

FAQS

➤ **Who regulates the third-party medical device reprocessing industry?**

In the United States, the Food and Drug Administration (FDA) regulates the reprocessing of single-use medical devices in the same manner they regulate the original manufacture of medical devices. The FDA's guidance document of August 2000 entitled "Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals,"¹ placed single-use device reprocessors in the same regulatory framework as original equipment manufacturers (OEMs). In 2002, the Medical Device User Fee and Modernization Act (MDUFMA)² mandated additional requirements for SUD reprocessors.

➤ **What is the difference between hospital-based and third-party reprocessing?**

Hospital-based reprocessing for REUSABLE devices is limited to cleaning and sterilization only, whereas third-party reprocessing for SINGLE-USE devices entails validated protocols for decontamination, manual and automated cleaning, functional testing, and sterilization.

Hospital-Based Reprocessing

- REUSABLE devices only
- Cleaning and sterilization only

Third-Party Reprocessing

- REUSABLE and SINGLE-USE devices
- Multi-step decontamination and cleaning process, sterilization, and functional testing
- Validated methods in accordance with FDA regulations
- FDA 510(k) obtained as warranted prior to marketing

➤ **Is it required to inform patients when they are being treated with a reprocessed SUD?**

The FDA does not require that patients be informed when one (or more) reprocessed devices are to be used.

➤ **What requirements are there for labeling medical devices 'SINGLE-USE ONLY'?**

The 'single-use' label is a designation chosen by the original equipment manufacturer (OEM), not the FDA. In a document made public on March 3, 2008, the U.S. Government Accountability Office (GAO) wrote:

"The decision to label a device as single-use or reusable rests with the manufacturer. To market a reusable device, a manufacturer must provide data demonstrating to FDA's satisfaction that the device can be cleaned and sterilized without impairing its function. Thus, a device may be labeled as single-use because the manufacturer believes that it cannot be safely and reliably used more than once, or because the manufacturer chooses not to conduct the studies needed to demonstrate that the device can be labeled as reusable."³

NOTE: OEMs do choose to label some devices as 'reusable' (e.g. surgical instruments, endoscopes) and to perform the necessary validation studies to support such labeling. In fact, some manufacturers simply shifted the labels on certain devices from "reusable" to "single-use," or provided cleaning instructions to hospitals so they could reuse SUDs.

➤ **How can devices be reprocessed multiple times and still be safe and effective?**

Medical device reprocessors must, in many cases, include in their premarket submissions data that OEMs are not required to submit,⁴ including "validation data ...regarding cleaning and sterilization, and functional performance" to show that the reprocessed device "will remain substantially equivalent...after the maximum number of times the device is used and reprocessed as intended."⁵ By contrast, OEMs, who also must validate their processes, are not required to submit such reusability or cleaning data as part of their single-use device premarket submissions.

➤ **Are there any special labeling requirements for reprocessed single-use devices?**

Reprocessed single-use device labeling must prominently and conspicuously bear the statement "Reprocessed device for single-use. Reprocessed by <insert reprocessor name>."⁶

➤ **How many times can devices be reprocessed?**

Sterilmed performs validation studies on every category of reprocessed devices to determine how many times it may be successfully reprocessed. Validation studies evaluate device compatibility with reprocessing methods, 100% ethylene oxide (EO) sterilization and confirm that devices will consistently meet all cleanliness, functionality and sterility criteria in accordance with FDA guidelines. Depending on the device, they are currently validated for one through five times each.

References

1. Guidance for Industry and for FDA Staff, Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals (August 14, 2000). <https://www.fda.gov/RegulatoryInformation/Guidances/ucm107164.htm> . Accessed September 21, 2017.
2. Medical Device User Fee and Modernization Act 2002 (MDUFMA). Approved October 26, 2002. <https://www.fda.gov/ForIndustry/UserFees/MedicalDeviceUserFee/ucm454029.htm> . Accessed September 21, 2017.
3. U.S. Government Accountability Office, GAO-08-147, Reprocessed Single-Use Medical Devices: FDA Oversight Has Increased, and Available Information Does Not Indicate That Use Presents an Elevated Health Risk.
4. MDUFMA requires that the labeling of reprocessed devices bear the reprocessor's name and state that the device was reprocessed. 21 U.S.C. § 352(v), effective January 25, 2004. The law also requires that, in many instances, reprocessors include validation data in their premarket submissions. 21 U.S.C. § 360(o)(2)(B); see also 68 Fed. Reg.38071(June 26, 2003).
5. 68 Fed. Reg. 23139 (April 30, 2003), citing 21 U.S.C. § 360(o) (emphasis added). For a full description of the validation data reprocessors must submit on a premarket basis, including more particular guidance on cleaning, functional testing, and sterilization data requirements, see CDRH, FDA, Guidance for Industry and FDA Staff: Medical Device User Fee and Modernization Act of 2002, Validation Data in Premarket Notification Submissions (510(k)s) for Reprocessed Medical Devices (Sept. 25, 2006), at 15.
6. <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/ucm109133.htm> Accessed September 21, 2017.