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Hospitals Reuse Medical Devices To Lower Costs

By LAURA LANDRO



In a bid to save costs and stem a rising tide of medical waste, hospitals are recycling a growing number of medical devices labeled as single-use, from scissors and scrubs to the sharp blades surgeons use to saw through bones.



Ascent Healthcare Solutions
Employees sort medical devices at a recycling firm.

Recycling medical devices labeled for single use is legal as long as certain Food and Drug Administration guidelines are followed. But the practice, which involves shipping devices to reprocessing facilities to be cleaned, sterilized and tested for reuse, has raised concerns about safety. Medical device makers say their single-use products are just that, and pose a higher risk of failure and harm when recycled. Reprocessing companies, hospital associations and environmental groups counter that the devices they reprocess are as safe as new thanks to modern sterilization methods, cost 40% to 60% less, and can eliminate thousands of tons of waste from landfills.

In January, after reviewing eight years of FDA data, the Government Accountability Office weighed in with a report concluding there is no evidence that reprocessed single-use devices create an elevated health risk for patients. About 100 devices -- just 2% of all devices labeled for single use -- are now reprocessed.

But while the GAO report tilts the debate strongly in favor of reprocessing and opens the door to more widespread use, device makers are sticking to their guns. They are lobbying in several states for legislation that would require health-care providers to obtain "informed consent" from a patient before using a reprocessed device during a procedure. Utah already has approved liability protections for original equipment makers, and other state bills include measures that would free original manufacturers from liability if a reprocessed device fails and causes injury or death.

Device makers maintain that their products labeled for single use aren't designed to hold up to harsh sterilization chemicals and processes. Even when the devices are sterilized, blood, tissue or other bodily fluids on porous surfaces and in tiny crevices could allow transmission of viral and bacterial infections, they say. In general, "single-use devices present an increased safety risk to patients because they are designed for optimal performance and safety in a single patient," says Tara Federici, vice president of technology and regulatory affairs at AdvaMed, a trade group that represents leading device makers.

For example, heart stabilizers, the devices used to position a beating heart during surgery, have hollow tubes and other parts that device manufacturers say could harbor blood and tissue and become

The Medical Recycle Bin

Some commonly reprocessed single-use medical devices:

Device	Usage	New price*	Reprocessed price*
Pneumatic Tourniquet Cuff	Reduces or blocks circulation to a limb during surgery	\$20-40	\$10-18
Pulse Oximetry Sensor	Measures blood oxygen level via attachment to patient's finger or toe	\$10-20	\$6-10
Cardiac Stabilizers/Positioners	Helps position the heart during open-heart surgery	\$600-1,100	\$300-500
Saw Blade	Used to cut hard or soft tissue and bone	\$30-65	\$15-40
Ultrasound Catheters	Provides detailed images of cardiac anatomy	\$2,400-3,200	\$1,300-1,600
Laparoscopic Scissors/Shears	Used in general and OB/GYN surgery	\$100-150	\$50-75

*Approximation

Source: Association of Medical Device Reprocessors

weakened during reprocessing in ways that might not be evident during inspection. A study by the University of Minnesota of stabilizers made by **Medtronic Inc.** found that while new devices showed little or no manufacturing debris, a majority of reprocessed devices had corroded parts and traces of human hair and protein, bringing into question the effectiveness of the reprocessing efforts.

Last year, the FDA began requiring that reprocessed heart stabilizers undergo more rigorous premarket clearance reviews, and a Medtronic spokesman says the company plans to repeat the tests to see if the more stringent requirements improve performance. Until then, he

says, the company stands by its position that the devices can't safely be reprocessed.

The Association of Medical Device Reprocessors, a trade group whose members reprocess the majority of devices, counters that it recycles only products made from rigid, hard metals or durable polymers and plastics that can safely be reused between two and five times, depending on the device. The group has petitioned the FDA to require new heart stabilizers to undergo the same premarket review as reprocessed ones, because the device itself is high-risk. Since 2001, the group notes, there have been 73 adverse events reported to the FDA involving devices used to stabilize the heart, including incidents in which pieces have broken off and fallen into the chest cavity.

Dan Vukelich, president of the group, says reprocessed devices can be safer in some cases because each must be inspected before reuse, while original manufacturers test new devices only in batches. He also contends that device makers label many products as single-use merely to be able to sell more new devices to hospitals and thwart competition -- a contention that medical device makers dismiss.

About \$31.5 billion of single-use medical devices are sold annually in U.S. hospitals and surgery centers, of which around \$150 million are recycled, according to Ascent Healthcare Solutions, a leading reprocessing company. John Grotting, Ascent's chief executive, estimates that about \$3.6 billion of single-use devices are safe for reprocessing, which could save the health-care industry about \$1.8 billion a year. Ascent hospital customers eliminated about 1,684 tons of waste from their local landfills last year, a 31% increase over 2006, by using reprocessed devices, Ascent says.

Mr. Grotting says reprocessed devices are as safe as new ones. Of 65 events reported to the FDA from October 2003 to July 2006 involving or suspected to involve reprocessed devices, the device was just one of several possible causes of harm, and the adverse events were of the same type reported for new, nonreprocessed devices, the FDA found.

Manufacturers began labeling more products as single use starting in the 1980s, partly in response to concern about the spread of infectious diseases like AIDS. Single-use items such as tongue depressors, bandages, adhesive tape, urinary catheters and breathing tubes are discarded after one use. FDA-approved reprocessing, with sterilization methods that would result in only a one-in-a-million chance of a contaminant surviving the process, is very different from cases such as a recent outbreak of hepatitis C in Nevada traced to the reuse of unprocessed syringes.

But hospital administrators and other experts say many products such as saw blades that were historically designated as reusable now carry single-use labels, with no obvious difference in the product.

"Single-use labeling is a real scam for a lot of devices, and by not using reprocessed devices where possible it is wasteful and not environmentally responsive, since these items have to be disposed of as biomedical waste," says Kenneth Kizer, a consultant and former undersecretary for health at the U.S. Department of Veterans Affairs. "The reuse of medical devices that are labeled for single-use only is a well-established and safe practice regulated by the FDA and utilized by most of the top-ranked hospitals in the country."

Dr. Kizer testified last year at a congressional hearing that the VA could save up to \$30 million in 2008 by using reprocessed medical devices. The VA, with 153 hospitals, has had a longstanding policy against the use of reprocessed devices on the grounds that it can't determine if they are safe, noting that manufacturers didn't design them to be used more than once and don't provide instructions on cleaning and sterilizing the devices. A spokesman says the VA reviews the policy from time to time but has no plans to change it at present.

The FDA has stepped up its oversight of reprocessing, including more plant inspections, after new legislation in 2002 began requiring devices to be labeled if they are reprocessed. The FDA says it is working on a new strategy for monitoring and communicating information about reprocessed devices, and conducting research on "acceptable" single-use device-cleaning criteria.

AMDR, the reprocessing group, is fighting efforts to require that patients go through formal informed-consent processes. Mr. Vukelich says informed consent is meant for experimental treatments and clinical trials, and not for devices that are legally marketed and approved by the FDA. For patients, however, it may be reassuring to ask physicians whether a reprocessed single-use device will be used during an invasive procedure and what steps have been taken to ensure it carries no additional risk

Oakland, Calif.-based health-care giant Kaiser Permanente started working with Ascent to reprocess single-use devices more than a decade ago, and sharply increased its use of reprocessed devices in 2006. Dean Edwards, vice president and chief procurement officer, says Kaiser shaved about \$3.5 million from its device costs in 2007, and eliminated about 45.7 tons of medical waste.

At Catholic Healthcare West, the nation's eighth-largest hospital system, a wide range of medical devices labeled as "single use" are reprocessed each year. Last year, the San Francisco-based concern figures it reduced waste volume by 41 tons and saved \$1.8 million.

"The safe use of these reprocessed devices helps us conserve resources so we can be more cost-effective in delivering care" says Sister Susan Vickers, vice president of community health. "And we are diverting significant amounts of medical waste, which definitely benefits our planet."

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