

# RFID-enabled Surgical Sponges a Step Closer to OR

Approved by the FDA, ClearCount's redesigned SmartSponge System is currently being tested in several U.S. hospital operating rooms.

By Beth Bacheldor

June 27, 2007—[ClearCount Medical Solutions](#), a Pittsburgh, Penn.-based company focused on improving surgical safety, is getting closer to launching a commercial version of its SmartSponge System, designed to help prevent medical teams from inadvertently leaving sponges inside surgical patients. The company has redesigned the sponge-tracking system, clinical trials are underway and the system has received clearance from the [U.S. Food and Drug Administration](#) (FDA).

Earlier this month, the FDA approved ClearCount to market surgical sponges embedded with passive RFID tags. The SmartSponge System uses [Texas Instruments'](#) Tag-it HF-I tags, which operate at 13.56 MHz and support the ISO 15693 and 18000-3 standards. The FDA granted clearance under Section 510(k) of the Food, Drug and Cosmetic Act. With such clearance, the SmartSponge System can be marketed and commercially distributed in the United States.

An independent organization, [No Thing Left Behind](#), is half-way through clinical trials testing ClearCount's RFID-enabled sponges, interrogators and companion software, in surgical cases in five different medical centers across the country. The No Thing Left Behind project's overall objective is to help hospitals, surgeons, perioperative care nurses and patients work together to ensure that surgical tools used in an operation are never left inside a patient.

Recent studies have estimated that cases of surgical objects left in patients occur between 1 out of every 100 to 1 out of every 5,000 surgical procedures, ClearCount says, and other studies have shown that two thirds of all retained foreign bodies are surgical sponges. ClearCount first unveiled its RFID system about a year ago (see [Surgical Sponges Get Smart](#)).

The SmartSponge System has been redesigned so surgical teams can more easily—and accurately—verify the number of sponges at the start of an operation with the number of sponges actually used during the procedure. The system can be wheeled from OR to OR, and now has a built-in RFID interrogator that records the number of tagged sponges in pre-packs as workers set them on a tray affixed to the interrogator at the start of an operation.

After an operation, used sponges are discarded into a bucket, also affixed to the interrogator, which records the tags in discarded sponges. A small LCD screen displays the counts, confirming whether there's a match. Because each tag embedded into the sponge contains a unique ID number associated in the ClearCount software with a specific sponge type—either a laparotomy sponge or a 4 in. by 4 in. sponge—the system can also account for different sponge types. The SmartSponge System comes with an RFID interrogator in the form of a wand, enabling surgical teams to scan a patient during postoperative safety checks and locate any

sponges mistakenly left behind.

Presently, surgical nurses must manually count the sponges (which have X-ray-detectable threads sewn into them) before and after every operation. If a discrepancy exists, hospitals must X-ray the patient as well. Since few operating rooms have a dedicated X-ray machine, one must be located and wheeled in, which can take time. In addition, radiologists have to be called to examine any X-rays taken, and even that isn't fail-proof, because if the sponge is hidden behind a bone, X-rays might not detect it.

When ClearCount first designed the system, it only included the RFID-enabled wand. More research and feedback from the clinical trials underway, however, led to its redesigning the system and including an RFID interrogator that would automate the counting of sponges before and after operations. "When you just use the wand, you would scan the patient, and unless something is found, there's no feedback," says Gautam Gandhi, who co-founded the company with Steve Fleck. "So the question was, 'Is it working, or is there really nothing found?'"

Hospitals need to count sponges before and after operations. Not only are manual counts time-consuming, however, errors can—and are—made. "That is the biggest problem," Gandhi says. Statistics show that in 85 percent of cases where a surgical sponge was left behind in a patient, the nurses' counts appeared correct.

Thus, the ClearCount team started working on a redesign that could assist in the manual counting, both before an operation and upon its completion. The new design includes an interrogator that automatically counts sponges beforehand and afterward. This, Gandhi says, provides greater assurance that no sponges are left inside patients' bodies. "If the counts don't correlate," he explains, "that tells you something is missing—and if that happens, you'd never let a patient go."

For added assurance, ClearCount recommends surgical teams scan every patient with the wand after surgery. "It only takes five seconds, so you might as well," Gandhi says. By the end of 2007 or early 2008, the firm expects to make a commercial solution available that can be implemented in operating rooms and integrated with surgical processes.

**RELATED\_ARTICLES** ClearCount has been testing its system in a series of clinical trials run by the No Thing Left Behind project since April 2006. "This is a multi-center study to look at the way the SmartSponge system works" says Verna C. Gibbs, MD, "and the goal is to test the system in 400 to 500 operations, conducted in five different centers throughout the United States." Gibbs, a consultant with the No Thing Left Behind project, is a professor of clinical surgery at the [University of California, San Francisco \(UCSF\)](#) and an attending surgeon at the [U.S. Department of Veterans Affairs' San Francisco VA Medical Center](#).

According to Gibbs, the project team is about half-way through the clinical trial, and will now begin testing the re-designed SmartSponge System for the remainder of the pilot. The RFID-enabled sponges are utilized "exactly the same way they would be used in any other case. They function in the same way, and the surgeons use them in the same way," Gibbs says, noting that manual counts are still conducted for each operation nonetheless. "The standard of care has been that a manual count of all sponges is always done, so in the clinical trial, of course there is always a manual count." Gibbs could not release any findings from the clinical trials, because they are still ongoing.

Copyright ©2005 RFID Journal, Inc. All Rights Reserved