NoThing Left Behind®
The Prevention of Retained Surgical Items Multi-Stakeholder Policy-Job Aid-Reference Manual

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NoThing Left Behind® is a National Surgical Patient Safety Project to Prevent Retained Surgical Items (RSI) which I started in October 2004. We have met with a great deal of success in getting hospitals around the country to zero retained surgical sponges for ≥ one year (in some instances now 5yrs) using the Sponge ACCOUNTing System (SAS) sponge management practice. This practice is one of the deliverables of the NoThing Left Behind® project. Over the past 14 years we have worked primarily with hospitals and interested healthcare entities to prevent patient harm from inadvertent retention of surgical material. We have also seen the “other side of the earth” (that is our world as seen from the moon and an MRI image of a retained lap pad on the cover) studying clinical cases (unfortunately yes, they still occur) from across the United States and have a deeper knowledge about the consistent human failures that lead to retention of surgical items.

For the prevention of retained surgical sponges the essential understanding for doctors, is to perform a methodical wound exam before closing every wound, and that includes examining the vagina after a birth. For nurses, the essential understanding is not just to “count” the surgical sponges, but to separate them (on the in and the out counts, technological adjuncts or not) and then get them all in one place so they can be accounted for. Surgeons and nurses are the primary defenders against retention and only system change can impact on shaping safer behaviors to prevent patient harm. There is new information in here on the prevention of retained small miscellaneous items (SMI), devices (e.g. guidewires) and device fragments, sharps, needles and instruments.

This policy/job-aid represents a safe, rational and reasonable set of current practices. As a practicing surgeon and surgical safety advocate, I can say without any reservation whatsoever, that there is something in here that every hospital operating room (OR), ambulatory surgery center, perinatal birthing center and procedural area can adopt to make it safer for patients that receive care in their facilities.

Much of what is in this policy/job-aid is a result of reading focused reviews, event analyses and studying clinical cases where there have been retained surgical items. Additional information has been obtained from talking with OR personnel and reviewing OR policies during the work NoThing Left Behind® has been engaged in since this project began. It is not intended to be a competitive offering to that provided by the Association of periOperative Registered Nurses (AORN) but is rather a complementary effort in ensuring OR safety. This document was sent out and reviewed by many, is being used in many hospitals and represents what I think, are best practices. It is practical and action oriented and represents a culmination of ideas and solutions from many people (surgeons and nurses) at many different institutions from around the country. This third revision from the original (February 2011) has points and suggestions for improvement which were received from OR personnel and reviewed by nurses, surgical technologists, surgeons and radiologists.

There are new sections on:
- Prevention of RSI in the Emergency Department (ED)
- Prevention of retained guidewires after central venous catheter (CVC) insertion
- An orifice packing process to prevent retained vaginal packing
- Management of hemostatic trauma pads and dressings to prevent retention
- OR towel management

Revisions and updates have been added to sections on:
Multi-stakeholder safety rules for all content experts in surgical item management - nurses and surgical technologists, surgeons, radiologists and radiology technologists, anesthesiologists

The surgeon must determine if the case is an extreme emergency condition not the nurse so appropriate confirmatory examinations will be ordered and performed as needed

Clear definitions of the IN and OUT counts (e.g. Closing versus Final count), a frequent source of communication failure, which expands upon the AORN definitions

The SAS practice incorporated into the body of the policy – as an example of how a specific practice (process steps that people follow) should be incorporated into a policy so there is a standardized process used by everyone. The intent is to remove variation in practice so you can see defects in the process as it is being used and prevent error, or if error does occur analyze when and how the mistake or slip occurred.

A SAS practice for labor and delivery and one for non-OR areas (e.g. cardiology suites)
Methodical Wound Exam (MWE) guidelines for doctors
A sample incorrect final count report
Promulgation of use of a “Chain of Command” as a communication strategy
“Out of the OR” definition of when a surgical item is considered retained
Needle count practice with X-ray exclusions
SMI, device and unretrieved device fragment (UDF) safety rules
The Missing Surgical Item (MSI) imaging primer for safe intraoperative x-rays
“Points of Discussion” to enhance understanding and implementation
Monitoring and Education guidelines with shared learnings (we call it Collective Wisdom).

The emphasis is on sharing knowledge and information through in-services, newsletters and meetings to disseminate information on a regular basis to prevent complex and intelligent failures. This is important when dealing with rare events so people can learn from the experiences of others. I hope that each individual doesn’t have to be personally involved in an event, before they will move to change unsafe behaviors.

The intent of this effort is to have a practical multi-stakeholder resource of all the necessary information in one place. While the entire document is more than 50 pages it is designed to be flexible for individual site use. There are parts that require individual site-specific definitions be developed. In the points of discussion section the evidence is case based and anecdotal. This information is from front-line communications and represents one kind of evidence. It is worthwhile to remember that there is not only experimental evidence but experiential evidence from event analyses, that are also valid.

This policy is beyond a “count” policy which directs the actions of hospital nursing and surgical technologist activities. It is a multi-stakeholder reference manual and should be thought of as the “rules of engagement” for all who take care of patients in procedural areas. Therefore medical staff and radiology staff buy-in is required. The means of policy use, approval and application will have to be determined by each facility.

Good luck.
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SAFETY RULES, PRACTICES AND POLICY RECOMMENDATIONS

I. PURPOSE:

A. To provide practices and safety rules for perioperative registered nurses and surgical technologists, to use in the management of soft goods, sharps, small miscellaneous items and instruments; and actions to prevent retention of devices and device fragments.
B. To provide safety rules for doctors in the performance of a methodical wound exam and actions to prevent unintended retention of surgical items, devices and device fragments.
C. To provide safety rules and guidelines for radiology technologists and radiologists in the performance of intra-operative x-ray examination and information to aid interpretation and read-back of x-rays obtained to find a missing surgical item (MSI) or identify a potential RSI.
D. To provide safety rules for anesthesiologists and anesthesia personnel to prevent RSIs
E. To provide safety rules for Emergency Department (ED) providers to prevent retention of surgical items used during procedures performed in the ED.
F. To assist in the accounting of all surgical items and devices and minimize inventory loss.
G. To encourage and support all efforts in OR/procedural teamwork.

II. BACKGROUND:

Prudent medical practice and laws in all states, require that medical and surgical items not intended to remain inside of patients, not be negligently left behind. Inadvertently leaving devices, needles, sponges, instruments or other miscellaneous items inside of patients (retained surgical items) is a preventable event and is generally considered to be a “never event”. An RSI is a surgical patient safety problem. An event occurs because of problems with faulty procedural practices and poor communication strategies between personnel. To prevent RSIs, it is important to change practice and the exchange of knowledge and information, with an understanding of human fallibility in perception and risk assessment. This policy/job-aid contains directives to help people implement safe practices for all to use, in all procedure areas, wherever and whenever, surgical items are used. These are the “safety rules” which all have to follow.

III. DEFINITIONS:

A. SURGICAL ITEMS – Supplies, devices and equipment used in and around a surgical site or wound, to aid in the performance of the operation or procedure, to provide exposure and to absorb blood and other body fluids.

Taxonomy: There are two groups of surgical items.

Group I consists of four (4) classes; (these items usually compose the surgical counts)
1) SOFT GOODS
2) SHARPS
3) INSTRUMENTS
4) SMALL MISCELLANEOUS ITEMS
1. Soft Goods are cotton, disposable cloth or gauze items of various sizes, used as dressings, drapes and adjuncts to an operative procedure (note: packs are considered dressings). Within the category of soft goods are:
   a. Surgical sponges and surgical towels (16”x26”), which are white soft goods that contain a radiopaque marker, are used within the surgical wound and are included in a surgical count. Surgical sponges include but are not limited to: standard laparotomy pads (18”x18”), mini laps (12”x12”), baby laps (4”x18”), trauma “supersize” sponges (17”x26”; 18”x36”; 36”x36”), raytex (acronym for radiopaque textile) 4”x4” or 4”x8” sponges, tonsils/rondics, peanuts/kittners and cottonoids/patties.
   b. Blue, green or unbleached drape towels are made of a coarser grade of cotton and are intended to be used as drapes, wipes or covers. They should not contain radiopaque markers and are not to be placed inside of patients and are not included in a surgical count.
   c. Dressings used for orifice packing contain a radiopaque marker e.g. vaginal lap sponges (8”x36”) and vaginal packing (e.g.1”,2”,4”x36”,48”,72”,96”). Dressings used in wound care such as dressing sponges, perineal pads, prep swabs, wound-vac sponges, iodoform gauze and ribbon gauze do not contain radiopaque markers. All are managed and documented as dressings. Dressings are not included in a surgical count.

2. Sharps are metallic, pointed or cutting objects of various sizes which include but are not limited to: suture needles, scalpel blades, hypodermic needles, cautery tips. Sharps are included in a surgical count.

3. Instruments are surgical tools designed to perform a specific function such as cutting, dissecting, grasping, holding, suturing or retracting. These items are usually stored and sterilized on surgical trays and individually may have multiple parts. Examples of such items include but are not limited to: clamps, knife handles, needle holders, malleable/ribbon retractors, scissors. Instruments are included in a surgical count.

4. Small miscellaneous items (SMI) are other objects used during surgical procedures that are often single use, often not radiopaque, may be plastic, may be composed of multiple parts and include but are not limited to: bovie scratch pads, vessel loops, rubber shods, suture booties, umbilical tapes, laparoscopic or thoracoscopic ports, disposable instrument inserts, cotton-tip applicators, marking pens, suture reels, screws, nails, safety pins, ligaclip bars, bulldogs, vascular inserts, Z fold hemostatic material, nasal suction bulbs, Asepto bulb syringes, visceral “fish” retainers. SMI are included in a surgical count.

Note: If a whole instrument is retained this would be considered a retained instrument but if an intact part of a surgical instrument or tool is retained, this is more appropriately considered a retained small miscellaneous item and is documented as such.

**Group II** consists of:
1) DEVICES which are used during operations and procedures
2) DEVICE FRAGMENTS which are the result of breakage or separation of a device.

1. Devices are essentially any piece of equipment or a tool that has a designated function used during a procedure and may have electronic or mechanical component parts. Devices include for example; staplers, drains, and catheter insertion sets and stone retrieval kits. Retained devices are intact items which may be left in any body cavity, intravascular or
interstitial space. A retained device includes the entire unbroken item such as an intact guidewire inadvertently left in a central vein (which is the most common retained device) or catheter sheath or introducer.

2. Device fragments are broken parts or a piece of a tool or device. Examples include drill bits, a broken tip or part of an instrument, a broken part of a catheter or drain or piece of a stent or tip of a guidewire. If the surgeon makes a clinical decision that a device fragment cannot or will not be retrieved, this is an unretrieved device fragment (UDF).

B. RETAINED SURGICAL ITEM – A surgical item that was not intended to remain in a patient and is found in any part of the patient’s body after an operation, procedure or vaginal birth ends.

Using the National Quality Forum definition -
An operation ends after
A. all incisions or procedural access routes have been closed in their entirety,
B. devices have been removed,
C. final surgical counts have concluded
D. and the patient has been taken from the operating/procedure room.
A procedure ends when all devices and equipment have been removed from the patient regardless of setting (e.g. post anesthesia recovery unit, cath lab, emergency room, radiology suite, endoscopy unit).

Using an obstetrical consensus definition of when a birth ends
A vaginal birth ends after the mother’s immediate recovery period (2 hours post birth of the fetus). This period is also referred to as the fourth stage of labor which lasts about 2 hours after the birth of the fetus.

[A retained surgical item is generally considered to be preventable. It is a serious reportable event. It is also a sentinel event but The Joint Commission has a different interpretation of when an item is considered to be retained. see Point of Discussion #1]

C. SURGICAL COUNT – A process involving two people whereby they look at the items together, one person manually separates each item and they audibly count the number of items (“see, separate and say” – 3S’s). The four classes of surgical items included in a surgical count are surgical sponges and surgical towels, sharps, instruments and small miscellaneous items. For a surgical count performed in the operating room one of the two people must be a registered nurse.
Surgical counts must be performed in procedures in which an incision is made or a wound is created and surgical items are used. A vaginal birth is considered a procedure and the post-birth vagina is considered a wound.
The surgical count is performed to identify any packaging errors and to monitor the number of items used during the operation or procedure. The surgical count is a defined process composed of multiple steps which should be uniformly practiced.
There are six AORN defined counts: INITIAL, CAVITY, CLOSING, PERMANENT RELIEF, ANYTIME and FINAL. These names of the counts should be used rather than referring to the counts with ordinal numbers (e.g. 1st count, 2nd count).

[To enhance communication and reduce confusion it is important to have a common language between personnel using the surgical counts. See Point of Discussion #2]
D. MEDICAL RECORD – The permanent paper or electronic intraoperative record of an operation or procedure usually completed by the circulating nurse (Attachment A).

E. EXTREME EMERGENCY PROCEDURE – An operative procedure conducted on an extreme emergency basis to preserve a life or prevent loss of a limb or organ or the patient status deteriorates, such that standard routine procedures may not be able to be performed or completed.
In consultation with anesthesia personnel, the surgeon must determine and verbally declare that such an extreme emergency condition exists. This circumstance must be documented in the medical record by the circulating nurse.
Supplementary procedures (e.g. x-ray imaging) to prevent retention or mitigate patient harm from an RSI should be outlined on an incorrect final count report (Attachment B) when an extreme emergency procedure has been documented.

IV. SCOPE AND APPLICABILITY:

This policy/job-aid applies to all operating rooms (OR), procedure rooms, labor and delivery areas, and all other areas where a wound is created (any incision is made in the skin) or procedures are performed (including a spontaneous vaginal birth) and surgical items are used in or on a patient.

V. DOCUMENTATION AND COLLECTIVE WISDOM:

A. A registered nurse is responsible for medical record documentation.
B. Use the names (not ordinal numbers) of the six required surgical counts: INITIAL, CAVITY, CLOSING, PERMANENT RELIEF, ANYTIME, FINAL
C. Use specific terminology for sponge, sharp, instrument and small miscellaneous item counts in the medical record, depending on the vendor or format of the operation or procedure report. There should be the same means to document each class of surgical item included in the surgical counts. (Attachment A)
D. Enter the surgical counts and other required information concurrently with an occurrence or at the end of the case. Documentation in the medical record serves as legal evidence of what practices were performed.
E. Document the rationale and identify the primary decision-maker (e.g. surgeon declared case an extreme emergency procedure and no instrument counts were performed) in the incorrect final count report if any count or action is not performed according to policy. (Attachment B)
F. The final count is taken when items are no longer in use and have been removed from the surgical field. The final count can only be recorded as correct or incorrect. A final count that is unsubstantiated, pending, unresolved or incomplete is documented as incorrect.
G. In the instance of an incorrect final count, an incorrect final count report must be filled out and given to the supervisor/manager who must communicate the information up the chain of command. The report will outline all the actions that were taken during the case and actions that need to be taken at the next level of care. The report will be written in the electronic...
Event Reporting System (ERS) or as a paper report depending on the reporting system developed at each facility. (Attachment B)

H. If a package of any surgical item is found to be defective when opened (e.g. wrong number, damaged, contaminated) or a device breaks (e.g. plastic sponge holder pocket tears) the package and its contents should not be used. Bad packs of sponges will be removed immediately from the field, placed in a plastic bag, labeled and taken from the operating room. Other broken or defective devices or items will be sequestered. The supervisor/manager should be notified and a miscount report completed. (Attachment C) The inventory information should be given to supply purchasing for notification to the distributor. OR staff should be told about the packaging error or defect at staff educational meetings. It is important to share information about these events and defective items to inform personnel about their frequency, which may alter staff perceptions. For example, they may realize that bad packs “can happen to them”. Device defects represent manufacturing error and with regard to surgical sponges, separating the sponges to find bad packs is an essential element in a safe sponge management practice.

I. If a medical device or instrument breaks or fragments, all effort should be made to retrieve the separated parts. The device and its parts should be removed from the field and sequestered. (Attachment D) If an intact part of a device is retained this is a retained SMI and would be considered a reportable event but if a broken fragment of a device or tool is retained and the surgeon decides that it is a UDF, these are usually not reported. For both circumstances, an incorrect final count report must be completed (Attachment B) and given to the supervisor/manager who must communicate the information up the chain of command. The retained device or UDF should be documented in the medical record and the event reported through manufacturer and regulatory reporting systems as required. A disclosure discussion with the patient should be conducted.
IX. ANESTHESIA PROVIDER PROCEDURES AND SAFETY RULES

A. ANESTHESIA EQUIPMENT AND SOFT GOODS MANAGEMENT
1. Keep anesthesia-related trash and equipment separate from surgical disposal units.
2. Use a trash receptacle that is visually distinct from any used for the surgical field.
3. Do not discard anesthesia-related equipment into “kick buckets” or other surgical receptacles.
4. Do not allow surgical equipment to be discarded into the anesthesia trash.
5. Do not borrow equipment such as scissors or sponges from the surgical field.
6. Be sure to remove any equipment used for anesthesia procedures (such as clamps and needles used for central line placement and dressing gauze) from the operating table before surgery starts.
7. Make sure that throat packs, bite blocks, and other such devices are removed from the oropharynx at the appropriate time.
8. If items fall from the surgical field, be sure to inform the surgical team, including the circulator, immediately. Dropped items need to be appropriately managed to ensure that they are properly accounted for.
9. If anesthesia providers assist the scrub team by retrieving items such as extra sutures or sponges for the instrument table, inform the circulator promptly of exactly what was opened. Opening extra equipment without properly adding items to the count will lead to a discrepancy at the end of the procedure.
10. If called upon to review the sponge holders with nursing personnel review the counts on the dry erase board and look to see that there are no empty pockets in any of the holders.

B. PREVENTION OF RETAINED GUIDEWIRES AFTER CVC INSERTION
1. At the conclusion of all procedures performed by anesthesia personnel inspect the anesthesia area and site to ascertain that all items used during the procedure are intact and on the field (e.g. guidewire is present).
2. X-rays must be obtained after central line insertion for any indication, performed from any insertion site (e.g. internal jugular, subclavian, femoral), in which a Seldinger technique (guidewire directed catheter insertion) is used and the guidewire(s) has not been visually verified and accounted for.

C. COMMUNICATION AND ENGAGEMENT WITH OR PROVIDERS
1. During team accounting procedures, try not to disturb or distract unless absolutely necessary.
2. When performing milestone actions such as reversal of neuromuscular blockade or extubation, be aware whether or not the final count is completed. If the count is incorrect, plan the patient’s emergence from anesthesia accordingly. In most cases it is desirable to keep the patient anesthetized until all items have been accounted for.
3. Plan anesthetic milestone actions so that these actions don’t pressure the surgical team to do a less than diligent accounting or wound exam.
4. If the patient’s medical condition is such that prolonged anesthesia or further delay is in your opinion inappropriate, discuss this directly with the surgeon so that a joint decision can be made which weighs the relative risks of a possible retained item versus the risks of continuing anesthesia and surgery.
X. ALL STAKEHOLDERS

A. ACTIONS TO RECONCILE AN INCORRECT COUNT:
1. The circulating nurse must inform the surgeon there is an incorrect count of an item. If the item is missing, while the OR staff are looking, the surgeon should stop closing the wound and repeat the methodical wound examination. This is a Missing Surgical Item (MSI). Use the Incorrect Count Checklist to help guide the team’s actions. (Attachment N)
2. The circulating nurse must tell the surgeon what specific type of item is missing.
3. If the item is not found, portable x-ray(s) MUST be obtained if the item is radiopaque and not a <15mm needle missing in a large cavity.
4. Cover the wound with a sterile non-radiopaque towel or plastic drape.
5. Remove extraneous objects from the field.
6. Tell the radiologist specifically what item is missing e.g. not “sponge” but lap pad, raytex
7. Help the radiology technologist obtain x-rays of the entire region of interest (side to side, top to bottom, this may require more than one film) (see Attachment G).
8. Have the radiology technologist obtain two views (AP and oblique/lateral)
9. The scrub person will search all sterile areas.
10. The circulator will search the holders, linen, drapes, floor and trash.
11. Anyone who has left the room will be contacted and the circulator will review any visitors in the room or opportunities for the item to have been inadvertently removed from the room e.g. with a pathology specimen, with a newborn taken to the nursery.
12. Wait for radiologist read-back results before completely closing the wound.
13. Follow radiologist recommendations for additional views or requests for further information before the patient leaves the OR.
14. The circulating nurse will document an Incorrect Final count in the medical record and complete Attachment B – Incorrect Final Count Report if the item is not found.
15. Notify the administration and risk manager if the item is not found.
16. Disclose to the patient if the item is not found.
17. Plan additional radiographic (e.g. CT scan) or diagnostic testing to find the object or prove with certainty that it is not in the patient.

B. ACTIONS TO TAKE IN AN EXTREME EMERGENCY PROCEDURE
1. In consultation with anesthesia personnel, the surgeon must determine and verbally declare if a case is an extreme emergency procedure. By so doing, the MD is acknowledging that some of the surgical counts may be aborted and mandatory x-rays must be obtained at the earliest and safest time.
2. This condition must be documented in the medical record by the circulating nurse and Attachment B – an Incorrect Final Count Report completed.
3. Under these circumstances standard counting practices may need to be changed. Sponge and sharp counts are usually performed but full instrument and SMI counts are usually not possible. It’s usually the inability to perform instrument counts that invokes this exclusion. Sponge counts should be performed, even if only a single person initial sponge count is done. The Sponge ACCOUNTing System should be used throughout the procedure. The circulating RN will continue to put the sponges in the holders throughout the case and use this information to aid in sponge management. Aborting a count does not mean not doing anything. It is better to
not have to rely solely on the reading of an intra-operative x-ray to determine if all sponges have been accounted for.

5. X-rays of the operative site, to rule-out any retained surgical items, must be ordered by the surgeon and reviewed by a radiologist as soon as clinically possible during or after completion of the operation. The MSI guidelines apply and the radiologist must be informed that the x-ray is being obtained in-lieu of surgical counts. Two views are optimal to call an image negative.