Action Alert

Topic	Permanent Injunction in *Innovative Health v. Biosense Webster*
Market Area	U.S. Hospitals, Health System Supply Chains, Compliance, and Commercial Reprocessors
Product(s)	All regulated, commercially reprocessed single-use medical devices (SUDs)
Date	August 28, 2025

Issue

Issue 1: The U.S. District Court for the Central District of California entered a permanent injunction yesterday after a jury found Johnson & Johnson MedTech's Biosense Webster unit liable for unlawful tying, monopolization and attempted monopolization. The injunction issues non-financial penalties separate from the $442 million that was already awarded to Innovative Health.
Issue 2: The injunction prohibits Biosense Webster from conditioning clinical support or system access to the use of their own devices; and from discriminating against customers that use reprocessed alternatives. The Court found that this tying practice locks-in customers and suppresses competitor reprocessors.
Issue 3: Biosense Webster is prohibited from deploying new blocking technologies (e.g., EEPROM "chips") designed to prevent devices reprocessed by Biosense Webster's competitors from functioning.
Issue 4: Biosense Webster is prohibited from hoarding used devices that it does not reprocess. The trial revealed that Biosense engaged in this practice explicitly to prevent reprocessors from obtaining source materials.
Issue 5: The Court requires semi-annual compliance reports and allows Innovative Health to establish an independent hotline to collect non-compliance complaints. AMDR has previously issued an Action Alert urging hospital staff to report anti-reprocessing practices.

Technical Background

- Innovative Health reprocesses electrophysiology catheters compatible with Biosense Webster's CARTO™ 3 mapping platform. Evidence and testimony entered during the trial showed Biosense Webster revoked case support from hospitals using Innovative Health's reprocessed products, deployed EEPROM chips to prevent reprocessing, and hoarded used catheters to choke reprocessor supply—conduct the jury deemed anticompetitive.
- The jury determined Biosense Webster's tying scheme and blocking technologies harmed competition; the Court held that monetary damages alone cannot restore market choice and therefore ordered injunctive relief to "unfetter locked-in customers" and "restore competition."
- The order targets three abuse categories: (1) tying of clinical support, (2) anti-reprocessing technology, and (3) anticompetitive collection of used devices. Ancillary provisions create compliance, transparency, and enforcement mechanisms.
- The injunction is in effect for five years.

Recommendations

1. **Review OEM contracts and policies.** Eliminate any provisions tying clinical support or service to exclusive use of new OEM devices.
2. **Be vigilant of blocking technology.** Document firmware updates, error messages, or console lockouts that might signal prohibited blocking technology. Preserve logs and screenshots.
3. **Report violations promptly.** Continue using AMDR's *Reprocessing Interference Incident Intake Form* (click here to download) to document suspected breaches; include emails, console logs, and service notes.
4. **Sustain competitive sourcing.** Maintain or expand purchasing of FDA-regulated, commercially reprocessed devices from AMDR member companies; the injunction strengthens your legal footing against OEM push-back.
5. **Stay informed.** AMDR will continue to circulate updates and guidance about how hospitals can protect their supplies and purchasing independence. We will summarize reported incidents for submission to the FTC, FDA, and other regulatory bodies.

For More Information

Contact your AMDR-member commercial reprocessing partner or visit our website for more information, news coverage, and guidance about this landmark case.