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Statement from AMDR

Separating the Facts from the Myths about FDA Regulated, Reprocessed LigaSures™

In September 2020, a Medtronic-funded study purporting to show soiled reprocessed LigaSure devices was published in the Journal Surgical Endoscopy.[1] After an exhaustive, year-long independent review by the publisher, an important correction was added to the article, indicating that funding from Medtronic was not disclosed properly. The study authors were also found to have failed to disclose that the alleged soiled devices were not supplied by the users of the devices, but instead were procured, tested, and supplied by the study authors by Medtronic.

Medtronic has a vested interest in inhibiting the FDA regulated practice of reprocessing because every device reprocessed is one fewer device sold. These disclosure failures call into question the research integrity of the study. Failure to disclose the chain of custody for any product evaluated in a study, especially one purporting to show product soiling, is especially troubling.

Recently, misleading claims based on this data have surfaced questioning the safety of reprocessed devices. Medtronic has published a website dedicated to the promotion of the claims made in the journal article – without (again) disclosing that Medtronic funded the study and that Medtronic supplied the allegedly soiled devices.

That's doubling-down on bad science, and it's beneath Medtronic. The medical community should join in demanding that Medtronic immediately stop promoting biased research.

AMDR calls on Medtronic to remove the website and for Medtronic sales representatives to stop promoting misleading information.

Background on FDA Regulated Reprocessing

Reprocessing refers to the cleaning, testing, and repackaging of "single-use" medical devices that are regulated by the FDA or similar national regulatory authorities so they may be returned for reuse by hospitals and clinics.

[1] Chivukula, S.R., Lammers, S. & Wagner, J. Assessing organic material on single-use vessel sealing devices: a comparative study of reprocessed and new LigaSure™ devices. *Surg Endosc* **35**, 4539–4549 (2021). https://doi.org/10.1007/s00464-020-07969-8

The practice applies to over 300 types of "single-use" devices that are FDA-cleared or regulated because regulatory authorities have found the reprocessed devices to be as safe and effective as the original device. Reprocessing occurs off-site from hospitals, at AMDR-member commercial reprocessing facilities.

Use of reprocessed devices is one of the most celebrated innovations in the healthcare industry because use of these devices reduces cost, waste, and greenhouse gas emissions. Reusing devices also strengthens the supply chain by keeping these medical device assets closer to home, minimizing reliance on products shipped from overseas and the materials used to create them. Over a dozen countries have regulatory frameworks that oversee and allow regulated, reprocessed single-use devices.

These benefits have led the most prestigious hospitals in the world to embrace reprocessing to provide better care through smarter use of resources.

Today, over 11,900 hospitals and surgical worldwide centers (including the Mayo Clinic, Cleveland Clinic, all *US News & World Report* "top hospitals," and 80 U.S. military hospitals) work with AMDR-member regulated, commercial reprocessing companies and use reprocessed single-use devices. In 2023 alone, nearly 31 million devices were reprocessed and safely reused.

As Safe and Effective as Virgin Devices

Despite hundreds of millions of reprocessed devices used for over 24 years, no increased risk to patient safety has ever been identified. An exhaustive independent analysis by the U.S. General Accounting Office compared device defect rates and found no increased risk to patient safety from the use of regulated, reprocessed single-use devices. These devices must meet or exceed the same sterilization assurance level (SAL 10-6) as their new counterparts, ensuring that reprocessed devices are just as sterile as new devices used in surgery.

Some peer reviewed, published studies have found that reprocessed devices fail less than original equipment, because when a new device fails, it's discarded and removed from the reprocessing stream. Every reprocessed device is function tested prior to its return to a hospital.

Environmental and Economic Benefits: Beyond safety and efficacy, medical device reprocessing provides significant environmental and economic benefits. Reprocessed devices help reduce medical waste by diverting thousands of tons of devices from landfills each year. By reprocessing devices, healthcare providers can significantly lower their costs, leading to more efficient allocation of resources without compromising patient outcomes.

Numerous peer reviewed life cycle assessments find that reprocessed devices reduce greenhouse gas emissions by, on average, 41% compared to the use of virgin devices.

The Association of Medical Device Reprocessing firmly stands by the safety, efficacy, and environmental benefits of reprocessed medical devices. We urge healthcare providers to rely on independently verified data, regulatory guidance, and clinical evidence when making decisions regarding the use of reprocessed devices. The misleading claims from competitors should be viewed with skepticism, as they prioritize financial gain over patient safety, cost-effectiveness, and sustainability.

Reprocessed devices are a proven, safe, and innovative solution that contribute to better patient care, reduce healthcare costs, and support a sustainable future. As an organization dedicated to advancing reprocessing practices, AMDR remains committed to ensuring that healthcare providers can continue to rely on reprocessed devices with confidence.

About AMDR

The Association of Medical Device Reprocessors (AMDR) is the global trade association for the regulated, commercial "single-use" device reprocessing and remanufacturing industry. Founded in 1997, AMDR has advocated for reprocessing and remanufacturing as an important healthcare strategy that helps hospitals and healthcare providers increase quality, reduce costs, waste, and emissions, and strengthen the supply chain.

AMDR protects the interests of its members in regulation, legislation, and standard-setting. AMDR members include Arjo ReNu Medical, Innovative Health, Medline Renewal, Stryker Sustainable Solution, Sustainable Technologies (a Cardinal Health Business), and Vanguard AG. Having played a key role in the establishment of the reprocessing industry, AMDR continues to push the global medical technology industry, leading the way for remanufacturing to play a defining role in the evolution of new device technologies.

For more information, please visit www.ResponsibleReuse.org or contact info@amdr.org.

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