Action Alert

Topic	Misleading Promotional Tactics by Medtronic Regarding Vessel-Sealing Devices
Market Area	Hospitals & Health Systems; Surgeons; Supply Chain; Compliance
Product(s)	Medtronic LigaSure™ vessel-sealing devices and FDA-regulated, commercially reprocessed equivalents
Date	March 6, 2026

Issues

Issue 1: Surgeon-targeted advertising disparaging reprocessed devices. Medtronic ran a full-page advertisement in *General Surgery News* asserting that testing showed "critical differences" between original and reprocessed LigaSure vessel-sealing devices. The advertisement directs readers to a "full study" supporting its claims and promotes the supposed advantages of Medtronic's devices. The claims rely on alarming visuals and language to raise doubts about the safety of FDA-regulated reprocessed "single-use" devices.

Issue 2: Use of an industry-funded "study" with disclosure and methodological failures. The advertisement promotes a 2020 study that purported to detect organic material on reprocessed vessel-sealing devices. However, after a year-long investigation, the publisher required the authors to issue a correction clarifying that Medtronic funded the study and supplied the allegedly contaminated devices, rather than sourcing them directly from hospitals or end users. The authors had not properly disclosed these facts.

This conduct raises serious concerns about chain-of-custody, study design, and the independence of the research. Nonetheless, Medtronic continues to promote the study—using its original, pre-correction citation—in marketing materials aimed at surgeons.

Issue 3: Long-term pattern of misleading, anti-reprocessing marketing. Medtronic has used this study to suppress reprocessor competition since at least September 2024, when AMDR publicly challenged the company to stop promoting it on its website. AMDR has issued Action Alerts and cease-and-desist letters alleging similar conduct by Medtronic involving other FDA-regulated reprocessed SUDs, including ClosureFast™ catheters and Nellcor™ pulse oximeter sensors.

Beyond reprocessing, Medtronic recently lost a major lawsuit when a U.S. federal jury found it had unlawfully monopolized the vessel-sealing device market, again to suppress competition with the LigaSure. The jury ordered Medtronic to pay nearly $382 million in damages.

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Technical Background

- **Reprocessed SUDs are safe.** The FDA requires reprocessed SUDs to meet the same safety and performance standards as original devices. A considerable body of research—which is not industry-funded and typically sources devices from hospitals directly—has consistently demonstrated that reprocessed SUDs are safe under this framework.
- **Comparative advertising must be supported by reliable scientific evidence.** FDA labeling rules (21 C.F.R. § 801.6) and FTC regulations prohibit false or misleading comparative claims between products. Advertising claims about safety or superiority must rely on competent, reliable, and independent scientific evidence.

Recommendations

1. **Educate staff.** Ensure that clinical and procurement staff understand how proven regulatory frameworks ensure that reprocessed SUDs are as safe and effective as any other medical device. Refer to the extensive body of independent evidence validating this. Please see AMDR's Technical Tip about navigating clinician hesitancy and safety concerns for more information and resources.
2. **Ask for independent evidence.** If a manufacturer claims superiority over reprocessed devices, request peer-reviewed studies conducted by independent investigators. Carefully scrutinize claims that cast doubt on the safety or efficacy of products that have been cleared by the FDA, especially when based solely on internal or industry-funded research.
3. **Verify regulatory status.** Confirm whether products referenced in marketing materials have been cleared through appropriate regulatory pathways. FDA-regulated reprocessed SUDs must undergo extensive validation to demonstrate equivalent safety and performance standards as original devices.
4. **Maintain competitive sourcing.** Hospitals should not allow misleading or biased marketing campaigns to limit access to cost-saving, environmentally beneficial reprocessed SUDs. Please see AMDR's Hospital SUD Reprocessing Policy Template and other resources for hospitals to maximize the benefits of your reprocessing program.
5. **Document and report misleading claims.** If you witness unsupported marketing claims about the safety of reprocessed devices—or other common anti-reprocessing tactics—by medical device suppliers, document those materials and share them with hospital compliance leadership. AMDR also welcomes reports of such conduct.

For More Information

Please contact your AMDR-member commercial reprocessing partner. If you are aware of anti-reprocessing marketing, please write to info@amdr.org. If requested, your anonymity will be honored.