Action Alert

Topic	Misleading "Off-Label Use" Claims by Verathon
Market Area	U.S. Hospitals & Health Systems
Product(s)	Verathon® GlideScope® and GlideRite® single-use devices (SUDs) and FDA-regulated, commercially reprocessed equivalents
Date	September 9, 2026

Issue

Issue 1: Verathon is telling customers that use of reprocessed devices constitutes "off-label use."

AMDR is aware of a letter Verathon circulated to healthcare customers regarding reprocessing of its GlideScope® and GlideRite® SUDs. Verathon states that it has not "partnered with, nor authorized, any third party to reprocess its single-use products" and claims that using reprocessed variants of these products constitutes "off-label use."

This characterization misrepresents the regulatory status of commercially reprocessed SUDs. It suggests that buy purchasing and using a reprocessed SUD, a hospital is simply "reusing" the device, thereby disregarding Verathon's original SUD labeling. In actuality, FDA regulation recognizes reprocessed SUDs *as SUDs*—separate products which are lawfully manufactured, labelled, and marketed by a third-party reprocessor *for an additional single use*.

Issue 2: Verathon uses its own lack of authorization and validation to raise unsubstantiated safety concerns about third-party reprocessing.

Verathon warns customers of potential device failure and cross-contamination and emphasizes that it "cannot validate or ensure the effectiveness of any reprocessing technique." Verathon provides no evidence for these claims, which contradict the established body of evidence demonstrating the safety and efficacy of reprocessed SUDs.

Issue 3: Verathon suggests that use of reprocessed SUDs may affect technical support, raising potentially serious ethical and competitive concerns.

The letter states that Verathon "may not be able to provide technical support or system troubleshooting" when hospitals use reprocessed devices with Verathon monitors and cables. AMDR does not know whether Verathon has actually denied support to a customer because it used lawfully reprocessed devices.

Nevertheless, *hospitals should take such language very seriously*. OEM restrictions on clinical or technical support, software or platform access, warranties, and other services are well-recognized forms of anti-reprocessing interference that have been reported by AMDR members and successfully challenged in court.

Technical Background

- **The FDA, not the OEM, regulates the reprocessing of SUDs.** The FDA regulates third-party SUD reprocessors as manufacturers and holds them to the same or greater regulatory requirements. These include premarket review, quality systems, performance testing, and postmarket obligations, in addition to validation for the permitted number of reprocessing cycles. Congress and FDA created this system specifically to ensure that reprocessed SUDs are as safe and effective as any other FDA-regulated product.
- **Use of reprocessed SUDs is not "reuse," and the SUD label does not prohibit reprocessing.** Reprocessed SUDs not being reused, but are manufactured, labeled, and marketed by a third-party reprocessor for an *additional single use*. The FDA expressly states that the SUD label—and the absence of reprocessing validation by the OEM—"does not mean the device is unable to be reprocessed."
- **Conditioning support on non-usage of reprocessed SUDs raises serious ethical and competitive concerns.** Some OEMs resort to unethical practices to prevent hospitals from using reprocessed SUDs—including tying case support to exclusive purchasing of OEM devices. At least one federal court has found that this violates the law, and prohibited a major OEM from this and other discriminatory practices.

Recommendations

1. **Do not accept "off-label" assertions at face value.** If an OEM claims that using a regulated reprocessed device constitutes "off-label use," ask it to provide the regulatory basis for that assertion in writing. Verify that the reprocessed product's FDA clearance, labeling, and intended use with your reprocessing partner. *Do not assume that a third-party reprocessor needs the OEM's authorization to lawfully reprocess a device.*
2. **Ask for evidence supporting safety claims.** If an OEM raises contamination, performance, or other safety concerns about regulated reprocessed SUDs, request substantiating evidence. If evidence is provided, verify that it is independently peer-reviewed and not industry-funded or misleading, as has occurred on multiple occasions.
3. **Document and report any threat to support or system access.** Preserve any written communications in which a supplier states or implies that using reprocessed SUDs will affect clinical support, software or platform access, warranties, or other services. Ask that any such policy be provided in writing. Report any such communications to AMDR and to internal supply chain, compliance, or legal departments.
4. **Protect competitive sourcing.** Evaluate purchasing decisions based on hospital needs. Consider using AMDR's free resources for hospitals—including our SUD Reprocessing Policy Template and Procurement Checklist—to protect your reprocessing program.

For More Information

Please contact your AMDR-member reprocessing partner. If you are aware of misleading "off-label use" claims, threatened or actual support restrictions, or other anti-reprocessing conduct, please write to info@amdr.org. If requested, your anonymity will be honored.