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FDA clearance for world's first RFID Surgical Sponge Counting System to prevent retention of surgical sponges

Pittsburgh, June 13, 2007 – ClearCount Medical Solutions, a Pittsburgh-based company focused on developing smarter solutions to improve patient safety inside the operating room, announced today that its patented SmartSponge™ System based on radio frequency identification (RFID) received Food and Drug Administration (FDA) 510(k) clearance.

David Palmer, ClearCount's President & CEO said, "We are optimistic the SmartSponge™ System will address the pervasive problem of retained surgical sponges. This is the world's first RFID system that detects and counts surgical sponges and towels during surgical procedures." Mr. Palmer continued, "With an estimated 3,000 – 5,000 incidents a year, retained surgical sponges are a considerable problem. The SmartSponge™ System can improve patient safety and efficiency by alerting staff when there is a missing sponge."

The ClearCount SmartSponge™ System is a novel, RFID-based solution that was designed after extensive work with nurses and surgeons at leading healthcare institutions. The SmartSponge™ System uses Texas Instruments Inc.'s Tag-it™ HF-I portfolio of high-frequency products to automate the process of managing surgical sponges during surgery. The sponges are permanently affixed with passive RFID tags smaller than a dime. Steve Fleck, Co-Founder and Chief Technology Officer added "Unlike other technologies, ClearCount's RFID-based SmartSponge™ System allows users to simultaneously count and differentiate between types of sponges. Additionally, since RFID does not require a line-of-sight between the reader and tags, there is no need to physically separate sponges or orient the tags in any way to scan them. This minimizes the handling of soiled sponges by nursing staff."

Gautam Gandhi, Co-Founder and Chief Marketing Officer, said, "A retained sponge incident can lead to serious complications, including sepsis, unnecessary x-rays, need for repeat surgeries and even death. The economic benefit is clear – the SmartSponge™ System advances operating room safety and reduces hospital and surgeon liability."

According to Verna Gibbs M.D., director of the *No Thing Left Behind* initiative, which aims to prevent retained surgical items (www.nothingleftbehind.org): "The problem of surgical sponges being left behind in various body spaces is something that every surgeon and perioperative care nurse in this country has at least thought about, even if they have not directly experienced the problem. These events are the product of poor communication and faulty processes of care that cause patient injury. The ClearCount SmartSponge™ System is an ingenious and simple solution to address both problems in communication and problems in counting practices. This is an exciting new modality which could help surgeons and nurses do a better job in the OR and deserves to be evaluated."

The FDA clearance is another milestone for ClearCount Medical Solutions, which supported a study titled “Initial clinical evaluation of a handheld device for detecting retained surgical gauze sponges using radiofrequency identification technology”. The study was published in the medical journal, Archives of Surgery, in 2006. Alex Macario, MD, MBA, professor of anesthesia at the Stanford University School of Medicine and lead author of the study, said that although procedures are in place to track objects during surgery, errors do still occur. “This risk significantly increases in emergencies, with unplanned changes in procedure and with patients that have a higher body-mass index,” he said.

According to another study in Massachusetts, foreign objects were left in the body in one out of every 10,000 surgeries. Those objects added four days to an average hospital stay and resulted in 57 deaths in 2000. Two-thirds of all objects left in the body cavity were surgical sponges.

Current procedures for tracking instruments and sponges involve a baseline count before surgery begins, a second count before the surgeon begins sewing the incision, a third count at wound closure and a final count before closing the skin. This manual process is time consuming and subject to human error. When there is a discrepancy in the counts, at most hospitals, an X-ray is required before leaving the operating room. Additionally, many hospitals call for X-rays for high risk cases such as emergencies, transplants and surgeries greater than five hours in order to assure no retained objects.

ClearCount expects to make available a commercial solution that fully integrates into the current workflow of the operating room by the end of this year.

About ClearCount Medical Solutions

ClearCount Medical Solutions is a privately held medical device company founded in 2004 and headquartered in Pittsburgh, Pennsylvania. ClearCount’s mission is to develop automated systems that improve patient safety in the operating room. The company’s revolutionary SmartSponge™ System will automate the current manual, error-prone system of tracking surgical items in the operating room. For more information see: www.clearcount.com or call 412-322-4110.

About RFID

Radio Frequency Identification (RFID) systems are comprised of two basic components: a reader and tags which are applied to the items to be tracked. RFID tags contain small integrated circuits that contain unique identification codes as well as programmable memory that can be used to store information about the items being tracked. ClearCount’s RFID tags are passive- they have no power supply of their own. They are powered by the radio signal from the scanner. These signals are designed to be read between a few inches and several feet away, and no line-of-sight is required between reader and tag in order for data to be communicated.

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