

AORN GUIDANCE STATEMENT: REUSE OF SINGLE-USE DEVICES

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Preamble

AORN (Association of periOperative Registered Nurses) recognizes the need for each health care facility to provide cost-effective quality care to patients. Current healthcare trends reflect both cost-driven market forces and consumer-driven demands for quality, safety, and effectiveness. Many facilities in today's marketplace are reprocessing and reusing devices labeled for single use. Devices are reprocessed either within the facility or by an external third party contracted to provide the reprocessing service. Program protocols and/or methodologies, including device-testing results, often are not documented.

Guidance Statement

The practice of reprocessing and reusing medical devices labeled by the original equipment manufacturer (OEM) for single use is highly controversial. It is the role and responsibility of each healthcare facility to determine whether and/or to what extent it will engage in such practice. As licensed professionals, perioperative nurses must demonstrate accountability to the nursing profession, to other members of the healthcare team, and to the public they serve.¹ AORN, the professional organization of and for perioperative nurses, believes certain basic tenets must underpin any reprocessing program. The foremost concern is for the patient's safety. Therefore,

- a) if a device cannot be cleaned, it cannot be reprocessed and reused;
- b) if sterility of a post-processed device cannot be demonstrated, the device cannot be reprocessed and reused; and
- c) if the integrity and functionality of a reprocessed single use device (SUD) cannot be demonstrated and documented as safe for patient care and/or equal to the original device specifications, the device cannot be reprocessed and reused.

While some operational savings may be realized by reusing certain devices, any cost-benefit analysis would necessarily include labor costs; program costs including quality system requirements such as sterility and post-processing devices testing (see section on Quality System requirements); documentation costs; and the potential cost of device failure. Using the results of a thorough cost-benefit analysis, each provider facility must make an informed choice as to whether it wishes to invest the necessary resources to develop a safe reprocessing system within the facility. Use of an external reprocessor presents a different, but related set of factors for consideration. When a decision is made in favor of using an external reprocessing company, it is the user facility's responsibility to assess the quality of services provided under the contractual arrangement.² The user facility should review the processes used by the contracted agent and determine whether correct procedures are being followed.³ Regardless of whether an internal reprocessing program is developed or an external reprocessing company is selected, the user facility should be aware that the U.S. Food and Drug Administration (FDA) views any reprocessor as a manufacturer and, as such, subject to federal regulations.⁴

Federal Regulatory Requirements

In August 2000, the FDA issued its final guidance on the practice of reprocessing and reusing medical devices intended to be used only once. The FDA's goal in issuing this regulation is to ensure a reprocessing and reuse regulatory program that is based on good science and protects the public health. At the same time, FDA intends to ensure equitable regulatory requirements for all parties engaged in reprocessing. In its final guidance document,⁵ the FDA indicates that hospitals and third parties that reprocess SUDs are subject to the same regulation as the original equipment manufacturers, including requirements for:

- registration and listing,
- medical device tracking,
- medical device reporting,
- corrections and removals,
- device labeling,
- Quality system regulation, and
- premarket notification requirements.

Registration and Listing

All persons or entities owning or operating establishments that manufacture, prepare, or process devices must register with the FDA. The FDA uses this information to identify and locate establishments that it is required to inspect. When registering, the following information must be provided:

- name and address,
- business names used,
- business name of owner or operator, and
- establishment type.

When registering for the first time, a specific FDA form is required. An additional registration form must be submitted annually thereafter.

In addition to registering with the FDA, each reprocessing entity must provide a list of the devices it intends to reprocess. A separate listing form must be submitted for each device to be reprocessed. Devices are listed by category. The following information is required:

- FDA classification name,
- FDA product code,
- brand name, and
- common or usual name.

Additional information about registration and listing is available in the Code of Federal Regulations (21 CFR, Part 807)⁶. The necessary forms can be obtained from the Office of Compliance, Center for Devices and Radiologic Health (HFZ-307), Food and Drug Administration, 2094 Gaither Road, Rockville, Maryland 20850. The Center for Devices and Radiologic Health (CDRH) offers an additional document, *CDRH Guidance for Industry: Instructions for Completion of Medical Device Registration and Listing Forms FDA 2891, 2891a, and 2892*. This document can be obtained from the Division of Small Manufacturers Assistance (DMSA) at telephone number 301-443-6597 or email address DMSA@CDRH.fda.gov.

Medical Device Tracking

Medical device tracking is intended to ensure that manufacturers(reprocessors) of certain devices can locate those devices should corrective action and/or notification about such devices become necessary. Original equipment manufacturers (OEM) are subject to the medical device tracking regulation only when the FDA issues a tracking order for a device manufactured by the OEM. Reprocessors are subject to the medical device tracking regulation only when the FDA issues an order for the specific device(s) being reprocessed. For additional information on device tracking, including the types of devices currently subject to tracking orders, consult *Guidance on Medical Device Tracking* available at www.fda.gov/cerh/modact/tracking/pdf or from the Center for Devices and Radiologic Health (CDRH) at 301-827-0111. Request document number 169.

Medical Device Reporting (MDR)

Under MEDWATCH, the FDA's medical device reporting program resulting from the Safe Medical Devices Act of 1990 (Public Law 101-629),⁷ both manufacturers and users are required to report deaths or serious injuries to the FDA if it can be reasonably determined that a medical device may have caused or contributed to the incident. Manufacturers also must report certain device malfunctions.⁸ Because FDA considers reprocessors to be manufacturers when they reprocess an SUD,⁹ hospital reprocessors have dual reporting responsibility. They are subject to manufacturer's reporting requirements (21 CFR, Part 803 Subpart E)¹⁰ as well as those for the device user facility (21 CFR, Part 803 Subparts A and C).¹¹ While user facilities must report only deaths or serious injury, manufacturer's reporting requirements are more extensive and require additional supplemental information. Manufacturers(reprocessors) also must report any event that requires the manufacturer(reprocessor) to take immediate remedial action. The January 26, 2000, Federal Register¹² contains the most recent MDR requirements. Hospitals that reprocess SUDs are subject to both user facility reporting and the more comprehensive manufacturer reporting requirements.

Corrections and Removals

Device correction and/or removal from the point of use must be promptly reported to the FDA when the correction or removal is initiated by the manufacturer(reprocessor) to reduce a health risk to the user or to correct a violation of the Food, Drug, and Cosmetic Act. For example, if a facility reprocessed an SUD that resulted in a patient's adverse reaction and the hospital chose to remove the remainder of the lot of those reprocessed SUDs from circulation to decrease the possibility of other patients having adverse reactions, that action would be a removal and the facility would be required to report the removal to the

FDA. Corrections are defined as "the repair, modification, adjustment, relabeling, destruction or inspection of a device without its physical removal from its point of use."¹³ Removal is defined as the physical removal of a device from its point of use to some other location for repair, modification, adjustment, relabeling, destruction, or inspections."¹⁴ Distributed devices withdrawn from the marketplace due to a minor violation of the Food, Drug, and Cosmetic Act or as a matter of stock rotation need not be reported. Stock recoveries need not be reported, nor should devices removed for routine servicing. The term "stock recoveries" refers to devices that have been prepared for use, but have not left the physical premises and jurisdiction of the manufacturer(reprocessor) (eg, devices that have not left the reprocessing area). However, each correction and/or removal must be documented regardless of whether it is reported to the FDA.

When a report must be filed with the FDA, the report must be filed within 10 days of the correction/removal action. The report should include the following information:

- registration number of the entity manufacturing/reprocessing the device;
- date of the report;
- sequence number of the report from that entity;
- name, address, and telephone number of the reporting entity;
- name, title, address, and telephone number of individual responsible for the correction/removal action;
- brand name, classification name¹⁴, and common name of the device and its intended use
- marketing status of the device;
- model, catalog, and code number of the device and the manufacturer's(reprocessor's) lot, serial, or other identification number for the device;
- description of event leading to correction/removal action;
- any injuries resulting from the device use;
- total number of devices manufactured(reprocessed) subject to the correction/removal action;
- date of manufacture/distribution/reprocessing and expected shelf life of the device;
- name, address, telephone number of all to whom the device has been distributed and the number of devices distributed to each; and
- copy of all communication regarding the correction/removal action and the names and address of all recipients of the communication.

For additional information about correction and removal requirements, consult 21 CFR, Part 806.¹⁵

Device Labeling

The FDA directions for labeling can be found in 21 CFR, Part 801.¹⁶ The term "labeling" includes package inserts as well as the information printed on the actual label of the package. Labeling requirements include the name and location of the manufacturer(reprocessor) and adequate direction for the device's intended use. If the manufacturer(reprocessor) knows of uses other than the intended use of the device, FDA requires the manufacturer(reprocessor) to provide adequate labeling for alternate uses of the device as are known. For additional information about labeling requirements, obtain a copy of the FDA guidance document, Labeling Regulatory Requirements for Medical Devices from www.fda.gov/cdrh/dsma/470.pdf or contact the Division of Small Manufacturers Assistance (DSMA) by phone at 301-827-0444 or at email address DMSA@CDRH.fda.gov.

Quality System Regulation

All manufacturers, including hospital and third-party reproducers, are subject to FDA Good Manufacturing Practices (GMP) requirements. These requirements are presented in the Quality System regulation which governs the methods, facilities, and controls used for designing, manufacturing, packaging, labeling, storing, installing, and servicing medical devices.¹⁷ Quality System refers to the organizational structure, responsibilities, procedures, processes, and resources for implementing quality management. For device manufacturers including reproducers, this system is required in addition to any quality improvement program that may be in place as required by other regulatory bodies. The Quality System regulation addresses the following:¹⁸

- management responsibility (21 CFR, Part 820.20, 22, 25);
- design controls (21 CFR, Part 820.30);
- document controls (21 CFR, Part 820.40);
- purchasing controls (21 CFR, Part 820.50);
- product identification and traceability (21 CFR, Part 820.60, 65);

- production and process validation (21 CFR, Part 820.70, 72, 75);
- acceptance activities such as inspections, tests, or other verification activities (21 CFR, Part 820.80, 86;)
- nonconforming product control (21 CFR, Part 820.90);
- corrective and preventive action (21 CFR, Part 820.100);
- labeling and packaging controls (21 CFR, Part 820.120, 130);
- handling, storage, distribution, and installation controls (21 CFR, Part 820.120, 140, 150, 160);
- records including device master record, device history record, quality system record, and complaint files controls (21 CFR, Part 820.180, 181, 184, 186, 198);
- servicing controls (21 CFR, Part 820.200); and
- use of statistical techniques to establish, control, and verify the acceptability of process capability and product characteristics.(21 CFR, Part 820.250).

Good Manufacturing Practices as required in the Quality System regulation are necessarily detailed, complex, and comprehensive. An in-depth discussion of the Quality System regulation is beyond the scope of this document. Specific and detailed requirements for each of the above categories are articulated in the 21 CFR, Part 820.¹⁹

In addition to the 21 CFR, Part 820, the following documents provide information and guidance on the various aspects of the Quality System regulation:

- *Guideline on Principles of Process Validation* - available through the Division of Small Manufacturers Assistance at telephone 301-443-6597.
- *Design Control Guidance* - available at www.fda.gov/cdrh/ode/425.pdf
- *Quality System Inspection Technique* - at www.fda.gov/ora/inspect_ref/igs/qsit/QSITGUIDE/PDF
- *Medical Device Quality Systems Manual: A Small Entity Compliance Guidance* - available at www.fda.gov/cdrh/dsma/gmp_man.html.

Premarket Notification Requirements

After registering with the FDA and submitting a list of devices to be manufactured(reprocessed) and distributed for use, the registered entity must meet premarket submission requirements for each listed device. Certain devices may be exempt from the premarket submission requirement. If exempt, the device need only be listed with the FDA. Additional information about exemptions can be found in 21 CFR, Part 807.75.²⁰ The FDA has defined a phase-in period for premarket submissions to accommodate entities that are presently engaged in reprocessing. Following the phase-in period, a premarket submission must be submitted for any new device to be manufactured(reprocessed) at least 90 days before beginning distribution of the device.

There are two types of premarket submissions - a premarket notification (510k) and a premarket approval (PMA) application. The type of submission required is based on the device classification, as defined in 21 CFR, Part 814.²¹ Unless specifically exempted, a premarket notification (510k) is required for all Class I and Class II devices. A premarket notification (510k) submission must contain enough information for the FDA to determine whether the particular device is "substantially equivalent" to another device that has been previously judged to be safe and effective and has been cleared for marketing/reprocessing. The predicate device selected must have the same intended use as the device for which the 510k is submitted. The predicate device may be the original SUD of the OEM provided the 510k compares the unique characteristics of the submitted device to those of the predicate device so the FDA can determine equivalency with respect to safety and effectiveness. The following information is required for a premarket notification (510k) submission:

- Device trade name, proprietary name, usual name, or classification name;
- Entity registration number;
- Device classification;
- Action taken to determine device performance standards;
- Proposed labels, labeling, and advertisements to describe the device, its intended use, and the directions for its use, including photos and/or engineering drawings if appropriate;
- Appropriate data to show that the registered entity has considered the consequences and effects any changes or modifications in the device might have on the safety and effectiveness of the device;
- 510k summary or 510k statement as defined in 21 CFR, Part 807.92, 93²²;
- Financial disclosure statement;

- Statement certifying truth, accuracy, and completeness of material submitted; and
- Any other information requested by the FDA.

For specific guidance on preparing 510k submissions, consult *Regulatory Requirements for Medical Devices* available at www.fda.gov/cdrh/manual/510kprt1.html or contact the Division of Small Manufacturers Assistance. Locate other relevant guidances at www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfGGPSearch.CFM

All Class III devices require a PMA. A PMA application must include valid scientific evidence demonstrating the safety and effectiveness of the original and/or reprocessed device. Each PMA application should evaluate the unique characteristics of the submitted device. Clinical data (eg, results of clinical trials) may be required. Some clinical trials require FDA approval of an investigational device exemption (IDE) application for the device(s) to be studied. For additional information, consult the following sources

- 21 CFR, Part 814.20.²³
- 21 CFR, Part 812²⁴
- *Guidance for Preparation of PMA Manufacturing Information* available at www.fda.gov/cdrh/ode/448.pdf
- *Significant and Non-significant Risk Medical Device Studies* available at www.fda.gov/cdrh/manual/idemanul.html
- *IDE Policies and Procedures* available at www.fda.gov/cdrh/ode/idepolicy.html

The FDA also requires a satisfactory inspection of the manufacturing(reprocessing) facilities before approving a PMA application. The application should include a comprehensive manufacturing(reprocessing) section that clearly identifies all manufacturing(reprocessing) controls.

Enforcement Priorities

The FDA phase-in timeline for enforcement of its regulatory requirement as issued in August 2000 is as follows:²⁵

NON-PREMARKET REQUIREMENTS (Registration, Listing, Corrections/Removals Quality System Regulation, etc)

Hospital reproprocessors	August 2001
Third-party reproprocessors	Currently enforced with no planned change

PREMARKET SUBMISSION REQUIREMENTS (510k/PMA)

Device Class III	
Hospital reproprocessors	February 2001
Third-party reproprocessors	February 2001
Device Class II	
Hospital reproprocessors	August 2001
Third-party reproprocessors	August 2001
Device Class I	
Hospital reproprocessors	February 2002
Third-party reproprocessors	February 2002

Federal Regulation Applicability

The effective date of the FDA regulation is August 2000 for third-party reproprocessors and February 2001 for hospital reproprocessors.²⁶ OEMs have been regulated for more than 20 years. The regulation applies only to used devices, excluding those that have been opened, but not used.²⁷ The FDA intends to expand applicability of the regulation to other provider entities that manufacture(reprocess) SUDs (eg, ambulatory surgery centers, physician offices, dental offices).

Unless so stipulated by the OEM, it is unknown what effect reprocessing may have on the safety and efficacy of any SUD. AORN believes that unless the OEM provides specific, written, reprocessing instructions for the SUD, an opened but unused device (eg, compromised package integrity, accidental contamination upon opening, etc) should be subject to the same rigorous reprocessing protocols, including quality system regulations, as the used device.

Definitions

Class I Medical Device: A medical device for which general controls provide reasonable assurance of the safety and effectiveness of the device or, if there is insufficient evidence to reasonably ensure safety and effectiveness, the device is not life-supporting or life-sustaining, its use is not substantially important in preventing impairment of human health, and/or its use "does not present a potential unreasonable risk of illness or injury."²⁸

Class II Medical Device: A medical device for which general controls alone do not provide reasonable assurance of device safety and effectiveness but for which there is sufficient information to establish special controls (eg, performance standards, guidelines, patient registries, postmarket surveillance) to provide that assurance.²⁹

Class III Medical Device: A medical device for which neither general controls nor special controls provide reasonable assurance of device safety and effectiveness and the device is life-supporting or life-sustaining or its use "is of substantial importance in preventing impairment of human health" or "presents a potential risk of illness or injury."³⁰

Opened-but-unused Device: A device whose sterility is compromised before being introduced onto the sterile field and which is not contaminated with blood and/or other potentially infectious materials (OPIM) external to the sterile field.³¹

Reprocessing: Includes all operations to render a contaminated reusable or single-use device patient ready. Single-use devices to be reprocessed may be either used or unused. Reprocessing steps include cleaning, decontamination, and sterilization/disinfection.³²

Resterilization: The repeated application of a process intended to remove or destroy all viable forms of microbial life, including bacterial spores.³³ Because sterility is not an absolute, the accepted sterility assurance level (SAL) is usually defined as 10^{-6} .

Reuse: The repeated or multiple uses of any medical device whether marketed as reusable or single-use. Repeated/multiple use may be on the same patient or on different patients with applicable reprocessing of the device between uses.³⁴

Single-Use Device: A device intended by the manufacturer to be used on one patient during one procedure. The device is not intended for reprocessing and/or use on another patient or on the same patient at another time. Device labeling may or may not identify the device as single-use or disposable, but manufacturer instructions for reprocessing are absent.³⁵

Third-party Reprocessor: A business establishment, separate from the user facility and the device manufacturer, one of whose primary businesses is to reprocess single-use/disposable medical devices.

Notes

1. "ANA code for nurses with interpretive statements-Explications for perioperative nursing," in *AORN Standards, Recommended Practices, & Guidelines* (Denver: AORN, 2001) 53-70.

2. Joint Commission on Accreditation of Healthcare Organizations, "The accreditation cycle: Official policies and procedures," CAMH Update 3 (August 1998) in *Comprehensive Accreditation Manual for Hospitals (CAMH) 2000*, AC-3.

3. "Letter Re: Reusable Medical Devices Rented or Leased from Third Parties," at www.fda.gov/cdrh/comp/rentleasetthird.html (accessed December 2000).

4. "Quality system regulation, Definitions," in *Code of Federal Regulations (CFR) 21: Food and Drugs*, Part 820.3 (Washington DC: U.S. Government Printing Office, 2000) 139; "Letter to American College of Healthcare Executives: Reuse of Single-Use or Disposable Medical Devices," at www.fda.gov/cdrh/comp/policymayapply.html (accessed December 2000).

5. Center for Devices and Radiological Health, Food and Drug Administration, U.S. Department of Health and Human Services, *Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals* (Washington, DC: U.S. Government Printing Office, August 14, 2000).

6. "Establishment regulation and device listing for manufacturers and initial importers of devices," in *Code of Federal Regulations (CFR) 21: Food and Drugs*, Part 807 (Washington, DC: U.S. Government Printing Office, 2000), 59-74.

7. "Public Law 101-629: Safe Medical Devices Act of 1990," at <http://thomas.loc.gov/> accessed December 2000).

8. "Medical device reporting: General provisions, Scope," in *Code of Federal Regulations (CFR) 21: Food and Drugs*, Part 803.1 (Washington DC: U.S. Government Printing Office, 2000) 39.

9. "Letter to American College of Healthcare Executives: Reuse of Single-Use or Disposable Medical Devices," at www.fda.gov/cdrh/comp/policymayapply.html (accessed December 2000).

10. "Manufacturer reporting requirements," in *Code of Federal Regulations (CFR) 21: Food and Drugs*, Part 803, Subpart E (Washington, DC: U.S. Government Printing Office, 2000) 52-55.

11. "Medical device reporting: General provisions," in *Code of Federal Regulations (CFR) 21: Food and Drugs*, Part 803, Subpart A (Washington, DC: U.S. Government Printing Office, 2000) 38-47; "User facility reporting requirements," in *Code of Federal Regulations (CFR) 21: Food and Drugs*, Part 803, Subpart C (Washington, DC: U.S. Government Printing Office, 2000) 49-51.

12. Food and Drug Administration, U.S. Department of Health and Human Services, "Medical device reporting: Manufacturer reporting, importer reporting, user facility reporting, distributor reporting," in *Federal Register*, Vol 65 No 17 (January 26, 2000) 4112-4121.

13. "Medical devices: Reports of corrections and removals, Definitions," in *Code of Federal Regulations (CFR) 21: Food and Drugs*, Part 806.2 (Washington, DC: U.S. Government Printing Office, 2000) 56.

14. *Ibid.*

15. *Ibid*, 55-59.

16. "Labeling," in *Code of Federal Regulations (CFR) 21: Food and Drugs*, Part 801 (Washington, DC: U.S. Government Printing Office, 2000) 13-23.

17. Center for Devices and Radiological Health, Food and Drug Administration, U.S. Department of Health and Human Services, *Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals*, 17.

18. "Quality system regulation," in *Code of Federal Regulations (CFR) 21: Food and Drugs*, Part 820, 137-150.

19. *Ibid.*

20. "Exemption from premarket notification," in *Code of Federal Regulations (CFR) 21: Food and Drugs*, Part 807.75, (Washington DC: U.S. Government Printing Office, 2000) 68-69.

21. "Premarket approval of medical devices," in *Code of Federal Regulations (CFR) 21: Food and Drugs*, Part 814 (Washington, DC: U.S. Government Printing Office, 2000) 115-137.

22. "Content and format of a 510k summary," in *Code of Federal Regulations (CFR) 21: Food and Drugs*, Part 807.92 (Washington DC: U.S. Government Printing Office, 2000) 70-71; "Content and format for a 510k statement," in *Code of Federal Regulations (CFR) 21: Food and Drugs*, Part 807.93 (Washington, DC: U.S. Government Printing Office, 2000) 71-72.

23. "Premarket approval application," in *Code of Federal Regulations (CFR) 21: Food and Drugs*, Part 814.20 (Washington, DC: U.S. Government Printing Office, 2000) 119-123.

24. "Investigational device exemptions," in *Code of Federal Regulations (CFR) 21: Food and Drugs*, Part 812 (Washington, DC: U.S. Government Printing Office, 2000) 97-115.

25. Center for Devices and Radiological Health, Food and Drug Administration, U.S. Department of Health and Human Services, *Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals*, 25-31, 42,43.

26. *Ibid*, 11.

27. *Ibid*.

28. "Medical device classification procedures, Definitions," in *Code of Federal Regulations (CFR) 21: Food and Drugs*, Part 860.3 (Washington, DC: U.S. Government Printing Office, 2000) 157

29. *Ibid*.

30. *Ibid*.

31. Center for Devices and Radiological Health, U.S. Food and Drug Administration, U.S. Department of Health and Human Services, *Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals*, 40.

32. *Ibid*.

33. *Ibid*.

34. *Ibid*; Center for Devices and Radiological Health, Food and Drug Administration, U.S. Department of Health and Human Services, "FDA's proposed strategy on reuse of single-use devices, Docket no. 99N-4491," *Federal Register*, November 3, 1999, Vol 64, No 212, Notices, 59782-59783.

35. Center for Devices and Radiological Health, Food and Drug Administration, U.S. Department of Health and Human Services, *Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals*, 40.