe for reuse.	4. CSTs complete continuing education to remain current in their knowledge of sterile processing, blood-borne pathogens rules, Standard Precautions, and preventing the transmission of infectious diseases.[14]

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Glossary

OEM: Original equipment manufacturer; the manufacturer that first produced the product.

Reprocessing: A term that applies to cleaning, packaging and sterilizing an item that has been used or opened to prepare the item for patient use.

Reuse: The repeated or multiple use of any medical device (SUD or reusable) that has been reprocessed (cleaned, disinfected and sterilized) between use on patients.

SUD: Single-use device; a disposable device intended to be used one time on one patient during a single procedure.

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