



UNC Health Care Researchers, RF Surgical, Report Positive Results from Largest Ever Multi-Center Study on Use of Medical Technology to Help Prevent and Detect Retained Surgical Objects

Groundbreaking Study Presented at American College of Surgeons Clinical Congress

BELLEVUE, Wash. & CHAPEL HILL, N.C.--([BUSINESS WIRE](#))--Researchers from [UNC Health Care](#) today reported positive, interim results from the largest ever prospective multi-institution study of any medical device aimed at helping surgical teams prevent and detect retained foreign objects in surgery. The ongoing study examined the use of radio-frequency detection technology (RF Surgical Detection System, [RF Surgical](#)) as an adjunct to the standard practice of manual counting.

“Effectiveness of Radio-Frequency Surgical Detection System to Promote Patient Safety During an Operative Procedure by Improving the Process by which Doctors and Nurses Track Sponges Prior to Wound Closure”

The poster, “*Effectiveness of Radio-Frequency Surgical Detection System to Promote Patient Safety During an Operative Procedure by Improving the Process by which Doctors and Nurses Track Sponges Prior to Wound Closure*,” included findings from more than 3,500 surgical procedures at five centers. While long-term follow-up is ongoing, key interim conclusions reported at the American College of Surgeons Clinical Congress include the following:

- RF detection can speed identification and avoid use of radiation to locate missing sponges, thereby improving both patient safety and clinical workflow efficiency in the operating room.
- Retained foreign objects (RFOs) occur regardless of whether the manual counts were correct, affirming the need for a check-and-safety balance with adjunctive detection technology.
- In almost 90% of operations, nursing staff reported that radio-frequency (RF) detection offered less stress during wound closure and improved overall confidence that no foreign objects were left in the patient.

While manual counting by operating room personnel is the standard-of-care in preventing RFO, process enhancements and effective technology are needed to further improve patient safety and reduce the incidence of RFO to zero. According to a report published in the *New England Journal of Medicine* one in every 5,500 patients had a RFO inside of them after surgery, according to a review of more than 190,000 patients who underwent surgery at Mayo Clinic in Rochester, Minn., over a three-year period. In addition to their threat to patient safety, retained surgical objects also exact a significant economic burden on hospital systems. RFOs are classified among the growing list of “never events” for which Centers for Medicare and Medicaid Services (CMS) and private insurers will no longer provide reimbursement.

“UNC Health Care is very pleased to have uncovered actionable findings that can be immediately applied to improve patient safety in the operating room (OR) and enhance clinician confidence in a treatment setting where rapid decision-making is required,” said Dr. Christopher Clarence Rupp, surgeon and principal investigator at UNC Health Care. “While manual counting is an effective practice and the overall incidence of RFO remains relatively low, our goal is always to achieve zero mistakes and the cost-effective, adjunctive technology we evaluated in this study aligns seamlessly with the standard-of-care. It is clear that RFSD

technology is easy to operate and offers a valuable check and balance to enhance patient safety in the surgical setting.”

“We are gratified to see positive results from such a landmark study in the movement to eradicate RFO as a patient safety threat and contributor to OR staff stress, which has been the sole focus of RF Surgical Systems since we pioneered the use of medical technology for this very purpose,” said Dr. Jeffrey Port, co-founder, RF Surgical Systems. “These data further validate our confidence in radio-frequency surgical detection technology as a critical adjunctive safety net that cost-effectively complements the standard-of-care, and we look forward to learning even more as ongoing follow-up continues.”

About the RF Surgical Detection System

Cleared by the U.S. Food and Drug Administration (FDA) in 2006, the RF Surgical Detection System was the first medical device solution to address the problem of retained surgical objects in patients. The System safely and accurately reads through deep cavity tissue, fluids and bone to detect if any radio frequency tagged surgical sponges, gauze or towels remain in a patient following surgery. The system consists of a self-calibrating console, hand-held wand, RFmicro-tags and gauze, sponge supplies and is designed for all open-cavity surgeries including emergency, trauma, labor and delivery. To date, it has been used in more than 1,000,000 surgical procedures nationwide.

About RF Surgical Systems, Inc.

RF Surgical Systems, Inc. is the market leader in the prevention and detection of retained surgical sponges. The RF Surgical Detection System is the preferred solution in more than 1,000 operating rooms, trauma and labor & delivery suites nationwide. RF Surgical Systems is based in Bellevue, Washington with R & D facilities in San Diego, California. The advanced technologies used in the RF Surgical Detection System are protected by U.S. patents. Regulatory clearance to market the system was granted by the U.S. Food and Drug Administration in November 2006. The company is online at www.rfsurg.com.

About UNC Health Care

The UNC Health Care System is a not-for-profit integrated health care system, owned by the State of North Carolina and based in Chapel Hill. It exists to further the teaching mission of the University of North Carolina and to provide state-of-the-art patient care. A distinguishing characteristic of UNC Health Care is its association with the UNC-Chapel Hill School of Medicine, a nationally eminent research institution. This relationship gives UNC Health Care a powerful pathway for moving the results of biomedical research from medical school laboratories to patient care settings. UNC Health Care has been granted broad powers by the North Carolina General Assembly to assure its management flexibility and competitiveness in a rapidly changing health care business environment. The enterprise is governed by a board of directors appointed by the University of North Carolina.

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