

Action Alert

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Торіс	Reporting OEM Anti-Reprocessing Interference Following Innovative Health v. Biosense Webster Verdict
Market Area	Hospitals, Health-System Supply Chains & Commercial Reprocessors
Product(s)	All regulated, commercially reprocessed single-use medical devices (SUDs)
Date	June 30, 2025

Issue

Issue I: A federal jury found Biosense Webster (BSW) engaged in unlawful tying and unlawful monopolization under federal and state law. Evidence showed BSW revoked or at least threatened to revoke case support when hospitals used reprocessed devices, deployed forced obsolescence strategies such as installing chips/firmware BSW devices to block reprocessing, and hoarded used devices to cut off reprocessor supply. Please see <u>AMDR's</u> <u>statement</u> about the case for more information.

Issue 2: Similar misconduct by BSW—or any other OEM—may persist despite the verdict and affects health systems in the U.S., Canada, the UK, EU, and other jurisdictions. AMDR is therefore launching a *Medical Device Reprocessing Interference Incident Intake Form* (click here to download) to document ongoing or new anti-competitive behaviors.

Technical Background

- The verdict confirms that anti-reprocessing tactics can constitute unlawful tying and monopolization. These tactics undermine hospital efforts to lower cost, waste, emissions, and to strengthen supply-chain resilience through regulated, commercially reprocessed devices.
- AMDR will compile incident reports and supply anonymized or full evidence—as indicated on the form—to the relevant legal and regulatory authorities.

Recommendations

1. **Report interference immediately.** Please <u>click here</u> to download AMDR's *Medical* Device Reprocessing Interference Incident Intake Form and submit it with supporting evidence to <u>info@amdr.org</u>.

- 2. **Capture evidence.** Save e-mails, console screenshots, software-update notices, rep communications, shipping records, or any other evidence that demonstrate coercive anti-reprocessing tactics. The intake form outlines the key documents to attach.
- 3. **Escalate internally.** Notify your compliance, legal, and procurement teams, as well as clinical staff, of any OEM conduct that limits access to reprocessed devices.
- 4. **Maintain procurement independence.** Continue sourcing regulated, commercially reprocessed devices; do not allow threats of withdrawn support to dictate clinical or procurement choices.
- 5. **Stay informed.** AMDR will continue to update its member companies, their customers, and the wider healthcare, medtech, and regulatory communities on follow-up actions.

For Further Information

Contact your AMDR-member commercial reprocessing partner, or write to <u>info@amdr.org</u>. If requested, your anonymity will be honored.