



#2 on the Joint Commission List: Retained Foreign Objects⁴

By Alecia Cooper, RN, BS, MBA, CNOR

“Foreign objects like sponges, scalpels and surgical instruments should never be left in the body cavity after an operation. Surgeons who commit this serious and completely avoidable medical error must be held accountable. At Friedman, Domiano & Smith, our lawyers file medical malpractice lawsuits in Ohio courts, calling attention to this serious problem and working to achieve the best possible results for our clients. To talk confidentially about how a retained object has affected you, contact the law offices of Friedman, Domiano & Smith.”¹

“Admitted to a Macon, GA, hospital in 2004 for surgery for diverticulitis of the colon, Lucille Davis, then 67, left with an undetected and dangerous souvenir: a surgical sponge. The error resulted in a \$10 million settlement.”²

“These cases require a thorough understanding of appropriate operating room procedures and the various roles of the surgeons and surgical nursing staff. At Williamson & Lavecchia, L.C., our attorneys have successfully handled many cases involving retained objects during surgery. Examples include sponges left during surgery to remove a gallbladder, a hysterectomy, and a Cesarean section. In each case, the patient required further surgery, lengthy recuperation and the patient incurred significant medical expenses.”³

Whether or not you have been part of a retained objects lawsuit, it's important to know that the issue of retained foreign objects (RFOs) is a serious, preventable complication that is increasing in incidence and complexity.

The California Department of Public Health reported 141 retained foreign objects in patients during fiscal year 2007-2008, and the count increased to 196 for 2008-2009. In addition to sponges, found objects included catheters, dentures, drill bits, electrodes and screws.⁵

The Joint Commission considers retention of a foreign body a sentinel event. They recommend taking the following steps if a foreign object is retained in the patient:⁶

- Report the incident according to state regulations
- Report the incident to the Joint Commission. Although this step is not mandatory, unreported sentinel events can adversely affect accreditation.
- Conduct a root cause analysis to thoroughly investigate how and why the situation occurred.
- Develop a detailed action plan to prevent similar occurrences in the future

For FY 2007, CMS recorded 750 incidents of foreign objects retained after surgery, which incurred an average cost of an additional \$63,631 per case. As of October 1, 2008, CMS introduced new regulations that deny reimbursement for healthcare expenses related to retained for-

eign objects and other hospital-acquired conditions.⁷ It's still too soon to tell whether this measure will help reduce the incidence of these conditions.⁷

Reasons for RFOs

With sponge counting as a routine procedure in most ORs, and heightened awareness of patient safety, why are foreign objects continuing to be retained after surgery? Several studies suggest possible explanations.

A 2003 study by Gawande et al. reviewed medical records associated with a retained surgical sponge or instrument between 1985 and 2001. The study included 54 patients and a total of 61 retained foreign bodies.⁸ Findings showed that patients with retained foreign bodies were more likely to have had emergency surgery or an unexpected change in surgical procedure. These patients also had a higher mean body mass index (BMI) and were less likely to have had counts of sponges and instruments performed during their surgery.

In another study that reviewed 191,168 operations performed at the Mayo Clinic from 2003 to 2006, there were 34 cases of retained foreign objects discovered after the patient left the OR. Root cause analysis of the events showed the most common contributing factor was breakdown in communication, particularly failure of team members to communicate when an item was placed in the body.⁹

Ways to avoid RFOs

The two most frequently used methods to try to prevent retained foreign objects are counting sponges, instruments and sharps before and after surgery and X-raying the body cavity before a procedure closes. (OR sponges and towels often contain X-ray detectable material inside for this purpose.)

Despite these measures, many studies have shown foreign objects being found inside the body after surgery in a significant number of cases in which counts were performed and reconciled or radiographs came up negative for foreign bodies before closing. A few of these studies are summarized below.

In 2008, 1,564 reports received by the Pennsylvania Patient Safety Authority involving incorrect sponge, sharps or instrument counts indicated that a radiograph was performed. In 1,123 (71 percent) of those reports, the radiograph was negative for a retained foreign object.⁹

Another study found that 88 percent of retained foreign objects were associated with a count that was thought to be correct. Similarly, a study by Cima et al. showed that 62 percent of retained foreign object cases involved a correct sponge, sharp and instrument count.⁹

In a study looking at the reasons for count discrepancies, 41 percent of the discrepancies were attributed to human errors involving addition mistakes, incorrect documentation or miscounting. For these reasons, the American College of Surgeons (ACS) and the Association of periOperative Registered Nurses (AORN) recommend methodical wound exploration in addition to a surgical count.⁹



Factors that affect surgical count accuracy⁶

- Failure to develop and implement an effective policy and procedure for surgical counts
- Failure to follow the policy and procedure
- Disruptions during the performance of surgical counts
- Change in personnel during a procedure and the lack of proper handoff
- Staff fatigue, especially during lengthy and emergency cases
- A knowledge deficit about performance of surgical counts by any team member
- Failure to use X-ray detectable items (such as sponges)
- Failure to count all components of an instrument (all removable parts) and failure to inspect all items for completeness (a broken needle, for example)

Innovative products to minimize the risk of RFOs

In addition to the use of X-rays to detect surgical objects inside the body, medical device companies have developed several options to minimize the retention of foreign objects and assist with surgical counts. New systems such as these are recommended by the Pennsylvania Patient Safety Authority as additional safety measures and technological support to further reduce the risk of retained foreign objects.⁹

Integrated laparotomy pad/retractor.¹⁰ This device is composed of an outer lap pad consisting of 12 layers of absorbent cotton wrapped around a malleable inner stainless steel mesh. The device reduces the use of individual pads while also providing needed retraction. It may be shaped to the individual needs of the operating field, providing excellent exposure while also reducing the risk of retained foreign bodies. In addition, the radiologic image of the laparotomy pad/retractor is significantly more radiopaque than a traditional lap pad, providing a greater sense of security that the device will be detectable by X-ray.

RFID.¹¹ The RFID (radiofrequency identification) system consists of a mobile console with an electronic monitor screen, a scanning surface for counting sponges “in” and a waste bucket for counting sponges “out.” Each RFID sponge has its own unique identification tag sewn into it, which the system reads. Sponge counts are then displayed on the monitor in real time. Also included is a wand that may be passed over the patient’s body to detect sponges before the case is closed.

Developers of the RFID system note that the idea for the device was conceived by an operating room nurse. After conducting observations in operating rooms across the country, the nurse concluded that sponge counts were problematic in every surgery. Therefore, the RFID system was created with an internal counting mechanism to safeguard against miscounts.

RF.¹² The RF system is similar to the RFID system, but it consists of a wand device only, which is passed back and forth and side to side over the patient’s body to detect sponges before the case is closed. It can also be used to scan the floor and other surfaces for missing sponges. The system consists of three components: a handheld scanning wand connected to a compact, self-calibrating console and micro RF tags that are embedded in surgical gauze, sponges and towels.

Bar codes. Similar to the electronic RF and RFID tags, bar codes are placed inside sponges as a tracking mechanism. An individual data matrix code is embedded onto each sponge. Each sponge is scanned by a handheld computer before being placed into the patient and after surgery is completed.¹³



In a study to determine the effectiveness of bar codes,¹⁴ a total of 33 incidents of misplaced sponges were detected. Of those misplaced, 30 sponges were found in the trash, under drapes, on the floor or elsewhere on the sterile field outside the patient. The remaining three sponges were found inside the patient. The bar code system was found to be more effective than manual counting for the detection of sponges; however, it also takes longer than manual sponge counting, according to the study.

What does the future hold?

Although technology has focused mainly on the detection of sponges, methods for detecting surgical instruments are also under development.¹⁰ Clearly, more research and technological advances are needed to further pinpoint the reasons for retained foreign objects and reduce their occurrence.



AORN Recommended Practices for Sponge, Sharp and Instrument Counts¹⁵

- I. Sponges should be counted on all procedures in which the possibility exists that a sponge could be retained.
- II. Sharps and other miscellaneous items should be counted on all procedures.
- III. Instruments should be counted for all procedures in which the likelihood exists that an instrument could be retained.
- IV. Additional measures for investigation, reconciliation, documentation, and prevention of retained surgical items should be taken.
- V. Sponge, sharp and instrument counts should be documented on the patient's intraoperative record by the registered nurse circulator.
- VI. Policies and procedures for sponge, sharp, and instrument counts should be developed, reviewed periodically, revised as necessary, and readily available in the practice setting.

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