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## Fight over cleaned, reprocessed medical supplies gets dirty

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ATLANTIC CITY — A bloody-looking catheter. Dirt-specked coils from biopsy forceps. A grimy medical device identified as an “endoscopic clip applier.”

The heading warns: “Can This Single-Use Medical Device be Reprocessed and Used Again on You and Your Family?”

The Web site for PatientGUARD, a self-described consumer advocacy group, doesn't say much about where the pictures came from, but it doesn't have to. A picture is worth 1,000 words, and these pictures are just plain gross.

“... (M)edical devices designed for one-time use only are being picked from the medical waste stream and reused, despite the dangers of infection, complications, and disease,” the Web site,

**www.patientguard.org**

warns, and there is “little oversight and regulation” of the practice.

Creeped out yet?

If so, you're invited to sign a petition demanding that New Jersey lawmakers “protect our families” and download a form demanding that only new devices be used during your surgery.

If you bite, you've just been drawn into a pitched battle between two sworn enemies — companies that make medical devices labeled “single-use” and companies that clean, sanitize and retool them for re-use, saving hospitals about 50 percent off the cost of buying new.

Over the past few months, through news conferences, lobbying legislators and its Web site, PatientGUARD — which is backed by the medical device and pharmaceutical industry group HealthCare Institute of New Jersey, or HINJ — has been campaigning to make patients believe that when they enter a hospital, they're at risk of being operated on with someone else's germ-ridden, re-used scalpel.

The reprocessing of single-use medical devices is actually a highly technical, FDA-monitored process that takes about a week of repeated sterilizations, examination and testing of each device. But that's not what the single-use device manufacturers would have you believe. According to PatientGUARD and its growing number of allies — some of which are legitimate consumer groups — recycling single-use medical devices is akin to playing with fire.

Quiet on reprocessing

What is reprocessing and who does it? The answer may surprise you. While several area community hospitals vehemently distanced themselves from reprocessed devices in interviews for this article, the area's largest and most comprehensive hospital, AtlantiCare Regional Medical Center, acknowledges that it reprocesses and re-uses devices labeled “single-use.”

Nationwide, according to the Association of Medical Device Reprocessors, or AMDR, some of the best and best-known hospitals reprocess single-use devices. They include 13 of 14 "honor roll" hospitals identified in 2006 by U.S. News and World Reports, along with all of the magazine's Top 10 heart and surgery hospitals and nine of the Top 10 orthopedic hospitals.

AMDR members also serve 87 percent of the nation's top hospitals, as rated by Solucient, an information products company serving the health-care industry. These include all Top 25 teaching hospitals, 14 of the 15 best "major teaching hospitals" and all of the Top 20 large community hospitals.

In other words, reprocessing is no dirty, dangerous fly-by-night operation, at least in the eyes of some of the top hospitals in the nation.

But that doesn't mean hospitals are eager to let patients in on their little secret.

"We think it would needlessly upset patients," said Christina Kales, a senior policy analyst with AMDR. "You can imagine if your doctor said to you: 'I'm going to use a device on you that I've used on another patient.'"

AtlantiCare said it doesn't inform patients if reprocessed medical devices will be used on them, either.

"We're not required to tell patients that we're using reprocessed devices," said AtlantiCare's Rene Bunting. "That's because ... they're every bit as safe and sterile (as original devices) and we observe all the regulations."

For hospitals, the benefits of reprocessing are clear. Until about 20 years ago, many of the devices used in hospitals were intended for re-use, and were re-used — usually after being washed and disinfected in-house. But new "single use" devices have become more common, creating a glut of medical waste and pushing up the cost of care.

Do surgical saw blades, drills, scissors and orthodontic braces really need to be thrown out after one use? What about pressure cuffs, or that little clip a nurse puts on your finger to measure your blood oxygen content?

Single-use device manufacturers say "yes."

The hospital industry, which saves about 50 percent of the cost of buying new by reprocessing, is increasingly saying "no."

"This industry was started by a group of physicians and engineers who worked for the original equipment manufacturers. They knew that these (single-use devices) had a life well beyond a single use," Kales said.

Although PatientGUARD alleges there is "little oversight and regulation" of medical device reprocessing, the Food and Drug Administration — which regulates the industry — begs to differ. In fact, the FDA says, reprocessors are subject to more stringent regulation and more frequent inspections than the original manufacturers.

According to Daniel Schultz, director of the FDA's Center for Devices and Radiological Health, data going back to 2003 indicates "no clear causative link between a reprocessed (single-use device) and subsequent patient injury or death."

In fact, he told a congressional committee in September, reprocessed devices that meet FDA's standards are "as safe and effective as a new device."

"Each and every reprocessed device has been tested before being sent back to the hospital," Kales said. "The safety of (reprocessed) devices is excellent. It's in fact far better than the (original) out-of-the box single-use device."

#### Business of refusal

PatientGUARD, however, says patients have a right to know if hospitals plan to use reprocessed single-use devices in their care, and have the right to refuse.

"These devices are not manufactured to be used more than once," said Ernest Landante, a spokesman for PatientGUARD. "They're not made, nor designed, to be used again on a patient. ... They're designed to withstand the rigors of one use."

Landante cites examples of reprocessed devices failing, such as a June 2005, incident in which a reprocessed surgical trocar exploded inside the abdomen of a patient getting colon surgery.

But the organization has its own reasons to publicize the fact that the saw blades, drills and catheters used in your surgery may have spent time in a few other patients' bodies.

Though it describes itself as "a coalition of organizations working together to protect the public" PatientGUARD is, in fact, sponsored by New Jersey's pharmaceutical and medical device industry — an industry that stands to lose money when devices marked "single-use" are reprocessed.

Bob Franks, president of the industry group backing PatientGUARD, HealthCare Institute of New Jersey, said there has never been an effort to hide the link between the single-used device manufacturers and PatientGUARD.

"The concern my companies have is that the reproprocessors are making money .... by selling our original devices after they have been reprocessed," said Franks, a Republican former congressman. "We have serious questions regarding whether or not reprocessing of the devices both encourages the transmission of communicable diseases, as well as impairs the functionality of these devices."

Medical device reproprocessors believe PatientGUARD's motives are less than altruistic.

"I always say, 'Follow the dollar,'" said Arthur Goodrich, vice president of marketing and business development for Ascent Healthcare Solutions, a medical device reprocessing company based in Phoenix. "We're helping hospitals reduce waste and products going into landfills, (and) we're also helping them maximize efficiency. ... That money has to come from somewhere. It comes out of the pockets of those folks who are selling that device new, and they're not happy about it."

He adds, "It's a marketing strategy. If it were me driving the strategy, it's probably the same thing I'd do."

#### Mixed messages

The debate over reprocessed medical devices has been further confused by blatant misinformation in mainstream media articles — followed by little-noticed corrections.

On July 30, for example, the Associated Press reported that since early 2004, the Food and Drug Administration had received 13 reports of patient deaths involving reprocessed single-use devices

and 130 reports of serious patient harm, out of a total of 421 reprocessed-device trouble reports. The article also discussed the case of an infant who was permanently injured by a damaged reprocessed tracheal tube in 2001.

Two days later, another Associated Press story quoted an official as saying that three brain-surgery patients had been infected with Creutzfeldt-Jakob Disease in recent years because of improperly sterilized medical equipment.

But on Aug. 2, the AP issued a correction to the second article, saying the president of the Creutzfeldt-Jakob Disease Foundation had been "misquoted."

And on Aug. 11, the AP acknowledged in a second correction that there had been no FDA reports of deaths caused by reprocessed single-use medical devices; and fewer than 10 injuries and fewer than 10 device malfunctions were attributable to reprocessed single-use devices during that time period. The AP attributed the error to incorrect information from the FDA.

Furthermore, the correction acknowledged, the FDA didn't oversee reprocessing of medical devices at hospitals in 2001, and has not authorized the reprocessing of tracheal tubes.

Several area hospitals were quick to distance themselves from the controversy when asked if they reprocess items.

"We don't, under any circumstances, use reprocessed disposable devices," said Greg Potter, a spokesman for South Jersey Healthcare, which has hospitals in Vineland and Elmer. "Any item identified as 'one use' clearly is not used more than once at SJH, without exception." The reason, he said, is that "our goal is to protect patient safety."

"Southern Ocean County Hospital does not use reprocessed medical devices," spokeswoman Lisa Weinstein said in a brief, one-line e-mail.

On the other side of the line is AtlantiCare Regional Medical Center, which has been reprocessing some medical devices since 2002 and had saved nearly \$90,000 in the first 10 months of 2002.

"This is really very heavily regulated by the Food and Drug Administration," said Joan Brennan, vice president for quality and performance excellence at AtlantiCare. "Safety is our top priority and patient care is what it's all about. We make sure we follow the highest level of standards related to the guidelines (for reprocessing) that are out there."

She said the hospital has never had any problems associated with the reprocessed items.

That wasn't the experience of staff at Shore Ambulatory Surgery Center in Somers Point, run by Wills Eye Health System. A spokeswoman said the surgery center tried reprocessing one device about two years ago, but stopped because doctors were "unhappy with the quality." She declined to elaborate.

Meanwhile, Shore Memorial Hospital does not currently use reprocessed medical devices, but is investigating the option.

"We have not used reprocessed devices because the manufacturers would not guarantee reprocessed products and there (were) no regulations in place regarding their use," Shore Memorial spokeswoman Margie Barham said in an e-mail. "That practice seems to be changing, and there are more regulations to assure safer reprocessed products. Also, the FDA has even given its blessing for some items to be reprocessed. Because of this regulation, Shore is considering the use of certain reprocessed products, but currently does not use any reprocessed devices."

## Gathering support

Despite its somewhat tangled roots, PatientGUARD has gained support within the patient advocacy community, and now counts several nonprofit organizations as members.

"There have been reports of traces of DNA and other tissues still on the (reprocessed) instrument," said Joseph Roney, CEO of the New Jersey Pharmacists' Association, citing "a whole lot of published literature."

PatientGUARD counts 20 other organizations among its members, ranging from the Creutzfeldt-Jacobs Disease Foundation to Autism Family Services of New Jersey. Contacted by telephone, representatives of several of the organizations said they had been asked to join PatientGUARD by HINJ, and expressed little first-hand knowledge of any reprocessing "risks."

For example, the News Jersey Association of Osteopathic Physicians and Surgeons got on board after being approached by HINJ, and joined in part because of prior partnerships, said executive director Robert Bowen.

"For the same reason — quality of patient care — we're interested in the concerns that have been raised in this area," Bowen said. "They've been very up-front about their relationship (with single-use medical device reprocessors) but we'll see where the data leaves us." He said his organization hasn't taken a position specifically opposing medical device reprocessing, but believes reprocessing "may very well be a reason for concern."

Roney said his organization is aware of PatientGUARD's connection to single-use medical device reprocessors, but isn't concerned by it.

"My main concern isn't about vested interest. It's about patient safety," he said. "We really don't have a dog in this fight. We are sympathetic to the HealthCare Institute of New Jersey's position."

Kales believes organizations as diverse as the Latino Leadership Alliance of New Jersey and Autism Family Services of New Jersey are attaching themselves to PatientGUARD's cause because it helps them get publicity.

"Why would those people care about reprocessed medical devices? It's because it gives them an opportunity to get some more attention for their cause," she said.

Also, the HealthCare Institute of New Jersey's members are power charitable contributors, giving away about \$4.4 billion worldwide in 2005, \$152 million of that in New Jersey.

Kales says single-use medical device manufacturers are simply using the PatientGUARD front — and their connections — to shut down the reprocessing business.

"They create these organizations that look to be credible so they can try to generate some anxiety in the public," she said. "They want to eliminate the reprocessed devices so that they can make (more) money. It's very unfortunate that these people (patient advocacy groups) have been involved in what is basically a scam."

Landante argues that patients have the right to know what's being used on their bodies when they enter a hospital.

"It seems to be nothing less than common decency that a patient should know and be able to make a decision that either yes, you can use a recycled device on me, or no, I want a brand-new

one.”

But should you really be concerned if your catheter isn't brand spanking new? Not according to the FDA. Not according to the New Jersey Hospitals Association, which says it has repeatedly surveyed its members about the reuse of reprocessed devices and has “yet to hear of any adverse outcomes,” according to its president, Gary Carter.

And not according to the New Jersey Department of Health and Senior Services, which will begin asking hospitals to specifically report medical errors related to the use of reprocessed devices beginning in January, but hasn't seen any indication that the devices are unsafe.

“Right now we just haven't seen any reliable data on whether there is a problem or not,” said DHSS spokeswoman Marilyn Riley.

Commonly reprocessed devices

n surgical saw blades

n surgical drills

n laparoscopy scissors

n orthodontic (metal) braces

n electrophysiology catheters

n electro-surgical electrodes and pencils

n respiratory therapy and anesthesia breathing circuits

n endotracheal tubes

n balloon angioplasty catheters

n biopsy forceps

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