

Action Alert

Topic	False and Misleading Claims by Medtronic Regarding Reprocessed ClosureFast™ Catheters
Market Area	Hospitals & Health-Systems; Service-Line Leaders; Supply Chain; Compliance
Product(s)	ClosureFast™ venous ablation catheters and FDA-regulated, commercially reprocessed equivalents
Date	October 23, 2025

Issue

Issue 1: Anti-reprocessing campaign targeting catheters. Medtronic released an online video that disparages FDA-regulated, commercially reprocessed ClosureFast-type catheters. The video encourages patients to be suspicious of reprocessed devices, promotes misleading safety claims based on an unpublished, self-funded “study,” and equates reprocessed devices to “used cars with no guarantee.”

Issue 2: Unlawful comparative claims. The study and video advance superiority/sterility assertions about Medtronic’s SUD catheters versus 510(k)-cleared reprocessed alternatives without competent, reliable, independent evidence—potentially violating the FD&C Act (misbranding), Sections 5 & 12 of the FTC Act, and the Lanham Act. AMDR has sent a [cease-and-desist](#) (C&D) to Medtronic regarding this situation.

Issue 3: Contradiction of peer-reviewed science and regulatory clearance. Medtronic (via Covidien) itself obtained 510(k) clearance for a reprocessed ClosureFast catheter in 2013, and peer-reviewed data report equivalence of reprocessed and original—demonstrating that reprocessed ClosureFast catheters meet FDA safety requirements.

Issue 4: Pattern of conduct. AMDR has already sent a C&D to Medtronic [in June 2025](#) in response to similar misleading claims around Nellcor™ sensors and issued an [Action Alert](#) to warn hospitals. Those materials documented misbranding/superiority claims, similarly built on non-peer-reviewed, internal papers.

Technical Background

- **Why the claims are unlawful:** FDA labeling rules (21 C.F.R. § 801.6) prohibit false/misleading comparative claims; FTC requires substantiation and clear conflict-of-interest disclosures; the Lanham Act bars deceptive competitor-disparaging ads—

including innuendo and omissions. The video relies on undisclosed, biased research and inflammatory visuals, failing these standards.

- **What the evidence says:** [Peer-reviewed literature](#) shows reprocessed ClosureFast catheters performed equivalent to originals, and [Covidien's own 510\(k\)](#) confirms FDA has cleared a reprocessed ClosureFast device as meeting its strict safety requirements—facts Medtronic's ad downplays or omits.

Moreover, the safety and performance of reprocessed devices is well-established due to strong regulatory frameworks, and confirmed by decades of research (please see AMDR's resource on the [safety of reprocessed devices](#) for more information).

- **Two C&Ds in five months:** AMDR's June 2025 C&D and Action Alert addressed Medtronic's misuse of "remanufactured" vs "reprocessed" designations on Nellcor™ sensors and unsubstantiated superiority claims; AMDR believes some of Medtronic's promotions were removed after that action.

Recommendations

1. **Do not rely on the video's claims.** Treat the ClosureFast anti-reprocessing video as marketing that lacks independent substantiation and conflicts with FDA history and peer-reviewed data. Disregard or route to Compliance/Value Analysis for review.
2. **Ask for evidence—then verify.** If presented with superiority or cleanliness claims, demand peer-reviewed, third-party studies and check FDA records (e.g., prior 510(k) for **reprocessed** ClosureFast—K131614). Decline claims backed only by internal, unpublished papers.
3. **Maintain competitive sourcing.** Do not allow fear-based advertising to restrict access to cost-saving, FDA-regulated, commercially reprocessed products. To learn more and protect your reprocessing program, please see AMDR's [resources for hospitals](#), including our [Hospital SUD Reprocessing Policy Template](#).
4. **Document and report.** Save links/screens of the video, sales emails, presentation decks, and any other hospital-facing materials echoing these claims. Share with your Compliance team, and [report anti-reprocessing conduct](#) to AMDR for potential referral to appropriate regulatory authorities such as FDA and FTC.
5. **Brief clinical teams.** Reinforce that FDA-regulated, commercially reprocessed catheters are held to the same safety/performance standards as new devices; peer-review and FDA history contradict the video's message. For more guidance on how to navigate discussions of reprocessing safety, please see AMDR's [Technical Tip](#).

For More Information

Please contact your AMDR-member commercial reprocessing partner, or write to info@amdr.org. If requested, your anonymity will be honored.