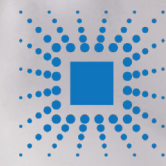




CHARME

Collaborative for Healthcare Action
to Reduce MedTech Emissions



SUSTAINABLE
PURCHASING
LEADERSHIP
COUNCIL

CHARME PLAYBOOK

EXPANDING SINGLE-USE DEVICE REPROCESSING IN HEALTHCARE

ABOUT CHARME



CHARME, the Collaborative for Healthcare Action to Reduce MedTech Emissions, is an initiative convening health systems, medical device and equipment suppliers, distributors, GPOs, and other key industry stakeholders to define, implement, and champion best practices to reduce emissions from the MedTech supply chain.

Learn more at sustainablepurchasing.org/CHARME.

CHARME is Convened by



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Advised by



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WHO SHOULD USE THIS GUIDE

This playbook is designed for health care leaders who want to:

- Reduce supply chain and device costs
- Advance sustainability, waste reduction, and Environmental, Social, and Governance (ESG) goals
- Implement or expand single-use device reprocessing programs

Ideal audiences include:

- Supply chain, value analysis, and procurement leaders
- Sustainability and ESG teams
- Health system executives and finance leaders

HOW TO USE THIS PLAYBOOK

TO GAIN BUY-IN:

- The **Background, Key Terms, and Frequently Asked Questions** appendixes support greater awareness, knowledge, and confidence among stakeholders less familiar with single-use device reprocessing.
- The **Potential for Cost Savings** and **Sustainability Impact and Emissions Reductions** sections make a persuasive case for reprocessing that can be shared with organizational leaders.

TO INITIATE REPROCESSING:

- The **Quick Start Guide** outlines a step-by-step approach to launch or grow a reprocessing program.
- The **Contracting Guidance, Vendor Partnership and Program Implementation, and Operational and Facility Considerations** sections offer practical guidance on setting up a program for success during contracting and building relationships with vendors.

TO IMPROVE PROGRAM PERFORMANCE:

- The **Stakeholder Engagement** and **Training and Communication** sections offer insights on developing clinician champion programs and building cross-functional governance structures to bring oversight, guidance, advocacy, and visibility to reprocessing programs.
- The **Program Maturity Assessment** allows organizations to benchmark their progress and assess opportunities for improvement.

01

EXECUTIVE SUMMARY

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EXECUTIVE SUMMARY

Adopting and expanding single-use device (SUD) reprocessing is a proven strategy for health systems to advance sustainability and financial performance. Reprocessing reduces waste, lowers purchasing cost, and decreases the environmental footprint of medical devices used in care delivery.

Single-use device reprocessing encompasses devices from many clinical areas, including cardiovascular, orthopedic, general surgery, laparoscopic, and patient care items. FDA-cleared reprocessed devices must demonstrate “substantial equivalence” to new products through rigorous cleaning, inspection, functional testing, and quality controls.

This playbook—authored by experts and practitioners from medical device manufacturers, third-party reprocessors, health systems, and industry-leading NGOs—is designed to guide health care leaders to grow and strengthen their reprocessing programs.

It outlines practical steps for implementing or expanding reprocessing programs, highlights regulatory and clinical considerations, and shares best practices for engaging clinicians, supply chain teams, and suppliers.

Key Takeaways

- **Proven Cost Savings**—Reprocessing reduces device purchasing costs by 30-50% (Association of Medical Device Reprocessors ([AMDR website](#), 2025)—generating significant savings for health systems without compromising patient care.
- **Emissions Reductions**—Diverting single-use devices from landfills and purchasing reprocessed devices helps health systems and MedTech companies meet emissions reductions goals.
- **Regulatory Assurance**—Reprocessed devices are FDA-regulated, tested, and validated for safety and performance, providing confidence for clinicians and supply chain leaders alike.
- **Operational Integration**—Success depends on clear workflows for device collection, clinician engagement, and supply chain alignment to maximize savings and sustainability outcomes.
- **Strategic Value**—Reprocessing programs not only cut costs and reduce waste but also demonstrate leadership in environmental stewardship, positioning health systems as innovators in sustainable care delivery.

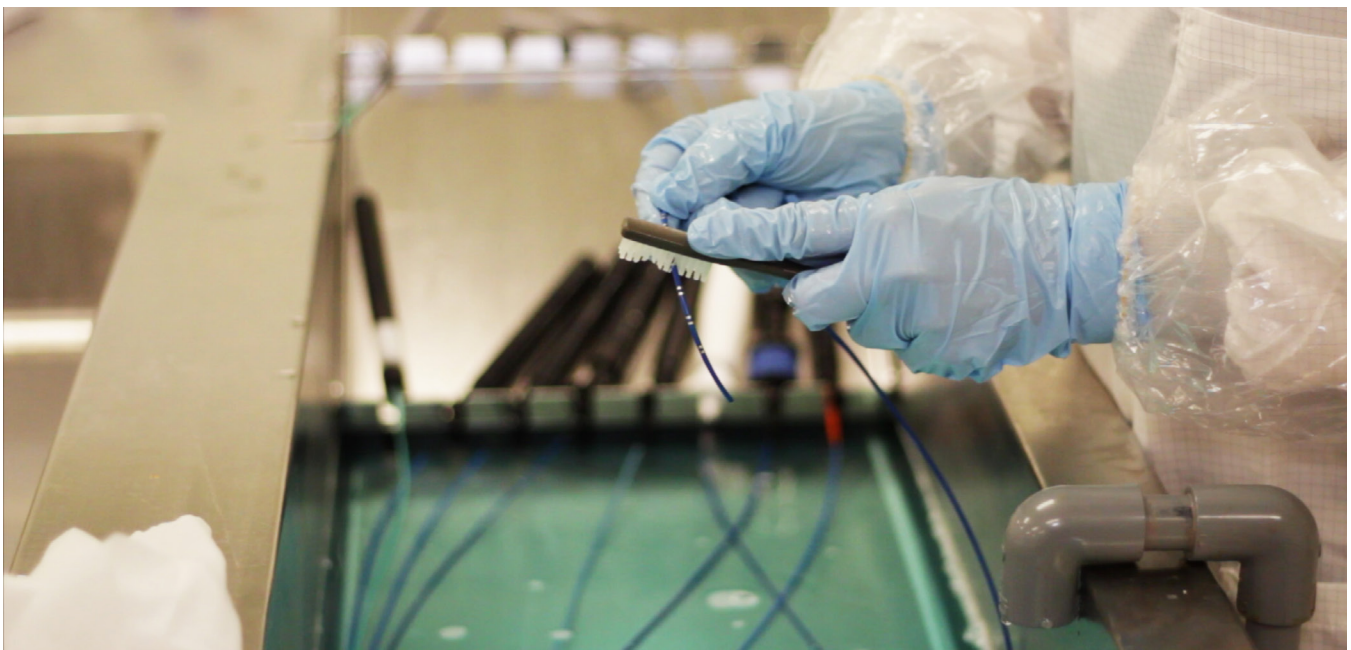


Image Source: AMDR, 2026

02

BACKGROUND

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01 BACKGROUND

Over the past 25 years, single-use device (SUD) reprocessing has evolved from an unregulated practice into a highly regulated and trusted strategy for United States hospitals. Since 2000, the FDA has exercised regulatory oversight of the third-party reprocessing industry and requires 510(k) clearance for many reprocessed single-use devices, based on device type and risk classification. Reprocessors must demonstrate that devices can be safely cleaned, tested, and reused, and that the reprocessed device is substantially equivalent to a new device without introducing additional patient risk.

Prior to 2000, many hospitals reprocessed single-use devices in their Sterile Processing Departments (SPD), treating them like reusable instruments. The 2000 guidance ended in-hospital reprocessing and established that only technologically advanced, FDA-cleared companies could legally reprocess devices.

Regulatory requirements for third-party reprocessors mirror those applied to original device manufacturers—and in many cases are more stringent. Reprocessed devices are subject to rigorous validation, inspection, and functional testing to ensure they are substantially equivalent in safety and performance to new devices. Reprocessors must clearly label products as reprocessed and assume full liability as the legal manufacturer. To meet these standards, most third-party reprocessors function-test every single device prior to clinical use, ensuring consistent performance and patient safety.

The industry formalized with the creation of the [Association of Medical Device Reprocessors \(AMDR\)](#) in 2000, and early pioneers quickly secured more than 100 FDA clearances. Between 2006 and

2011, reprocessing expanded rapidly across hospital departments and service lines. Strict regulation and a growing safety record built confidence among administrators, clinicians, and service line managers. Studies confirmed that reprocessed devices were as safe as, and in some cases more reliable than, new devices. Hospitals increasingly recognized the financial and clinical value of reprocessing. Reprocessors refined their service models with business reviews, customized distribution, and on-site support, helping hospitals build a culture of reprocessing.

Cost savings have long been the primary driver of reprocessing. Hospitals and surgery centers can save 30-50% per device, amounting to hundreds of thousands or even millions of dollars annually (AMDR, 2025). In recent years, sustainability has become equally important. Life Cycle Analyses (LCAs) show that reprocessing significantly reduces CO₂ emissions, broadening support beyond supply chain leaders to clinicians seeking to reduce their carbon footprint.

Today, commercial reprocessing is a \$580 million industry. Nearly every hospital system in the United States has a reprocessing program in place. According to [AMDR's 2024 report](#), nearly 9,500 hospitals and surgical centers use reprocessed single-use devices, preventing an estimated 12.2M pounds of medical waste, saving \$451M, and eliminating 115.4M pounds of CO₂e (AMDR, 2025).

03 POTENTIAL FOR COST SAVINGS

A person in a white lab coat is using a black calculator and holding a white pen. They are standing over a desk with various medical documents, including one with a stethoscope image and another with a heart diagram. A laptop is visible in the background. The scene is brightly lit, suggesting a clinical or office environment.

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03 POTENTIAL FOR COST SAVINGS

Hospitals can achieve significant cost savings through single-use device reprocessing. According to AMDR, [reprocessed single-use devices can cost 30-50% less than the original devices](#).

AMDR's 2024 survey of member companies found that hospitals and surgical centers saved upwards of \$451 million through purchasing lower-cost reprocessed devices and reducing waste management costs. ([Annual AMDR Member Survey Results](#), 2024).

Case studies of health system reprocessing programs cite significant savings:

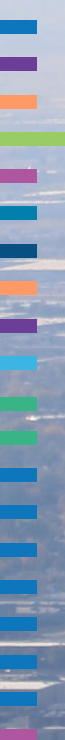
- Northwestern Medicine, an 11-hospital non-profit system based in Chicago, IL, estimates upwards of 25% savings per reprocessed device purchased ([Health Care Brew](#), 2024)
- Beth Israel Lahey Health, a 12-hospital non-profit system based in Boston, MA, saved \$1.7 million in 2023 ([Connecticut Hospital Association](#), 2025)
- Advantus Health Partners, a 49-hospital system headquartered in Cincinnati, OH, saved \$4.9 million through a reprocessing program focused on electrophysiology equipment ([Advantus Health Partners](#), 2025)
- HCA Healthcare, a 186-hospital for-profit health system headquartered in Nashville, TN, estimated \$29 million in savings through reprocessing in 2017 ([Practice Greenhealth](#), 2025)
- Advocate Health, a 68-non-profit hospital system headquartered in Downers Grove, IL, estimates an average of \$3.5M of annual savings. (NYU Stern Center for Sustainable Business, 2024)
- Northwell Health, a 28-hospital non-profit system based in New Hyde, New York, saved over \$3 million in 2024 (shared in a CHARME presentation in 2025).

These data points make a strong financial case for reprocessing. Still, it is critical to conduct a custom analysis to arrive at accurate estimates for your organization and avoid overestimating cost savings. Hospitals can refer to pricing in their existing contracts and the opportunities available to purchase reprocessed devices.

Beyond savings, single-use device reprocessing supports sustainability goals by reducing reliance on disposables that contribute to both greenhouse gas emissions and waste volumes. By lowering material consumption and waste disposal costs, and mitigating supply vulnerabilities, reprocessing creates financial and environmental resilience.



Image Source: Innovative Health 2026



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04 SUSTAINABILITY IMPACT AND EMISSIONS REDUCTIONS



Decarbonizing the value chain requires shifting from a linear “take-make-dispose” model to a circular economy that retains material value and minimizes life cycle impacts. Single-use device reprocessing is a measurable and credible strategy to move towards a sustainable health care system by reducing both upstream and downstream emissions.

On the front end, single-use device reprocessing reduces the purchase and production of virgin devices, lowering emissions tied to raw material extraction, component manufacturing, transportation, and upstream logistics. On the back end, reprocessing decreases end-of-life emissions by extending a product’s useful life and reducing the volume of single-use products sent through carbon-intensive disposal methods, such as incineration.

AMDR publishes a [Reprocessing Carbon Emissions Calculator](#) that generates high-level emission reduction estimates. The calculator is based on third-party published life cycle analyses (LCAs).¹

While greenhouse gas (GHG) reduction estimates vary based on the device type, process, and life cycle assumptions, AMDR analysis based on LCA data finds that using reprocessed devices can reduce emissions by 40% on average, compared to original devices.

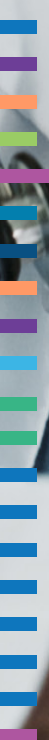
In 2024, [based on AMDR data](#), the use of reprocessed devices diverted over 12 million pounds of medical waste from incinerators and landfills.

Under the GHG Protocol, reprocessed products that are reused instead of discarded can be assigned zero [end-of-life emissions](#), provided that volumes are accurately tracked and verified. This enables both suppliers and healthcare systems to claim emissions reductions.²

With proper oversight, documentations, and third-party verification, reprocessing can be a high-impact lever for supply chain decarbonization in the health care and medical device industry.

¹ Claims of emissions savings must be supported by third-party certified carbon footprint assessments aligned with ISO 14067:2018, or verified life cycle assessments aligned with ISO 14040 and ISO 14044.

² For MedTech suppliers, these Scope 3 emissions reductions fall under the Greenhouse Gas Protocol Category 1, Purchased Goods and Services, and Category 12, End-of-Life Treatment of Sold Products; for health systems, Category 1 and Category 5, Waste Generated in Operations.

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05 STAKEHOLDER ENGAGEMENT

Effective single-use device reprocessing programs require coordinated, multidisciplinary effort across supply chain, clinical, sustainability, operational, and executive functions. When these groups are aligned on program goals, health care organizations can maximize collections and buy-back rates, realize cost and waste-reduction benefits, and leverage reprocessing to advance long-term strategic goals.

The table in Appendix D maps out how each stakeholder can contribute to and support comprehensive reprocessing programs.

Bright Spot: Stakeholder Engagement and Program Governance at Northwell Health

Engagement Through Rounding

Northwell Health, a 28-hospital non-profit system based in New Hyde, New York, leverages site-level rounding as a core engagement strategy to grow its reprocessing program. By visiting clinical units directly, the sustainability team can observe workflows, educate staff, and address barriers in real time.

These rounds proved to be the most effective method for building awareness of the benefits of SUD reprocessing and securing frontline participation. For example, quizzing staff on the volume of waste generated per patient per day (24 pounds) was an effective conversation starter and highlighted the environmental impact of clinical operations.

Site Champions Approach

Clinician and staff champions are critical to the program's success, serving as liaisons between the reprocessing initiative and their peers. Northwell has built a network of more than 80 champions across facilities, supported through quarterly meetings, monthly communications, and recognition of site-level performance.

These champions emerged organically—staff who cared about environmental impact and wanted to be part of the solution. At one facility, an anesthesiologist's passion for sustainability transformed compliance rates from among the lowest to nearly the highest system-wide. He now chairs the hospital's sustainability committee and integrates reprocessing data into all discussions.

These champions are driven to deliver high-quality, sustainable patient care—and play a pivotal role in shifting local culture and normalizing participation in the program. Leaders find that recognition and data sharing are more effective motivators for staff than incentives or prizes.

Governance and Leadership Engagement

To reinforce organizational commitment, Northwell established a reprocessing committee in 2024 that includes senior executives such as the Chief Quality Officer and the Head of Infection Prevention. The committee initially focused on concerns of safety and quality assurance but quickly shifted to celebrating progress, addressing system-level barriers, and pushing for expanded goals.

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06 TRAINING AND COMMUNICATION

Successfully implementing single-use device reprocessing requires strong communication with staff—including consistent training materials, clear signage, and actionable educational resources. Health systems have found the following strategies to be effective in supporting staff to adopt new processes to support reprocessing program goals.

Communication Approaches

Brevity and clarity are important when communicating a process change with busy staff, such as new workflows to collect single-use devices for reprocessing:

- **Stanford Health Care**, a health system based in Palo Alto, CA with two main hospital campuses and more than 100 ambulatory facilities, delivers updates through short in-service training and “one-page lessons,” or “OPLs,” that are customized to patient care areas or units. In a single slide, they share changes to the program, what to look for, and how to engage staff in the program expansion during rounding.
- At **Memorial Sloan Kettering Cancer Center**, QR codes placed on anesthesia machines link to surveys for staff to offer feedback on their experience using reprocessed pulse oximeters. They also noticed that bin labels needed to be placed on the inside of a hamper lid, rather than on the top, to ensure that signage is visible when the hamper is open.
- At **Northwell Health**, the sustainability team created one-page summaries for each reprocessed product, including SKU numbers, reprocessability status, buyback performance, and contractual conditions. This approach supports both clinician education and leadership decision-making. Northwell also uses QR code-based surveys to gather feedback.



Social Media Sustainability Quiz

To overcome survey fatigue, Northwell has shifted from traditional staff surveys to a social media-based quiz with giveaways to engage staff. The quiz revealed that while staff were knowledgeable about environmental care, only 5% were aware of Northwell's reprocessing programs. The site champion program is expected to improve these rates.

Culture and Communication

Northwell places a strong emphasis on communication at every level, including monthly staff updates, feedback channels, internal team platforms, and regular presentations to leadership committees. This sustained effort helps embed sustainability into the organizational culture. Staff experience pride and engagement in the reprocessing program, which serves as a visible demonstration of Northwell's commitment to climate action and workplace sustainability.

07

PROGRAM MEASUREMENT

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07 PROGRAM MEASUREMENT

Facility-Owned Reports

Health care organizations should maintain internal tracking systems to measure single-use device reprocessing goals. This ensures data ownership and security.

Methods can include:

- **Excel Workbook:** a simple, customizable tool for tracking core metrics.
- **Dashboard (e.g., Power BI, Tableau):** a scalable, visual reporting solution that can be built in collaboration with vendors, but owned by the hospital.
- **Vendor Portal Integration:** data pulled directly from vendor systems into hospital dashboards. This requires IT collaboration and data-sharing agreements.

Reprocessing Vendor Data Reports

Below are data points health systems frequently request and receive from vendors:

1. **Devices Collected:** Total number of devices collected for reprocessing, by SKU. Ideally this can be tracked at the unit level or facility level.
2. **Devices Reprocessed Successfully:** Number of devices that were collected and successfully reprocessed (i.e. not discarded). The inverse of this is the “reject rate.” Ideally, reproducers can share whether a device is discarded due to end of life or another avoidable factor.

3. **Landfill Diversion:** Total weight of devices diverted from landfill, calculated by multiplying the number of reprocessed devices by their individual weights.
4. **Estimated Savings:** Comparison of Original Equipment Manufacturer (OEM) prices to reprocessed device equivalents. While some health systems provide procurement and utilization data to vendors to calculate potential cost savings and collection rates, other health systems rely on their supply chain teams to provide procurement and utilization data to measure savings and collection rates.

Opportunities in Data Tracking and Transparency

At Northwell, data tracking for the reprocessing program is resource-intensive. Each month the procurement team compares vendor collection rates against purchase history to calculate compliance, and monitors buyback rates. Performance varies by facility—some sites excel while others lag—so the team uses the data to target support and interventions.

Standardization remains a challenge, as vendors reports vary and weight estimates don't always align with item counts. The Northwell team would like to report on reprocessing program metrics at the department level—and receive requests from clinicians for that level of data granularity—however, items are often collected in different locations, and it can be difficult to map where products are purchased and where they were used.

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08 CONTRACTING GUIDANCE

Contracting: Understanding Contracts, Perceived Barriers, and Common Misconceptions

Single-Use Device Reprocessing is often perceived as contractually complex or constrained by existing Original Equipment Manufacturer (OEM) agreements. In practice, many barriers stem not from actual contract language, but from misunderstandings about how reprocessing fits within traditional supply chain contracting models. Clarifying these misconceptions early is critical to program success.

Reprocessing Contracts Are Part of a Category Strategy

A foundational misconception is that reprocessing requires a wholly new or unfamiliar type of contract. In reality, a reprocessing agreement is best understood as a hybrid contract that combines:

- A medical device product agreement, and
- A supporting service agreement

From a supply chain perspective, reprocessed devices are not a separate category—they are an alternative supply option within an existing product category. Category strategy should assume coexistence of new and reprocessed devices, not wholesale replacement.

As such, reprocessing contracts should include the same components and core protections used for new OEM medical devices, including defined specifications, pricing, delivery expectations, quality requirements, payment terms, and supply assurances.

Reprocessing depends on reliable logistics and operational support, including:

- Collection and pickup schedules
- Bin placement and quantity
- Reporting and traceability
- Onsite support or representation
- Escalation pathways when issues arise

These service expectations are not unique to reprocessing—they align closely with standard service contract templates already familiar to supply chain teams.

Perceived Contractual Barriers Are Often Overstated

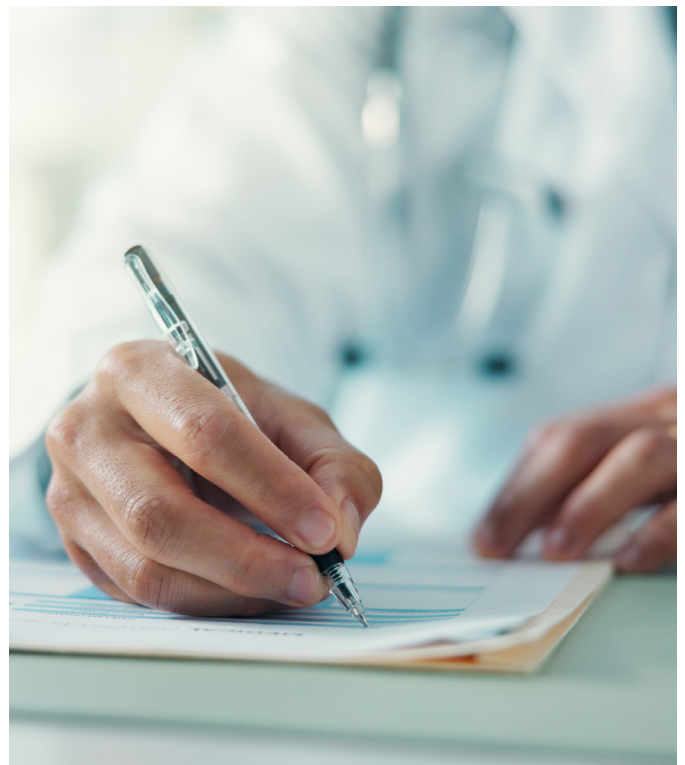
One of the most common reasons reprocessing programs stall is the belief that existing OEM contracts prohibit participation. In practice, this belief is frequently based on assumption rather than documented language.

Two contract structures warrant closer review:

1. Explicit restrictive clauses, where pricing eligibility is directly tied to exclusive OEM use
2. Tiered pricing arrangements, where reduced OEM volume may affect price tiers

Explicit anti-reprocessing clauses are relatively rare and tend to be limited to specific products or manufacturers. Tiered pricing is more common but manageable when addressed proactively as part of a balanced category strategy.

Organizations should review actual contract language rather than rely on informal interpretations. Where restrictive language does exist, it can often be addressed during contract renewal periods.



Addressing Restrictive OEM Language

As reprocessing programs mature, OEM contracts should be reviewed for language that explicitly or implicitly restricts reprocessing. Examples that warrant heightened scrutiny include:

- Clauses that prohibit reprocessing outright
- Pricing penalties triggered by reprocessing volume
- Rebates or incentives specifically designed to discourage reprocessing

Not all rebates or incentives are problematic. General volume-based rebates unrelated to reprocessing are common and often appropriate. By contrast, incentives that are explicitly tied to avoiding reprocessing should be challenged.

Health systems should reserve the right to explore reprocessing opportunities and avoid contract language that removes that flexibility. These discussions are most effective when positioned as part of broader category management and market share negotiations, rather than as isolated sustainability requests.

AMDR OFFERS RESOURCES FOR HOSPITAL LEADERS, INCLUDING:

- Hospital SUD Reprocessing Policy Template
- Procurement Checklist to Preempt OEM Anti-Reprocessing Efforts

Contracting Should Follow Opportunity Assessment—Not the Other Way Around

Before contracting with a third-party reprocessors, hospital leaders should take the following steps to develop a clear understanding of the opportunity:

1. Assess the opportunity
 - Request FDA-cleared catalog numbers from reprocessors
 - Cross-reference with internal purchasing data
 - Identify eligible devices by department and care setting
2. Quantify realistic potential
 - Focus on utilization patterns, not national averages
 - Avoid relying on industry savings indices, which frequently overestimate results
3. Issue an RFI or RFP grounded in actual data
 - Use opportunity sizing to define scope
 - Evaluate vendors on quality, service capabilities, and operational fit before price

Supply chain teams are far more receptive when presented with clear, organization-specific opportunity data rather than aspirational savings targets.



Internal Considerations Before Contracting

Before entering or expanding a reprocessing agreement, health system leaders should align internally on strategic intent and operational readiness.

Key questions include:

Financial strategy:

- Is the goal to maximize adoption of reprocessed single-use devices across categories or proceed one category at a time?
- How much OEM volume reduction is acceptable within this category?
- How will reprocessing impact existing OEM pricing tiers or rebate structures?

Operational readiness

- Do we have internal data to size the opportunity realistically?
- Do we have shelf space to manage two SKUs (OEM and reprocessed)?
- Can staff manage parallel products without workflow disruption?
- Does our ERP or ordering system allow for primary and secondary vendors within a category?
- Are we prepared to add collection bins in the relevant clinical areas?

Clinical Readiness

- Have we engaged clinical teams early on to identify barriers (including workflow, such as stocking processes, or cultural, such as stigma against reprocessed single-use devices) that could impact implementation?
- Have we offered clinicians the opportunity to conduct a trial of reprocessed devices to build internal confidence and support?

Clarifying these questions upfront helps avoid overpromising savings or underestimating implementation complexity.

Balanced Contracting Enables Long-Term Success

Continuously maximizing the opportunity to reduce emissions, save costs, and lower waste through a comprehensive reprocessing strategy is a laudable goal. However, reprocessing cannot completely replace OEM supply. Most health systems approach reprocessing through balanced contracting. A dual-source model allows health systems to purchase both OEM and reprocessed devices, actively managing volumes to balance savings, pricing stability, and flexibility during shortages or demand fluctuations.

Sole-Source vs. Multiple Reprocessing Vendors

Health systems should also consider whether to contract with a single reprocessing vendor or multiple vendors, depending on category complexity and internal capacity.

Sole-source reprocessing

- Simplifies operations and reporting
- Reduces training and logistics complexity

Multiple reprocessing vendors

- Can expand eligible device coverage
- Can introduce price competition
- Requires greater operational and contracting sophistication

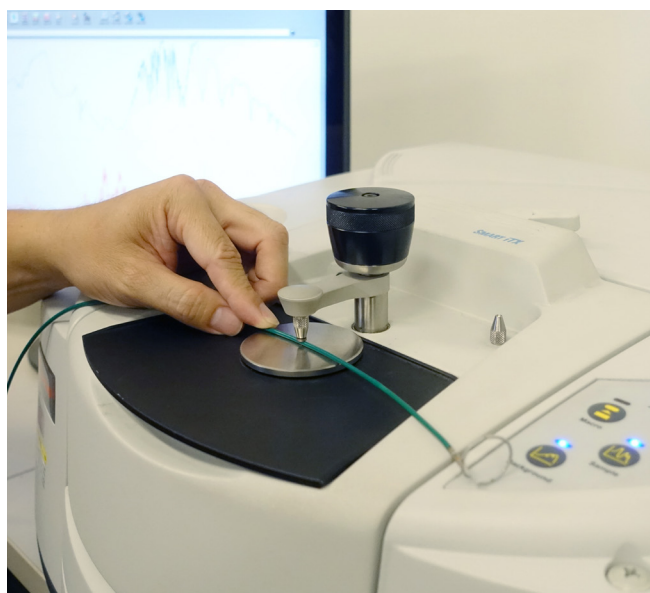
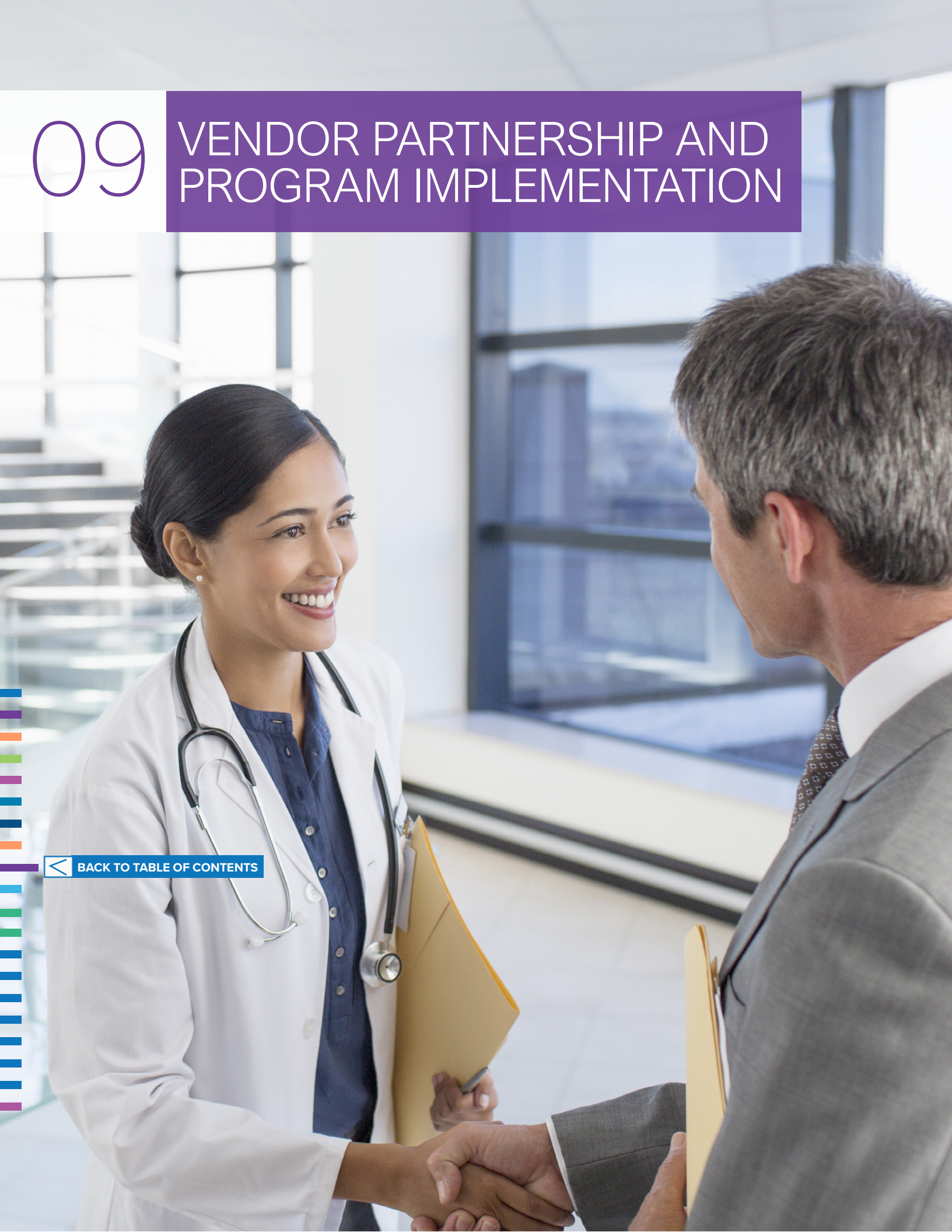


Image Source: AMDR, 2026

09

VENDOR PARTNERSHIP AND PROGRAM IMPLEMENTATION



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09 VENDOR PARTNERSHIP AND PROGRAM IMPLEMENTATION

After the contract is signed, health care organizations work with their reprocessing vendor(s) on an implementation plan that defines when collection bins will be installed, how frequently they will be serviced, and how staff training and education will be supported.

PHASE 01: Alignment

Define goals for the single-use device reprocessing program, and ensure that vendor KPIs and service levels in the agreement support those goals.

Common Service Levels or KPIs to include in Vendor Contracts:

1. Pick up frequency: this is established during program implementation and varies by facility.
2. Service expectations: # of bin overflows or service complaints that are acceptable per month; days until service issue resolution.
3. Fill rate / availability: % of requested reprocessed devices available.

PHASE 02: Planning

Identify a staff person to serve as the key contact and on-site champion to work closely with the reprocessing vendor. The on-site champion should have insights into product use, workflows, and space constraints to inform walkthroughs with the vendor.

Walkthroughs accomplish several purposes:

- Initial education of clinicians and staff, highlighting the purpose of the reprocessing program and the importance of disposing SUDs in collection bins.
- Identifying the best placement of collection bins through the facility, to produce the best yield rates.

- Establishing bin servicing frequency, which will vary based on volume and product type. For example, two pick-ups per week is common for patient care items such as compression sleeves, but not necessary for electrophysiology (EP) labs.

PHASE 03: Go Live

Following facility walkthroughs, the reprocessing vendor will set a date with the site champion for installation and collection bin delivery. The vendor will install bins at the locations identified and educate clinicians on proper disposal of used product in the correct bins.

PHASE 04: Support

Health care organizations should clarify how quickly collection data will be available once device collection begins. These reports determine if the program is tracking towards established KPIs. Health care leaders should also request quarterly business reviews with the vendor to review collections data to evaluate progress and identify opportunities for improvement.

Bright Spots: Overcoming Operational Challenges through Strong Vendor Partnerships

Bin fatigue, space limitations, and collections overflow can constrain reprocessing throughput and lead to staff frustration and disengagement with the program. Strong vendor partnerships are essential to ensure smooth, consistent collection and processing, and address common sources of friction.

At Northwell, the team heard frustration from staff with collection bin issues, including overflow, missed pickups, and unclear escalation paths. To address this, they created a structured process: staff first call the number on the bin, then the vendor contact, and finally escalate to Northwell's sustainability team if unresolved.

The team also implemented bi-weekly meetings with vendors. Detailed performance trackers and clearer contractual expectations helped improve vendor responsiveness. Over time, vendors have dedicated additional resources to support Northwell, including specialized technicians for system-wide coordination.

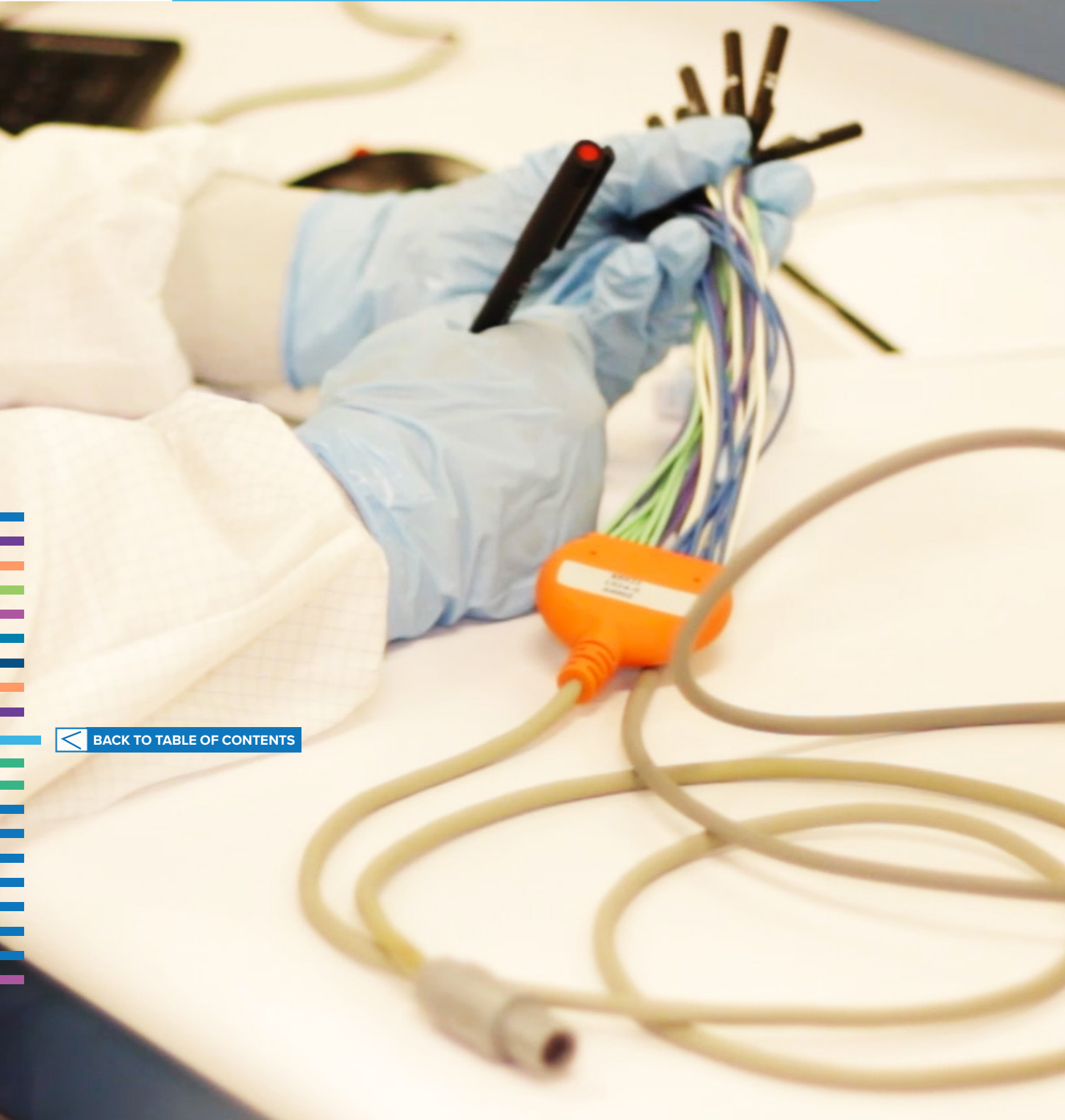
Stanford Health Care has also expanded reprocessing successfully, in part through consolidating bins and increasing vendor pick-up. Five technicians come daily to accommodate collection of bulky items such as hover mats and DVT sleeves.



Image Source: AMDR, 2026

10

OPERATIONAL AND FACILITY CONSIDERATIONS



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10 OPERATIONAL AND FACILITY CONSIDERATIONS

Strategies for Bin Placement and Labeling

Customize placement of collection bin based on size and facility design:

Collection bins come in a variety of sizes depending on the type of products being collected and the area of care.

- Soiled utility rooms on patient care floors can house larger hampers.
- A nurses station can accommodate a 2- or 5-gallon bin intended to collect smaller products such as ECG wires or SP02 sensors.
- Wall-mounted bins in patient care rooms can improve compliance and collection rates.

Avoid confusion with sharps or other medical waste containers:

- Placement of collection bins may be in the vicinity of other bins for sharps collections or other medical waste. Clear, vibrant signage ensures medical waste like sharps—which pose a risk to reprocessing staff—are not being put in the collection bins.

Build staff confidence with clear information:

- Post collection container lists by site, with associated pick-up frequencies, so staff know when to expect bins to be serviced.
- Make available a list of vendors and contact information: If service issues arise, such as overflowing bins, staff need to be able to access a list of vendors and how to reach them.

Keep signage consistent:

- Stanford Health Care has standard signage design throughout its waste management function, so all visuals, including for single-use device reprocessing collection bins, are consistent.

Ensure visibility of key information:

Memorial Sloan Kettering found that collection bin labels needed to be placed on the inside of the lid, rather than the top, so signage is visible when the hamper is open during an operation.



Image Source: AMDR, 2026



CASE STUDIES:

PILOTING REPROCESSED PULSE OXIMETERS
AT MEMORIAL SLOAN KETTERING CANCER
CENTER AND SINGLE-USE DEVICE
REPROCESSING AT KAISER PERMANENTE



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CASE STUDY: PILOTING REPROCESSED PULSE OXIMETERS AT MEMORIAL SLOAN KETTERING CANCER CENTER

Memorial Sloan Kettering Cancer Center (MSK), a health system with a main hospital in New York City, NY and 16 outpatient facilities, has maintained a single-use device reprocessing program since 2013, focusing primarily on non-invasive devices. The hospital collects nearly two dozen types of products. MSK's repurchasing of a limited set of reprocessed single-use devices, including SCD sleeves and ECG lead wires, avoided \$232K of purchasing costs in 2024.

Pulse Oximeters Pilot

The sustainability team is currently focused on transitioning to reprocessed pulse oximeters, following a successful pilot program in the anesthesia department.

Leaders first presented the proposal to the value analysis committee to secure approval for a pilot with MSK's Department of Anesthesiology and Post Anesthesia Care Unit (PACU) team.

Prior to commencing the trial, the project team partnered with the manufacturer of the reprocessed pulse oximeters to produce a brief three-minute educational video about single-use device reprocessing, the appearance of the reprocessed pulse oximeters, and how to use them. The team shared the educational video with the anesthesia department, along with Instructions For Use (IFU) that match those of the original equipment manufacturer. This ensured compliance with The Joint Commission requirement that IFUs are made available to staff.

The team also emphasized that instructions for use—required by the Joint Commission to be made available—are identical to those from the original equipment manufacturer (OEM).

The weeklong trial involved placing 100 devices in carefully selected Operating Rooms and inviting feedback from staff on the experience. The project team designed a form in Microsoft Teams and made it available to staff through a scannable QR code places on the anesthesia machines. The form asked staff to comment on whether:

- The sensor was easy to apply
- The sensor was durable
- They had confidence in the accuracy of the SpO2/HR measurement in normal conditions and during low perfusion
- The sensor had the same appearance as a newly manufactured sensor
- The reprocessed sensor was a clinically acceptable solution for their facility

With nearly 40 responses and positive results in hand, the team presented the trial results to the MSK's value analysis committee to and were approved for full implementation. They signed a contract agreement outlining the terms of the collections and repurchases of a blended mix of new and reprocessed devices.

Success Factors

MSK leaders share that the success of the pilot required deep stakeholder engagement across departments. The team was intentional in starting with the anesthesia department, due to their critical need for pulse oximeters and their openness to sustainability initiatives.

Engagement of clinical staff and identification of clinician champions has been essential. Peer validation has proven particularly influential; when clinicians hear from colleagues that reprocessed devices perform as well or better than originals—adoption becomes easier.

What's Next

The project team's next focus is advocating to transition lateral transfer air mats to reprocessed versions—especially in areas where process flows do not allow for cleaning of reusable mats.

Although lateral transfer air-assist mats are non-invasive and seem straightforward, their reprocessing involves significant logistical complexity. Product types vary in size, function, and applicability to clinical settings. Manufacturers provide proprietary inflation devices for use with these mats, and some manufacturers allow only some types of mats to be reprocessed. These nuances require the hospital to make strategic vendor selections, train both clinical and non-clinical staff on new workflows, and manage the collection and removal of large, bulky products in a dynamic and busy hospital environment.

However, the financial opportunity is substantial: reprocessed lateral transfer air-assist mats could deliver at least \$1 million in annual cost savings at MSK due to high volume usage, potential collection yields, and discounts associated with purchasing reprocessed versions.

Program Challenges

Data management remains a barrier. While vendors provide basic reports on collections including product codes and quantities collected, MSK must manually reconcile this information with its own data to measure purchasing cost savings and environmental benefits. MSK also must maintain its own Power BI dashboard to enable stakeholders to evaluate reprocessing trends and identify improvement opportunities specific to individual products and departments.

Conclusion

Overall, MSK's reprocessing program demonstrates both the complexities and opportunities of scaling sustainable supply chain practices. While challenges remain in product standardization and data integration, the potential for cost savings, environmental benefits, and clinician acceptance continues to drive momentum.



Image Source: AMDR, 2026

CASE STUDY: SINGLE-USE DEVICE REPROCESSING AT KAISER PERMANENTE

About the Organization

Kaiser Permanente is a 55-hospital integrated health system headquartered in Oakland, CA with more than 800 facilities across eight states and the District of Columbia. With over two decades of experience in reprocessing single-use medical devices, KP operates one of the most comprehensive and mature programs in the United States.

Program Background

Kaiser Permanente began reprocessing single-use devices (SUDs) twenty-five years ago as part of its commitment to environmental stewardship and financial accountability. KP partners with several third-party reprocessors for a wide range of devices and has steadily expanded its program to achieve significant environmental and financial returns.

Metrics

A centralized dashboard tracks the program's performance with metrics such as:

- OEM and reprocessed device spend
- Units collected and processed
- Percent buyback (percentage of eligible OEM devices purchased as reprocessed)
- Cost savings and missed opportunities
- Waste diverted (395 tons in 2024 alone)
- Year-over-year growth (25% growth in both reprocessing spend and waste diverted)

Facility- and category-level data enable benchmarking and healthy internal competition. High-performing teams are publicly recognized.



Image Source: AMDR, 2026

Lessons Learned

Internal Change Management and Stakeholder Engagement

- Start with pilot initiatives in high-volume areas and demonstrate throughput before emphasizing savings.
- Lead with clinical quality, not just cost savings—ensure all devices meet the same standards as OEMs.
- Work with clinicians and infection prevention to build trust in the safety and efficacy of reprocessed devices.
- Use data and dashboards to demonstrate performance, savings, and missed opportunities.

Develop Strong Partnerships with Manufacturers

- Maintain regular business reviews and transparent communication with both OEMs and reprocessors.
- Use interdisciplinary governance teams to review product performance, approve new devices for reprocessing, and evaluate vendor compliance.
- Encourage facility walk-throughs with manufacturer representatives to share an understanding of space constraints, pick-up frequency needed, and processes clinical staff will follow to successfully collect devices.

Challenges

- **Contracting Complexity:** OEM agreements often contain clauses that discourage or restrict reprocessing.
- **Cultural Resistance:** Some clinicians and departments are hesitant to adopt reprocessed devices due to safety or performance concerns.
- **Logistical Hurdles:** Managing space for bins and ensuring consistent collection and throughput require cross-department coordination.

Success Factors

- **Culture and Alignment:** KP's reprocessing program is tightly aligned with its mission and sustainability goals.
- **Interdisciplinary Collaboration:** Oversight includes physicians, sustainability, supply chain, and infection prevention.
- **Actionable Analytics:** Dashboards track and benchmark reprocessing outcomes across facilities and categories.
- **Recognition and Incentives:** High-performing facilities receive awards to reinforce participation and pride in the program.



A

APPENDIX A - F

KEY TERMS, QUESTIONS, QUICK START GUIDE, MAP, EVALUATION CRITERIA, ASSESSMENT TOOL, DO'S AND DON'TS



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APPENDIX A: KEY TERMS

Buyback: A health care facility purchasing reprocessed devices from a reprocessing company.

Collection Bins: Bins placed in health care facilities to collect used single-use devices for reprocessing.

Collection Program: A hospital or health system process to collect used SUDs for reprocessing instead of discarding them as waste.

Contract Compliance: Ensuring that clinicians use contracted reprocessed devices when available, often tracked as a key performance indicator (KPI) in supply chain or sustainability dashboards.

Cost Savings: The difference between the cost of purchasing new OEM devices and the cost of purchasing reprocessed equivalents.

Denial of Use (DOU): A clinician's refusal to use a reprocessed device—typically addressed through education, peer support, and documented clinical evidence.

Emissions: Substances and especially pollutants discharged into the air (as by a smokestack or an automobile). Research consistently shows reductions in polluting emissions through the use of reprocessed medical devices.

Environmental Impact of Reprocessing: The reduction in medical waste and carbon footprint achieved by diverting SUDs from landfills through reprocessing.

FDA Clearance (510(k)): A required regulatory clearance based on a submission demonstrating that a reprocessed device is substantially equivalent in safety and effectiveness to a legally marketed device.

Greenhouse Gas (GHG) Emissions: Greenhouse gas emissions (GHG) refer to the release of gases into the Earth's atmosphere that trap heat, leading to the greenhouse effect and contributing to global warming and climate change. Research consistently shows 40 to 60% reductions in GHGs through the use of reprocessed devices.

Life Cycle Analysis (LCA): A systematic analysis of the environmental impacts associated with all the stages of a product's life from cradle to grave. LCAs comparing original to reprocessed devices show a 40 to 60% reduction in greenhouse gas emissions for the reprocessed device.

Lifecycle Cost: The total cost of a device over its useful life, including purchase, reprocessing, and disposal. Reprocessing often lowers this total cost.

Linear Economy: A linear economy is an economic model based on the 'take, make, dispose' principle, where resources are extracted, transformed into products, used, and then discarded as waste. This model emphasizes short-term consumption and does not account for resource regeneration or the long-term sustainability of resource use. In healthcare, the linear economy model is exemplified in the overreliance on disposable, "single-use" medical devices, which drives up costs, waste, and greenhouse gas emissions in the healthcare sector.

Original Equipment Manufacturer (OEM): The original manufacturer of a medical device. OEMs often label devices as single-use to limit liability or preserve sales volume.

Premarket Requirements: These requirements relate to submissions that contain safety and effectiveness information that FDA reviews prior to allowing a manufacturer to market a device. The two types of premarket submissions that may be required before an SUD is reprocessed are: (1) an application for premarket approval (PMA); and (2) a premarket notification submission (510(k)).

Quality Assurance (QA): The set of protocols a reprocessor uses to ensure reprocessed devices meet safety, performance, and safety standards.

Remanufacturing: The act of restoring a used device to its original performance and safety specifications. FDA regulation differentiates between reprocessing and remanufacturing (FDA, 2025).

Reprocessable Device: A device that has been validated by a third-party reprocessor and approved by the FDA to undergo safe reprocessing and reuse.

Reusable Device: Device that has been designed for multiple uses. These devices are reprocessed (cleaned, disinfected, sterilized) between uses, typically in the hospital's own Sterile Processing Department (SPD). In the United States, to market a device as "reusable," a manufacturer must meet increased data requirements and invest the resources necessary to demonstrate to FDA that the product can be safely reprocessed by a hospital. Manufacturers of reusable medical devices are responsible for having labeling that bears adequate directions for use, including instructions on preparing a device for use.

Scope 3 Emissions: Scope 3 emissions are indirect greenhouse gas emissions that are not produced by the company itself but are associated with the company's chain, including both upstream and downstream emissions.

This encompasses emissions from sources such as the extraction and production of purchased materials, and use and end-of-life of sold products and services. Scope 3 emissions make up the vast majority of emissions in the health care sector, making supply chains a key area for environmental improvements—and reprocessing an easy, "low-hanging fruit" solution to healthcare emissions.

Single-Use Device (SUD): A medical device labeled by the original manufacturer as intended for one-time use on a single patient during a single procedure.

Single-Use Device (SUD) Reprocessing: The validated process of cleaning, inspecting, testing, sterilizing, and repackaging a SUD to prepare it for safe reuse on another patient. Reprocessing includes all the steps performed to make a contaminated single-use device safe, effective, and ready for patient use. The steps may include cleaning, functional testing, inspection, repackaging, relabeling, disinfection or sterilization.

In the United States, Canada, and Japan, reprocessing (in Europe referred to as

remanufacturing), the reprocessing/remanufacturing of SUDs is strictly subject to full medical device manufacturer requirements.

SKU Rationalization: The process of evaluating and standardizing product use, often favoring reprocessed devices to reduce variation and cost.

Third-Party Reprocessor or Commercial Reprocessor: An FDA-regulated company that specializes in reprocessing SUDs. A regulated business that, at the request of a hospital or surgical suite customer, collects, inspects, function tests, cleans, packages, and sterilizes (when required) medical devices labeled by the original manufacturer as "single-use" in such a manner that:

- The quality, physical characteristics, and functionality of the devices are not adversely affected and functionality is substantially equivalent to a new device;
- The devices remain safe and effective for an additional single-use; and
- The devices are reprocessed in full compliance with U.S. Food and Drug Administration (FDA) or similar oversight agency's regulations.

Legal and regulatory liability for the device shifts from the OEM to the reprocessor when the device is commercially reprocessed.

Waste Diversion: The act of keeping SUDs out of the regulated medical waste stream through reprocessing. Often reported in pounds or tons annually.

Yield Rate: The percentage of collected devices that can be successfully reprocessed and reused. Higher yield rates typically result in greater cost savings.

APPENDIX B:

FREQUENTLY ASKED QUESTIONS

1. IS IT SAFE TO REUSE SINGLE-USE DEVICES?

Yes. When reprocessed by FDA-regulated third-party reprocessors, many single-use devices can be safely reused. These devices undergo rigorous cleaning, inspection, and functional testing and must demonstrate substantial equivalence to new devices without added patient risk.

2. WHAT DEVICES CAN BE REPROCESSED?

Different reprocessors offer reprocessed devices in different categories. Reprocessable devices can be found in these healthcare areas:

- Cardiovascular
- Arthroscopic/Orthopedic
- General surgery
- Laparoscopic
- Non-invasive

AMDR's website features a [list of commonly reprocessed devices](#). Reprocessing companies will provide a full list of approved and cleared devices by category and SKU.

3. WILL THE DEVICE PERFORM THE SAME AS A NEW ONE?

Yes. FDA-cleared reprocessed devices must demonstrate "substantial equivalence" in safety and performance to new devices. Internal and third-party testing ensures they meet all functional specifications.

4. HOW MUCH MONEY CAN WE SAVE BY REPROCESSING?

Savings vary by organization but can be hundreds of thousands to millions of dollars annually, depending on devices included in program, utilization volume, and compliance. Reprocessed devices typically cost 30–50% less than new OEM equivalents.

5. HOW DO WE START A REPROCESSING PROGRAM?

You typically start by:

1. Partnering with an FDA-registered third-party reprocessor
2. Identifying reprocessable SKUs already in use
3. Setting up collection bins and logistics
4. Training staff on collection and usage practices
5. Tracking savings and sustainability metrics

6. WHAT IF A CLINICIAN REFUSES TO USE A REPROCESSED DEVICE?

Clinician education is key. Sharing peer-reviewed data, FDA approval status, cost and sustainability benefits can help address concerns. Some organizations use clinical champions to build confidence in reprocessed devices.

7. HOW IS QUALITY ASSURED?

Reprocessors typically have advanced quality management systems and they must follow strict quality requirements to comply with FDA guidance.

For example:

- Visual inspections
- Functional testing of every device
- Cleaning and sterilization validation
- Batch-level or item-level traceability

These processes are regularly audited by the FDA or a designated body such as the Medical Device Single Audit Program (MDSAP). You can ask your reprocessor to account for their quality management system.

8. CAN REPROCESSED DEVICES BE USED IN HIGH-ACUITY CASES?

Yes, as long as the device is FDA-cleared for the intended use and as long as its use follows institutional guidelines. Many hospitals successfully use reprocessed devices in high-acuity areas such as cardiology, electrophysiology, and ORs.

9. IS THERE A RISK OF CROSS-CONTAMINATION?

Not if proper protocols are followed. Reprocessed devices are sterilized and tested for bioburden, endotoxins, and functionality. The sterility assurance level (SAL) meets the same standards as new devices.

10. HOW DOES REPROCESSING SUPPORT SUSTAINABILITY GOALS?

Reprocessing single-use medical devices (SUDs) offers significant environmental, economic, and social benefits, making it a valuable strategy for advancing healthcare sustainability goals.

11. HOW CAN WE TRACK PROGRAM SUCCESS?

Work with your reprocessing partner to:

- Monitor utilization and yield rates
- Track cost savings
- Measure waste diversion & carbon footprint reduction
- Analyze compliance by department or clinician

Dashboards and quarterly reports support continuous improvement.

12. WHAT IS THE FAILURE RATE OF REPROCESSED ITEMS?

All medical device manufacturers must report adverse events through the FDA's publicly available MAUDE (Manufacturer and User Facility Device Experience) database. There is no evidence that reprocessed devices fail for any other reason or in higher frequency than OEM predicate devices. [Banner Health published an independent study](#) that reported "OEM devices are nearly five times more likely to be defective than reprocessed single-use devices." The Government Accountability Office (GAO) reviewed the FDA's oversight of reprocessed devices and the MAUDE database and issued [a report](#) that the use of reprocessed devices "pose no elevated health risk to patients."

13. WHAT IS DONE WITH PRODUCTS THAT A REPROCESSOR IS NOT CLEARED TO REPROCESS?

When a reprocessor is not cleared to reprocess a

device, the product is directed to appropriate end-of-life pathways. Whenever possible, materials are recovered and recycled—such as pelletizing plastics or reclaiming metals for use in downstream manufacturing. Devices that cannot be recycled may be sent through energy recovery processes, commonly referred to as waste-to-energy, with incineration used only as a last resort.

14. HOW CAN COMMERCIAL REPROCESSORS REPROCESS AND SELL DEVICES THAT ARE LABELED AS "SINGLE-USE"? IS THAT LEGAL?

Yes, single-use device (SUD) reprocessing is legal if the appropriate regulatory pathways are followed. This means that reprocessing companies must adhere to FDA policies and procedures—which can include achieving an FDA 510(k) clearance—or provide regulatory justification internally to subsume a device under an existing clearance. Additionally, companies engaging in reprocessing must undergo FDA registration, adhere to the FDA's quality systems regulation (QSR), report adverse events, undergo routine inspections, and participate in various other controls. The choice to label a device as "single-use" is one that has been made by the original manufacturers (OEM). To label a device as "single-use," the OEM has shown that the device is just as safe and effective as a predicate device that was or is legally marketed in the United States. Similarly, to legally market a reprocessed SUD, a reprocessing company must prove that their devices are as safe and effective as the predicate device, the new original device.

15. HOW MANY TIMES CAN THE DEVICES BE REPROCESSED? HOW IS THE MAXIMUM CYCLE DETERMINED?

It varies by device. The number of times a device can be safely reprocessed depends on the design and materials of the new device, and the unique characteristics and proprietary processes used to reprocess each device. For example, some electrophysiology catheters may be reprocessed up to six times while other devices, such as laparoscopic sealers and dividers, are cleared to be reprocessed once. Similarly, some "reusable products," like

electrophysiology cables, are indicated for up to 20 uses if properly cared for. The reprocessor must provide data to support a certain number of reprocessing cycles when submitting to FDA.

16. HOW DO REPROCESSORS KEEP TRACK OF THE NUMBER OF TIMES A DEVICE HAS BEEN USED?

There are a number of ways in which a device can be marked to indicate reprocessing cycles. Devices can be pad printed, indelibly marked, or a serial number may be used. Additionally, a unique device identifier (UDI) number is assigned to every product reprocessed. That identifier can either be scanned or is readable by a human. This number is encoded with device identifier information such as name of company responsible for selling product and the model/part number. It also contains production identifier data including the lot and/or serial number. The UDI number may be used to track the number of reprocessing cycles a device has reached.

17. DOES THE PERFORMANCE OF THE DEVICE DEGRADE WITH ADDITIONAL CYCLES?

Single-use devices are not designed to be used indefinitely. FDA's clearance of a device to be reprocessed implies that the reprocessor has supplied data to prove that the limited number of times the device is reprocessed do not involve

degradation. Additionally, although a reprocessor may be approved to reprocess a device multiple times, not all devices pass multi-point inspections and in-line performance testing designed to reject devices not fit for another use. Each like device must meet the same standards regardless of the number of times that particular device has been reprocessed.

18. HOW DO REPROCESSORS ACCOUNT FOR HIV/MRSA PATIENTS?

Human immunodeficiency virus (HIV) by definition is a "virus" and does not survive if it has no host. The virus is inactivated very quickly when removed from the active blood stream. The cleaning solutions utilized during the cleaning process inactivate and/or remove these viruses. Reprocessing sterilization processes are validated to kill the most resistant strain of bacteria (*Bacillus atrophaeus*) and provide a Sterility Assurance Level of 10⁻⁶ for devices labeled as sterile. Reprocessor sterilization cycles are validated in accordance with the current revision of the industry and FDA consensus standard ANSI/AAMI/ISO 11135. Additionally, most validated sterilization processes ensure the appropriate removal of Ethylene Oxide gas residuals to prevent irritation to patients or clinicians. This is performed in accordance with the current revision of ANSI/AAMI/ISO 10993-7.



Image Source: AMDR, 2026

APPENDIX C:

QUICK START GUIDE

STEP 1: Assess the Opportunity (Weeks 1–4)

What to do:

- Request the list of FDA cleared catalog numbers from reproprocessors.
- Cross-reference with your organization's purchasing history.
- Identify the opportunity for collection (collecting single-use devices to be reprocessed) and buy-back (purchasing reprocessed devices.)

The largest medical device reproprocessors include:

- Innovative Health
- J&J MedTech
- Medline ReNewal
- Medtronic
- NorthEast Scientific
- Renu, an Arjo company
- Stryker
- Sustainable Technologies, a Cardinal Health business
- Vanguard Medical Remanufacturing

- Certain reproprocessors specialize in specific product categories (e.g. cardiology devices used in electrophysiology (EP) cath labs) while others reprocess the full spectrum of devices.
- For a list of commonly reprocessed devices, see the Association for Medical Device Reprocessors (AMDR) [website](#).

Who to involve:

- Supply Chain (to provide purchase history and utilization data)
- Sustainability team (to align with organizational goals)
- Clinicians
- Service line management

STEP 2: Build Your Core Team (Weeks 2–6)

What to do:

- Form an interdisciplinary working group.
- Identify clinical champions and engage infection prevention to ensure confidence in use of reprocessed devices.

Who to involve:

- Physician and nursing champions
- Infection prevention
- Value analysis committee members
- Supply chain leaders
- Sustainability leaders
- Category managers and product council representatives

STEP 3: Pilot and Logistics Planning (Weeks 6–12)

What to do:

- Choose 1–2 departments for a pilot, e.g. electrophysiology (EP) cath labs, ICU, or the OR.
 - Many health systems start with non-invasive devices before moving to invasive devices.
 - The operating room (OR) is a source of high volume of single-use devices; however, some health systems find that it can be difficult to gain buy-in for SUD reprocessing.
- Conduct walkthroughs with your reproprocessor(s) to determine collection bin placement, pickup schedules, and reporting needs.
- Define how throughput will be monitored (what gets collected, what gets reprocessed, and what is bought back).

Who to involve:

- Departmental staff (to ensure buy-in and compliance)
- Reprocessing vendor representatives
- Facilities/operations (for collection bin placement and space considerations)

STEP 4: Contracting and RFP (Months 2–6)

What to do:

- Review contracts with Original Equipment Manufacturers (OEMs) for restrictive clauses that may limit reprocessing.
- See Contract Guidance section for more detail, and reference AMDR's Resources for Hospitals page, which offers contract policy templates and guidance for health system leaders.

Consider an RFI

- Issuing a Request for Information (RFI) before a Request for Proposal (RFP) is useful for a new area of purchasing.
- An RFI serves as a low-risk, low-effort way to gather market intelligence before committing to a full procurement process.
- The RFI lets health systems understand the market landscape, refine scope and requirements, improve budget accuracy, pre-qualify vendors, reduce organizational risk, and accelerate the following RFP process.
- The RFI phase ensures the RFP is realistic, competitive, well-defined, and aligned to the organization's needs—ultimately leading to a better vendor selection and smoother implementation.

Draft or amend contract with reprocessors to cover both product terms (pricing, quality, logistics) and service terms (pickup frequency, reporting, escalation).

Engage supply chain Enterprise Resource Planning (ERP) system team on inventory management

- Buyback items (devices purchased from reprocessors) need to be added to the ERP item master to include in demand planning, including periodic automatic replacement (PAR) levels, which determine ideal minimum stock quantities.

Who to involve:

- Supply chain contracting team
- Legal/compliance
- Finance (to review potential savings and missed opportunity reports)
- Enterprise Resource Planning (ERP) team

STEP 5: Education and Culture Shift (Months 3–6)

What to do:

- Train staff on why and how to collect devices.
- Reinforce alignment with quality, safety, and sustainability goals.
- Share early pilot data to build confidence.

Who to involve:

- Frontline staff in pilot areas
- Clinical educators
- Communications/engagement teams

STEP 6: Measure, Scale, and Sustain (Months 6–12 and ongoing)

What to do:

- Launch a dashboard tracking OEM vs. reprocessed spend, percent buyback, units collected, and waste diverted.
- Benchmark across facilities and consider creating friendly competition between sites by transparently sharing results.
- Scale to new departments after successful pilot demonstration.
- Schedule monthly review calls and quarterly business reviews with reprocessors.

Who to involve:

- Oversight committee (supply chain, clinicians, infection prevention, sustainability)
- Reprocessing partners
- Facility leadership (for accountability and recognition)

APPENDIX D: STAKEHOLDER MAPPING

SUPPLY CHAIN & OPERATIONS

STAKEHOLDER	ROLE IN SUPPORTING REPROCESSING PROGRAM
Supply Chain	Provide purchase history, utilization data, and inventory visibility to identify and track reprocessable devices.
Supply Chain Leaders	Oversee program coordination, communication, and operational execution.
Category Managers / Product Council Representatives	Assess product categories for reprocessing eligibility and optimize sourcing strategies.
Supply Chain Contracting Team	Negotiate and manage reprocessing agreements to ensure value and accountability.
Facilities/Operations	Manage bin placement, storage, and logistics to support efficient device collection.
Data Analyst (Supply Chain, Value Analysis, Sustainability)	Track performance metrics, generate dashboards, and identify improvement opportunities.

CLINICAL

STAKEHOLDER	ROLE IN SUPPORTING REPROCESSING PROGRAM
Physician or Nursing Champions	Advocate for clinical participation, address concerns, and model compliance with reprocessing workflows.
Infection Prevention	Validate that reprocessed devices meet all infection control and sterilization standards.
Departmental Staff	Support daily device collection, segregation, and adherence to reprocessing procedures.
Frontline Staff in Pilot Areas	Participate in early implementation, provide feedback, and demonstrate proof of concept.
Clinical Educators	Train staff on proper collection protocols and reinforce best practices across units.
Value Analysis Committee Members	Evaluate clinical efficacy, safety, and cost-effectiveness of reprocessed devices.

ADMINISTRATIVE & FINANCIAL

STAKEHOLDER	ROLE IN SUPPORTING REPROCESSING PROGRAM
Finance	Analyze savings, verify cost avoidance, and track missed opportunity reports for leadership.
Legal/Compliance	Review contracts and ensure adherence to FDA, regulatory, and organizational standards.
Oversight Committee (Supply Chain, Clinicians, Infection Prevention, Sustainability)	Provide governance, monitor outcomes, and resolve cross-functional challenges.
Facility Leadership	Ensure accountability, allocate resources, and recognize departmental achievements.
C-Suite (CSO, VP of Sourcing, COO)	Champion the program at the executive level and integrate it into strategic organizational goals.

SUSTAINABILITY & COMMUNICATIONS

STAKEHOLDER	ROLE IN SUPPORTING REPROCESSING PROGRAM
Sustainability Team	Align program efforts with organizational sustainability and waste reduction targets.
Sustainability Leaders	Integrate reprocessing into broader decarbonization and waste management strategies.
Communications/Engagement Teams	Promote awareness, celebrate milestones, and share success stories organization-wide.
Reprocessing Vendor Representatives	Provide training, regulatory expertise, and data reporting for ongoing optimization.
Reprocessing Partners	Offer operational support, analytics, and continuous improvement recommendations.

APPENDIX E:

SAMPLE EVALUATION CRITERIA AND SCORING FOR RFP

PROCEDURES, PERFORMANCE & SUPPORT

- Metrics demonstrating that reprocessed devices meet original manufacturer specifications. Evidence reprocessed devices function properly within existing clinical workflows, including interoperability with OEM capital equipment. Evidence that reprocessing does not degrade device materials, coatings or functionality.
- Number of validated reprocessing cycles before disposal, and any performance changes after multiple cycles? How does the company track the number of times a device has been reprocessed? As required by the FD&C Act, 510(k)s for certain reprocessed SUDs must include validation data, including functional performance data, that demonstrates that the SUD remains as safe and effective as (substantially equivalent to) the predicate device after the maximum number of times the device is intended to be reprocessed as identified by the reprocessor. Evidence that reprocessed devices perform equivalently to new devices, including clinical studies or third-party evaluations.
- Detail clear identification of reprocessed devices to avoid confusion with new or single-use devices.
- Ability to buy back and turnaround times reprocessed devices. Are there any limitations on ability to buy back devices beyond the number of regulated reuses? Does the reprocessor have any contracting terms that require purchase of a certain number of virgin devices for every remanufactured/reprocessed device? Does the company design products that would otherwise be reprocessable in a way that forces obsolescence and subsequent purchase of a new vs reprocessed device? Please provide detailed example of any product category where this might apply.
- Is sterilization performed by a commissioned and certified sterilization system, in accordance with ANSI/AAMI/ISO ST 11135 ST 1994?
- Is the sterilization cycle requalified annually, routinely calibrated and tested?
- Validation that reprocessing eliminates contamination risks (e.g., sterility assurance levels, endotoxin testing).
- Documentation of post-market surveillance, recalls, and any reported patient safety issues.

LOGISTICS & REPORTING

- Ability to integrate reprocessed devices into established supply, storage, and usage patterns and understanding how reprocessed devices are stocked and replenished.
- Detail pick-up and delivery process, including scheduling and tracking capabilities.
- Detail geographic coverage and service availability.
- Detail contingency plans for supply disruptions. Ensure reprocessing timelines align with clinical demand to avoid shortages.
- Detail technology integration with hospital supply chain and inventory systems. Compliance with hospital data security and privacy requirements.
- Tracking and reporting capabilities for reprocessed devices, including ability to provide data that demonstrates cost and carbon emission savings from operating reprocessing engagements. Availability of dashboards or real-time tracking tools.
- Provide regular business reviews and educational services that maximize staff participation. Ongoing support for clinical staff on proper use and handling of reprocessed devices and addressing issues.

ENVIRONMENTAL SUSTAINABILITY & SOCIAL RESPONSIBILITY

- Describe your company's Environmental and Social Responsibility commitments (e.g., responsible sourcing, human rights), principles, initiatives and practices. If applicable, please attach or link your most recent sustainability and/or social responsibility report. Please provide details if you have GHG emissions reduction target(s) aligned with or validated by the Science Based Target Initiative (SBTi) or if you're in the process of doing so. If not, please note upon a potential award and contract your organization may be expected to set a science-based emissions reduction target.
- Are you able to provide life cycle assessments (LCAs) or product level emissions data for the reprocessed product, distribution and disposal? Detail how you plan to reduce your carbon emission through the reprocessing and/or transportation of the product.
- Are you able to provide the total volume of water and energy consumed in the reprocessing process of product(s)? Additionally, please outline any water and energy conservation measures or technologies utilized to minimize usage.
- Does your reprocessing process use any of these chemicals of concern (please specify): Formaldehyde, per and poly-fluorinated compounds (PFAS), polyvinyl chloride (PVC), DI (2-ethylhexyl) phthalate (DEHP), antimicrobials, flame retardants (where code permits), Ethylene oxide (EtO), heavy metals, or hazardous materials defined by the EU RoHS directive. Please detail if and what is used in the reprocessing process. Has the company been flagged for EtO emissions and do they have proper procedures in place to ensure stakeholders are not exposed to EtO?
- Does the company recycle the raw materials from a device when it is no longer capable or eligible to be reprocessed? How are devices that are unfit for reprocessing (too many uses, broken, not allowable for reprocessing) handled at end of life? Are they disposed of as Regulated Medical Waste (RMW)? As another kind of waste? Is there any attempt to recycle or recover material? Does the reprocessor provide feedback about what % contamination there is in bins or what % of devices collected/shipped are actually put back into rotation?
- Detail how you will reduce or eliminate the amount of single use plastic used for packaging.
- Can you certify that your services are rendered without the use of forced labor or unethical labor practices? If so, please provide documentation or certifications verifying compliance with labor standards. Outline the steps your company takes to ensure fair labor conditions.
- Provide details on how you establish transparency to validate environmental sustainability, human health and safety claims, accurate and credible identification of sustainable products, disclosures of chemicals of concern and any applicable third-party certifications for your products and/or services (e.g. EnergyStar, EPEAT, EU Ecolabel, Water Sense, Green Seal, etc.)? (Please specify applicable products, categories and /or services).

SCORING MATRIX: SUSTAINABILITY CRITERIA

- Did the vendor provide detailed responses regarding their overall sustainability strategy and commitment including specific examples? Please rate based on the detail and maturity of their sustainability strategy / commitment(s).
- Did the vendor provide emissions, energy, and water data relative to the reprocessed product, distribution and disposal? Please rate based on the detail and maturity of data provided.
- Does the vendor exhibit use of sustainable practices throughout the product reprocessing lifecycle? Please rate based on the detail, maturity and impact of their sustainability practices
- Did the vendor disclose the use of any chemicals of concern in the product reprocessing lifecycle? Please rate based on the detail and maturity of data provided.
- Did the vendor provide specific examples of mitigating environmental impact at product end of life? Recycling, etc. Please rate based on the detail, maturity and impact of their sustainability practices.
- Did the vendor provide third-party evidence establishing fair labor practices throughout their operations? Please rate based on the detail and maturity of evidence provided.
- Did the vendor provide third-party evidence such as certifications, industry qualifications, awards, etc., demonstrating their sustainability commitment? Please rate based on the detail and maturity of evidence provided.
- Did the vendor provide third-party evidence such as certifications, industry qualifications, awards, etc., demonstrating their sustainability commitment? Please rate based on the detail and maturity of evidence provided.

APPENDIX F:

PROGRAM MATURITY ASSESSMENT

Use this guide to assess the current state of your hospital's reprocessing program and identify opportunities to advance to the next level of maturity.

DIMENSION	LEVEL 1 – EMERGING	LEVEL 2 – DEVELOPING	LEVEL 3 – ESTABLISHED	LEVEL 4 – ADVANCED	LEVEL 5 – OPTIMIZED
Program Governance	Exploratory discussions with vendors or reprocessors.	Small-scale collection of devices for reprocessing. Limited awareness of reprocessing opportunities.	Sourcing or Contracting team and/or Supply Chain responsible for the reprocessing program.	Program governance features a multidisciplinary steering committee (supply chain, infection prevention, clinicians, finance, etc.).	Reprocessing-specific goals are fully integrated into organization's sustainability and supply chain strategic plans.
Device Collection & Segregation	Inconsistent collections. Little staff training.	Select units collect targeted devices relatively well, but collections are limited or nonexistent throughout the rest of the hospital.	Standardized collection bins and labeling across all commonly high-volume units.	Hospital-wide collection program with accountability assigned to units.	Fully optimized collection system guided by continuous feedback and training loops.
Stakeholder Engagement	Awareness limited to Sourcing/ Contracting or Supply Chain and one or two units.	Basic, regular communication to a limited group of stakeholders about the program.	Regular staff education, posters, and reminders. Clinical champions identified.	High engagement across departments; reprocessing integrated into onboarding and competency training.	Culture of ownership and pride in reprocessing success; clinicians, EVS, and supply chain jointly drive improvement.

DIMENSION	LEVEL 1 – EMERGING	LEVEL 2 – DEVELOPING	LEVEL 3 – ESTABLISHED	LEVEL 4 – ADVANCED	LEVEL 5 – OPTIMIZED
Financial Performance & Cost Savings	No savings recognized through buyback; donor account only.	Modest cost savings from device collection and small-scale purchasing of reprocessed devices.	Clear ROI established; regular tracking of cost avoidance and savings.	Financial savings goals related to SUD reprocessing are established annually.	Data-driven optimization across categories; savings reinvested into other sustainability or clinical programs.
Sustainability Measurement	No measurement or tracking.	Basic reporting of pounds diverted from landfill.	Regular sustainability reporting (e.g., pounds of waste diverted, GHG reduction) to select stakeholders.	Reprocessing metrics integrated into sustainability reporting. SUD reprocessing is understood as a key Scope 3 emissions reduction tactic.	Active collaboration with vendors to measure and improve on sustainability metrics.
Innovation & Continuous Improvement	Reactive; limited awareness of what device categories are currently available for reprocessing.	General awareness of device categories the hospital is not currently reprocessing. Responsive to efforts by reprocessing vendors to add new device categories. Pilot testing new categories with vendor guidance.	Regular, proactive solicitation of expanded SUD reprocessing opportunities. Semi-regular evaluation of internal protocols to gauge their effectiveness at maintaining and expanding collection and buyback levels.	Collaborative projects with established multi-stakeholder reprocessing team (see above) as well as reprocessors to expand categories, improve collections, and maximize buyback.	Co-development with vendor(s) of next-generation reprocessable devices and closed-loop recovery systems.

APPENDIX G: REPROCESSING CONTRACTING DO'S AND DON'TS

WHAT TO DO AND WHAT TO AVOID

Successful single-use device (SUD) reprocessing programs depend as much on contracting strategy as on clinical acceptance or sustainability goals. Health systems that silo reprocessing programs from overall contracting strategies can encounter resistance, unintended cost increases, or stalled implementation. The guidance below reflects lessons learned from health systems, suppliers, and group purchasing leaders.

WHAT TO DO

1. Approach OEM and reprocessed devices with a unified category strategy

Reprocessed devices should be considered alongside new OEM devices—not as a separate or competing contract. Effective programs align OEM purchasing and reprocessing volumes within the same product category to optimize total cost, supply reliability, and clinical acceptance.

2. Start with an RFI to assess readiness and opportunity

Before issuing an RFP, use a Request for Information (RFI) to:

- Understand which devices are eligible for reprocessing
- Estimate realistic reprocessing capture rates
- Quantify potential cost savings and waste reduction

This step helps build a credible business case and brings supply chain leaders into the conversation early.

3. Size the opportunity using real purchasing data

Map eligible reprocessed devices to historical OEM purchasing volumes and pricing.

This allows teams to:

- Identify categories where reprocessing is financially viable
- Anticipate impacts on OEM price tiers
- Avoid overestimating savings or utilization rates

4. Plan for balanced—not 100%—reprocessing

Most categories cannot support full conversion to reprocessed devices. Instead, aim for balanced contracting, where a portion of volume is reprocessed and the remainder is purchased new. Setting realistic expectations protects clinical relationships and OEM pricing.

5. Review OEM contracts for actual (not perceived) restrictions

Concerns about “anti-reprocessing clauses” are common—but often overstated. Review contracts directly to identify:

- Explicit language tying pricing eligibility to exclusive OEM use
- Tiered pricing structures that may shift with reduced volume

Understanding these terms enables proactive planning rather than avoidance.

6. Engage supply chain early with clear financial data

While sustainability and clinical champions often initiate reprocessing efforts, supply chain teams move programs forward when presented with quantified savings, contract implications, and risk mitigation strategies.

WHAT TO AVOID

1. Don't assume reprocessing is prohibited without reviewing contracts

Many organizations delay or abandon reprocessing based on informal interpretations rather than actual contract language. This can unnecessarily limit viable programs.

2. Don't pursue reprocessing in isolation from OEM negotiations

Implementing reprocessing without considering OEM pricing impacts can result in higher net costs and undermine long-term program viability.

3. Don't expect or promise 100% reprocessing adoption

Overly aggressive targets can strain clinician trust, disrupt workflows, and destabilize OEM relationships. Unrealistic expectations are a common reason programs fail.

4. Don't issue an RFP before defining the opportunity

An RFP without a clearly defined scope, target volume, and savings estimate risks confusion, weak responses, and internal misalignment.

5. Don't treat contracting as a one-time event

Reprocessing programs evolve over time. Contracts should allow for adjustment as utilization patterns, clinical acceptance, and eligible device lists change.

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