



DUKE UNIVERSITY MEDICAL CENTER

Sterile Processing

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April 10, 2000

Dockets Management Branch (HFA-305)
Division of Management Systems and Policy
Office of Human Resources and Management Services
Food and Drug Administration
5603 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. 99N-4491, FDA's Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals and Reprocessing and Reuse of Single-Use Devices: Review Prioritization Scheme

Ladies and Gentlemen:

I am writing in response to the FDA's two draft guidance documents: Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals and Reprocessing and Reuse of Single-Use Devices: Review Prioritization Scheme. As a management professional in the sterile processing field, I belong to a community of professionals who have been instrumental in the development of safe and effective techniques for reprocessing medical devices. This issue is an important one for our profession and is critical to the delivery of health care.

I am currently the Director of the Sterile Processing Department, Duke University Hospital. My current responsibilities include the planning, directing and coordination of activities involved in the acquisition, decontamination, storage, assembly, cleaning and sterilization of medical, surgical and related supplies, materials and equipment utilized in the care and treatment of patients at Duke University Hospital. I have been responsible for the administration of the sterile processing functions at Duke for more than 28 years. I have presented at numerous educational seminars for ASHCSP, APIC, AORN, AAMI and various manufacturers. I am the recipient of the Doctor John J. Perkins Memorial Award, the Leonard A. Leibus Award and the United Nations Environment Programme (UNEP) Citation of Excellence. I am a member of the ASHCSP and have served the ASHCSP in various capacities to include President. I am currently Chairperson of the ASHCSP Regulatory Advocacy Committee and have participated in numerous seminars and document development activities related to the Reuse of Single Use Devices (SUD's).

99N-4491

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I am very encouraged by the FDA's decision to take action on this issue to ensure and enhance patient safety. The FDA's risk-based categorization scheme is a sound approach to regulatory oversight. Factors such as risk of infection and device performance are critical in determining whether or not reprocessing is appropriate, safe, and effective. I would like to take this opportunity to respond to specific issues raised in the draft documents, as follows:

I applaud FDA for recommending that opened but unused medical devices be exempt from the regulatory guidance. There is no scientific evidence that would establish a public health risk with the reprocessing of these devices. Since they have not, by definition, been previously used on a patient, the reprocessing of these devices do not raise the same level of concern as the reprocessing of devices that have been used on a patient. In addition to exempting opened but unused devices, the FDA should require Original Equipment Manufacturers (OEMs) to provide special sterilization instructions as part of the labeling requirement to ensure that the proper method of sterilization is used on those devices whose sterility may be breached and would require re-sterilization.

Exempting non-acute facilities such as ambulatory care centers, clinics, and physicians' offices from regulatory guidance is counter-productive to the FDA's efforts to ensure and enhance patient safety associated with the reuse of SUDs. These healthcare facilities oftentimes lack the necessary resources and protocols to ensure safe and effective reprocessing of single-use items. I strongly encourage the FDA to apply reasonable guidelines to all healthcare facilities that reprocess not just hospitals.

I urge the FDA to seek uniformity from OEMs in the process and manner in which devices are labeled. There are no standards in place which guide multi-use vs. single-use labeling. An OEM should not be permitted to label a device for single-use if it is aware of safe and effective reprocessing and sterilization procedures; further, I would encourage FDA to sanction OEMs for "economic fraud" if an OEM intentionally mislabels a device to enhance market share. The device label should include the number of times the device will perform without failure as validated by the OEM. The release of FDA's final guidance documents should be delayed until the FDA addresses this labeling issue.

Furthermore, if hospitals and third party reproducers are expected to utilize the flow chart as outlined in the Review Prioritization Scheme, the materials, coatings, and components of a device must be known. And finally, in all cases, OEMs should be required to provide instructions for acceptable, validated methods of sterilization and/or re-sterilization for all devices.

A listing of most commonly reprocessed devices has been included with the guidance documents. The FDA asserts that those SUDs not on the list are automatically categorized as high risk. Does this mean that a plastic, sterile connector labeled single-use is high risk? FDA should remove this statement from its guidance. The FDA should provide a rationale for each device categorized as high risk. All the answers to the questions posed in the flowcharts, as well as all supporting documentation used in establishing a risk categorization for a particular type of device, should be published and publicly available. In addition, FDA should work with a panel of multidisciplinary professionals to determine the final list of SUDs and their risk category. In this way, if there is additional evidence about the safety of reprocessing a particular device, there would be an established and timely process set out for adding this evidence to the record and potentially changing the risk categorization of a SUD. Final guidance documents should not be released until this multi-disciplinary panel can be identified to determine the final list of SUDs and their risk category.

The moderate category serves only to complicate an already complicated scheme. I would recommend the FDA consider only two device categories – low and high risk devices. The FDA needs to be decisive about the safety and risks associated with the reprocessing of every SUD.

As far as devices categorized as low risk, by definition, the reprocessing of low risk devices does not present a risk to public health. As such, hospitals who engage in the reprocessing of low risk SUDs should be exempt from all and any pre-market notification and approval requirements. To ensure that reprocessing of low risk devices is safe and effective, decontamination, assembly and sterilization standards or recommended practices should be disseminated to hospitals. The American Society for Healthcare Central Service Professionals (ASHCSP) has developed recommended practices on all facets of reprocessing which could serve as a "community best practices" model.

With respect to high risk devices, most facilities will be unable to comply with the proposed guidelines and should seek a commercial reprocessor for reprocessing.

Hospitals are already subject to reporting requirements as a device user as outlined in the Safe Medical Devices Act. There is no need for hospitals to comply with manufacturers' reporting requirements. This would be redundant and an inefficient use of already limited resources. Hospitals would benefit from further education and communication on the Act not a duplicative process for reporting adverse events.

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Should the FDA proceed with enforcing all pre-market and notification requirements on hospitals, it is highly probable hospitals will elect to discontinue internal reprocessing activity. The investment of resources necessary to comply with pre-market and 510(k) application requirements would diminish any cost savings hospitals would realize by reprocessing single-use devices. I believe this would be an unfortunate outcome that would only serve to increase the costs of care in hospitals without significantly adding to the already safe and effective reprocessing activity in which hospitals are currently engaged.

Respectfully submitted,

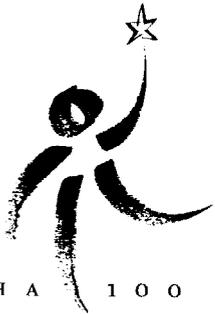


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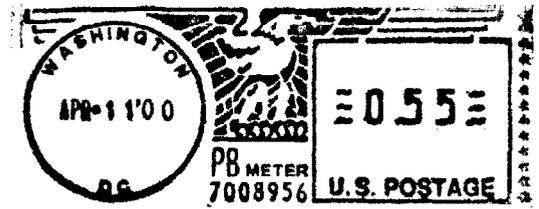


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