Action Tip

Topic	Addressing Misinformation Regarding Patient Informed Consent and FDA-Regulated, Commercially Reprocessed Devices
Market Area	U.S. Hospital Legal/Compliance, Supply Chain & Risk-Management Teams
Product(s)	All FDA-regulated, commercially reprocessed single-use devices (SUDs)
Date	August 22, 2025

Issue

Issue 1: No U.S. state requires hospitals to obtain patient informed consent before using FDA-regulated medical devices, including commercially reprocessed SUDs—yet some original equipment manufacturers (OEMs) claim otherwise.
Issue 2: Some OEM sales representatives have historically disseminated false or misleading information designed to instill uncertainty about reprocessing and suppress hospital adoption.
Issue 3: Informed-consent rules under 21 C.F.R. Part 50 apply only to investigational or experimental devices; reprocessed devices are *neither*. They are regulated by the FDA as "substantially equivalent" to new devices.
Issue 4: Since 2010, OEM-backed bills attempting to mandate informed consent for reprocessed devices have been introduced in multiple states—and rejected every time.

Technical Background

- Commercial reprocessing is FDA-regulated manufacturing. Reprocessors must meet exactly the same Quality System, pre-market clearance (510(k)), and post-market surveillance obligations as OEMs.
- Once cleared, commercially reprocessed devices are legally *"as safe and effective as a new device,"* per FDA testimony and guidance.
- Because reprocessed devices are not investigational or experimental, *no federal or state informed-consent requirement exists.* Requiring consent would mislead patients by implying lower safety.

Recommendations

1. **Correct the record.** Distribute this Alert to clinicians, Value Analysis, procurement, and risk-management staff to clarify that informed consent is *not* required for FDA-regulated, commercially reprocessed devices.
2. **Challenge OEM misinformation.** Request written citations for any claim that patient consent is legally mandated; escalate unsupported claims to Compliance and AMDR.
3. **Strengthen transparency policies.** Update vendor-access and sales-rep credentialing policies to discipline or bar representatives who disseminate false compliance information.
4. **Promote competitive sourcing.** Continue or expand purchasing of FDA-regulated, commercially reprocessed devices to reduce costs and carbon emissions, strengthen supply chains, and resist OEM-driven fear tactics.
5. **Educate clinicians & patients.** Emphasize that reprocessed devices meet identical FDA safety and performance requirements as new devices (and often exceed them), reinforcing trust in hospital reprocessing programs.

For Further Information

Contact your AMDR-member commercial reprocessing partner.

If you are aware of false and misleading claims about informed consent requirements for reprocessing programs, please write to info@amdr.org. If requested, your anonymity will be honored.