Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling

Guidance for Industry and Food and Drug Administration Staff

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This document supersedes: "Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: FDA Reviewer Guidance" (available at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM080268.pdf) issued April 1996.

The draft of this document was issued on May 2, 2011.

For questions regarding devices regulated by the Center for Devices and Radiological Health, contact the Infection Control Devices Branch (INCB) at (301) 796-5580. For questions regarding devices regulated by the Center for Biologics Evaluation and Research (CBER), contact the Office of Communication, Outreach and Development at 800-835-4709 or 240-402-7800.

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

Center for Biologics Evaluation and Research

L. Reuse Life

The labeling should either 1) inform the user how many times the device can be reused, based on testing; or 2) provide the user with a mechanism or method to ascertain whether the device has exceeded its use life. In the latter case, the labeling should identify a method to establish that the device is still within performance specifications, as well as instructions for appropriate disposal of devices that fail. For example:

- labeling that refers to a device design feature, such as a built-in, automatic pre-check function;
- labeling that identifies a performance test that should be passed prior to reuse;
- labeling that recommends visual inspection along with acceptance or failure criteria (e.g., unacceptable deterioration such as corrosion, discoloration, pitting, cracked seals).

Whichever method is chosen, labeling should recommend how to evaluate deterioration in difficult to see areas of complex devices, especially those with lumens (e.g., leak testing).

Reuse life may also be addressed by validating the number of times the product can be reprocessed and reused, and providing this specification in the labeling. If the reuse life of a device is limited to a specific number of use/reprocessing cycles, the labeling should also describe a specific tracking method for the number of reuse cycles. It may be appropriate for labeling to remind the user that the specific number of reuse cycles is dependent on full compliance with the directions for use of the device.

M. Additional Labeling Recommendations