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# Are Your Endoscopes Validated for Reprocessing After Repair?

By Melinda Benedict, MS, CIC, CFER

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***When endoscope damage occurs and repairs are required, you can further safeguard your endoscopes and patient safety by ensuring that repairs are performed by the OEM.***

**F**lexible endoscope reprocessing continues to be a major focus in infection prevention. To minimize, and ultimately prevent, infection risk, attention is placed on following essential standards and recommendations for flexible endoscope reprocessing: pre-cleaning, leak testing, manual cleaning, visual inspection, high-level disinfection or sterilization, storage and documentation. Beyond the standards for reprocessing procedures is an important factor that is often overlooked in the discussion of flexible endoscope reprocessing—the impact of non-OEM (third-party) repairs on the scopes. It is important to be aware: Once an endoscope is repaired by a third-party repair company, the OEM can no longer validate that the endoscope can be reprocessed as designed.

## Reprocessing Validation

Medical device manufacturers validate the reprocessing instructions for their endoscopes in order to prove that, when followed, the instructions result in a device that has been effectively disinfected and is ready for use on subsequent patients. The validated reprocessing protocol typically includes cleaning, disinfection and/or sterilization in order to remove soils and inactivate microorganisms. The hazards of third-party repairs

If an endoscope is repaired by a third-party vendor, the OEM can no longer ensure that the reprocessing validation studies that were performed on the original device are still applicable, even when the instrument's instructions for use (IFU) are followed precisely.

Here's why:

- ◆ The use of after-market (non-OEM) parts and materials for endoscope repairs may affect the device's material compatibility with reprocessing protocols and chemicals.
- ◆ An OEM has no oversight of third-party repairs (which are not regulated by the FDA) nor knowledge of the repair parts and materials used by various third-party vendors. Once a scope has been modified by a third-party vendor during the repair process, the OEM can no longer guarantee

that the validated reprocessing instructions provided in the manual are still effective.

What to do:

- ◆ If you choose to use a third-party vendor for endoscope repairs, ask them directly for validation on the repaired device. You need to know if the device continues to be compatible with your facility's reprocessing methods and chemistries based on the parts, materials and repair processes the vendor uses for repairs. This is the only way to ensure that your facility is following safe and validated reprocessing instructions.
- ◆ Likewise, contact your automated endoscope reprocessor (AER) manufacturer for usage instructions and reprocessing validation for scopes repaired by third-party companies.

## The Case for OEM Repairs

Unlike third-party repair vendors, medical device manufacturers are regulated by the FDA. The FDA requires reprocessing validation data to be submitted by the OEM as part of the 510(k) premarket notification process, ensuring that a device is safe and effective for clinical use. When endoscope damage occurs and repairs are required, you can further safeguard your endoscopes and patient safety by ensuring that repairs are performed by the OEM. Repairs performed by the OEM return the device to its original factory specifications, ensuring the device is still validated for reprocessing. **[CT]**

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## Addressing the Misconceptions About Using ISOs for **Endoscope Repair**

By David Anbari

There are many misconceptions about using independent service organizations (ISOs) for endoscope repair. Perhaps the one with wide-ranging implications is the misconception that using an ISO for service will invalidate the device's 510K, instructions for use (IFU), or automated endoscope reprocessor (AER) validation.

According to the Food and Drug Administration (FDA)'s guidance, servicing a device without significantly changing its performance, safety or intended use does not require a new 510K. It follows that if the original 510K remains valid, then the device's original IFU, reprocessing instructions, and AER validation are also unaffected by using an ISO for service.

It should come as no surprise that ISOs can provide a high-quality repair. Many ISOs have already adopted and are audited to the internationally recognized ISO 13485 standard for quality manufacturing of medical devices. Although the FDA currently applies its Quality Systems Regulation (21 CFR 820) to original equipment manufacturers (OEMs), ISO 13485 is virtually identical to the FDA's regulation and requires compliance with all applicable government regulations. In fact, the two standards are so well aligned that the FDA has indicated it will adopt ISO 13485.

Objective evidence proves that hundreds of thousands of flexible scopes are repaired

by ISOs without incident. According to an ECRI study of medical device failure data reported to the FDA, less than 0.005 percent of all device failures associated with patient harm had any connection to servicing activity.

So, if repairs do not impact reprocessing efficacy, then what factors do? The FDA has researched the factors affecting quality of reprocessing and has concluded that there are three factors unrelated to repairs that impact reprocessing quality: (1) device design; (2) re-processing methodology and (3) methods for validating the cleaning and high-level disinfection and sterilization instructions.

ISOs were born decades ago so healthcare providers had a high-quality alternative to expensive original equipment manufacturer (OEM) repairs. Over time, ISOs have evolved to offer much more than quality repairs at lower prices and faster turnaround time than OEMs. ISOs provide a superior customer experience because of local, focused representatives that can assist with loaners, education, repair prevention and face-to-face customer service. The FDA agrees stating "the continued availability of third-party entities to service and repair medical devices is critical to the functioning of the U.S. healthcare system."

As a device owner, you have a right to service that device as you see fit and

a responsibility to ensure that the service activity does not adversely impact the device. We encourage you to ask your ISO for information concerning the quality of their repairs. [\[5\]](#)

*David Anbari is chairman of the board of the Association for Medical Device Service Organizations (AMDSO.org).*

#### References:

1. Refer to the FDA's guidance document titled Deciding When to Submit a 510(k) for a Change to an Existing Device Guidance for Industry and Food and Drug Administration Staff. Available online at: <https://www.fda.gov/media/99812/download>
2. Refer to the FDA's document located at <https://www.fda.gov/media/123488/download> for the specific plans.
3. There are multiple references to the ECRI study's conclusions in the FDA Report on the Quality, Safety, and Effectiveness of Servicing of Medical Devices, which can be accessed at: <https://www.fda.gov/media/113431/download>
4. Refer to the FDA's report titled "Factors Affecting Quality of Reprocessing," which can be accessed at: <https://www.fda.gov/medical-devices/reprocessing-reusable-medical-devices/factors-affecting-quality-reprocessing>
5. Refer to the FDA's report to Congress titled "FDA Report on the Quality, Safety, and Effectiveness of Servicing of Medical Devices," which can be accessed at: <https://www.fda.gov/media/113431/download>