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Regulated Medical Device Reprocessing and Fair Contracting Policy

Using regulated, commercially reprocessed “single-use” devices (SUDs) is one of the most impactful single actions a health system can take to reduce costs, greenhouse gas emissions, and vulnerability in its supply chain.

Yet, even though over 9,000 hospitals worldwide enjoy the benefits of reprocessing, many do not yet have official policies supporting their hospital’s right to use of reprocessed devices. This is necessary, as some device vendors deploy contractual and technical practices that serve no other purpose than to restrict hospitals from using reprocessed devices. In the U.S., a federal court has found some such practices to be [illegal](#).

AMDR has created the attached “Right to Reprocess” template to help healthcare leaders formalize their commitment to using reprocessed SUDs. It combines three objectives—cost savings, sustainability, and protection against anti-competitive practices—into one policy you can adopt system-wide and reference in every contract and purchasing decision.

How to use it:

1. Delete this cover page before final publication or distribution.
2. Fill in the information specific to your health system or facility. If your facility is in the EU or UK, regulated SUD reprocessing is known as remanufacturing, so replace terms as necessary.
3. Review Section 4 (“Fair Contracting & Anti-Interference Rules”) with your legal counsel or contracting office to be sure the remedies and reporting pathways align with your existing vendor-management policies.
4. Review Section 6 and determine who at your organization should manage complaints.
5. Circulate the completed policy for executive, clinical, supply-chain, and sustainability leadership review and signatures.
6. Attach the signed policy as an exhibit (or cite it by reference) in new capital-equipment, devices, and other procurement contracts.
7. Provide a copy to every vendor representative who enters your clinical areas.

The language has been drafted to stand on its own, but we encourage you to add site-specific requirements as needed. The more clearly your organization signals its expectations, the less room there is for confusion—or for practices that undermine regulated, cost- and emissions-cutting reprocessing.

[Organization]’s Regulated Medical Device Reprocessing and Fair Contracting Policy

1. Purpose & Scope

- 1.1. By agreeing to work with [Organization], (hereafter “organization”), [Vendor] (hereafter “vendor”) agrees to never interfere with the organization’s commitment to cut greenhouse-gas emissions and waste through maximum use of regulated, commercially reprocessed “single-use” devices (SUDs), nor with the organization’s right to choose such products through any contractual or technical barrier.

Embedding these principles in every purchase order, service agreement, and clinical workflow strengthens our supply chain, frees budget for patient care, and advances our sustainability efforts.

2. Reprocessing Principles

- 2.1. The organization is committed to finding safe and effective ways to reduce cost, waste, greenhouse gas emissions while building more resilience into the supply chain.
- 2.2. The organization prioritizes the purchase of reusable or regulated, commercially reprocessed SUDs over disposable SUDs, whenever possible. We will maximize opportunities to reprocess SUDs and buy back reprocessed devices to support reuse and resource conservation.
- 2.3. All original equipment manufacturers (OEMs) of SUDs that wish to sell products to the organization are informed that the organization intends to make optimal use of the devices we acquire, and that reprocessing is an important piece of this effort. Vendor acknowledges that the organization will reject any contractual term or technical measure that impedes the hospitals right to collect devices for reprocessing or to use reprocessed SUDs (see §4).
- 2.4. The organization prioritizes reprocessing over recycling, given its widely accepted higher ranking in the waste reduction hierarchy (reduce, reuse, recycle—in that order—because recycling consumes considerable energy and other environmental inputs). Nevertheless, to avoid landfill and incineration as much as possible, the organization will seek services aimed at reducing waste in a sustainable manner (such as by recycling, OEM take-back programs, etc.) from SUDs that have reached their end of life or are not able to be reprocessed.
- 2.5. The vendor has reviewed this policy standard and agrees to abide by its terms.

3. Evidence-Based Product Evaluation

- 3.1. The organization believes in science-based decision-making and thus, as the organization evaluates the cost, sustainability and other benefits of products, it will rely on credible measures and reports for their ability to reduce costs, greenhouse gas emissions and improve supply chain resilience. The organization prioritizes in its evaluation of products reports from suppliers that include the total carbon footprint of their products and/or peer reviewed Life Cycle Assessments. We will track annual cost savings, waste diversion, and carbon reductions and will report these metrics to executive leadership.

4. Fair Contracting & Anti-Interference Rules

- 4.1. All vendors and their field representatives are hereby notified that any interference—technical, contractual, or verbal—with the organization’s reprocessing program is prohibited. Vendors are

expected to continue their practices as usual, including the technical support of clinical cases, and are not to interfere in any way with the organization's reprocessing program, including engaging in any activity that undermines the reprocessing program and its financial savings.

4.2. The organization specifically forbids vendors from engaging in the following activities:

4.2.1.1. Conditioning clinical support, software access, warranties, pricing, or other services on exclusive use of Vendor-branded devices.

4.2.1.2. Implementing new *kill-chips*, encryption keys, or other hardware/firmware "updates" intended to disable reprocessed SUDs.

4.2.1.3. Retaining, withholding, or destroying used devices that the vendor does not have clearance to reprocess themselves, for the purpose of preventing reprocessing by competitors.

4.3. Breach of any item above constitutes material default; the organization may terminate the agreement, seek damages, and report the violation to the Federal Trade Commission or other authorities.

4.4. *Legal precedent:* In *Innovative Health LLC v. Biosense Webster, Inc.*, a jury in a federal court found the above activities to be in violation of state and federal antitrust and monopoly statutes, and the judge awarded over \$442 million in damages, and issued a five-year injunction enjoining a major OEM from continuing them (see amdr.org/courtcase).

5. Vendor Conduct & Communications

5.1. Per §3.1, OEMs of SUDs or their representatives are not to disseminate at our facility white papers or other literature, including that which has not gone through peer review, that uses false or questionable claims regarding the safety or functionality of reprocessed SUDs. For example, industry funded studies that do not explain the chain of custody of reprocessed SUDs studied, are not to be disseminated.

6. Incident Reporting & Remedies

6.1.1. Staff who observe or suspect vendor interference with the organization's goals should document the incident (date, device, people involved), notify supply chain, legal, or other relevant departments within 24 hours, and report the incident to either of the following:

6.1.1.1. For general reports of anti-reprocessing conduct: Reprocessing Interference Reporting Form (see amdr.org/action-alerts).

6.1.1.2. For potential violations of the *Innovative Health LLC v. Biosense Webster, Inc.* ruling: AMDR's Anonymous Reporting Hotline (report.syntrio.com/reprocessing; 855-893-7002).

7. Non-retaliation: Employees reporting in good faith are protected from reprisals.

Signatures

[President, CEO, or other C-Suite Equivalent]

Date:

[Chief Medical Officer or equivalent]

Date:

[Chief Supply Chain Officer or equivalent]

Date:

[Chief Sustainability Officer or equivalent]

Date: