

Technical Tip

Topic	Clinician hesitancy and safety concerns about regulated, commercially reprocessed single-use devices (SUDs)
Audience(s)	Healthcare professionals (including clinicians, nurses, techs, infection prevention, value analysis), regulatory officials, researchers, and advocates
Product(s)	All regulated, commercially reprocessed SUDs
Date	September 19, 2025

Issue

Issue 1: Some clinicians are hesitant to use commercially reprocessed SUDs due to safety concerns, despite decades of data, oversight, and routine hospital use demonstrating equivalent safety and performance to original SUDs. This is a common barrier to the adoption of cost-, emissions-, and waste-reducing reprocessing programs.

Issue 2: The “single-use” label is sometimes assumed to mean a device cannot be safely reprocessed, despite FDA regulation and guidance clarifying otherwise.

Issue 3: Regulated commercial reprocessing of SUDs is sometimes conflated with unregulated in-house reuse, which lacks oversight and should be discouraged.

Technical Background

- **Reprocessors are manufacturers.** Commercial reprocessors must meet the same safety and performance requirements as original equipment manufacturers (OEMs).
- **Reprocessed and original SUDs are clinically indistinguishable.** Reprocessed SUDs undergo extremely rigorous premarket review and must demonstrate substantial equivalence to legally marketed devices in intended use, safety, and performance—including at the maximum number of permitted cycles.
- **Decades of evidence and routine use demonstrate safety.** Extensive peer-reviewed research and government inquiry have consistently found no increased patient risk versus original SUDs. Thousands of hospitals on multiple continents use regulated reprocessed SUDs as standard care.
- **“Single-use” label does not imply that a device cannot be reprocessed.** Regulatory authorities permit reprocessing of a SUD when adequate evidence demonstrates safe single-patient use after validated reprocessing; reprocessed SUDs are still cleared and labeled for “single-use” so that the end-user knows not to

reuse/reprocess the devices themselves, but that label does not preclude commercial reprocessing. According to the FDA, a device may bear the single-use label simply because the OEM chose not to conduct a cleaning validation.

- **Unregulated reuse is discouraged.** In jurisdictions without robust regulation or commercial reprocessing, reuse of SUDs within hospitals lacks oversight and quality controls and should not be conflated with regulated reprocessing.

Recommendations

1. **Reinforce confidence in regulation.** Communicate that, when regulated by the FDA or comparable national authorities, commercially reprocessed SUDs are held to the same safety, performance, and quality standards as every other device.
2. **Explain the evidence.** Point to the considerable [body of research](#), [major government reports](#), and decades of successful use in hospitals that have consistently demonstrated that [reprocessed SUDs are safe](#).
3. **Clarify the “single-use” label.** Explain that, according to [FDA guidance](#), the “single-use” label does not mean a device cannot be safely reprocessed. Often, it simply means the OEM made the decision not to perform the necessary validation testing to demonstrate that it can be.
4. **Reinforce safe reprocessing.** Ensure your facility adheres to optimal collections processes, traceability, and other [best practices](#).
5. **Avoid conflation with reuse.** Distinguish third-party reprocessing from in-house reuse; use only regulated reprocessed SUDs and discourage unregulated practices.
6. **Report misinformation.** Some OEMs [interfere with reprocessing](#) by, among other practices, making misleading claims about the safety of reprocessed SUDs. Please see our other [Action Alerts and Technical Tips](#) for common examples of such claims and how to [report them to AMDR](#).

For More Information

Contact your AMDR-member commercial reprocessing partner, write to info@amdr.org, or visit our [online resource](#) about reprocessing safety.