



Keeping Count

By Scott Mace
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“Radio tags” help eliminate retained foreign bodies

On Valentine’s Day 2006, the U.S. Patent and Trademark Office granted Patent No. 6,998,541 to Sharon Morris, RN, BSN, and her husband, Dean, nearly three years after they filed their application. Their invention may revolutionize patient safety in the operating room.

It all started 10 or 15 years before. “I was working in a large blood-loss case,” Morris says. “It appeared like the lap sponges were just piling up on me. I was given a lot of blood products, trying to keep track of everything. I just thought to myself, “The way we do this is so antiquated. There’s got to be a better way.”

She went home and talked to Dean, a portfolio manager. “He’s like, “What? You dig in buckets and you wear gloves? And you have to separate [the sponges]?” And I said, “Yeah, I’ve been doing it my whole career.” They realized technology could play a role in the detection and counting of surgical items.



“Wand” device (left) and special sponges embedded with RFID tags. Courtesy of ClearCount.

Sponges detected by “magic wand”

Fast-forward to fall 2005. The Morris’ idea is given a test run at the Stanford University School of Medicine in Stanford, Calif., where anesthesiologist Alex Macario, MD, and two surgeons used a specially-prepared set of sponges in the operating room on eight patients. One surgeon planted some of the sponges inside the abdomen of the patient, while the other surgeon looked away. Then the second surgeon, before closing each incision, waved a

“wand” actually, a device the size of a small notebook over the patient. Each time one of the special sponges was present, it was detected by the device and was removed.

Media excitement over this new way to remove retained foreign bodies built this past summer when Macario published the findings of his study, which was funded in part by the National Institutes of Health. The Morris’ invention is in the initial stages of the FDA approval process, and the American College of Surgeons was hoping to launch www.nothingleftbehind.org, a web site with resources for solving the retained foreign bodies problem in operating rooms, in October.

How does the new technology work? Each special sponge has a tiny, unique radio-frequency identification (RFID) chip embedded inside. RFID devices, passive pieces of silicon that emit a digital signature when scanned, are appearing in everything from library books to toll-collection systems to blood bags to passports. The Morrises, via a startup called ClearCount Medical Solutions, aim to provide their sponges to every hospital operating room.

Age old problem

The problem of retained foreign bodies is as old as surgery itself. But new patient-safety reporting systems in states like Minnesota, Pennsylvania, and New York are bringing such cases to light. And despite Sharon Morris’ epiphany following a major surgery, the problem occurs more often during minor surgeries that involve far fewer sponges.

Verna Gibbs, MD, professor of clinical surgery at the University of California, San Francisco (UCSF) and attending surgeon at the San Francisco VA Medical Center, is leading the www.nothingleftbehind.org project. She estimates 10,000 retained foreign body cases occur per year in the U.S. While individual hospitals may not have any incidents occur in the span of a year, the annual average is more than one per U.S. hospital, she says.

These incidents don’t cause death, Gibbs says. “But it does cause morbidity if you have a retained sponge,” she adds. “You have to go back to the operating room to get it out.”

Of course, the push to eliminate retained foreign bodies must ultimately extend beyond technology for sponges. Some items, such as needles, are still too small to incorporate anything like an RFID chip. But the ability to track sponges will cover a vast majority of cases.

While creating a new sponge counting and detection technology is one thing, persuading surgeons and nurses to adopt it is another. So far, the ClearCount system has been tested in limited hospital settings. The hospitals testing the system declined to comment for fear of creating a perception that they have a problem with retained foreign bodies. But larger trials, including one at UCSF starting in October, are on the way. And once the FDA grants approval, serious clinical trials, and the work of convincing hospitals to try the system, begin in earnest.

Working out the details

The invention itself is being miniaturized still further: The RFID chip embedded in the sponge has shrunk from nickel-sized in the Stanford test to a dime-sized one today, and surgeons and nurses are discovering best practices for its use. How will the “wand” be kept sterile, or should it be disposable? If the “wand” is hooked up to a display, what information should the display present in the OR? Testing continues, according to Gautam Gandhi, co-founder and chief marketing officer of ClearCount. Still, he hopes for initial FDA approval by the end of this year.

Although advocates such as Gibbs prefer not to dwell on this aspect, the eventual cost savings to health care could be substantial. Routine X-rays taken post-surgery to detect retained foreign bodies could be eliminated. So, too, could nurses’ lengthy, duplicative, manual-counting procedures.

Can it be fool-proof?

Morris also believes something the rest of the world will have to be convinced of: that the ClearCount RFID system can be made foolproof. "That's what I've always said from day one," she says. "If it could never be, then I wouldn't trust it and I couldn't use it. So it has to be."

"If you have five sponges altogether packed behind the liver, can they be detected?" Gibbs asks. "That work remains to be seen. Every hospital may not need a highfalutin RFID sponge counter."

Lori Couzens, RN, BSN, CNOR, Gibbs's colleague at UCSF, is "every impressed" with the RFID technology. "It takes some of the guesswork out of where the sponge is located." But she cautions, "With any technology, there's always some potential for operator error, so I don't know that you can make anything particularly foolproof. What it does is work in conjunction with human policy and procedure and practice, and helps to reduce the potential for error, significantly."

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