RFID Solution Enhances Safety in Surgery

Patient safety is of paramount importance during a surgical procedure, while avoiding preventable errors during the procedure can result in significant cost savings. This article showcases a system that utilizes RFID technology to track sponges during a surgery, in addition to addressing both of the aforementioned issues.

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Leaving surgical items in patients is a problem as old as surgery itself. Known in the medical community as retained foreign bodies (RFB), these forgotten objects include needles, tools, and sponges. In fact, surgical sponges account for more than two-thirds of all RFB. There's even a medical term for a retained sponge—*Gossypiboma*, derived from the Latin *gossypium* (cotton) and the Swahili *boma* (place of concealment).

Dime-sized SmartSponge tags can be detected quickly and accurately through blood and bloody tissue

Retained sponges occur in roughly 1 in 1,500 intra-abdominal surgeries performed annually in the United States. Statistics aren't as clear for other types of surgery, but estimates show a retained sponge incidence rate between 1 in 100 to 1 in 5,000 surgeries.

At a typical large hospital performing 20,000 surgical cases each year, about 4 patients will go home with retained sponges. The porous characteristics of sponges promote inflammatory reactions and infections, ensuring that a patient will be returning for a costly, and sometimes risky, re-operation. The inevitable lawsuits resulting from such mistakes cost about $125 million annually, out-of-court settlements estimated to be much higher. Lawsuits, lost operating room (OR) productivity, and re-operations cost the U.S. healthcare system more than $1.5

billion per year.

Meeting a Critical Need

ClearCount Medical Solutions, a company spun out of Carnegie Mellon University, is a pioneer in recognizing the persistent problem that counting and managing sponges in the OR presents, and knows the inherent risks of relying on 15 to 30 minutes of nursing time devoted to manual counts (and x-rays in the event of a miscount) to prevent retained sponges.

ClearCount’s patented SmartSponge System is the first FDA-cleared device that integrates counting and detection for sponge management during surgeries. It uses rugged, encapsulated radio frequency identification (RFID) tags with robust communication protocols to automate the counting process, and provide a fast, accurate patient scan to check for retained sponges. SmartSponge employs unique RFID tags sewn into sponges of different shapes and sizes. These passive (i.e., battery-less) tags are about the size of a dime and may be detected quickly and accurately through blood and body tissue.

SmartSponge's SmartBucket reconciles sponges "scanned in" and "scanned out," and displays the information on-screen

Although barcodes are useful for counting, they require a line-of-sight between label and reader, and are prone to failure when inside the packaging or the patient, soiled with blood, or cracked from routine use. Electronic article surveillance (EAS) technology also falls short because it conveys no unique information on each tag and is unable to count sponges and differentiate them by type.

In contrast, the RFID-enabled SmartSponges are tallied by the ClearCount SmartBucket device, a self-contained cart with an embedded RFID reader and a large color digital display. The SmartBucket also features a tethered SmartWand, which can be removed from the cart and passed over the patient as an additional safety check to ensure that no sponges have been “retained.”

Through the use of RFID, SmartSponge provides an automated method for ensuring accurate sponge counts, as well as a faster and more reliable method for scanning the patient.

SmartSponge integrates seamlessly with OR workflow and conforms to current guidelines for sponge counts.

SmartSponge in Action

To use the system, the circulating nurse begins by placing each pack of sponges near the “In Scanner” portion of the SmartBucket. This step allows the device to read each tagged sponge through the sterile packaging, and to verify that each sponge contains a functional, uniquely-numbered tag before the package is opened.

The SmartWand (left) may be passed over the patient to ensure that no sponges (right) have been retained

Within seconds, the device will give audible and visual confirmation that each pack is verified, and the quantity of sponges “scanned in” to the surgical case will be updated on the display. Additional SmartSponges may be added to the inventory at any time, and sponges of different shapes and sizes are differentiated automatically on the screen.

SmartSponges may be used like all standard surgical sponges. Their embedded RFID tags are designed to withstand the harshest surgical conditions, including submersion in blood and other body fluids, crushing force from surgical tools, and defibrillation.

After each SmartSponge is used in surgery, it is discarded into the SmartBucket’s integrated sponge receptacle, which is covered with a disposable liner. As SmartSponges are thrown into the receptacle, they are “scanned out” automatically. Regardless of how many sponges are discarded, there is no need to separate bloody sponges, reducing significantly the risk of handling bio-hazardous materials.

Finally, the SmartBucket reconciles the list of sponges “scanned in” and “scanned out,” displaying the information on-screen. This feature allows the surgical team to see immediately how many sponges remain in the “surgical field.”

The SmartSponge System’s use of RFID and robust tag/reader communication protocols eliminate false positive and negative detections. That’s because the SmartBucket reader and SmartWand sense items with ClearCount RFID tags only, eliminating the possibility of other RFID-enabled items, such as staff access badges, from causing an error. SmartSponge has also been tested successfully for its compatibility with other OR devices.

Successful Collaboration

To ensure SmartSponge's superior engineering and ergonomics, Cygnus Manufacturing Co. (CMC) worked with ClearCount to design the neck pivot on the SmartBucket and make the detachable SmartWand as versatile as possible. The neck pivot allows OR nurses to rotate the console-screen unit 360° and position it for optimal viewing.

ClearCount Solutions' SmartSponge integrates counting and detection for sponge management during surgeries

CMC is also bringing its expertise to bear on SmartSponge by manufacturing the device for ClearCount. This arrangement reflects the growing trend of medical device designers partnering with engineering-intensive contract manufacturers to take advantage of Design for Manufacture/Design for Service expertise and benefit from the cost savings realized through such relationships.

Conclusion

As the demand for RFID applications in medical environments continues to increase, the cost of technology-enabling chips is declining. That's good news for any hospital totally committed to the well-being of its patients from check-in to discharge.

Online

For additional information on the technologies and products discussed in this article, see *MDT* online at www.mdtmag.com and the following websites:

- www.clearcount.com
- www.cygnusmfg.com

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