Factors Affecting Quality of Reprocessing

The following examples outline safety concerns identified by the FDA, based on our evaluation of reports received and available literature:

- **Device design**
- **Reprocessing methodology**
- **Methods for validating the cleaning and high-level disinfection and sterilization instructions**

Device Design

The designs of some types of reusable medical devices, endoscopes in particular, have become more complex. This can make optimal cleaning, high-level disinfection or sterilization more complicated.

The FDA's evaluation of adverse event reports and other information identified design features that are prone to retaining debris and biological materials, including:

- Long, narrow interior channels (lumens), including those with internal surfaces that are not smooth, have ridges or sharp angles, or are too small to permit a brush to pass through;
- Hinges;
- Sleeves surrounding rods, blades, activators, inserters, etc.;
- Adjacent device surfaces between which debris can be forced or caught during use;
- O-rings;
- Valves that regulate the flow of fluid through a device (stopcocks); and
- Devices with these or other design features that cannot be disassembled for reprocessing.

Other device-design-related concerns:

- Post-market design changes that do not take into account how the changes impact the ability to properly clean and disinfect the device.
- Lack of communication between manufacturers and/or between manufacturers and device users when medical devices used for reprocessing are modified and instructions are revised.

Top

Reprocessing Methodology

Reprocessing is detailed, labor intensive, time-consuming, and can be prone to errors.

Each reusable medical device requires specific reprocessing steps or techniques appropriate for that device. Many variables impact the effectiveness of reprocessing reusable medical devices:

- Reprocessing challenges at individual facilities, such as:
  - Staff responsible for steps in the process
  - Training available to the staff
  - Equipment (e.g. appropriately sized brushes) available for use.
- Quality and completeness of the reprocessing instructions provided by the manufacturer.
- Access to the manufacturer's instructions.

These variables are always changing because medical device technology is constantly evolving and reprocessing requires precision, as well as periodic retraining to assure staff competence.

Top

Methods for Validating Cleaning and High-Level Disinfection or Sterilization Instructions

Manufacturers are required to validate their reprocessing instructions by documenting that the recommended cleaning, disinfection, or sterilization process consistently results in an adequately reprocessed device. In general, cleaning validation experiments involve soiling of the devices (from clinical use, or simulated soiling with a test soil), cleaning of the device, and finally a method to measure residual components of the test soil remaining on the device.

FDA's *Final Guidance for Industry and FDA Staff: Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling (/media/80265/download)* provides detailed recommendations regarding validation testing methods for reprocessing reusable medical devices.

FDA review of manufacturer-supplied validation data indicates that many studies designed inadequate test conditions and used inappropriate measurement methods to validate that the tested device was clean. For example, some manufacturers have not used a clinically relevant

test soil as part of the validation testing of their cleaning instructions for use, resulting in cleaning instructions that may not adequately remove soil such as blood, tissue and bone.

Manufacturers have commonly used a suspension of bacterial spores as a test soil, and measured the reduction in spores after cleaning as part of the validation of cleaning instructions; however it is unclear whether or not the removal of bacterial spores directly correlates to the removal of patient material such as blood and tissue from the devices. For that reason, the FDA does not recommend the use of spore log reduction testing as a method to determine the effectiveness of the cleaning methodology.

FDA also reviewed cases where the ability to clean internal device components were not considered as part of the design validation and evaluation of instructions for cleaning the device.

Proper validation of cleaning instructions should use a test soil that adequately simulates the worst case clinical soil, the worst case soiling conditions, and quantifies an appropriate component of residual soil. The need to disassemble a device for proper reprocessing should also be considered. Failure to take these steps may result in cleaning instructions that do not adequately describe how to remove residual patient soil.

More information about validation methodologies is available in FDA's *Final Guidance for Industry and FDA Staff: Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling (/media/80265/download)*.

Top