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Is Reprocessing Single-use Devices for You?

Here's how to determine if reusing one-use items makes financial and practical sense for your facility.

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On paper, reprocessing single-use devices looks like an attractive way to save on your supply costs as well as on waste disposal. Here's how it works: You send your eligible used or opened but unused SUDs to a third-party reprocessor, which returns one-use items to you ready for reuse. Eligible items include compression sleeves, oxygen masks, trocars, and orthopedic bits and blades. You stand to save your supply budget up to 50 percent of what you'd pay to buy such items new. But as you'll see in this article, you'll have to consider a few key factors before you rush out and select a reprocessing service.

1. Getting surgeons on board

Perhaps the most important buy-in you'll need for reprocessing SUDs is the surgeons who'll be their chief users. Andy Beck, RN, CASC, CNOR, CAPA, the director of surgical services at Providence Surgery Center in Missoula, Mont., learned that lesson during his facility's attempt to have arthroscopic shaver blades reprocessed. "In the initial cost-benefit analysis, it looked good on paper, saving 50 cents on the dollar," he recalls. "But if surgeons keep opening them and saying, 'It's dull, get me a new one,' are you really saving?"

Without the surgeons on board, the blade-reprocessing program lasted only about a year. "We were saving money, but it wasn't worth the negativity we got from the surgeons," says Mr. Beck, "and we needed to keep them coming."

If you're able to convince your surgeons to try reprocessed SUDs, the potential cost savings they'll bring to the budget will likely be the most compelling evidence. Additionally, reprocessing vendors' reps are often willing to meet with physicians to share documents on their FDA registration, testing reports and studies from clinical journals, says Mary C. Wilson, BSN, RN, CNOR, clinical preceptor for West Virginia University Hospitals in Morgantown, W.Va., which sends orthopedic external fixation devices, pulse oximeter sensors, tourniquets and sequential compression sleeves for reprocessing.

At Ms. Wilson's hospitals, some doctors requested that SUDs be reprocessed while others resisted. "The doctors who wanted it campaigned their peers," she said. A sales rep from the company lobbying a surgeon is one thing, she says, but the persuasion of peers can have a very different impact.

While their voices may be the loudest, surgeons are by no means the only voices in the reprocessing decision-making process. The more staff behind the effort, the better the results will be. Ms. Wilson suggests that you first meet with risk management, infection control and value analysis personnel to review the reprocessor's documentation, ensure that safety standards would be met and determine that cost savings would actually be realized. Then invite OR and sterile processing staff to contribute their views based on their expertise.

2. Price and service

Since the primary motivation for reprocessing single-use devices is to economize on purchasing costs, plot out the costs of a reprocessing service in order to ensure that the end result is a return for your facility. Does the service charge by the piece? If so, what is the rate? For some services, it's as low as half of an item's original retail price. Don't forget to factor in the possibility of shipping charges.

Reread any supply contracts you've arranged with manufacturers, distributors or GPOs for the types of items you're planning to reprocess. If the pricing for those items has been based on a previously designated purchasing volume, your supply cost may rise as your demand for new stock falls.

A reprocessor's turnaround time for a batch of SUDs is nearly as important as the service's cost. "If you don't keep a lot in stock, will your reprocessing program provide you with enough devices to stay in supply?" says Ms. Wilson. Ask the company in advance for its maximum turnaround time for each type of device you plan to send it. The reprocessing site's distance from your facility may be a limiting factor here.

A reprocessing firm should in-service your staff on what they have to contribute to the process, whether it's just dropping items into company-supplied bins or nominally washing and packing the items — since leaving bioburden to dry on instruments may result in a suboptimal reprocessing success rate, says Becky Chillemi, RN, BSN, CNOR, OR director at the Stillwater Surgery Center in Stillwater, Okla.

But the company's service quality should be judged on how much it does, says Ms. Wilson, from easy collection and convenient pickups for the facility to inventory management and item tracking for quality control. "The reprocessing should be labor-intensive for the company, not for us," she says.

3. Is your reprocessor reputable?

Recent federal action may open the market for more SUD reprocessors to operate. In January, the Government Accountability Office delivered a congressionally commissioned report on reprocessed single-use devices to the House of Representatives' Committee on Oversight and Government Reform. The report found that the Food and Drug Administration had strengthened its oversight of reprocessing firms over the past eight years and that the data they'd collected didn't suggest that the use of reprocessed SUDs put patients at greater risk.

The GAO's report noted that FDA officials had reviewed 11 U.S. firms that, as of July 2007, actively marketed or planned to market SUD reprocessing services, either as a part of their operations or as their sole means of business. The report did not identify the firms by name, but it did mention that their services reprocessed more than 100 different types of medical devices.

If you're considering hiring such services, it's your responsibility to investigate aggressively to determine the propriety of their procedures, the quality of their services and the effectiveness of the reused devices for the safety of your patients. How do you choose a reputable reprocessor?

Reprocessing firms should be able to provide you with a list of facilities that use their services for use as references. Some original equipment manufacturers offer reprocessing of their own SUDs. You might also ask your distributor. Some have contracted with reprocessing firms as a value-added service beyond their primary supply business.

Otherwise, call around to other facilities that are sending their SUDs out for reprocessing and find out who they've hired. Or ask surgeons and staff which services they've seen at other facilities. Ms. Chillemi says she and her surgeons had dealt with a reprocessor during their tenure at another local facility. The previous experience made the question of who to send trocars, sheaths, shaver blades and other devices to an easy one.

That hands-on account from users is what you're looking for, says Mr. Beck. "Drive to a facility that uses [the reprocessing service], if it's close enough," he says. "If you call the administrator and materials manager, they'll tell you, 'Yes, it saves money,' but on the worker level, maybe there's a different view."

You'll want to ask frontline staff as well as administrators how happy they are with the service, says Mr. Beck, whose facility has its pneumatic compression stockings reprocessed. Does the collection process burden the end user with more work, or has the company made it extremely easy? Does the facility consistently get its own items back? How's the quality of the reprocessed items? Have they noticed any changes in their infection rate?

"Certainly longevity is a factor," says Ms. Chillemi. "Look for a company that gives you a track record," as evidence of their reputation and the service they stand behind. A reprocessor should also employ

experienced biomedical engineers familiar with the original equipment manufacturer's instructions and applicable government and healthcare industry regulations for guidance. A company representative who is easy to work with is a plus as well.

Other qualifications are hard-and-fast essentials. Reprocessing firms must register with the FDA as medical device manufacturers annually and provide them with a list of the devices they service. As suggested by the GAO's report, this registration is a fair indicator that the firm is in compliance with the FDA's standards and requirements. If it's not, the FDA's post-inspection warnings and the extent to which problems have been corrected are also evidence of the company's reliability. You'll also want to ascertain whether the company carries adequate liability insurance coverage against the possibility of a reprocessing failure — or an instrument failure — that leads to a surgical or post-surgical complication. The company is most likely insured to limit its own liability, but protect your center by ensuring that your contract with the reprocessor — if not your own insurance carrier — indemnifies you as well.

"Those are all givens, the FDA approval, the track record, support and liability," says Ms. Wilson. But you've also got to educate yourself on the reprocessing vendor's process. Do they have clearly written and explained policies for decontamination, refurbishing, testing, inspection, sterilization and packaging? Does their waste disposal meet applicable regulations? Do you understand the details of their quality assurance process? These are also questions you should answer periodically after you hire a reprocessor's services.

On the Web

GAO's report on reprocessed single-use devices - www.gao.gov/new.items/d08147.pdf

FDA's single-use device reprocessing page - www.fda.gov/cdrh/reprocessing

Association of Medical Device Reprocessors - www.amdr.org

Rationale for reprocessing

"As a society, and especially in the medical community, we need to look at reusing things," says Mr. Beck. "Healthcare is a disposable society. The amount of stuff even a small facility like ours goes through is amazing." By reprocessing single-use devices, "you could realize some significant savings," he says.

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