# BUSINESS CASE FOR USE OF ADJUNCT TECHNOLOGY TO PREVENT UNINTENTIONALLY RETAINED SURGICAL SPONGES

**Executive Summary and Background**

Never events are extremely rare, avoidable medical errors that no patient should ever have to experience. The Agency for Healthcare Research and Quality recognizes a retained surgical item (RSI) as a never event.[1] The Joint Commission defines a sentinel event as a "patient safety event . . . that reaches the patient and results in any of the following: death, permanent harm, [or] severe temporary harm and intervention required to sustain life."[2] The Joint Commission considers an RSI to be a sentinel event that should result in an immediate investigation and response. Between 2005 and 2020, 1,732 RSIs were reported to The Joint Commission.[2]

Annual rates of RSIs are difficult to determine because they are thought to be underreported[3] and underestimated.[4] Additionally, RSIs may not be discovered and reported for years or even decades after the actual occurrence.[5] Rates of RSIs between 0.31 to 1.99 per 10,000 procedures have been reported in the literature.[5] When averaged, the incidence rate comes to 1.07 RSIs per 10,000 procedures, or approximately one RSI per 10,000 procedures.

The most often retained items are surgical sponges.[4,6] However, retained instruments, needles, device fragments, and guidewires have also been reported.[7,8] In a series of studies, Steelman and colleagues retrospectively reviewed different types of RSIs reported to the Joint Commission.[7-9] In one of the studies, the researchers reviewed reports of unintentionally retained surgical sponges during a 5-year period.[9] Of the 319 retained soft goods reported during the study period, 310 (97.2%) may have been prevented if adjunct technology had been used correctly. The other nine retained items (ie, cotton pledgets, peanut sponges, Kerlix gauze, and a non-radiopaque sponge from an anesthesia kit) are not currently available with imbedded adjunct technology and therefore would not have been identified even if the technology had been used.[9]

The patient, health care personnel, and the health care organization can suffer consequences when there is an unintentionally retained item.[5] Patients with unintentional RSIs may experience pain, nausea and vomiting, digestive problems, a prolonged hospital stay or readmission, infection, peritonitis, sepsis, abscess, adhesions, fistulas, bowel obstruction, emotional harm, and death.[5] Health care personnel can suffer from a phenomenon known as "second victim," which can cause them to experience shame, anxiety, or fear about the event and potential future events.[10] The reputation of the health care organization may also be negatively affected from news reports and social media posts after an RSI. This may cause individuals to choose a different facility in which to have a future surgery.

### Current Practices to Prevent RSIs

Some of the current practices to prevent RSIs include manual counting of surgical sponges, instruments, needles, and miscellaneous items and use of intraoperative radiological imaging.[5] Manual counting can be susceptible to human error. In cases of RSIs, the count has been reported as correct between 62% to 88% of the time.[3,4,11] Additionally, intraoperative imaging used to detect RSIs may not be 100% effective. Cima et al[4] found that intraoperative x-rays detected only 12 of 18 RSIs, a 67% success rate. Using intraoperative imaging also carries the risk of radiation exposure to patients and personnel.

### Cost of an RSI to Health Care Organizations

Because of the harm of RSIs, they can be associated with substantial costs. However, the exact costs of an RSI incident are unknown and may be variable due to how the event is handled (eg, lawsuit, settlement).[5] Costs associated with RSIs can include additional days in the hospital and care, such as reoperation for removal of the RSI. The Centers for Medicare & Medicaid Services will not reimburse hospitals for selected hospital-acquired conditions that were not present on admission.[12] A foreign object retained after surgery is included in the list of nonreimbursable hospital-acquired conditions.[13]

Other costs can include medical litigation and settlement fees and state penalties.[5] Legal settlements are becoming more common than court cases[14] and may include nondisclosure agreements. Therefore, much of the data on costs from settlements is older and may not be representative of legal costs for an RSI today. In a 2013 study of malpractice settlements and judgments of surgical never events during the 20-year period between September 1990 and September 2010, the researchers reported that there were 4,857 events involving an RSI.[15] Malpractice payments specific to RSI events had a mean cost of $86,247 and a range of $51 to $3,988,829. However, these figures did not include the costs for additional care related to the RSI event, legal fees, or damage to the reputation of the health care organization or physician.[15]

Counting discrepancies increase the risk of an RSI by more than 100 times.[16] Researchers have reported that counting discrepancies occur in one of every eight procedures and take an average of 13 minutes to resolve.[17] Every counting discrepancy can lead to increased costs from time searching for misplaced items and the use of intraoperative radiography. The average length of time associated with obtaining an intraoperative radiograph has been reported to be 18 minutes.[18]

### Types of Adjunct Technology

Radio-frequency identification (RFID) systems are wireless and consist of two components—tags and readers. Tags use radio waves to communicate identifying information to the nearby reader. Passive tags are powered by the reader. Surgical sponges are tagged with an RFID chip. The reader has one or more antennas that emit radio waves and receive signals back from the RFID tags when they detect the surgical sponges tagged with an RFID chip.[19-21]

In radio-frequency (RF) sponge detection systems, sponges are embedded with an RF tag, and scanners (ie, wand, body mat) are connected to a console. During the counting process, the wand, body mat, or both are used to detect the RF tag on surgical soft goods. If a sponge with an RF tag is detected, the console generates an alert.[22]

Data-matrix technology is an adjunct to the manual counting process. Early research studies referred to data-matrix-coded sponges as bar-coded sponges. The data-matrix is a two-dimensional bar-code with a unique pattern that helps the bar-code scanner identify the symbol specific to an individual item. Sponges and towels embedded with unique bar-codes are passed under a bar-code reader, providing a tally of the sponges and towels to a tablet.

## Using Adjunct Technology to Prevent RSIs

Adjunct technology using RF, RFID, or data-matrix-coded sponge (ie, bar-coded sponge) systems can supplement manual sponge counting processes. Discrepancies in the surgical count add time to the procedure, as personnel search for the retained item in the patient, room, trash, and linen bins. The use of adjunct technology can decrease time spent reconciling count discrepancies involving surgical soft goods.[23]

In one study, researchers compared time and costs before and after implementation of an RF adjunct technology system.[23] Using a cost estimate of $37.45 per minute of OR time, the researchers reported a cost of $4,778.99 per 1,000 procedures before implementation and a cost of $975.95 per 1,000 procedures after implementation. The cost savings from reduced time spent searching for misplaced sponges was $3,803.04 per 1,000 procedures. Using a cost estimate of $286 per radiographic image taken, the cost for images was $1,116.35 per 1,000 procedures before implementation and $599.37 per 1,000 procedures after implementation. The researchers also reported a reduction in time of 54.23 minutes spent obtaining radiographs, which they calculated to be a cost reduction of $2,030.91 per 1,000 procedures. The researchers reported a total annual cost savings of $6350.93 per 1,000 procedures from reduced time spent searching for misplaced sponges and decreases in radiography use.[23]

The use of adjunct technology is recommended by the Association of periOperative Registered Nurses (AORN) to verify the outcome of manual counting procedures for soft goods or to verify the location of surgical soft goods when possible.[5] The American College of Surgeons recommends use of technology (eg, radiologic imaging, adjunct technology) to prevent the retention of surgical items.[24] The Joint Commission recommends reviewing the adjunct technologies available to supplement manual counting procedures.[25]

Currently, there is information published on two of the available adjunct technology systems, radio-frequency and data-matrix-coded sponges.[5] The evidence suggests that some adjunct technology systems can identify or reduce near misses; count discrepancies; time spent searching for soft goods or resolving count discrepancies; the number of radiographs taken with associated time, costs, and patient and staff exposure; additional procedures to remove a retained sponge; costs; and potential for contamination of personnel going through trash bins to find a sponge.[5]

## Conclusion

Unintentional RSIs have implications for patients, health care providers, and health care organizations. Patients with an unintentional RSI can experience considerable physical and mental harm.[5] The health care organization can incur substantial costs. Use of adjunct technology can decrease time and costs spent reconciling count discrepancies related to surgical soft goods, thus preventing potential patient harm and saving the health care organization time and money.

## Hypothetical Business Case Example

Below are a series of tables built from information in published literature.[18,23,26,27] Data from the studies was converted to numbers per 10,000 procedures. The reason for this was two-fold. First, an estimate of one RSI per 10,000 procedures was used to correspond with a current average of RSI incidence rates. RSI incidence rates are typically reported per 10,000 procedures. Second, this estimate can help perioperative leaders easily convert the data to usable information based on the numbers of procedures performed annually and rates of RSIs at their facility.

Implementation of adjunct technology can include the cost difference of purchasing soft goods imbedded with adjunct technology and the cost of purchasing sterile covers when part of the device

is used on the sterile field.[18] The literature indicated that use of the RF device on the sterile field is variable and may not always be needed.[18] Therefore, the number of sterile covers needed will vary depending on the adjunct technology device the facility chooses. For instance, data-matrix-coded sponge systems may not require covers at all. Researchers in one study stated that the adjunct technology devices were provided by the vendor at no cost due to the anticipated high volume of disposable supply purchases.[18] There also may be other less-obvious costs to consider, including time spent converting stored supplies and providing education on device use.

The cost savings associated with adjunct technology use include a reduction in the time spent in the OR searching for a misplaced sponge when there was a count discrepancy, a decrease in the time spent obtaining radiographic images, and a reduction in costs associated with radiographic imaging.[18,23] Additional cost savings associated with preventing an RSI included eliminated medical costs (eg, readmission, surgery), legal costs (eg, litigation, settlement), and state penalties.[18,26] Other institutional cost savings may be harder to quantify but could include time spent by perioperative, leadership, quality, and risk management personnel performing root cause analyses and quality improvement projects after an RSI occurs and the potential loss of patients when an incident occurs and the organization's reputation is affected. Blanchfield et al[27] reported that the costs of investigating and processing, public reporting, and internal reporting; costs related to finance and administration; and other costs to a single urban academic medical center for five RSIs that occurred in 2013 was $40,675, for an average of $8,135 per event.[27]

In the example below, the potential cost savings for preventing one RSI per 10,000 procedures with the use of adjunct technology is calculated to be $417,328.30. However, preventing even one RSI is priceless.

**Table 1. Costs of Implementing Adjunct Technology Devices per 10,000 Procedures[18]**

| Budget Item | Cost Estimate | Number Needed | Total Cost |
|---|---|---|---|
| Cost difference to switch to adjunct technology soft goods | $0.55 per sponge | 30 per procedure | $165,000 |
| Cost of sterile covers for devices used on the sterile field (when applicable) | $1.95 per cover | Covers used during 30% of procedures (10,000 x 0.3 = 3,000) | $5,850 |
| Cost of obtaining capital equipment | $0 | One device per OR | $0 |
| **Total Costs per 10,000 Procedures** | | | **$170,850** |

**Table 2. Cost Savings from Implementing Adjunct Technology Devices per 10,000 Procedures[23]**

| Budget Item | Cost Savings per 1,000 Procedures | Total Savings |
|---|---|---|
| Decreased OR time spent reconciling count discrepancies | $3,803.04[a] | $38,030.40 |
| Decreased costs for radiography | $516.98[b] | $5,169.80 |
| Decreased or time spent performing radiography | $2,030.91 | $20,309.10 |
| **Total Cost Savings per 10,000 Procedures** | | **$63,509.30** |

[a] Using an estimate of $37.45 per minute of OR time

[b] Using an estimate of $286 per radiographic image taken

| Table 3. Additional Costs Associated with 1 RSI[18,26,27] | |
|---|---|
| **Item** | **Cost per RSI Incident** |
| Non-reimbursed readmission and reoperation for RSI removal | $141,534 |
| Legal costs | $300,000 |
| Investigation and processing, internal and public reporting, finance and administration, and other costs | $8135 |
| Public reporting and State penalties[a] | $75,000 |
| **Total** | **$524,669** |
| [a] Penalties may vary by state and could depend on the number of incidents (ie, up to $125,000) | |

| Table 4. Costs and Potential Savings for Use of Adjunct Technology to Prevent 1 RSI per 10,000 Procedures | | |
|---|---|---|
| **Item** | **Costs** | **Potential Savings** |
| Costs of adjunct technology implementation[a] | $170,850 | N/A |
| Cost savings from adjunct technology use[b] | N/A | $63,509.30 |
| Costs associated with an RSI[c] | N/A | $524,669 |
| **Totals** | **$170,850** | **$588,178.30** |
| **The total potential cost savings for preventing 1 RSI per 10,000 procedures using adjunct technology is $417,328.30 ($588,178.30 - $170,850).** | | |
| [a] Cost total from Table 1 | | |
| [b] Cost total from Table 2 | | |
| [c] Cost total from Table 3 | | |

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