

# Health Care Protocol: Prevention of Unintentionally Retained Foreign Objects in Surgery

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**First Edition  
September 2007**

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- physicians, nurses, and other health care professional and provider organizations;
- health plans, health systems, health care organizations, hospitals and integrated health care delivery systems;
- medical specialty and professional societies;
- researchers;
- federal, state and local government health care policy makers and specialists; and
- employee benefit managers.

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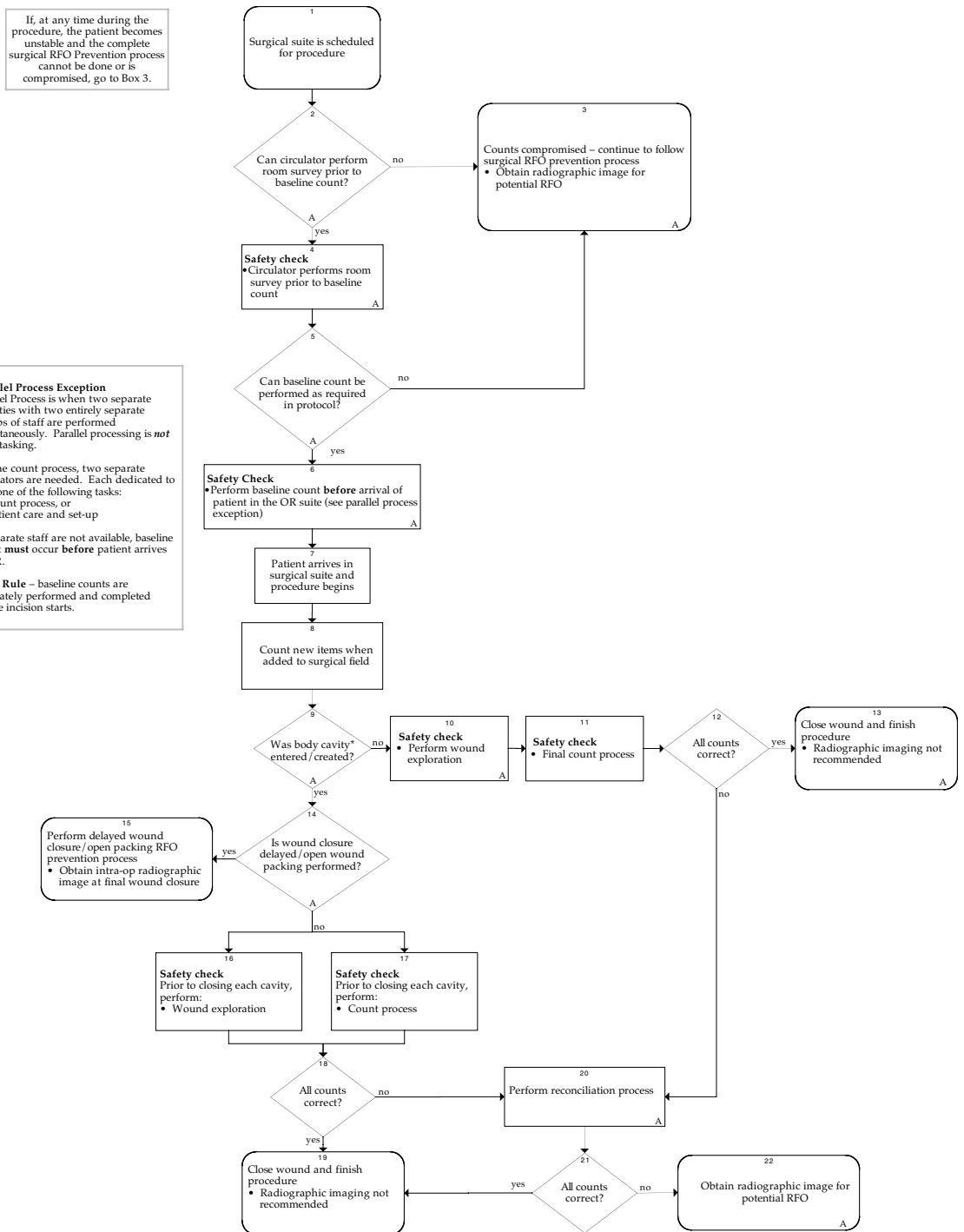
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## Health Care Protocol: Prevention of Unintentionally Retained Foreign Objects in Surgery

If, at any time during the procedure, the patient becomes unstable and the complete surgical RFO Prevention process cannot be done or is compromised, go to Box 3.

**6**  
**Parallel Process Exception**  
Parallel Process is when two separate activities with two entirely separate groups of staff are performed simultaneously. Parallel processing is *not* multitasking.  
  
For the count process, two separate circulators are needed. Each dedicated to only one of the following tasks:  
• Count process, or  
• Patient care and set-up  
  
If separate staff are not available, baseline count **must** occur **before** patient arrives in OR.  
  
\*Red Rule – baseline counts are accurately performed and completed before incision starts.

\* See definitions in protocol



A = Annotation

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## Foreword

### Scope and Target Population

This protocol will describe the necessary steps, which if implemented, will prevent the unintentional retention of a foreign object in patients in the operating room (OR).

### Clinical Highlights and Recommendations

- Establishing an accurate baseline count is the most critical step in the count process to ensure all subsequent counts are accurate. If the baseline count is not adequately performed, all subsequent counts should be considered compromised and a radiograph obtained to ensure that a foreign object has not been unintentionally retained.
- Distractions and interruptions should be kept to a minimum during the count process.
- A methodical wound exploration, when performed in conjunction with a reliable counting process, is an effective mechanism for early detection of an unintentionally retained foreign object. Generally, the type of surgical procedure performed guides the wound exploration technique employed.
- Good communication is necessary before and during the surgical procedure, when staff changes and/or at handoffs.

### Priority Aims

1. Eliminate unintentionally retained foreign objects during a surgical procedure.

### Key Implementation Recommendations

The following system changes were identified by the protocol work group as key strategies for health care systems to incorporate in support of the implementation of this protocol.

1. The work group recommends that a preformatted whiteboard be used as the primary record of the count. Documenting counts on a whiteboard allows all surgical staff, and in particular the scrub tech, to independently view the count record. A public display of the count record in an area where the entire surgical team can view it is likely to reinforce the importance of the count process. The work group also recommends that a count worksheet be used as a memory aid in ORs where the whiteboard is not easily accessible in a timely manner. The count worksheet should be used only as a memory aid for the baseline count and, if needed, for subsequent counts. It should be used rather than a piece of scratch paper. In contrast, if the whiteboard is located very close to the area in which the count occurs, and if the circulating nurse can easily write the counts on the whiteboard without leaving the count area, there will be no need to use the count worksheet.
2. Distractions and interruptions should be kept to a minimum during the count process.
3. Red rules\* should be established, followed by staff and physicians and supported by leadership (see below for specific red rules suggested for this protocol).

\*Red rules – the few, key rules created to prevent/address the specific actions that pose the highest level of consequence and risk to safety of patients or staff. The intention is to develop solid habits around these rules so that they are followed consistently and accurately each time. Individual responsibility to adhere to each red rule is imperative to ensure the safest environment and delivery of the care process.

Suggested red rules:

1. Sponges/soft goods and sharps will be counted for surgical procedures.
2. Baseline counts are accurately performed and completed before incision starts.
3. If count cannot be reconciled, imaging must be done appropriate to the patient's condition as outlined in this protocol.

## **Related ICSI Scientific Documents**

### **Order Sets**

- Surgical Site Infection Prevention for Adults Order Set
- Surgical Site Infection Prevention for Children Order Set

### **Protocols**

- Safe Site Surgery for All Invasive, High-Risk, and Surgical Procedures
- Prevention of Surgical Site Infection Protocol

## **Disclosure of Potential Conflict of Interest**

In the interest of full disclosure, ICSI has adopted the policy of revealing relationships work group members have with companies that sell products or services that are relevant to this protocol topic. The reader should not assume that these financial interests will have an adverse impact on the content of the protocol, but they are noted here to fully inform readers. Readers of the protocol may assume that only work group members listed below have potential conflicts of interest to disclose.

Stephanie Lach, MSN, MBA, RN has stock in 3M through a family member's employee benefit option.

No other work group members have potential conflicts of interest to disclose.

ICSI's conflict of interest policy and procedures are available for review on ICSI's Web site at <http://www.icsi.org>.

## **Introduction to ICSI Document Development**

Each guideline, order set and protocol is developed by a 6- to 12-member work group that includes physicians, nurses, pharmacists and other health care professionals relevant to the topic, along with an ICSI staff facilitator. Ordinarily, one of the physicians will be the leader. Most work group members are recruited from ICSI member organizations, but if there is expertise not represented by ICSI members, one or two members may be recruited from medical groups or hospitals outside of ICSI.

Prospective work group members are asked to disclose any potential conflicts of interest relevant to the topic of the document; disclosure forms are reviewed for unacceptable conflicts. At the beginning of each work group meeting, the potential conflicts of interest that have been disclosed are reviewed by the work group.

The work group meets for seven to eight three-hour meetings to develop the protocol. A literature search and review is performed and the work group members, under the coordination of the ICSI staff facilitator, develop the algorithm and write the annotations and literature citations.

Once the final draft copy of the protocol is developed, the protocol goes to the ICSI members for critical review.

## **Review and Comment Process**

The purpose of the review and comment process is to provide an opportunity for the clinicians in the member groups to review the science behind the recommendations and focus on the content of the protocol. Review and comment also provides an opportunity for clinicians in each group to come to consensus on feedback they wish to give the work group and to consider changes needed across systems in their organization to implement the protocol.

All member organizations are encouraged to provide feedback on protocols; however, responding to review and comment is not a criterion for continued membership within ICSI.

After the review and comment period, the work group reconvenes to review the comments and make changes, as appropriate. The work group prepares a written response to all comments.

## **Approval**

Each guideline, order set and protocol is approved by the appropriate steering committee. There is one steering committee each for Respiratory, Cardiovascular, Women's Health and Preventive Services. The Committee for Evidence-Based Practice approves guidelines, order sets and protocols not associated with a particular category. The steering committees reviews and approves each guideline based on the following:

- Member comments have been addressed reasonably.
- There is consensus among all ICSI member organizations on the content of the document.
- To the extent of the knowledge of the reviewer, the scientific recommendations within the document are current.
- Either a critical review has been carried out, or to the extent of the knowledge of the reviewer, the changes proposed are sufficiently familiar and sufficiently agreed upon by the users that a new round of critical review is not needed.

Once the guideline, order set or protocol has been approved, it is posted on the ICSI Web site and released to members for use. Guidelines, order sets and protocols are reviewed regularly and revised, if warranted.

## **Document Revision Process**

ICSI scientific documents are revised every 12-36 months as indicated by changes in clinical practice and literature. Every six months, ICSI checks with the work group to determine if there have been changes in the literature significant enough to cause the document to be revised earlier than scheduled.

Prior to the work group convening to revise the document, ICSI members are asked to review the document and submit comments. During revision, a literature search of clinical trials, meta-analysis and systematic reviews is performed and reviewed by the work group. The work group meets for one to two three-hour meetings to review the literature, respond to member organization comments, and revise the document as appropriate.

If there are changes or additions to the document that would be unfamiliar or unacceptable to member organizations, it is sent to members to review prior to going to the appropriate steering committee for approval.

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## **Evidence Grading System**

### **A. Primary Reports of New Data Collection:**

- Class A: Randomized, controlled trial
- Class B: Cohort study
- Class C: Non-randomized trial with concurrent or historical controls  
Case-control study  
Study of sensitivity and specificity of a diagnostic test  
Population-based descriptive study
- Class D: Cross-sectional study  
Case series  
Case report

### **B. Reports that Synthesize or Reflect upon Collections of Primary Reports:**

- Class M: Meta-analysis  
Systematic review  
Decision analysis  
Cost-effectiveness analysis
- Class R: Consensus statement  
Consensus report  
Narrative review
- Class X: Medical opinion

# Protocol

## **Counts Compromised – Continue to Follow the Surgical RFO Prevention Process**

If, at any time the patient's status is critical/emergent and/or there is not adequate time or staff to perform the steps of the protocol, counts should be considered compromised and inaccurate. The surgical team should continue to follow the Surgical RFO Prevention process and obtain radiographic imaging for potentially retained foreign objects.

## **Safety Check – Circulator Performs Room Survey Prior to Baseline Count**

- Designate and limit the number of receptacles for discarded items.
- Ensure the room and receptacles do not contain items from the previous procedure.
- Verify the whiteboard and other recordkeeping documents are clean and do not contain information from the previous case.
  - Note: The exception is the documentation required from a previous case when there was a missing item that was never recovered.

## **Safety Check – Perform Count Process**

- Items included in the count process include:
  - Sponges/soft goods – only radiopaque sponges will be present in the surgical field
  - Sharps
  - Miscellaneous items
  - Instruments, for procedures where the possibility exists that a particular instrument could be unintentionally left behind
  - In addition to the items listed above, all non-radiopaque items will be counted
- The count process will be performed at the following times:
  - A baseline count will occur before the patient is brought to the surgical suite unless parallel processing is used. For the count process using parallel processing, two separate circulators will be needed: one dedicated to the count process and one dedicated to patient care and set-up.
  - Before closure of a cavity within a cavity
  - Before wound closure
  - At the end of the procedure
  - Any time a member of the surgical team has concerns about the accuracy of the count process
  - Whenever there is a permanent staff change of the circulator
  - When closure of a wound is intentionally delayed (damage control), temporary implants are used, or a wound is temporarily closed with a non-radiopaque item (e.g., wound vacuum sponge)
- The count process will be performed in the follow manner:
  - The circulator and scrub person (one of whom must be an RN) will directly view the items being counted and will count out loud and concurrently.
  - The circulator will document the number and type of sponges/soft goods, sharps, miscellaneous items, and instruments on a preformatted whiteboard or other standardized, preformatted documentation record. The scrub person verbally confirms the number.
  - All items will be counted the same order for each count, usually in the order listed on the whiteboard.
  - Sponges/soft goods will be separated and counted individually.
  - Sponges/soft goods will have visual verification that the radiographic-detectible indicator is present.
  - Instruments will be counted in sets.
  - Counts will begin at the surgical field and move away from the patient.
  - Items added during the procedure will be counted prior to entering the surgical field and documented on the whiteboard as soon as possible.
  - Used sponges/soft goods will be unballied and pulled apart for the count process.
  - Instruments and sharps will be inspected for broken or missing pieces for the count process.

**Protocol**

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- Postprocedure tasks include:
  - No items will be removed from the surgical suite until all counts have been reconciled and inspections completed.
  - Items that accompany the patient will be communicated to the circulator and documented.
  - After all counts have been reconciled, all items will be removed from the surgical suite.
  - The whiteboard will be cleaned at the end of the procedure and before setup for the next procedure.
    - Note: The exception is the documentation required from a previous case when there was a missing item that was never recovered.

**Safety Check – Perform Wound Exploration**

- A methodical wound exploration will be performed prior to the closure of the wound and/or any cavity.
- The type of surgical procedure will guide the wound exploration technique employed.

**Close Wound and Finish Procedure**

- Radiographic imaging prior to wound closure does not need to be obtained when count processes are rigorously followed and all counts can be reconciled.

**Wound Closure Delayed/Open Wound Packing**

- Delayed wound closure/open wound packing presents a very high risk for an unintentionally retained foreign object.
- The number and type of items used in the wound packing will be documented in the procedure record.
- Any items removed or added to the wound must be counted and documented in the patient’s medical record.
- When the patient returns to the surgical suite for final wound closure, items used in the original packing will be isolated and counted separately from the items used in the final wound closure procedure. Both counts should be reconciled prior to wound closure.
- A thorough wound exploration will be performed.
- If radiopaque items were used, portable intraoperative imaging should be taken prior to final wound closure.

**Reconciliation Process for Count Discrepancies**

- When a discrepancy is identified, the number and type of item missing are reported to the surgical team by the circulator.
- If the patient’s condition permits, wound closure should be suspended until all steps to reconcile the count are exhausted.
- A manual inspection of the surgical suite is conducted, including a visual inspection of the area surrounding the surgical field, the floor, kick buckets, linens, and trash receptacle.
- The count is repeated and verified.
- The wound is reexplored.
- Portable intraoperative imaging is obtained if the counts cannot be reconciled.

## Imaging for Retained Foreign Objects

- Radiographs, whether portable images obtained in the surgical suite or postoperative images performed in a radiographic room, are not a substitute for performing accurate count procedures and methodical wound exploration.
- Portable intraoperative imaging considerations and limitations include:
  - Patient condition
  - Size and type of retained object (non-radiopaque items, micro needles)
  - Limited placement options of film cassettes under OR tables limiting anatomy included on the images
  - Lower portable tube power
  - Instruments obscuring the imaging area
  - Availability of portable radiographic equipment and staff
- Portable intraoperative imaging should be obtained when:
  - counts are off and cannot be reconciled,
  - the patient's condition did not allow for the count process to be followed (rushed counts, incomplete counts),
  - a member of the surgical team has concerns about the accuracy of the count process, or
  - before final wound closure for wounds that were previously intentionally left open/packed.
- Imaging requests include the following:
  - Callback number and surgeon
  - Location and status of patient (e.g., in OR with wound closure suspended, in PACU)
  - Type of surgery
  - Type of item missing
  - The surgeon will review the images to check for adequate anatomic coverage related to the operative procedure and site prior to the radiographic imaging being sent to radiology for interpretation.
  - The radiology technologist will review the images for quality and repeat imaging as necessary.
  - The radiologist and surgeon should simultaneously review the images both verbally and visually to correlate the anatomical coverage of the images, as well as a description of the potentially retained foreign object.
  - If a radiologist is not available, the immediate interpretation of the radiographic imaging to exclude a retained foreign object is the responsibility of the surgeon.
- Postoperative imaging in a radiographic room with fixed radiographic equipment and moving grid will be obtained when:
  - the patient's condition did not allow for portable intraoperative imaging,
  - the entire anatomic area was not included on the radiographic imaging,
  - portable intraoperative imaging failed to locate the retained foreign object and the counts could not be reconciled, or
  - the surgeon is not able to verify adequate anatomic coverage of the operative site on the radiographic images obtained with portable radiographic equipment.
- Imaging resource considerations include:
  - Films obtained to rule out the possibility of a retained foreign object should be obtained, processed, and available for reading within 30 minutes of request.
  - Clear communication regard the missing item and its potential anatomical location should be conveyed to the radiology staff and radiologist.
  - A mechanism for the radiologist to call into the surgical suite with the results of the radiograph interpretation should be developed.

# Algorithm Annotations

## Introduction

For as long as the medical community has been performing surgery or invasive procedures, we have had the risk and misfortune of unintentionally leaving items behind. Many measures have been instituted to mitigate the likelihood of an unintentionally retained item, but unfortunately they continue to occur. Exactly how often it happens is unknown; however, it has been estimated that on a national basis, approximately 1,500 patients per year will have a foreign body unintentionally retained following surgery (*Gawande, 2003*).

Professional organizations such as the American College of Surgeons (*American College of Surgeons, 2005*), Surgical Clinics of North America (*Gibbs, 2005*), the Association of Perioperative Registered Nurses (*AORN, 2006*), Department of Veterans Affairs Veterans Health Administration (*Eldrige, 2006; VHA Directive, 2006*), the Council on Surgical and Perioperative Safety (*Council on Surgical and Perioperative Safety, 2005*), American College of Obstetricians and Gynecologists (*ACOG, 2006*), and the Joint Commission (*Joint Commission International Center for Patient Safety, 2006*) have all developed guidelines for the prevention of retained items. In an article published in February 2006, the Association of Perioperative Registered Nurses (*AORN, 2006*) established a set of six practices that if implemented, would significantly reduce the risk of an unintentionally retained item.

The Joint Commission categorizes the unintended retention of a foreign body after surgery or other procedure as a sentinel event. Health care organizations are required to conduct a root cause analysis and to develop a corrective action plan designed to reduce the probability of a repeat occurrence.

In its first three reporting periods (June 2003-October 2006), the Minnesota Department of Health's Adverse Health Events Registry showed 179 surgical events with 99 of those (55%) involving unintentionally retained foreign objects. There was one death reported. Sponges were the most frequently unintentionally retained objects, almost seven times more frequently than the next largest category of retained items. Other categories with multiple retained items include needles, guidewires, broken or lost tips, screw and drill bits, and clips and clamps.

One of the unique challenges faced by the work group of this protocol was the definition of "retained." A number of sources were consulted and found to be in conflict or non-specific.

When developing the protocol's definition, the work group considered the object size, location of the patient, procedure time frames, and surgical stages.

The second challenge faced by the work group was the absence of peer-reviewed research studies to guide the development of the overall protocol recommendations.

Commercial aviation safety experts faced the same lack of evidence when they developed their, now generally accepted, standard operating procedures aimed at eliminating airplane accidents. Aviation has shown that by broadly and systematically employing processes that include standardized procedures to minimize variation, communication techniques such as crew resource management, and minimizing distractions during critical steps are successful in improving safety and reliability (*Helmreich, 2000*).

Anesthesiology has led the health care industry in safety. One of the key safety strategies deployed by this group was the adoption of standardized processes for how anesthesiologists monitor and respond to intra-operative changes in the patient's condition. Incorporating these standards together with human factors and communication strategies, anesthesia is the only health care discipline that has approached the Six Sigma level of performance (*Gaba, 2000*).

The work group incorporated these principles developed by aviation and anesthesiology into the development the Prevention of Unintentionally Retained Foreign Objects in Surgery Protocol. To aid in its future development it will be important to gather outcomes and costs associated with the implementation of the protocol.

*Supporting evidence is of classes: R, Not Assignable*

## Definitions and Specifications

**Body Cavity:** An anatomic cavity, orifice or the creation of a small cavity as a result of the procedure being performed. This does not include the initial surgical incision.

**Countable items:** Any item that could be unintentionally left behind during a surgical procedure (*AORN, 2006; American College of Surgeons, 2005; Council on Surgical and Perioperative Safety, 2005; Joint Commission International Center for Patient Safety, 2006; VHA Directive, 2006*). This includes:

- **Instruments:** Tools or devices designed to perform a specific function, such as cutting, dissecting, grasping, holding, retracting or suturing.
- **Miscellaneous items:** Includes vessel clips, vessel loops, suture reels, peripheral intravenous catheters and introducers, vascular inserts, cautery scratch pads, trocar sealing caps, catheter sheaths, non-radiopaque items such as hernia tapes, and other small items.
- **Sharps:** Items with edges or points capable of cutting or puncturing through other items. In the context of surgery, sharps include, but are not limited to, suture needles, scalpel blades, hypodermic needles, electro-surgical needles and blades, and safety pins.
- **Sponges:** Includes any soft goods such as gauze pads, cottonoids, peanuts, dissectors, tonsil sponges, laparotomy sponges, and towels used to absorb fluids, protect tissues or apply pressure or traction.
- **Tucked sponge:** Refers to any soft good used to stop bleeding or absorb liquid, or used in conjunction with an instrument or the surgeon's hand to obtain traction, and that is left in location for the duration of the procedure.

**Count Documentation:** A standardized form used in the retained foreign object (RFO) count process. This may in paper and/or electronic format. Organizations may or may not choose to store specific count information for future retrieval.

- **Whiteboard:** A preformatted dry erase board or computer screen, directly viewable by the entire surgical team, should be used to document sponges/soft goods, sharps, miscellaneous item counts, and when possible, instrument counts. The ability of the entire team to view the count information and assist in the correct identification of tucked and unaccounted for items enhances safety and reduces the risk of errors (*France, 2005*).
  - The whiteboard should use standard columns, rows and categories to record counts. In addition to the count, the whiteboard should include the patient's name and other pertinent or patient unique information.
  - A standardized, formatted paper count sheet may be used instead of the whiteboard or as a supplement for procedures where there is a large number and/or specificity of certain items (e.g., cardiac procedures). See Appendix B, "Sample Cardiovascular Blade and Needle Count Sheet" for an example.
  - It is the recommendation of the work group that, whenever possible, only one source of count information be used during the procedure.

**Algorithm Annotations**

- **Paper:** A paper count sheet may be used in organizations where the use of a whiteboard is not possible either due to space limitations and/or the ability of all the team members to view the board.
  - The paper form should be a standardized, preformatted form and when possible, specific to the procedure specialty/service.
  - Whenever feasible, a countable item should be preprinted on the form to minimize legibility or omission errors.

**Intraoperative image:** A radiographic image obtained within the surgical suite, usually with portable radiographic equipment.

**Micro needle:** A surgical needle that, for adults, is less than 13 mm in size. When using portable radiographic equipment, needles smaller than 13 mm in length are very difficult to detect in the adult torso (*Macilquham, 2003*); however, they may be visible in adult extremities or in children. Each organization will need to establish a policy for the use of intraoperative imaging when attempting to locate an unaccounted for micro needle. Unintentionally retained micro needles are not reportable as retained foreign objects.

**Notification:** If an unintentionally retained foreign object is found during a patient examination in a clinic, emergency department, or during a subsequent hospitalization, the facility that performed the original procedure should be notified.

**Parallel process:** Two separate activities performed simultaneously in the same area with two entirely separate groups of staff. Parallel processing is not multitasking. When parallel processing is used in relation to this protocol, two circulators will be needed: one dedicated to patient care and one dedicated to the baseline count process.

**Safety check:** Critical steps identified by the work group essential for reliably preventing an unintentionally retained foreign object.

**Surgical retained foreign object (RFO):** An object unintentionally retained after final closure of the wound, excluding micro needles.

**Surgical procedure:** A procedure performed in a surgical suite that involves an incision and general, regional, local, or monitored anesthesia, or conscious sedation.

**Radiology room image:** A radiographic image obtained in a radiographic room with a fixed tube and moving grid.

*Supporting evidence is of classes: C, D, Not Assignable*

## Special Considerations

- **Temporary Implants or Delayed Wound Closures/Open Wound Packing** – When the closure of a wound is intentionally delayed (damage control) or when temporary implants are used as part of the treatment the risk for an unintentionally retained foreign object is very high. Additional processes and procedures should be implemented to ensure all items have been removed prior to final wound closure (*AORN, 2006; Council on Surgical and Perioperative Safety, 2005*).
- **Temporary Wound Closure with Non-Radiopaque Items** – When a wound is temporarily closed with a non-radiopaque item (e.g., wound vacuum sponges) the risk for an unintentionally retained foreign object is very high. It is not unusual for patients to be sent home with these temporary items and have them removed at a later date. Organizations will need to develop strict processes for communication and handoff of information so that these items are completely removed as planned.

- **Communication of Unresolved Counts in Surgical Suites** – In the event that a countable item is lost and cannot be accounted for, surgical teams that may be performing subsequent procedures in the same room prior to its terminal cleaning should be alerted. The circulator should record the date, time, type and number of the missing item on the room's whiteboard, if present, or other documentation devices so that the next surgical team is aware of the unresolved discrepancy. Word of mouth is an insufficient means for communicating this information.

*Supporting evidence is of classes: R, Not Assignable*

## Prevention of Unintentionally Retained Foreign Objects in Surgery Annotations

### 2. Can Circulator Perform Room Survey Prior to Baseline Count?

If, at any time the patient's status becomes critical/emergent and/or there is not adequate time or staff to perform the steps in the protocol, counts should be considered compromised. The surgical team should continue to follow the Surgical RFO Prevention process and obtain a radiographic image to detect a potentially retained foreign object.

### 3. Counts Compromised – Continue to Follow Surgical RFO Prevention Process

Radiographic imaging, whether a portable radiographic image obtained in the OR or a postoperative image obtained in a radiographic room, is not a substitute for performing an accurate count process and methodical wound exploration.

An intraoperative radiographic image can be used to exclude the possibility of a retained foreign object. Portable radiographic imaging has limitations that should be considered, especially for visualizing micro needles. In addition, the type of imaging equipment (e.g., C-arm) used and cassette orientation relative to the surgical site should be considered.

The highest quality radiographic imaging is obtained in a radiographic room with fixed radiographic equipment and moving grid.

#### Portable imaging considerations and limitations

- Patient condition
- Size and type of retained item (non-radiopaque items, micro needles)
- Limited placement options of the radiographic film cassettes under OR tables limiting anatomy included on the images
- Lower tube power
- Instruments obscuring the image area
- Availability of portable radiographic equipment and staff

#### Portable intraoperative imaging should be obtained when:

- counts are off and cannot be reconciled,

**Algorithm Annotations**

- the patient's condition did not allow for the count process to be followed (rushed counts, incomplete counts),
- any individual has a concern about the accuracy of the counts, or
- before final closure when the wound was previously intentionally left open/packed.

**Imaging requests to rule out a possible RFO need to include the following information:**

- Callback number and surgeon's name
- Location and status of patient (e.g., in OR with wound closure suspended, in PACU)
- Type of surgery
- Type of item missing
- Details of the surgery as appropriate

The radiology technologist will review the radiographic images for quality and repeat the imaging as necessary.

Prior to the radiographic images being interpreted by radiology, the surgeon will review the radiographic images for adequate anatomic coverage related to the procedure and operative site. If the surgeon is unable to verify adequate anatomic coverage on the portable intraoperative images, postoperative radiographic imaging with fixed radiographic equipment should be obtained.

The work group recommends that the radiologist and surgeon simultaneously review the radiographic images both verbally and visually to correlate the anatomical coverage of the images with the surgical procedure, as well as a description of the potentially retained foreign object.

If a radiologist is not immediately available, the preliminary interpretation of the radiographic images to exclude a potentially retained foreign object is the responsibility of the surgeon.

**Postoperative radiographic imaging in a radiographic room with fixed radiographic equipment and moving grid should be obtained as soon as possible when there is a discrepancy in the counts and:**

- the patient's condition did not allow for intraoperative imaging to be obtained,
- the entire anatomic area was not included in the portable intraoperative imaging, or
- the intraoperative imaging failed to locate the retained foreign object and the counts could not be reconciled.

Prior to the radiographic images being interpreted by radiology, the surgeon will review the radiographic images for adequate anatomic coverage related to the procedure and operative site. The radiology technologist will review the radiographic images for quality and repeat the imaging as necessary.

(AORN, 2006; Council on Surgical and Perioperative Safety, 2005; VHA Directive, 2006)

*Supporting evidence is of classes: R, Not Assignable*

**4. Safety Check – Circulator Performs Room Survey Prior to Baseline Count**

Prior to the arrival of the patient in the surgical suite, the circulator will perform a room survey which includes the following:

- Designate and limit the number of receptacles for discarded items.

**Algorithm Annotations**

- Ensure the room and receptacles do not contain items from the previous procedure.
- Verify the whiteboard and other recordkeeping documents are clean and do not contain information from the previous procedure. The exception is the documentation required from a previous case when there was a missing item that was never recovered.

**5. Can Baseline Count Be Performed as Required in Protocol?**

There is evidence that distractions, multitasking and conflicting priorities, especially during critical cognitive steps such as counting, will, with high predictability, lead to an error (ACOG, 2006).

If the baseline count cannot be performed prior to the patient being brought to the surgical suite, the counts should be considered compromised and inaccurate. Continue to follow the Surgical RFO Prevention process and obtain portable, intraoperative radiographic imaging for a potentially retained foreign object.

Some organizations are utilizing parallel processing methods to improve OR turnover times. Parallel processing is when two separate activities with two entirely separate groups of staff are performed simultaneously. Parallel processing is **not** multitasking.

For the count process, two different circulators will be needed: one dedicated to the count process and one dedicated to patient care.

If separate staff are not available, the baseline count **must** occur **before** patient arrives in surgical suite.

**6. Safety Check – Perform Baseline Count Before Arrival of Patient in the OR Suite**

The counting recommendations outlined in this protocol are based on consensus statements and guidelines of the American College of Surgeons, the Association of Perioperative Registered Nurses, American College of Obstetrics and Gynecology, Council on Surgical and Perioperative Safety, Department of Veterans Affairs Veterans Health Administration, and the Joint Commission. In addition, articles on communication, teamwork, multitasking and interruptions and their relationship to unanticipated events were referenced. This protocol has identified staff responsible for the various steps based on their scope of practice and licensing requirement. Direct and explicit language (e.g., "will", "must") has been incorporated to reduce variation and to identify the steps of the protocol where variation could significantly increase the risk for an unintentionally retained object.

*(AORN, 2006; ACOG, 2006; American College of Surgeons, 2005; Council on Surgical and Perioperative Safety, 2005; Gibbs, 2005; Eldrige, 2006; Joint Commission International Center for Patient Safety, 2006; Brennan, 2004; ECRI, 2005; Haig, 2006; Harder, 2006; Leape, 1991; Leonard, 2004; Lingard, 2004; Thomas, 2000; Vincent, 2004; VHA Directive, 2006)*

Accurately accounting for all items that could potentially become unintentionally retained is a priority of the entire surgical team, with primary responsibility for performing the count process belonging to the circulator and scrub person. One of these individuals must be a registered nurse (AORN, 2006; American College of Surgeons, 2005).

Radiographic imaging is not a substitute for performing accurate count procedures. Count procedures may be omitted or modified in an extreme patient emergency. This exception will be documented in the patient's medical record and when the patient's condition allows, radiographic imaging should be obtained to rule out the possibility of an unintentionally retained foreign object.

*Supporting evidence is of classes: C, D, R, Not Assignable*

**What Items Will Be Included in the Count Process:**

Best practice is the use of radiopaque items in the surgical wound (*AORN, 2006; American College of Surgeons, 2005; Council on Surgical and Perioperative Safety, 2005; VHA Directive, 2006*).

The work group recognizes that not every item that may be used during a surgical procedure is radiopaque. It is the recommendation of the work group that radiopaque items should be used if that product is manufactured in a radiopaque form and all non-radiopaque items should be counted, regardless of whether that item is a required, countable item.

**Sponges/soft goods** – Sponges/soft goods will be counted for all procedures when they are used. Only radiopaque sponges/soft goods will be present within the surgical field (*AORN, 2006; American College of Surgeons, 2005; Council on Surgical and Perioperative Safety, 2005; VHA Directive, 2006*).

RayTec/laparotomy sponges will not be cut into pieces or otherwise used for dressing (*AORN, 2006; Council on Surgical and Perioperative Safety, 2005; VHA Directive, 2006*).

Non-radiopaque gauze used for dressing will be held in a separate area until the wound is closed (*AORN, 2006; American College of Surgeons, 2005*).

**Sharps** – Sharps will be counted for all procedures (*AORN, 2006; American College of Surgeons, 2005; Council on Surgical and Perioperative Safety, 2005; VHA Directive, 2006*).

An unintentionally retained micro needle is not reportable as a retained foreign object. Organizations will need to define a micro needle depending on their patient population (e.g., infants).

**Miscellaneous items** – Miscellaneous items will be counted for all procedures (*AORN, 2006; American College of Surgeons, 2005; Council on Surgical and Perioperative Safety, 2005*).

Examples of a miscellaneous item include vessel clips, vessel loops, vascular inserts, cautery scratch pads, trocar sealing caps, catheter sheaths, non-radiopaque items such as hernia tapes, and other small items.

**Instruments** – Instruments will be counted for all procedures when the possibility exists that an instrument could be unintentionally left behind (*AORN, 2006*).

Organizations will need to define instruments that are at risk for being unintentionally retained. The work group has listed the following guiding principles to assist organizations in defining instruments to be counted:

- Size of the wound relative to the instruments being used
- Instruments that leave the hand of the operator after being placed in the operative field
- Instruments that are obscured within the wound and not clearly visible throughout the procedure (clips, guide wires, small clamps, etc.)

It is the recommendation of the work group that instruments that are to be counted should be identified by specialty/service and specific to the procedure and surgical technique employed.

Examples of surgical procedures where instruments may be identified as a required countable item include chest, open abdominal, and pelvic procedures. See Appendix B, "Sample Cardiovascular Blade and Needle Count Sheet" and Appendix C, "Sample Count Sheet" for examples of a standardized instrument count sheet.

*Supporting evidence is of classes: C, R, Not Assignable*

**When the Count Process Will Be Performed:**

- The baseline count will occur before the patient is brought to the surgical suite unless parallel processing is used. For the count process using parallel processing, two different circulators will be needed: one dedicated to the count process and one dedicated to patient care.
- At the time of closure of a cavity within a cavity
- Before wound closure (e.g., fascia)
- At the end of the procedure/final closure (e.g., skin)
  - Sponges/soft goods used for wound debridement procedures for burn patients are exempt from the final count process. A final count, as outlined in the protocol, must be performed for all other items (sharps, miscellaneous items, instruments) used in wound debridement procedures for burn patients.
- Any time a member of the surgical team has concerns about the accuracy of the counts even when the counts appear correct
- Whenever there is a permanent staff change of the circulator:
  - All visible items will be counted and all items in use in the surgical field will be accounted for.
  - If there is a permanent change in a member of the surgical team other than the circulator, a report is required but a count is not.
  - When the circulator is changed for a short duration (e.g., lunch break), a report is required but a count is not.
- At final closure of a wound that was intentionally delayed (damage control), temporary implants are used, or a wound is temporarily closed with a non-radiopaque item (e.g., wound vacuum sponge)

(AORN, 2006; VHA Directive, 2006)

*Supporting evidence is of classes: R, Not Assignable*

**How the Count Process Will Be Performed:**

- The circulator and scrub person (one of whom must be a RN) will directly view the items being counted and will count out loud and concurrently (AORN, 2006; Council on Surgical and Perioperative Safety, 2005).
- Distractions and interruptions should be minimized during the count process (ACOG, 2006; American College of Surgeons, 2005). If the count process is interrupted, the circulator and scrub person will restart the count.
- The circulator will document the number and type of sponges/soft goods, sharps, miscellaneous items, and instruments on a preformatted whiteboard or other standardized, preformatted documentation record. The scrub person verbally confirms the number.
  - It is best practice for the circulator to document the number of each item immediately after counting them. This diminishes the likelihood that the number will be recalled incorrectly or the circulator will forget to document the number on the whiteboard.
  - Best practice is to use a preformatted whiteboard, directly viewable by the entire surgical team (France, 2005).

**Algorithm Annotations**

- For procedures where there is a large number and/or specificity of certain items (e.g., cardiac procedures), a standardized, preformatted document record may be used. See Appendix B, "Sample Cardiovascular Blade and Needle Count Sheet" for an example.
- It is the recommendation of the work group that, whenever possible, only one source of count information be used during the procedure.
- All sponges/soft goods, sharps, miscellaneous items, and instruments will be counted in the same order each time (*AORN, 2006*).
  - It is the recommendation of the work group that items be counted in the order they are listed on the preformatted whiteboard.
- Sponges/soft goods will be separated and counted individually (*AORN, 2006*).
  - Some organizations allow 4 x 8 sponges to be held by the bottom third and counted by individually separating the top two-thirds of each sponge. It is the work group's recommendation that best practice is to separate all sponges and count them individually.
- Every sponge/soft good will be visually inspected to ensure that the radiographic-detectible indicator is present (*AORN, 2006; American College of Surgeons, 2005; Council of Surgical and Perioperative Safety, 2005*).
  - If the indicator is not present, the entire package of sponges/soft goods will be removed from the suite and given to the designated person for follow-up with the manufacturer (*AORN, 2006*).
- Instruments should be counted in sets.
  - It is the work group's recommendation that best practice is for all instruments, regardless of whether they are required countable items or not, be added to the surgical field in pairs and retrieved in pairs.
- Packages where the labeling on the package does not match the number of items in the package will be removed from the suite and given to the designated person for follow-up with the manufacturer (*AORN, 2006*).
- Counts will begin at the surgical field and move away from the patient.
- Gauze and other soft goods used by anesthesia will not enter the surgical field or be mixed in with sponges/soft goods used and counted for the surgical procedure.
- Sponges/soft goods, sharps, miscellaneous items, and instruments added during a procedure will be counted prior to entering the surgical field (*AORN, 2006; Council on Surgical and Perioperative Safety, 2005*) and documented as soon as possible.
- Used sponges/soft goods will be unballied and pulled apart for counting.
- All sharps, miscellaneous items, and instruments will be inspected for broken or missing pieces when counted (*AORN, 2006; Council on Surgical and Perioperative Safety, 2005*).
- Any sponge/soft good, sharp, miscellaneous item, or instrument dropped during the procedure will be retrieved, shown to the person responsible for counting, and isolated from the surgical field to be included in the final count.
- Any item intentionally left behind in a patient because it would do more harm to retrieve will be documented in the patient's medical record.

*Supporting evidence is of classes: D, R, Not Assignable*

**Postprocedure Tasks:**

- Any item that accompanies the patient out of the surgical suite will be communicated to the circulator and documented (*AORN, 2006; Council on Surgical and Perioperative Safety, 2005*).
- After the counts have been reconciled, all items will be removed from the surgical suite. No items will be removed from the surgical suite until all counts have been reconciled and inspections completed.
- The whiteboard will be cleaned at the end of the procedure and before setup begins for the next procedure.
  - Note: The date, time, type and number of any accounted for item will be recorded on the whiteboard and communicated to each subsequent surgical team until the surgical suite is terminally cleaned.

*Supporting evidence is of classes: R, Not Assignable*

**9. Was a Body Cavity Entered/Created?**

Entering a body cavity, whether it is an open surgical wound or through a laparoscopic or hand-assisted procedure, increases the risk for an unintentionally retained foreign object. In some surgical procedures, an anatomic cavity is not entered; however, an artificial cavity is created. For the purposes of this protocol, this artificial cavity creates the possibility of retaining a foreign object. This does not include the initial surgical incision.

**10. Safety Check – Perform Wound Exploration**

A methodical wound exploration will be performed prior to the closure of the wound and/or any cavity (*AORN, 2006 Eldrige, 2006, American College of Surgeons, 2005; VHA Directive, 2006*). When applicable, surgeons will use both visualization and touch during the exploration. Generally, the type of surgical procedure performed guides the wound exploration technique employed.

A methodical wound exploration may be omitted or abbreviated in an extreme patient emergency or if the patient becomes critically unstable. This exception will be documented in the surgical record. If the count process cannot be reconciled, a radiograph should be performed as soon as is reasonable, based on the patient's condition.

**Methodical wound exploration recommendations:**

- A methodical wound exploration should be performed for all applicable wounds; the specific technique will be wound and procedure dependant.
- Best practice is to perform the methodical wound exploration the same way each time (e.g., top-to-bottom, quadrant-to-quadrant).
- For large open wounds, a methodical exploration should include both visual and tactile technique.

For an example of a detailed methodical wound exploration process for open abdominal, pelvic, or thoracic surgeries, see Appendix A for the Veterans Administration wound exploration process.

*(Eldridge, 2006; Gibbs, 2005; American College of Surgeons, 2005; Council on Surgical and Perioperative Safety, 2005; VHA Directive, 2006)*

*Supporting evidence is of classes: R, Not Assignable*

### 13. Close Wound and Finish Procedure

A radiographic image prior to closure of the wound does not need to be obtained when count processes are rigorously followed and all counts can be reconciled.

*Supporting evidence is of classes: R, Not Assignable*

### 14. Is Wound Closure Delayed/Open Wound Packing Performed?

When the closure of a wound is intentionally delayed (damage control) or when implants are used as part of the treatment (e.g., antibiotic beads, wound-vacuum sponges), the following will be performed:

- Radiopaque items will be used if that product is manufactured in a radiopaque form.
- The number and type of items used will be documented in the procedure record.
- Any sponges/soft goods packed in the OR and removed must be counted and documented in the patient's medical record.
- Any sponge/soft goods added to the wound must be counted and documented in the patient's medical record.
- When the patient returns to the OR for final wound closure, sponges/soft goods that were previously used for the original packing should be isolated from sponges/soft goods used in the subsequent procedure. Both counts should be reconciled prior to the closure of the wound.
- When there is a discrepancy between what was removed and what was previously documented, an attempt to reconcile the discrepancy is performed as described in Annotation #20, "Perform Reconciliation Process."
- A thorough wound exploration is performed prior to the closure of the wound.
- If radiopaque items were used, an intraoperative radiographic image should be obtained prior to final wound closure to ensure all items have been removed.

*(AORN, 2006; Council on Surgical and Perioperative Safety, 2005)*

*Supporting evidence is of classes: R, Not Assignable*

### 20. Perform Reconciliation Process

#### Process for Managing Count Discrepancies

When a discrepancy is identified, the number and what item is missing are reported to the surgical team by the circulator. If the patient's condition permits, wound closure should be suspended until all steps to reconcile the count are exhausted (*AORN, 2006*). The following steps should be performed if the patient's condition permits.

The work group recommends that organizations develop phrases for the circulator to use when notifying the surgical team that there may be an unintentionally retained foreign object. The key phrases should change as the urgency increases. For example, when the initial count is incorrect, the surgical team is made aware of the situation but closing continues. When reconciliation attempts fail to resolve the discrepancy, the key phrase should result in a cessation of closing until the lost item can be located.

**The following steps should be performed if the patient's condition permits:**

- A manual inspection of the surgical suite is conducted, including a visual inspection of the area surrounding the surgical field, the floor, kick buckets, linens, and trash receptacles.

**Algorithm Annotations**

- The count is repeated and verified. A discrepancy with the count must never be resolved by using the number listed on opened packages.
- Special attention should be paid to items such as sponges/soft goods. Sponges/soft goods will be unballied and separated for counting.
- The wound should be reexplored with special attention paid to the location of where that particular item may be retained (e.g., sponges tucked behind organs).
- Portable intraoperative imaging should be obtained and reviewed by the surgeon and radiologist before wound closure. See Annotation #22, "Obtain Radiographic Image for Potential RFO," for more information.
- If the counts cannot be reconciled, all the measures taken and the outcomes of those steps should be documented per the organization's policy. A radiographic image obtained in a radiology room with fixed equipment and moving grid should be obtained.

(AORN, 2006; VHA Directive, 2006)

*Supporting evidence is of classes: R, Class Not Assignable*

## 22. Obtain Radiographic Image for Potential RFO

Radiographic imaging, whether a portable radiographic image obtained in the OR or a postoperative image obtained in a radiographic room, is not a substitute for performing an accurate count process and methodical wound exploration.

An intraoperative radiographic image can be used to exclude the possibility of a retained foreign object. Portable radiographic imaging has limitations that should be considered, especially for visualizing micro needles. In addition, the type of imaging equipment (e.g., C-arm) used and cassette orientation relative to the surgical site should be considered.

The highest quality radiographic imaging is obtained in a radiographic room with fixed radiographic equipment and moving grid.

### **Portable Imaging Considerations and Limitations**

- Patient condition
- Size and type of retained item (non-radiopaque items, micro needles)
- Limited placement options of the radiographic film cassettes under OR tables limiting anatomy included on the images
- Lower tube power
- Instruments obscuring the image area
- Availability of portable radiographic equipment and staff

### **Portable intraoperative imaging should be obtained when:**

- counts are off and cannot be reconciled,
- the patient's condition did not allow for the count process to be followed (rushed counts, incomplete counts),
- any individual has a concern about the accuracy of the counts, or
- before final closure when the wound was previously intentionally left open/packed.

**Algorithm Annotations**

**Imaging requests to rule out a possible RFO need to include the following information:**

- Callback number and surgeon's name
- Location and status of patient (e.g., in OR with wound closure suspended, in PACU)
- Type of surgery
- Type of item missing
- Details of the surgery as appropriate

The radiology technologist will review the radiographic images for quality and repeat the imaging as necessary.

Prior to the radiographic images being interpreted by radiology, the surgeon will review the radiographic images for adequate anatomic coverage related to the procedure and operative site. If the surgeon is unable to verify adequate anatomic coverage on the portable intraoperative images, postoperative radiographic imaging with fixed radiographic equipment should be obtained.

The work group recommends that the radiologist and surgeon simultaneously review the radiographic images both verbally and visually to correlate the anatomical coverage of the images with the surgical procedure as well as a description of the potentially retained foreign object.

If a radiologist is not immediately available, the preliminary interpretation of the radiographic images to exclude a potentially retained foreign object is the responsibility of the surgeon.

**Postoperative radiographic imaging in a radiographic room with fixed radiographic equipment and moving grid should be obtained as soon as possible when there is a discrepancy in the counts and:**

- the patient's condition did not allow for intraoperative imaging to be obtained,
- the entire anatomic area was not included in the portable intraoperative imaging, or
- the intraoperative imaging failed to locate the retained foreign object and the counts could not be reconciled.

Prior to the radiographic images being interpreted by radiology, the surgeon will review the radiographic images for adequate anatomic coverage related to the procedure and operative site. The radiology technologist will review the radiographic images for quality and repeat the imaging as necessary.

(AORN, 2006; Council on Surgical and Perioperative Safety, 2005; VHA Directive, 2006)

*Supporting evidence is of classes: R, Not Assignable*

## **Appendix A – Veterans Administration Methodical Wound Exploration Process**

A methodical wound exploration will be performed prior to the closure of that cavity. Surgeons will use both touch and sight during the exploration whenever possible and should not rely on just one sensory perception.

A methodical wound exploration may be omitted or abbreviated in an extreme patient emergency or if the patient becomes critically unstable. This exception will be documented in the surgical record and if appropriate, a radiograph should be performed as soon as is reasonable, based on the patient's condition.

### **Abdominal and Pelvic Process**

Unless contraindicated for a specific patient, these steps should be performed prior to the removal of stationary or table-mounted retractors. The methodical wound exploration process includes the exploration of all four quadrants of the abdomen.

- Lift and exam around the transverse colon.
- Examine above and around the liver.
- Examine around the spleen.
- Examine within and between the loops of bowel.
- For the pelvis:
  - Examine behind the bladder.
  - Examine behind the uterus (if present).
  - Examine around the upper rectum.
- Examine the area inside of the vagina if it was entered as part of the procedure.
- Examine in and around any place a retractor or retractor blades were placed.

### **Mediastinum or Thorax Process**

Unless contraindicated for a specific patient, these steps should be performed for all procedures involving the mediastinum or thorax.

- For cardiac procedures:
  - Examine the heart by elevating the apex of the heart and examine the retrocardiac space.
  - Examine the transverse sinus to the right and left of the aorta and pulmonary vein.
  - For procedures involving the mediastinum, if the mediastinal pleura was opened, examine the ipsilateral pleural cavity.
  - For thoracic procedures:
    - Examine the thoracic cavity, paying particular attention to the thoracic apex and base of the lungs, paravertebral sulcus, and inferior recesses of the diaphragm. Examination includes placing a hand or finger behind the lung and palpating from apex to base.

## Appendix B – Sample Cardiovascular Blade and Needle Count Sheet

ITEM	NUMBERS IN USE	1 <sup>ST</sup>	2 <sup>ND</sup>	3 <sup>RD</sup>
General Closure Needles				
CV Needles				
Free (Eyed) Needles				
Hypo Needles				
Scalpel Blades				
4 X 8 Sponges				
Lap Sponges				
Kittners				
Vessel Loops				
Umbilical Tape				
Retract-O-Tape				
Suture Boots				
Grey Bulldog Clips				
Bull Dog/Serrefine Clamps				
Parsonette Retractor				
Irrigation Tips (Olive Tips)				
<b>Temporary Items</b>				

**CV MULTI PACKS:**

**GENERAL MULTI:**

	Surgipro	6-0 CV11	VP76MX	30 IN.		Ticron	0 GS21	3260-62	028316
	Surgipro	7-0 CV1	VP37MX	30 IN.		Tricon	2-0 GS21	3260-52	028320
	Surgipro	6-0 CVF11	VP126MX	24 IN.					
	Surgipro	7-0 CVF1	VP102MX	24 IN.					
<b>CV SINGLE PACKS:</b>					<b>GENERAL SINGLE:</b>				
	Surgipro	3-0 V20	VP522X	028230		Polysorb	0 GS21	CL954	028820
	Surgipro	4-0 V20	VP521X	028221		Polysorb	0 GS25	CL904	028402
	Surgipro	4-0 CV23	VP557X	028234		Polysorb	2-0 GS25	CL973	028437
	Surgipro	5-0 CV23	VP556 X	028233		Polysorb	3-0 P14	SL1679	028436
	Surgipro	6-0 CVF11	VPF726X	028254		Polysorb	3-0 GS21	CL810	028817
	Surgipro	7-0 CVF1	VPF702 X	028249		Polysorb	3-0 Sc-2	SL643	038078
	Surgipro	8-0 MV1355	VP902X	028255					
<b>VALVE SUTURE PLEDGET:</b>					<b>MISCELLANEOUS SUTURE:</b>				
	Ticron	2-0 Y-5	VCD-256	028360					
	Ticron	2-0 Y-31	VCD-656	028359					
<b>VALVE REPAIR SUTURE: NO PLEDGET</b>									
	Ticron	2-0 Y-5	3222-56	028122					
	Ticron	2-0 Y-31	2877-56	028121					

## Appendix C – Sample Count Sheet

ITEM	NUMBERS IN USE	1 <sup>ST</sup>	2 <sup>ND</sup>	3 <sup>RD</sup>
General Closure Needles				
Free (Eyed) Needles				
Hypo Needles				
Scalpel Blades				
4 x 8 Sponges				
Lap Sponges				
Tonsil Sponges				
Kittners				
Cottonoids				
Cotton Balls/Dental Rolls				
Penrose Drain				
Bowel Clamp Covers				
Retractor Fish Hooks				
Umbilical Tape				
Vessel Loops				
Suture Boots				
Vascular (Grey) Clips				
Bull Dog/Serrefine Clamps				
Irrigation Tips (Olive Tips)				
Safety Pins				
Antibiotic Beads				
<b>Fetal Scalp Electrodes</b>				
<b>Temporary Items</b>				

## Appendix D – Incorporating Human Factors Systems Design into Work Process Design

Two large population-based studies of medical injury published in 1991 and 2000 led to the initiation of many efforts to reduce medical error. The first of the studies, the Harvard Medical Practice Study (HMPS), examined the outcomes of 30,121 randomly chosen patient cases from 51 hospitals in New York State in 1984 (*Brennan, 1991; Leape, 1991*). In the second, the Utah and Colorado Medical Practice Study (UCMPS), the records of 14,052 randomly selected hospitalizations from 28 hospitals in Utah and Colorado in 1992 were reviewed (*Thomas, 2000*). Similar results were found in both studies, and extrapolation from the results of the most recent of the studies, the UCMPS, indicates that approximately 44,000 deaths recorded in 1997 in the USA could have occurred as a result of preventable adverse events. Many efforts to reduce medical error that were initiated as a result of these studies have included Human Factors methodology to investigate and improve health care systems.

Human Factors emphasizes designing systems and producing work processes that enhance human performance. Human Factors Systems Design considers weaknesses and strengths in the entire medical delivery process from diagnosis through the prescription and delivery of treatment, and includes examining the work processes of, for example, surgeons, anesthesiologists, nurses, scrub technicians, phlebotomists, pharmacists, and health unit coordinators.

Human Factors Systems Design focuses on how the work process and performance of health care providers are affected by issues such as work space design; the functionality and ease of using electronic medical records systems; distractions and interruptions; workload; the complexity, length and urgency of procedures, fatigue and personal stress; intra- and inter-departmental communication issues; staffing requirements; the use of float staff; shift changes; staff competencies; and training.

Human Factors Systems Design seeks to identify the probable and potential causes of errors and to identify factors contributing to safety gaps in medical processes. Then design improvements, based on Human Factors principles, are developed so that the errors and safety gaps are addressed without introducing problems elsewhere in the system. The goal is to foster better work environments, minimize potential errors, improve patient care, and enhance patient safety.

*Supporting evidence is of classes: C, D*

### **Communication Factors and Events**

In root cause analysis findings submitted to the Joint Commission in the ten years from 1995 to 2005, the number one reason identified as causal in all sentinel events was communication (*Joint Commission of Accreditation Organization, 2006*). In 2006, in an attempt to address these findings, the Joint Commission required accredited organizations to implement a national patient safety goal (NPSG) related to communication. While organizations have been given flexibility in determining how to meet the expectations of this goal, many have adopted SBAR (situation, background, assessment and recommendation) as one way of improving communication. While SBAR has its origins in the nuclear power and commercial aviation industries, it has been successfully adapted to the medical community (*Haig, 2006*).

One of the benefits of this communication model is that it addresses the different ways in which physicians are trained to communicate versus other health care professionals, especially nurses (*Leonard, 2004*).

One mechanism to decrease events, including retained items, is the use of preprocedural briefings. The purpose of a briefing is to ensure that all the members of the team are working toward a common goal and are aware of any concerns the physician/nurse midwife may have related to the procedure. The briefing also provides a platform for any member of the team to raise a misgiving (*ECRI, 2005*). At the conclusion

of the procedure, team members can debrief the process to identify what went well, what could have been done differently, and what can be done the next time (*ECRI, 2005*).

Both communication methodologies promote the use of "stop the line." Again, developed outside the health care industry, this concept allows any member of the team to speak up about a patient safety concern at any time during the procedure. Implementing a "stop the line" process requires a culture that promotes and rewards behaviors consistent with patient safety efforts. No matter the outcome, the willingness of the individual to raise a concern is directly related to the organization's administrative support of the action.

(*Lingard, 2004; Harder, 2006*)

*Supporting evidence is of classes: C, D, R, Not Assignable*

### **Distractions, Environmental Factors and Events**

When an event occurs, one of the contributing factors that is explored is the environment. Noise in the procedure room, including music, can interfere with the team's ability to communicate, increase stress levels and adversely affect motor skills (*Vincent, 2004*). Distractions (e.g., pagers in the Labor and Delivery room) and interruptions by individuals not directly involved should be kept to a minimum, especially during critical stages of a procedure (*ACOG, 2006*). Other factors that should be taken into consideration when evaluating the environment are adequate lighting in the room for team members to see clearly and read labels, unpleasant odors that may be a direct result of the procedure being performed, or the room temperature. While the latter two factors may be outside the direct control of the team members, nonetheless they should be taken into consideration and recognized as a risk factor for an event.

*Supporting evidence is of classes: R, Not Assignable*

**Document Drafted  
 Month – Month Year**

**First Edition  
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*The next scheduled revision will occur within 12 months.*

**Availability of references**

References cited are available to ICSI participating member groups on request from the ICSI office. Please fill out the reference request sheet included with your protocol and send it to ICSI.

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## **Brief Description of Evidence Grading**

Individual research reports are assigned a letter indicating the class of report based on design type: A, B, C, D, M, R, X.

A full explanation of these designators is found in the Foreword of the protocol.

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This section provides resources, strategies and measurement specifications for use in closing the gap between current clinical practice and the recommendations set forth in the protocol.

The subdivisions of this section are:

- Priority Aims and Suggested Measures
  - Measurement Specifications
- Key Implementation Recommendations
- Knowledge Resources
- Resources Available

## **Priority Aims and Suggested Measures**

1. Eliminate the occurrence of unintentionally retained foreign objects during a surgical procedure.

Possible measures for accomplishing this aim:

**Outcome Measure:**

- a. Rate or number of unintentionally retained foreign objects in surgery.

**Process Measures:**

- b. Percentage of surgical cases where the baseline counts was conducted prior to the patient arriving in the surgical suite.
- c. Percentage of surgical cases where there was a thorough wound exploration performed before closure of each layer.
- d. Percentage of surgical cases where counts were not reconciled and imaging was performed.

## Measurement Specifications

### Possible Success Measurement #1a

Number of unintentionally retained foreign objects in surgery

or

Rate of unintentionally retained foreign objects

### Population Definition

Patients of all ages who have a surgical procedure performed

### Data of Interest

# of unintentionally retained foreign objects (reported as a raw number)

$$\frac{\text{\# of unintentionally retained foreign objects}}{\text{Total \# of surgical cases per month}} \times N$$

N is determined based on the size of the denominator

If denominator is less than 100, use a rate of per 100

If denominator is greater than 100 but less than 1,000, use rate of per 1,000

If denominator is greater than 1,000 but less than 10,000, use a rate of per 10,000

If denominator is greater than 10,000 but less than 100,000, use a rate of per 100,000

### Numerator/Denominator Definitions

Numerator: Any object unintentionally retained after a surgical procedure.

Denominator: Surgery is defined as an invasive procedure that takes place in an operating room by a surgeon.

### Method/Source of Data Collection

Event data should be reported through an incident report or sentinel event report.

Total surgical cases can be collected through the surgical schedule, log, or hospital billing.

### Time Frame Pertaining to Data Collection

The suggested time period is a calendar month but three months could be consolidated into quarterly data points, as well, if caseload and/or event numbers are small.

### **Possible Success Measurement #1b:**

Percent of baseline counts conducted.

### **Population Definition**

Patients of all ages who have a surgical procedure performed.

### **Data of Interest**

# of patients having a baseline count conducted and documented on the whiteboard prior to surgical time out

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Total # of surgical cases

### **Method/Source of Data Collection**

Retrospective collection of any measures associated with documentation can be done by randomly sampling charts of patient cases.

Concurrently collection will need to be done through direct observation either by a quality/safety advocate or "secret shopper" – someone that has a dual function on the team but the observation and measurement function is not known.

### **Time Frame Pertaining to Data Collection**

Suggested sample size and time frame for any of these measures would be minimum of 10 per month. If it is a larger hospital with a large surgical caseload or particular invasive procedural area and adequate resources, the sample size can be larger.

## **Key Implementation Recommendations**

The following system changes were identified by the protocol work group as key strategies for health care systems to incorporate in support of the implementation of this protocol.

1. The work group recommends that a preformatted whiteboard be used as the primary record of the count. Documenting counts on a whiteboard allows all surgical staff, and in particular the scrub tech, to independently view the count record. A public display of the count record in an area where the entire surgical team can view, it is likely to reinforce the importance of the count process. The work group also recommends that a count worksheet be used as a memory aid in ORs when the whiteboard is not easily accessible in a timely manner. The count worksheet should be used only as a memory aid for the baseline count and, if needed, for subsequent counts. It should be used rather than a piece of scratch paper. In contrast, if the whiteboard is located very close to the area when the count occurs, and if the circulating nurse can easily write the counts on the whiteboard without leaving the count area, there will be no need to use the count worksheet.
2. Distractions and interruptions should be kept to a minimum during the count process.
3. Red rules\* should be established, followed by staff and physicians and supported by leadership (see below for specific red rules suggested for this protocol)

\*Red rules – the few, key rules created to prevent/address the specific actions that pose the highest level of consequence and risk to safety of patients or staff. The intention is to develop solid habits around these rules so that they are followed consistently and accurately each time. Individual responsibility to adhere to each red rule is imperative to ensure the safest environment and delivery of the care process.

Suggested red rules:

1. Sponges/soft goods and sharps will be counted for surgical procedures.
2. Baseline counts are accurately performed and completed before incision starts.
3. If the count cannot be reconciled, imaging must be done appropriate to the patients condition as outlined in this protocol.

## **Knowledge Resources**

### **Criteria for Selecting Resources**

The following resources were selected by the Prevention of Unintentionally Retained Foreign Objects in Surgery protocol work group as additional resources for providers and/or patients. The following criteria were considered in selecting these resources.

- The site contains information specific to the topic of the protocol.
- The content is supported by evidence-based research.
- The content includes the source/author and contact information.
- The content clearly states revision dates or the date the information was published.
- The content is clear about potential biases, noting conflict of interest and/or disclaimers as appropriate.

### **Resources Available to ICSI Members Only**

ICSI has a wide variety of knowledge resources that are only available to ICSI members (these are indicated with an asterisk in far left-hand column of the Resources Available table). In addition to the resources listed in the table, ICSI members have access to a broad range of materials including tool kits on CQI processes and Rapid Cycling that can be helpful. To obtain copies of these or other Knowledge Resources, go to <http://www.icsi.org/knowledge>. To access these materials on the Web site you must be logged in as an ICSI member.

The Knowledge Resources list in the table on the next page that are not reserved for ICSI members are available to the public free-of-charge.

## Resources Available

*	Title/Description	Audience	Author/Organization	Web Sites/Order Information
	Joint Commission of Accreditation of Healthcare Organizations (JCAHO)	Providers	Joint Commission of Accreditation of Healthcare Organizations (JCAHO)	<a href="http://www.jcaho.org">http://www.jcaho.org</a>
	Association of periOperative Registered Nurses (AORN)	Providers	Association of periOperative Registered Nurses (AORN)	<a href="http://www.aorn.org">http://www.aorn.org</a>
	VA National Center for Patient Safety (NCPS)	Providers	Department of Veterans Affairs Veterans Health Administration, Washington, DC 20420	<a href="http://www.patientsafety.gov/">http://www.patientsafety.gov/</a>
	American College of Surgeons	Providers	VA National Center for Patient Safety (NCPS)	<a href="http://www.facs.org">http://www.facs.org</a>

\* Available to ICSI members only.