PREVENTION OF RETAINED SURGICAL ITEMS

1. PURPOSE: This Veteran Health Administration (VHA) Directive provides policy to ensure that surgical items are not retained in a patient following surgery.

2. BACKGROUND

   a. Surgical items are foreign bodies defined as instruments, sharps, sponges, or any materials used by the surgical team to perform a surgical procedure. Sharps are surgical needles, aspirating needles, blunt needles, scalpel blades or any items with a sharp or pointed edge that pose a risk for skin puncture by members of the surgical team. Sponges include 4” x 4” sponges, 2” x 2” sponges, laparotomy pads, surgical towels or any absorbent materials designed to absorb blood or bodily fluids that are not intended to remain in the patient’s body after the surgical procedure is completed.

   b. Estimates of rates of retained surgical items have ranged from 1 in 19,000 to 1 in 1,500 operations (see subpar. 5b). Recent data based on the Agency for Healthcare Research and Quality’s Patient Safety Indicators suggest that the Department of Veterans Affairs (VA) rate in 2001 was approximately 1 in 6,000 inpatients (see subpar. 5c).

   c. To ensure that foreign bodies are not retained in a surgical patient from a procedure, counting surgical instruments, sharps, and sponges has been the traditional method to account for all items used by a surgical team during a surgical procedure. This method is useful but has not been uniformly effective in preventing retained foreign bodies. A recently published study based on tort claims data reported a correct count in 88 percent of patients subsequently discovered to have retained foreign bodies from a surgical procedure. Accordingly, in addition to counting, this directive outlines initiatives involving the surgical team, the radiology department, and administration to reduce the probability of retained foreign objects from surgical procedures.

3. POLICY: It is VHA policy that counts and additional preventive actions are required for all surgical procedures except for those where retention of a foreign body is virtually impossible such as: cataract extraction and diagnostic cystoscopy.

4. ACTION: The facility Director, or designee, is responsible for ensuring that a written facility policy must be in effect no later than May 15, 2006, which states that surgical teams must take the following necessary steps to prevent the retention of foreign bodies from surgical procedures:

   a. A methodical wound exploration must be performed before closing the surgical wound in every case (see Att. A).

THIS VHA DIRECTIVE EXPIRES APRIL 30, 2011
b. All surgical towels, sponges, laparotomy pads, and similar materials that are placed in the surgical field must be left in their original configuration and not be cut or used for dressings, and must be detectable by radiograph. For example, sponges, towels, gauze, and cotton pads without radiopaque materials must not be placed into, or peripheral to an operative wound in the surgical field. In addition, items in these categories that are used in the operating room (OR), but are not detectable by radiograph and are not used in the surgical field, for example, antiseptic pads to decontaminate the skin before inserting an IV, must be disposed in a separate waste receptacle so designated for that purpose and never in the same space with counted radiopaque pads, sponges, or towels. This step is intended to reduce the likelihood of inaccurate counts of radiopaque items. Available radiopaque materials for use in all surgical cases must be procured and used to the exclusion of similar materials and objects that cannot be detected by a radiograph.

c. Methods for counting instruments, sharps, and sponges must comply with the published 2005 standards of the Association of periOperative Registered Nurses (AORN), and AORN standards on this topic as directed by the VHA Director for Surgical Services. OR nurses and technicians must be allowed sufficient time for counting instruments, sharps, and sponges (see Att. B for more details).

d. Surgical sponges, laparotomy pads, towels, and sharps must be counted in every case except as noted in paragraph 3.

e. All surgical instruments must be counted with the only exception of surgical procedures routinely concluded by a radiograph taken prior to closing the surgical wound. Such an example would be an orthopedic case that concludes with a radiograph to verify proper anatomic alignment of a reduced fracture or an implant. In those procedures, if an instrument count is not performed, the radiograph must be reviewed to rule out a retained foreign object before the wound is closed.

f. The surgeon must be informed by perioperative personnel (nurse or OR technician) when any discrepancy in a count of surgical items is discovered. It is imperative that an appropriate search be undertaken to recover the item in question and resolve the discrepancy. Concerns of perioperative personnel about a discrepancy must be communicated to the surgeon and never dismissed without appropriate investigation and actions. Efforts should be made to inspect all possible sites in and around the surgical field for the missing item. In addition, whenever a count is “incorrect” (i.e., the preoperative count is greater or less than the postoperative count) radiography of the surgical field must be done to rule out a retained foreign body. If the surgical team finds the missing object by wound exploration or viewing the radiograph, there is no requirement for a radiologist to read the film in real time. However, if the surgical team does not find the missing item, a radiologist must interpret and report the findings of the radiograph to the surgical team in real time. For purposes of this Directive, real time is defined as personal communication within 30 minutes of the initial request for a radiograph by the surgical team. The attending surgeon has the discretion to close the surgical wound prior to receiving a report from the radiologist regarding a missing surgical item if delaying wound closure would substantially increase risk for the patient.
g. It is anticipated that radiologists will interpret radiographs taken in the OR in real time during normal working hours, but this may not be possible during off duty hours. Teleradiology will facilitate access to these films for a radiologist in a remote location from the hospital, but this functionality is not available in all VA medical center locations. Therefore, it is not presently expected that a radiologist will have the capability to interpret all radiographs in real time for every surgical case during off duty hours. VHA hospital resources should be allocated for necessary equipment and personnel in the Radiology Department to ensure timely radiographs requested for surgical patients in the OR. Sufficient resources should also be allocated to facilitate the access of digital radiograph images by radiologists in remote locations from the hospital (e.g., teleradiology) (see Att. C).

h. Pre-operative and post-operative surgical counts and other requirements described above may only be omitted in an extreme patient emergency. In such cases, the divergence from standard practice must be documented. The surgeon will include a statement in the operative report regarding the emergent nature of the procedure requiring omission of the counts. The circulating nurse will enter a statement in the “Nursing Care Comments” section of the computerized Surgery Package, which will appear in the Nurse Intra-operative Report. In these cases, performing a radiograph to rule out a retained surgical item must be accomplished while the patient is in the OR or Post Anesthesia Care Unit (PACU), unless contraindicated by the patient’s clinical condition. A routine radiograph taken at the conclusion of an emergency surgical procedure is not a replacement for routine counting of sharps, sponges, and instruments. All required cases where sponge, sharp, and instrument counts are not performed should be documented and reported quarterly to the National Surgical Quality Improvement Program (NSQIP) Program Office.

**NOTE:** VHA facilities are encouraged to develop specific standard local practices that enhance the general requirements of this Directive. A list of methods that may be considered for implementation can be found in Attachment D. Many of these methods derive from corrective actions implemented at VA medical centers after Root Cause Analyses of adverse events or close calls.

i. In surgical cases at higher risk for retained foreign bodies, radiographic screening may be considered even if surgical counts are documented as correct. Risk factors identified as increasing the likelihood of incorrect counts and/or retained surgical items include the following conditions: emergency surgical procedures, unexpected change in the conduct or scope of a surgical procedure, procedures involving more than one surgical team, extended length in time for a surgical procedure, unexpected transfusions defined as greater than four units of packed red blood cells, and morbidly obese patients.

j. Adverse events and close calls related to retained surgical items must be reviewed locally and reported to the VHA National Center for Patient Safety (NCPS) consistent with the guidance contained in VHA Handbook 1050.1, on conducting a Root Cause Analysis. Aggregate data will be reported annually to the NSQIP Program Office. **NOTE:** When a retained foreign object has occurred, disclosure to the patient of this adverse event is to be accomplished consistent with current VHA policy.
5. REFERENCES


6. FOLLOW-UP RESPONSIBILITY: National Director, Surgical Services (111B) is responsible for the content of this Directive. Questions may be directed to (202) 273-8504.

7. RECISSIONS: None. This VHA Directive expires April 30, 2011.

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ATTACHMENT A

METHODICAL WOUND EXPLORATION

1. A methodical exploration of the operative wound must be conducted prior to wound closure. The space to be closed must be carefully examined. Special focus should be given to closure of a cavity within a cavity (i.e., heart, major vessel, stomach, bladder, uterus, and vagina). Surgeons should strive to see and touch during the exploration whenever possible; reliance on only one element of sensory perception is usually insufficient. The surgeon should visually and manually make every effort to assure that no retained foreign objects have been left in body cavities prior to leaving the operating room (OR). The general process is to look and feel in the recesses of the wound under fatty protuberances and soft-tissue appendages.

2. Unless clinically contraindicated for a specific patient, the following steps should be taken for procedures performed in the abdomen or pelvis. These steps should be performed before removing stationary or table mounted retractors.

   a. Examine all four quadrants of the abdomen with attention to:

      (1) Lifting the transverse colon.

      (2) Checking above and around the liver and above and around the spleen.

      (3) Examining within and between loops of bowel.

      (4) Inspecting anywhere a retractor or retractor blades were placed.

   b. Examine the pelvis; look behind the bladder, uterus (if present), and around the upper rectum.

   c. The vagina should be examined if it was entered or explored as part of the procedure.

3. Unless clinically contraindicated for a specific patient, the following general steps should be taken for procedures performed in the mediastinum or thorax.

   a. In a mediastinal procedure, if the mediastinal pleura were opened, examine the ipsilateral pleural cavity.

   b. In a cardiac procedure, elevate the apex of the heart and examine the retrocardiac space. Examine the transverse sinus to the right and left of the aorta and pulmonary artery.

   c. In a thoracic procedure, examine the thoracic cavity with attention to the thoracic apex and base of the lungs, paravertebral sulcus, and inferior recesses of the diaphragm. Place a hand or finger behind the lung and palpate from apex to base.
d. If the surgeon is informed of an inaccurate count by the circulating nurse, while the OR staff are looking for the missing object, the surgeon should stop closing the wound and proceed with a methodical wound examination.
ATTACHMENT B

COUNTERING SURGICAL ITEMS

1. The practices recommended by the Association of periOperative Registered Nurses (AORN) pertaining to how to count surgical items must be followed. Time must be allowed for counts to be performed carefully and precisely. Independent of any subsequent changes to AORN recommendations, the following processes must be followed:
   a. Sponges, towels, laparotomy pads, and similar items must be counted.
   b. Sharps and related miscellaneous items must be counted.
   c. Instruments must be counted (for exceptions see following subpar. 10a).
   d. Surgical items are counted audibly and viewed concurrently by the operating room (OR) surgical nurse or technician, and the circulating nurse.

2. Counts need to be performed as follows:
   a. Before the procedure has begun to establish a baseline count,
   b. Before the closure of a cavity within a cavity,
   c. Before wound closure begins,
   d. At skin closure or end of procedure,
   e. At the time of permanent relief of either the scrub person or the circulating nurse.

3. When additional items are added to the field, they are to be counted when added and recorded as part of the count documentation.

4. Any time there is a question regarding the count, an additional count must be requested by the circulating nurse, the OR surgical nurse or technician, or the surgeon.

5. Perioperative personnel must never assume that the count on prepackaged sterilized items is accurate. The contents of each package must be counted individually by the scrub tech/nurse and circulating nurse. The circulating nurse will verbally confirm the count with the scrub/tech nurse. Retention bands will be removed from all items. Each item will be separated and counted individually to determine whether an item has been inadvertently added or deleted from the package. If the package has an incorrect number of items, and the procedure has not begun, the entire pack must be removed from the OR. If the procedure has begun, the pack must be bagged, properly labeled, and isolated from the other counted items.

6. All relief personnel are to be documented in the computerized Surgery Package and will appear in the Nurse Intra-operative Record.

7. Counts must be performed in the same sequence each time. The count should begin at the surgical site and the immediate surrounding area, proceed to the Mayo stand and back table, and
finally to the counted items (sponges, sharps, or instruments) that have been discarded from the field.

8. Sponge Counts

a. All sponges used during a surgical procedure must be left in their original configuration, not cut or used for dressings, and must be detectable by a radiograph. Sponges that are not detectable by a radiograph and that are used during preparation of the surgical site will be isolated and removed from the operating room prior to the start of the procedure. Radiopaque sponges intended for use during surgery may not be used during surgical preparation.

b. All counted sponges remain in the OR and/or the sterile field during the procedure. Neither linen containers nor trash containers will be removed from the OR until all counts are completed and resolved.

c. When removing sponges from the sterile field, sponges are placed in a count bag or other local device designed for counting sponges. Different types of sponges must not be mixed in the same container. Each sponge must have the radiopaque tape visible to enhance the viewing and counting process.

d. In the event that a counted sponge is intentionally used as a packing, the number and type(s) of sponges must be documented in the “Nursing Care Comments” section of the computerized Surgical Package which appears in the Nurse Intra-operative Report. The count must be verified as “correct” because all items are accounted for.

e. The count should be recorded on a dry erase count board, or if not available, using the locally developed OR Count Sheet as each category is counted. When additional sponges are added during the procedure, the circulating nurse providing the sponges will record them on the OR Count Sheet or dry erase count board.

f. The scrub nurse or technician must discard soiled sponges and packs in a prepared kick bucket or receptacle without touching the receptacle or contaminating gloved hands. The circulating nurse must transfer and count discarded sponges and place them in waterproof count bags or other approved local device according to type of sponge and standard number previously recorded. The circulating nurse must place the soiled sponges in the count bag using gloved hands and using other methods and tools appropriate for disposal of biological materials.

g. Counts omitted due to an extreme patient emergency will be documented by the circulating nurse in the nurse intra-operative report, and entered into the operative record by the surgeon. In these cases, performing a radiograph while the patient is in the OR or Post Anesthesia Care Unit (PACU) should be accomplished unless contraindicated by the patient’s clinical condition.

h. If the count is incorrect, the circulating nurse will notify the surgeon and the Nurse Manager and/or charge nurse. The surgeon will search the wound and/or cavity as appropriate. A thorough search of the room must be made including linen and trash. If unable to locate the
missing sponge, a radiograph is required post-operatively while the patient is still under anesthesia on the Operating Room table. \textit{NOTE: Generally, this needs to be done before wound closure, while the patient is under anesthesia.} If the sponge is not found, the action must be documented on the Operative Record and VA Form VA 10-2633, Report of Special Incident Involving a Beneficiary, or its electronic equivalent. The requirements described in Attachment C must also be followed.

9. Sharps Counts

a. Standard practice will be that sharps are transferred to the surgeon on an “exchange basis” through a no hand-to-hand pass technique such as a neutral or safe zone to minimize the possibility of a sharps injury and lost sharp item. This practice may be modified by the surgeon as necessary to assure eye contact with the operative field.

b. Sharps broken during a procedure will be accounted for in their entirety. Verification that all broken parts are accounted for prevents unintentional retention of a foreign body within the patient.

c. Used sharps must be kept in a disposable, puncture resistant needle container during the procedure and disposed of at the end of the procedure. This helps ensure their containment and minimizes the risk of injury to scrubbed personnel.

d. All counted sharps will remain within the OR and/or the sterile field during the procedure. If a counted sharp is passed or inadvertently dropped off the sterile field, it must be shown to the scrub nurse or technician, and isolated from the field to be included in the final count, thus assisting to eliminate the possibility of an incorrect count.

e. Counts omitted due to an extreme patient emergency must be documented by the circulating nurse in the nurse intra-operative report and dictated into the operative record by the surgeon. In these cases, performing a radiograph while the patient is in the OR or Post Anesthesia Care Unit (PACU) should be accomplished unless contraindicated by the patient’s clinical condition.

f. If the count is incorrect, the circulating nurse must notify the surgeon and the Nurse Manager and/or charge nurse. The surgeon must search the wound and/or cavity as appropriate. A thorough search of the room should be made including linen and trash. If unable to locate the missing sharp, a radiograph is required post-operatively while the patient is still under anesthesia on the OR table. Generally, this should be done before wound closure, while the patient is under anesthesia. If the sharp is not found, the action should be documented on the Operative Record and VA Form VA 10-2633, Report of Special Incident Involving a Beneficiary or its electronic equivalent. The requirements in Attachment C must also be followed.

10. Instrument Counts. All surgical instruments must be counted, except for procedures that are routinely concluded with a radiograph prior to closing the surgical wound (for example, an orthopedic case to assure proper alignment of a bone or implant). In these cases, a radiograph is mandatory if an instrument count is not performed, and reading the radiograph to determine if any instruments have been retained must be performed before the patient is transferred from the OR.
a. Except as noted in subparagraph 10a, instrument counts are always required and the following steps should be followed:

(1) When additional instruments are added to the field, they must be counted and recorded as part of the count documentation.

(2) All instruments will be accounted for and removed from the room during end-of-procedure cleanup.

(3) Instrument sets will be standardized with the minimum types and numbers of instruments needed for the procedure. Specialty instruments, if needed, can be opened and added to the count at the time of the procedure.

(4) Preprinted count sheets that are identical to the standardized sets will be used for documenting counts. The sheets are included in the sets upon assembly in Supply, Processing and Distribution (SPD).

(5) Instrument counts will be performed in the same sequence each time utilizing the preprinted count sheet.

(6) All counted instruments must remain within the operating room and/or sterile field during the procedure. They must not be removed from the operating room until all counts are completed and resolved. If a counted instrument is passed or inadvertently dropped off the sterile field, the circulating nurse should retrieve it, show it to the scrub nurse or technician, and isolate it from the field to be included in the final count. If the instrument is needed to continue the procedure, it may be removed from the OR for flash sterilization. The item requiring flash sterilization will be noted on the count sheet and OR autoclave logs, per current VHA policy. Upon return of the item to the OR, the circulating nurse must show it to the scrub nurse and/or technician and document its return to the sterile field on the count sheet.

(7) Component parts of an instrument system will be counted individually. Component parts are defined as any part of an instrument that can be removed through its design. Examples include: Balfour retractor, Bookwalter retractor, Fogarty clamps, Omni retractor, Yankauer suction with detachable tip, Poole suction, and other devices.

(8) Broken instruments will be accounted for in their entirety. A radiograph will be performed while the patient is under anesthesia if all parts of the broken instrument cannot be accounted for.

(9) Counts omitted due to an extreme patient emergency will be documented by the circulating nurse on the Operative Record. In these cases, performing a radiograph while the patient is in the OR or PACU should be accomplished unless contraindicated by the patient’s clinical condition.

(10) If the count is incorrect, the circulating nurse will notify the surgeon and the Nurse Manager and/or charge nurse. The surgeon will search the wound and/or cavity as appropriate. A thorough search of the room should be made including linen and trash. If unable to locate the
missing instrument, a radiograph is required post-operatively while the patient is still under anesthesia on the Operating Room table. **NOTE: Generally, this needs to be done before wound closure, while the patient is under anesthesia.** If the instrument is not found, the action must be documented on the Operative Record and VA Form 10-2633, Report of Special Incident Involving a Beneficiary, or its electronic equivalent. The requirements described in Attachment C must also be followed.

11. Incorrect Counts

a. If a count is incorrect, the circulating nurse will notify the surgeon and the Nurse Manager and/or Charge Nurse. A thorough search of the room should be made including linen and trash.

b. If the surgical counts are incorrect, a radiograph that visualizes the entire operative field is required before the conclusion of the procedure while the patient is still on the Operating Room table (see Att. C).

c. If the counted item is found or retrieved and the count can be reconciled prior to the patient leaving the operating room without an adverse patient outcome, the count will be considered correct.

d. If the room search and radiograph do not provide the location of the source of the incorrect count, the incorrect count will be recorded in the following manner:

1) The surgeon will include a statement in the Operative Record Report regarding the nature of the incorrect count.

2) The circulating nurse will enter a statement in the “Nursing Care Comments” section of the computerized Surgery Package, which will appear in the Nurse Intra-operative Report.

3) The action will be documented on a VA Form 10-2633, Report of Special Incident Involving a Beneficiary, or its electronic equivalent. This form will reflect the patient's name, procedure, date of procedure, surgeon, attending surgeon, circulating nurse(s), and scrub nurse(s) and/or technician(s).

4) The requirements described in Attachment C must also be followed.
ATTACHMENT C

USING RADIOGRAPHY AND RELATED TECHNIQUES TO FIND RETAINED OBJECTS

1. When there is a discrepancy in the count of surgical items, procedures outlined in Attachment B, paragraph 11 should be followed and the surgeon should stop closing and repeat the methodical operative site examination as described in Attachment A.

2. When a radiograph is requested to locate a missing item, the following information must be specified in the request:

   a. The type of foreign body that is missing: sponge, needle, instrument, or other item. As there are many types of sponges and instruments, the subtype should also be specified to the extent possible.

   b. The operating room (OR) suite number and the telephone number for that room.

   c. The name of the attending surgeon and the circulating nurse or designated person in the OR suite to receive call-back information.

3. If the surgical team finds the missing object by wound exploration, by viewing the radiograph prior to a radiologist reading and reporting the radiograph, or another method, there is no requirement for a radiologist to read the film in real time. Assuming that the radiologist has not been informed that the surgical team has located the missing item, and during normal working hours, a radiologist will read these radiographs in real time and report findings directly to the OR suite by phone contact with a member of the surgical team. During normal operating hours this report must occur within 30 minutes of the request for the radiograph. During off duty hours, there may be circumstances where a radiologist will not be available to read all of these radiographs within 30 minutes of the request for the radiograph. Radiographs that are not interpreted within 30 minutes by a radiologist must be interpreted by a radiologist within 16 hours in cases where a patient’s wound is closed with an unresolved incorrect count of any type (sponge, sharp, or instrument).

4. The radiologist on duty will review the digital images of the radiographs on the Picture Archiving and Communication System (PACS) and will call the specified OR suite with the interpretation of the film or with a request for additional radiological views to be obtained. In the event that the radiologist on duty should require additional consultation to establish a diagnosis, the surgical team should be notified that such a secondary review is underway.

5. The person who receives the radiographic interpretation from the radiologist by phone in the OR suite must be a member of the surgical team, specifically a nurse, surgeon, or anesthesia provider. The interpretation must have “read back” confirmation by the receiver to the radiologist, and the findings must be documented in the operative record.

6. Sufficient hospital resources should be allocated to ensure the timely completion of a STAT portable radiograph in the OR. Sufficient resources should also be allocated for teleradiology capacity to facilitate access of digital radiological images by computer for radiologists in remote locations from the hospital.
ATTACHMENT D

OTHER IDEAS TO CONSIDER IMPLEMENTING TO PREVENT RETAINED SURGICAL ITEMS BASED ON INPUTS FROM ROOT CAUSE ANALYSES PERFORMED BY DEPARTMENT OF VETERANS AFFAIRS (VA) MEDICAL CENTERS AND SUBMITTED TO NATIONAL CENTER FOR PATIENT SAFETY (NCPS)

1. Perform additional counts under the following circumstances: when unexpected complications arise; when the surgical wound is reopened; and when an unplanned event occurs during the conduct of the procedure.

2. Install and use dry-erase boards to document counts, particularly when free sponges are used. Do not erase counts until the final count is done.

3. Designate a responsible person outside the operating room (OR) suite for organization, movement, and flow of patients through the OR so as not to interrupt staff from count procedures.

4. Minimize personnel changes during surgical procedures. Consideration could be given to expanding guidelines for the charge nurse to lengthen OR staff assignments to maintain the consistency of a stable surgical team.

5. Provide a standardized orientation for counting procedures to all new physicians and nurses assigned to an OR. Annually assess OR staff competencies for identifying various sharps and sponges.

6. Consider how the conduct of surgical procedures could be planned and organized by the surgical team to facilitate the counting of sharps, sponges, and instruments in a timely fashion with minimal distractions.

7. Consider how improved procedures and corresponding communication methods can be implemented to permit STAT image interpretation for all intra-operative radiographs.

8. Ensure that anesthesia providers maintain and dispose of sponges and other working materials in receptacles that are separate and distinct from receptacles used exclusively for discarded items from the surgical field.