NOTE: Appendix 2 of this guidance has been superseded by **Attachment 1. List of SUDS Known to be Reprocessed or Considered for Reprocessing** at Medical Devices; Reprocessed Single-Use Devices; Termination of Exemptions From Premarket Notification; Requirement for Submission of Validation Data.

Guidance for Industry and FDA Reviewers

Reprocessing and Reuse of Single-Use Devices: Review Prioritization Scheme

Draft Guidance – Not for Implementation

This guidance document is being distributed for comment purposes only.

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U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health

Division of Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation

Preface

Public Comment:

Comments and suggestions regarding this document should be submitted by April 11, 2000 to Docket No. 00D-0053, Dockets Management Branch, Division of Management Systems and Policy, Office of Human Resources and Management Services, Food and Drug Administration, 5630 Fishers Lane, (HFA-305), Room 1061, Rockville, MD 20852.

Additional Copies:

Additional copies are available from the Internet. You may also send an e-mail request to CDRH-Guidance@fda.hhs.gov to receive an electronic copy of the guidance or send a fax request to 301-847-8149 to receive a hard copy. Please use the document number 1156 to identify the guidance you are requesting.

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Reprocessing and Reuse of Single-Use Devices: Review Prioritization Scheme[1]

Introduction

The practice of reprocessing devices that are intended for single-use (SUD's) began in hospitals in the late 1970's. Since that time, the practice of reprocessing and reusing SUDs has become widespread. FDA has not regulated original equipment manufacturers (OEM's), third parties, and hospitals that engage in reprocessing SUD's in the same manner. In particular, to date, FDA has enforced existing premarket submission requirements only against OEM's. FDA's premarket review of an OEM's device labeled for single-use does not ordinarily address whether reprocessing and reuse of such a device would present a risk to the public health.

The public health risk presented by a reprocessed SUD varies. Some devices, which are low risk when used only one time, may present an increased risk to the patient upon reprocessing. Other SUDs are low risk when used for the first time and remain low risk after reprocessing, provided that the reprocessor conducts cleaning and sterilization/disinfection of the SUD in an appropriate manner. Other SUDs, however, cannot be reprocessed safely and should not be reprocessed and reused under any circumstances. FDA is proposing to prioritize its enforcement of premarket requirements for reprocessed SUDs on the basis of the risk that is likely to be posed by the reuse of the device. This guidance document describes the factors the agency will consider to determine the level of risk associated with these devices and the way those factors will be applied to determine whether the risk is high, moderate, or low.

[1] This document is intended to provide guidance. It represents the Agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations or both.

Purpose

This document describes the process FDA would use to categorize the risk of SUDs that are reprocessed. The process, called the Review Prioritization Scheme (RPS), assigns risk categories to frequently reprocessed SUDs. The process itself is illustrated through flow charts in Appendix 1 and the risk categories assigned through the process to frequently reprocessed SUDs are listed in Appendix 2.

FDA anticipates using the RPS in the future in response to requests from the public on the category of a reprocessed SUD not listed in Appendix 2. Such requests should be directed, in writing, to the contact noted in the Preface. FDA will periodically publish a revised list of categorized devices based upon these requests.

The RPS assigns an overall risk to each SUD by addressing the risk of infection and the risk of inadequate performance following reprocessing. The FDA intends to utilize the overall risk level to prioritize the enforcement of premarket submissions for these devices. Enforcement priorities for reprocessed SUDs are further described in the companion draft guidance entitled: "Enforcement Priorities for Single-Use Devices Reprocessed by Third-Parties and Hospitals." FDA wants to clarify that neither of these guidance documents change the classification of devices under section 513 of the Federal Food, Drug, and Cosmetic Act or establish some system of classification outside that statutory process. The risk prioritization scheme is intended to help FDA and stakeholders determine the level of risk associated with the reuse of single use devices and the enforcement strategy guidance presents FDA's current thinking on the time table it will use to phase in the enforcement of regulatory requirements for third parties and hospitals that may intend to reprocess these products.

FDA is seeking input from users, original equipment manufacturers (OEMs), reprocessors, and the general public about this proposed approach for categorizing risk. The attached list in Appendix 2 of this draft RPS guidance identifies frequently reprocessed SUD's and their risk categorization. We acknowledge that this list may be incomplete or that the grouping of devices based on current classification regulations may be too broad. FDA will consider any SUD not on the current list or subsequently revised lists to be one that poses a high risk if it is reprocessed. FDA is soliciting public

comment on the list and may revise the factors to categorize risk and the category of risk assigned to specific devices based upon the comments. After receiving comments on this draft guidance, FDA will issue a final guidance. On December 10, 1999 FDA published an earlier version of this draft document on its Website and recently issued a Federal Register notice announcing the availability of the that earlier version. This draft guidance replaces the earlier version in its entirety.

Scope

This draft RPS guidance **IS** applicable to third party and hospital reprocessors of SUDs.

This draft guidance **DOES NOT** apply to:

1. Permanently implantable pacemakers. Questions regarding the reuse of permanent pacemakers are addressed in Compliance Policy Guide 7124.12 (issued on October 1, 1980 and revised in March 1995).

2. "Opened-but-unused" SUDs (as defined in Appendix A of the companion guidance: "Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals").

3. Health care facilities that are not hospitals[2].

FDA is aware that hospitals may not be the only health care facilities that reprocess devices labeled for single use. At this time, the agency is limiting its focus to SUD reprocessing by third party and hospital reprocessors. In the near future, FDA intends to examine whether it should include other establishments that may reprocess SUDs.

[2] For the purpose of this draft guidance, a hospital is defined as an acute health care facility.

General Approach

The RPS identifies two types of risks that arise as a result of using a reprocessed SUD: (1) the risk of infection; and (2) the risk of inadequate or unacceptable device performance following reprocessing. Based on the risk of infection and inadequate device performance, the scheme places SUDs in overall risk categories of low, moderate, or high. As noted above, these risk categories will be used in establishing FDA's enforcement priorities and periods of enforcement discretion for premarket requirements.

The worksheet and flowcharts attached (Appendix 1) to this guidance are the tools that FDA has used when applying the RPS. It is important to note that many of the questions asked in the flowcharts may require subjective responses. Despite the possibility of different interpretations, FDA has tried to make consistent categorizations across all SUD types.

Flowchart 1: Evaluating the Risk of Infection (Appendix 1)

One of the FDA's primary concerns is the risk of disease transmission during reuse of a reprocessed SUD. For a reusable device, the OEM provides the user with validated step-by-step reprocessing instructions or the methods to reprocess for reuse are commonly known and accepted. However, the OEM of a single-use device does not consider safety and effectiveness issues related to reprocessing the device for reuse. Flowchart 1 evaluates the risk of infection posed by reuse of a SUD following reprocessing.

FDA considers all implantable SUDs to be high risk. Implantable devices are defined in 21 CFR Part 860.3(d). Flowchart 1 pertains only to non-implantable devices.

Question 1: Is the SUD a non-critical device?

The chart asks how the device will contact the patient, or in some cases, the user or health care worker, by applying the definitions of the Spaulding criteria[3] for critical, semi-critical, and non-critical devices.

[3] Spaulding, E.H. 1972. Chemical disinfection and antisepsis in the hospital. J. Hosp. Res., 9, 5-31.

A non-critical device is a device that is intended to make topical contact and not penetrate intact skin. A non-critical device presents a low risk of disease transmission when reprocessed and reused.

A semi-critical device is a device that is intended to contact intact mucous membranes and not penetrate normally sterile areas of the body. A semi-critical device presents a greater risk of disease transmission than a non-critical device.

A critical device is a device that is intended to contact normally sterile tissue or body spaces during use and presents the greatest risk of disease transmission.

If the answer to question 1 is "Yes", then the risk of infection is low.

If "No", go to question 2.

<u>Question 2</u>: Does postmarket information suggest that using the reprocessed SUD may present an increased risk of infection when compared to the use of a SUD that has not been reprocessed?

If the device were determined to be critical or semi-critical, FDA would evaluate existing postmarket data (e.g., published data, laboratory reports, reports to FDA) to determine if the reprocessed SUD may present an increased risk of infection when compared to the use of a SUD that has not been reprocessed. FDA believes that the existence of significant adverse postmarket data is a compelling reason for concern and, therefore, FDA would consider the device to be high risk.

If the answer to question 2 is "Yes", then the risk of infection is high.

If "No", go to question 3.

<u>Question 3</u>: Does the SUD include features that could impede thorough cleaning and adequate sterilization/disinfection?

Some design features, such as narrow lumens and interlocking parts, can harbor debris that cannot be readily accessed and removed during cleaning unless the device can be disassembled or otherwise serviced and all surfaces of the devices exposed for manual cleaning. If a device cannot be adequately cleaned, terminal processing to disinfect or sterilize the device will not be successful and the SUD presents a greater risk of disease transmission. If a device does not incorporate any of these hard to clean features, then the SUD presents a low risk of disease transmission.

If the answer to question 3 is "Yes", then go to question 4.

If "No", then the risk of infection is low.

<u>Question 4</u>: Does a reusable device exist that has an equivalent design and the same intended use as the SUD?

In some circumstances, there will be cleared, approved, or exempt reusable devices (including designs with problematic construction or materials features) that are equivalent to a SUD with the same intended use. In this case, the risk is diminished because it is evident that cleaning and sterilization/disinfection can be accomplished with the reprocessed SUD by using techniques directed by labeling for the reusable device.

If the answer to question 4 is "Yes," then the risk of infection is low.

If "No," then go to question 5.

<u>Question 5</u>: Are there recognized consensus performance standards, performance tests recommended by the OEM, or a CDRH guidance document that may be used to determine if the SUD has been adequately cleaned and sterilized/disinfected?

FDA has recognized numerous domestic and international consensus standards that may be used for design and performance aspects of the

reprocessed SUD. The list of FDA-recognized standards is available on FDA's website www.fda.gov/cdrh/modact/recstand.html. OEM-recommended performance tests (e.g., manufacturer-developed test, standards that are not recognized) may also be applicable. In addition, there are CDRH guidance documents on FDA's website www.fda.gov/cdrh/guidance.html, which may include specifications, test protocols, and acceptance criteria.

If the answer to question 5 is "Yes", then the risk of infection is moderate.

If "No", then go to question 6.

Question 6: Is this a semi-critical device?

If the SUD is a semi-critical device, the risk of infection is moderate.

However, if a product is a critical device, the risk of infection is high.

Flowchart 2: Risk of Inadequate Performance (Appendix 1)

Another one of FDA's primary concerns is the risk of inadequate performance during reuse of a reprocessed SUD. For a reusable device, the OEM validates that the device will perform without failure for the number of times it is labeled to be reused. However, a manufacturer of a SUD validates that the SUD will perform without failure for only one use. In Flowchart 2, we evaluate the risk of inadequate performance posed by reuse of a SUD following use and reprocessing.

FDA considers all implantable SUDs to be high risk. Implantable devices are defined in 21 CFR Part 860.3(d). Flowchart 2 pertains only to non-implantable devices.

<u>Question 1</u>: Does postmarket information suggest that using the reprocessed SUD may present an increased risk of injury when compared to the use of an SUD that has not been reprocessed?

FDA evaluates existing postmarket data (e.g., published data, laboratory reports, reports to FDA) to determine if the reprocessed SUD may present an increased risk of injury when compared to the use of a SUD that has not been reprocessed. FDA believes that existence of significant adverse postmarket data is a compelling reason for concern and, therefore, would consider the device to be high risk. FDA does not consider the absence of relevant information to be either evidence of increased risk or proof of safety.

If the answer to question 1 is "Yes", then the risk of inadequate performance is high.

If "No", go to question 2.

<u>Question 2</u>: Could failure of the device cause death, serious injury, or permanent impairment?

For purposes of risk categorization associated with inadequate performance, Flowchart 2 distinguishes between those SUDs whose failure could cause death, serious injury, or permanent impairment and those SUDs whose failure would cause less severe harm.

If the answer to question 2 is "Yes", then go to question 3.

If "No", go to question 2a.

<u>Question 2a</u>: Are there recognized consensus performance standards, performance tests recommended by the OEM, or a CDRH guidance document that may be used to determine if the performance of the SUD has been altered due to reprocessing and use?

FDA has recognized numerous domestic and international standards that may be used for design and performance aspects of the reprocessed SUD. The list of FDA-recognized standards is available on FDA's WEBsite. OEM-recommended performance tests (e.g., manufacturer-developed tests, standards that are not recognized) may

also be applicable. In addition, there are CDRH guidance documents on FDA's WEBsite, which may include specifications, test protocols, and acceptance criteria.

If the answer to question 2a is "Yes", then the risk of inadequate performance is low.

If "No", then go to question 2b.

<u>Question 2b</u>: Can visual inspection determine if performance has been affected?

Visual, critical failure of the device may be self-evident before or during use of the device. Measures can then be implemented to correct the failure.

If the answer to question 2b is "Yes" then the risk of inadequate performance is low.

If "No", then the risk of inadequate performance is moderate.

<u>Question 3</u>: Does the SUD contain any materials, coatings, or components that may be damaged or altered by a single use or by reprocessing and/or resterilization/disinfection in such a way that the performance of the device may be adversely affected?

Materials, coatings, or components may be damaged or altered by a single use or by reprocessing. For example, battery life, material strength or flexibility, lubrication, and antimicrobial coatings may be adversely affected.

If the answer to question 3 is "Yes" then go to question 4.

If "No" then go back to question 2a.

<u>Question 4</u>: Are there recognized consensus performance standards, performance tests recommended by the OEM, or a CDRH guidance document that may be used to determine if the performance of the SUD has been altered due to reprocessing and use?

FDA has recognized numerous domestic and international standards that may be used for design and performance aspects of the reprocessed SUD. The list of FDA-recognized standards is available on FDA's WEBsite. OEM-recommended performance tests (e.g., manufacturer-developed tests, standards that are not recognized) may also be applicable. In addition, there are CDRH guidance documents on FDA's WEBsite, which may include specifications, test protocols, and acceptance criteria.

If the answer to question 4 is "Yes", then the risk of inadequate performance is moderate.

If "No", then go to question 5.

<u>Question 5</u>: Can visual inspection determine if performance has been affected?

Visual, critical failure of the device may be self-evident before or during use of the device. Measures can then be implemented to correct the failure

If the answer to question 5 is "Yes," then the risk of inadequate performance is moderate.

If "No," then the risk of inadequate performance is high.