



Guideline Statement for Reuse of Single-Use Devices in Surgery

Introduction

The practice of reprocessing SUDs continues to be a controversial issue and is driven by the overall attempts to decrease the cost of providing quality patient care. Reuse has been practiced in hospitals since the late 1970s.¹⁰ Despite the long history of SUD reprocessing, the Federal Food and Drug Administration (FDA) determined that a higher level of public and patient safety needed to be addressed. The lack of good manufacturing processes, including tracking devices, quality assurance and control, and the lack of validated reprocessing procedures create a potential hazard to the patient. Therefore, the FDA made the decision that original equipment manufacturers and third-party processors should be regulated under the Food, Drug, and Cosmetic Act.

In 2000, the FDA published its policies for the reprocessing and reuse of SUDs that must be implemented by hospitals and third-party reprocessors. Additionally, the FDA implemented the *Medical Device User Fee and Modernization Act of 2002* (MDUFMA), which has been updated for 2008-2012.that is further discussed below.⁶ The following is a brief timeline related to the regulation of SUDs¹¹:

- April 1999: AAMI and FDA co-sponsor a meeting on the topic of the reuse of SUDs.
- August 1999: Senator Durbin introduced the *Reprocessed Single Use Medical Device Patient Safety Amendments of 1999 (S.1542)*.
- October 1999: Representatives Eshoo and Upton introduced the *Reprocessed Single Use Medical Device Patient Safety Act of 1999 (H.R. 3148)*.
- November 1999: The FDA released its proposed regulatory strategy to the public.
- February 2000: The FDA releases two draft guidances: *Reprocessing and Reuse of SUDs: Review Prioritization Scheme* and *Enforcement Priorities for SUDs Reprocessed by Third Parties and Hospitals*.
- The purposes of the first guideline *Reprocessing and Reuse of SUDs: Review Prioritization Scheme* were to assess the risk of infection, when reprocessing SUDs and risk of affecting the functionality of SUDs when reprocessing.
- The purpose of the second guideline *Enforcement Priorities for SUDs Reprocessed by Third Parties and Hospitals* was to clarify the FDA's enforcement priorities and establish a timeline based on the level of risk of reprocessing SUDs.⁴
- June 2000: The Senate Committee on Health, Education, Labor and Pensions held a hearing in which the General Accounting Office presented its report titled, *Single-Use Medical Devices: Little Available Evidence of Harm from Reuse, but Oversight Warranted*.
- As of August 2002, the phase-in period has expired and all hospitals and third-party reprocessors must be in compliance with the pre-market and post-market requirements outlined in the FDA's final regulation.

- January 2008: FDA publishes *Enforcement Priorities for Single-Use Devices Processed by Third Parties and Hospitals* and presents updated fees for 2008-2012.⁶

The purpose of the following AST guideline statement is to review the FDA regulations for SUDs related to their use in the surgical environment.

AST Guideline Statement

AST recommends that each health care facility adopt a standard or standards of practice that are in compliance with federal regulations. AST also recommends that each health care facility should consider any relevant technical, scientific, legal, ethical, and economic issues, including to what degree will the facility reuse SUDs. When considering those issues, it should be remembered that the FDA guidelines established for the processing of new medical devices must also be followed for the reprocessing of an item for reuse. But several points related to the disinfection, sterilization, and reuse of SUDs should also be considered. As indicated in the US General Accounting Office report, *Single-Use Devices: Little Available Evidence of Harm From Reuse, but Oversight Warranted*, in order to reprocess a device that was used on a patient, institutions 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 the health care provider and patient.⁶

These same principles apply to reprocessing open, but unused SUDs. These are devices in which the sterility of the packaging has been compromised, but the SUD was not used on a patient, nor contacted any blood or body fluids. The FDA, medical device manufacturers, and hospitals agree that there is a decreased risk of reprocessing these devices, but the proper functioning of the SUD must still be guaranteed.

To summarize the above information as related to disinfection, sterilization, and function of SUDs that will be reused, health care facilities and reprocessors must be able to demonstrate that:

- The device can be properly disinfected and sterilized.
- The physical characteristics and quality of the device will not be affected by the disinfection and sterilization procedures
- The device will be safe and effective for its intended use

AST recommends that health care facilities follow the suggestions provided by the FDA in selecting a third-party reprocessor of SUDs in order to be assured the principles of disinfection, sterilization, and preservation of the device's function are met. When making the selection of a third-party reprocessor, the FDA suggests talking with other health care facilities to receive information regarding satisfaction with their services and arrange a visit of the reprocessor's facility.

According to a letter from DB Burlington, MD, in April 1997, the health care facility must ensure⁵:

1. The third-party processor has the proper facilities, equipment, processes, and trained personnel to properly perform the reprocessing of SUDs.
2. That its own personnel are properly trained to package and label SUDs to ship to the third-party processor.
3. The third-party processor knows the device manufacturer's recommendations and specifications for each SUD.

Recommended questions to ask the third-party reprocessor (FDA, 2002)

1. What were the results of the last facility inspection by the FDA?
2. Do you have documentation that can be reviewed that shows the facility has pre-market clearance and/or approval by the FDA for each type of SUD that it reprocesses?
3. How are the manufacturing processes monitored and what records are maintained in order to show compliance with the FDA's Quality System Regulation?
4. How does the facility validate the disinfection, packaging, and sterilization of SUDs?
5. Do you have documentation of the device manufacturer's recommendations and specifications for each SUD that is reprocessed?
6. Has your company set limits on the number of times an SUD can be reprocessed? How was the number determined?
7. Does the company have a tracking system and how does it work?

As evidenced by the above recommendations, the reuse of single use devices has legal implications for both the health care facility and third-party reprocessors that include:

- Any facility that reprocesses a SUD assumes some degree of responsibility for its safety and effectiveness.
- Because the original intent of SUDs is that they are not to be reused, health care facilities, which reuse SUDs are fully responsible for their safety and effectiveness.¹¹ Health care facilities 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.
- Any facility that reprocesses a SUD and distributes to a separate legal entity for use has the same legal obligations under the Medical Devices Regulations as the original manufacturer.

Therefore, AST recommends that the following technical issues be considered when reprocessing SUDs:

1. Inadequate Cleaning and Decontamination
The cleaning and decontamination process must allow for thorough cleaning of the medical device. Devices with lumens, coils, and odd shapes may not allow for proper reprocessing.
2. Material Alteration
Medical devices exposed to chemical and heat disinfection may become damaged during this process. Damaged devices would not be able to function with their intended purpose.
3. Mechanical Failure

Devices that are continuously reprocessed may become fatigued and weakened. These devices, such as saw blades and drill bits could break during use.

4. 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.

5. 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.

AST recommends that the health care facility 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 reprocessor 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.¹¹

In summary, it is the responsibility of the health care facility 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. Therefore, the key points to be considered by the health care facility 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 health care facility 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. The health care facility must be careful in its choice of a third-party reprocessor and ask the right questions of the reprocessor, as well as confirming it has the proper processes in place.

Regulations

The last portion of this document will focus on providing a listing of the regulations related to reprocessing and reuse of SUDs, and information concerning pre-market requirements. AST assumes that health care facilities have reviewed many of the regulations; however, additional information is provided to clarify a regulation when deemed necessary.

An important note regarding the regulation of SUDs – the FDA’s enforcement document does not currently apply to permanent pacemakers, health care facilities that are not hospitals, or unopened but unused SUDs.¹¹

First a quick note concerning The Joint Commission standards. A standard has not been published suggesting that SUDs should not be reprocessed and reused. However, they do require health care facilities to have policies and procedures established for the disinfection, packaging, and sterilization of reusable items.⁹

- “Federal Food, Drug, and Cosmetic Act,” *Code of Federal Regulations (CFR) Parts 800 – 1299*, www.gpo.gov. This is what that FDA bases its authority upon for the regulation of SUDs.
- “Enforcement Priorities for Single-Use Devices Processed by Third Parties and Hospitals,” www.fda.gov/cdrh/reuse/1168.html. Final regulation issued August 14, 2000.
- “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. As of February 2008, there are no class III devices that have been approved by the FDA for reuse.
- 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)
www.fda.gov/cdrh/osb/guidance/1334.pdf
- 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 80*.
- Pre-market Notification & Approval Requirements
- “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*
- “Pre-market Approval of Medical Devices,” *Code of Federal Regulations (CFR) 21: Food and Drugs, Part 814*
- “Pre-market Approval Application,” *Code of Federal Regulations (CFR) 21: Food and Drugs, Part 814.20*

- “Medical Device User Fee and Modernization Act of 2002,” (MDUFMA). Issued July 30, 2004. This act requires manufacturers of SUDs to submit 510(k) forms to ensure compliance with FDA standards.

The FDA kept in place its device classifications of class I, class II, and class III as listed in the Code of Federal Regulations in order 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 it 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.

Definitions

Opened-but-unused: An SUD that has not been used on a patient in which there has been no contact whatsoever with blood or body fluids, including the splashing of such biohazards, but the sterility of the packaging of the SUD has been compromised in some way.

Reprocessing: A term that applies to the cleaning, sterilization and packaging of an item that has been used or opened; in order 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.

Resterilization: A sterilization process that is designed to destroy all viable forms of microbial life to an acceptable sterility level.

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

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