Surgical Sponges Get Smart

A Pittsburgh-based startup has developed a system consisting of passive tags and a wand-like RFID interrogator that can detect if any sponges are mistakenly left inside a patient.

By Beth Bacheldor

July 26, 2006—In the next few months, Pittsburgh-based startup ClearCount Medical Solutions says it will introduce its first—and a first-of-its-kind—product: a surgical sponge with an embedded passive RFID tag about the size of a shirt button.

Called the SmartSponge System, the product is designed to prevent surgical teams from inadvertently leaving sponges inside surgical patients. While that's not an everyday occurrence, it does happen. According to ClearCount, recent studies have estimated that cases of retained foreign bodies occur between 1 out of every 100 to 1 out of every 5,000 surgical procedures, and studies have shown that two-thirds of all retained foreign bodies are surgical sponges.

With SmartSponge, surgical teams will be able to scan the patient with an RFID interrogator in the form of a wand during postoperative safety checks to find any sponges mistakenly left behind. The technology could supplant time-consuming manual counts done by at least two nurses several times during the course of a surgery, or costly and time-consuming X-rays that can detect threads sewn into the sponges.

ClearCount cofounders Gautam Gandhi and Steve Fleck first came up with the idea for SmartSponge while students at Carnegie-Mellon University. The two researched the problem and considered a variety of different RFID tag and reader technologies before realizing they'd have to design their own (the privately held company has declined to divulge technical specifics on its tags and readers). ClearCount now holds patents on the technology.

"The challenge we had was how to get the tag to be read through a body—with bone, muscle and flesh—and how to get an accurate read every time," Gandhi says. The read range between the tag and the interrogator had to be on average 15 inches, to account for the depth of a human body where a sponge might get left. In addition, the tags had to be able to withstand the standard sterilization process all sponges go through before being used during a surgery. After surgery, the sponges are thrown away.

ClearCount had tested its technology in a veterinary clinic, but the bigger question still remained: Would the system make economic sense?

"We knew it would work from a technological point of view," says Gandhi. "But we needed to find out if we would end up building a million-dollar mousetrap."

Consequently, ClearCount turned to Harrison Chow, clinical instructor and perioperative management fellow in Stanford University Medical Center's department of anesthesia, to conduct an independent economic analysis. In his study, which was developed using a spreadsheet economic model, Chow concluded that "RFID-tagged surgical sponges appear to be economically attractive from society's perspective, as long as this

new technology approximately cuts in half the time nurses spend counting sponges in the OR."

Next, Gautam and Fleck got in touch with Alex Macario, a physician and professor of anesthesia at Stanford University Medical Center, to plan a study involving humans. In early 2005, Macario oversaw a trial that tested the technology on eight patients undergoing abdominal or pelvic surgery. The trial included eight untagged sponges that served as the control to ascertain if the wand could detect non-tagged sponges (the researchers determined it could not), and 28 RFID sponges, according to a report published in the July issue of American Medical Association's Archives of Surgery by Macario and his two coauthors, both of whom own several patents related to tagged sponges and work for ClearCount.

During the trial, a surgeon placed one RFID sponge in the patient just before closure. The edges of the wound were pulled together "so that the inside of the cavity was not exposed during the detection experiments," according to the report. A second surgeon, who purposely did not watch the first surgeon place the sponge, then used the wand to find the sponge.

The wand detected all sponges correctly in less than three seconds, and there were no false-positive or false-negative results.

Gandhi says the trial yielded some additional information about the system, too.

"The surgeons all liked the concept, but some people felt that maybe the wand was a little bigger than what they had expected," he says. "But once they used it and felt how light it was, they liked it."

Also, there was concern about introducing a new step—the scanning of the patient with the wand—into the surgical process. "As a layman, you might think, 'What is the big deal?'" says Gandhi. "But when you consider a four-hour surgery, five seconds might seem important."

Gandhi and Fleck concluded the technology they were developing was economically and technologically justifiable. "The cost of the chips are declining rapidly," Gandhi says.

More importantly, if a sponge count at the end of a surgery is less than the sponge count at the start, hospitals typically call for an X-ray. Most operating rooms don't have a dedicated X-ray machine, so one has to be located and wheeled in, which can take time. In addition, radiologists have to be brought in to look at any X-rays taken. "That can all take 20 minutes, and an X-ray isn't foolproof. If the sponge is behind bone, the X-ray won't show the sponge," Gandhi says.

Of course, most importantly, if a sponge is left in, he says, "people can die."

ClearCount's SmartSponge System can count multiple sponges at once, but won't count the same sponge twice, and has the ability to distinguish different types of sponges, although Gandhi declined to explain how the system accomplishes this.

The company plans to begin shipping the sponges this fall but has yet to determine how they will be sold and distributed.