Winning converts to SUD reprocessing

Reprocessing of single-use devices is now mainstream, with an estimated 70% of US hospitals using single-use devices reprocessed by third-party companies, according to industry figures.

In an opinion piece in the March 2010 Academic Medicine, authors from The Johns Hopkins University School of Medicine call reprocessing a “common sense strategy” that has a reliable safety record while being environmentally friendly.

Third-party reprocessing has gained acceptance since 2000 when the Food and Drug Administration (FDA) stepped up oversight. The FDA requires entities that reprocess single-use devices to meet the same standards as original manufacturers. Hospitals opted out of the practice, leaving it to third-party companies that were better equipped to meet manufacturing standards.

The reprocessing industry has seen consolidation. There are now 2 major players, Ascent Healthcare Solutions (www.ascenths.com), and SterilMed (www.sterilmed.com), down from 11 in 2007, as identified by the Government Accountability Office (GAO).

In a 2008 report to Congress, the GAO said the available data, though limited, did not indicate reprocessed single-use devices pose an elevated health risk. The FDA, after analyzing adverse event reports for reprocessed single-use devices, concluded there were no patterns pointing to a risk, the report notes.

Still, there are holdouts. Some surgeons and staff continue to express concerns about the safety of the practice. Some strategies that have helped win converts, perioperative leaders say, are recruiting a surgeon advocate, arranging a tour of a reprocessing plant, and enlisting the staff to help educate surgeons.

Two large health systems, Banner Health based in Phoenix, Arizona, and Sisters of Mercy Health System headquartered in St Louis, have introduced broad-based programs for reprocessing of single-use devices. Their leaders talk about making the case to everyone in the organization.

Supply chain savings

In Banner Health, which has been reprocessing single-use devices for about a decade, all but 2 facilities in the 22-hospital, 14-surgery center system have adopted the practice. The facilities use Ascent, which in an interesting twist is now owned by Stryker, a medical device manufacturer.

“We became involved with reprocessing 10 years ago because we wanted to find ways to capture additional savings for our supply chain costs,” says Dee Whittington, RN, BSN, CNOR, Banner Health’s clinical supply manager, material management.
Environmental concerns weren’t at the forefront in the beginning, but Whittington says over time, the focus has turned more to the environmental benefits.

Banner Health began with noninvasive items, such as sequential compression devices, and then moved to include invasive instruments.

One Banner facility that has not adopted reprocessing is 342-bed Banner Baywood Medical Center in Mesa, Arizona, which has 10 ORs. Chris Halowell, RN, MS-HSA, CNOR, the director of perioperative services, says she is a strong proponent but has met resistance from surgeons who are preceptors for original device manufacturers. Other surgeons are leery about whether some endomechanical devices can be safely rebuilt, she says.

Halowell recommends educating staff and surgeons about the FDA regulations and arranging a tour of a reprocessing facility so they can see the process firsthand. Ascent has facilities in Phoenix and Lakeland, Florida. SterilMed’s reprocessing plant is in Maple Grove, Minnesota.

Perioperative leaders from her facility have taken tours and reported back to the staff and surgeons. The leadership team is trying to identify surgeon and staff champions so they can start a small program, such as reprocessing opened but unused stainless steel items such as bits, burrs, and blades.

Cost savings seen

The 22-hospital Sisters of Mercy Health System began a structured reprocessing program in 2009. The program has been rolled out in about half of the hospitals so far.

“We began the initiative because we knew there would be significant cost savings across the enterprise,” says Marita Parks, RN, MHA, CNOR, vice president, performance consulting.

Parks says the keys to implementation have been strong staff and physician education, strong support from reprocessing vendors, a logistics process, a communication plan, and a physician liaison.

The physician liaison position involves enterprise-wide responsibility for education of and ongoing communication with physicians regarding reprocessing and its benefits to Mercy.

“A physician liaison is absolutely crucial because we have met significant physician resistance,” says Parks. There has also been counter-detailing by some original device vendors, which Mercy addressed by sending letters to all of its vendors asking them to support Mercy policies and programs.

Ascent has assisted by providing details about the regulatory requirements and logistics of the remanufacturing process, notes Parks.

“It’s important to understand that we are the manufacturer of these devices,” says Monica Underwood, Ascent’s representative for Banner Health. The original device manufacturer sells the device as single use. After use, for reprocessed devices, Ascent takes on the liability and warranty for that product because Ascent is now the manufacturer, Underwood explains.

Whittington says that within Banner Health, failure rates for reprocessed items are less than failure rates for items from original manufacturers.

Seeing the process firsthand

Banner Gateway Medical Center, in Gilbert, Arizona, a short distance from Banner Baywood, has had a reprocessing program for 5 years. The hospital is licensed for 176 beds but is expanding. There are currently 9 ORs.

Penny Boone, RN, MSN-L, CNOR, director of perioperative services,
says after touring Ascent’s Phoenix facility, “I came away convinced that the standards under which Ascent functions are very high, and I felt a strong sense of confidence that this was a safe way to supply equipment for patients.”

But she did not believe the OR staff or surgeons would be convinced unless they also saw the process firsthand. Half of the OR staff and 1 surgeon toured the Ascent facility, and like her, she says, they came back convinced of the safety of the process.

Boone started small with a trial of several devices, which she says was successful because of the OR staff’s role in educating the surgeons.

“There was some resistance at first, especially from the orthopedic surgeons,” says Boone.

**Informal education helps**

One of the trial devices was an arthroscopic shaver. The circulating nurse and scrub person had both the original-manufactured and Ascent-remanufactured shavers available in the OR, and they asked the surgeons if they would like to try the Ascent shaver.

“In the beginning, some said yes, and some said no. Then slowly but surely they started trying the remanufactured items and found there was no difference,” says Boone.

The OR staff also educated the surgeons about the environmental and cost savings of the remanufactured items.

“It was really this informal education of the surgeons by the staff that turned them around,” says Boone.

Banner Gateway is now reprocessing every laparoscopic item for which Ascent has FDA clearance, including trocars and Harmonic Scalpels.

“Reprocessing is such a part of our culture now that it has become a non-issue,” says Boone.

**Savings from reprocessing**

In 2009, Banner Health saved more than $2 million by reprocessing and avoided more than 60,000 pounds of waste, Whittington says. Banner saves an average of 55% on reprocessed devices and 62% on open but unused items that do not have to be remanufactured, she notes.

From July 2009 to February 2010, Sisters of Mercy hospitals had actualized savings of $522,000 and project a $2 million annualized savings with the program, says Parks. Savings include the reduced cost of the remanufactured devices as well as environmental savings. In the 8-month period, 19,000 pounds of waste were saved from landfills.

**Making it easy for staff**

To collect items for reprocessing or recycling, Ascent provides a large, reusable collection container and a small sharps container for each OR. The scrub person places all single-use devices into the large bin and sharps into the small bin. The scrub person doesn’t have to worry whether a device can be reprocessed or take time to separate devices not on the FDA-cleared list, says Mike Hatton, service manager for perioperative services at Banner Gateway. The company does the separating.

Ascent reprocesses the approved devices and recycles items that can’t be reprocessed or have met the number of times they can be reprocessed.
Recycling program

“Only about 10% of what is captured in a facility can be remanufactured and returned,” says Underwood. The rest, which are made of heavy plastics and metals, are rendered harmless with a decontamination process. They are then broken down into their components and sent to a recycling plant to be turned into remanufactured products such as park benches or swing sets rather than being taken to a landfill.

Ascent does all the legwork, says Hatton. The company picks up the collection containers from the hospital and brings remanufactured items to the hospital when they are ordered.

“If Ascent doesn’t have an item I need, I will order it from the original manufacturer, but I always try Ascent first,” says Hatton.

Having worked for device manufacturers for 30 years, Hatton admits that 20 years ago when the reprocessing business began, he thought it was a “terrible idea” and held that belief until a few years ago. What convinced him the process was reliable and safe was watching the process at the Ascent plant in Phoenix.

“I saw first-hand how the reprocessors disassemble a device and then remanufacture it to the original equipment manufacturer specifications, replacing any parts that might have been compromised with use.”

—Judith M. Mathias, RN, MA

References


