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

I. PURPOSE 6

II. BACKGROUND 6

III. DEFINITIONS 6-9
   A. SURGICAL ITEMS
      TAXONOMY
      Group I
      1. SOFT GOODS
      2. SHARPS
      3. INSTRUMENTS
      4. SMALL MISCELLANEOUS ITEMS (SMI)
      Group II
      1. DEVICES
      2. DEVICE FRAGMENTS
   B. RETAINED SURGICAL ITEM (RSI)
   C. SURGICAL COUNT
   D. MEDICAL RECORD
   E. EXTREME EMERGENCY PROCEDURE

IV. SCOPE AND APPLICABILITY 9

V. DOCUMENTATION AND COLLECTIVE WISDOM 9-10

VI. NURSE & SURGICAL TECHNOLOGIST PRACTICES and SAFETY RULES 11-29

THE SURGICAL COUNT
   B. SOFT GOODS (SURGICAL SPONGES AND SURGICAL TOWELS)
      1. GENERAL RULES FOR SURGICAL SPONGE MANAGEMENT
      2. SPONGE ACCOUNTING SYSTEM FOR FREE SURGICAL SPONGES
      3. SAFETY RULES FOR THERAPEUTIC PACKING
      4. SAFETY RULES FOR ORIFICE PACKING
      5. OR TOWEL MANAGEMENT
      6. ELECTRONIC DEVICES FOR SOFT GOODS MANAGEMENT
   C. SHARPS
      1. GENERAL RULES FOR SHARPS MANAGEMENT
      2. NEEDLE MANAGEMENT TO REDUCE NEEDLE MISCOUNTS
   D. INSTRUMENTS
      1. GENERAL RULES FOR INSTRUMENT MANAGEMENT
      2. MANDATORY X-RAY IN LIEU OF AN INSTRUMENT COUNT
      3. THE SURGEON/SCRUBPERSON “CHECKOUT”
   E. SMALL MISCELLANEOUS ITEMS (SMI)
      1. GENERAL RULES FOR SMI MANAGEMENT
      2. MANAGEMENT OF HEMOSTATIC DRESSINGS AND PADS
F. DEVICES AND UNRETRIEVED DEVICE FRAGMENTS
G. MONITORING AND AUDITS
   1. PERIODIC AUDITS OF PRACTICE
   2. INCIDENT REPORTS
   3. MISCOUNT REPORTS (NEAR MISS REPORTING)
H. EDUCATION AND TRAINING

VII. SURGEON PRACTICES AND SAFETY RULES 30-33
   A. PERFORMANCE OF A METHODICAL WOUND EXAM
      1. GENERAL CONSIDERATIONS FOR ALL WOUNDS
      2. ABDOMEN AND PELVIS
      3. CHEST AND MEDIASTINUM
   B. USE OF THE ORIFICE PACKING PROTOCOL
   C. CLINICAL DECISION TO LEAVE A UDF IN THE PATIENT
   D. OPERATIVE REPORT DICTATION
   E. PATIENT DISCLOSURE

VIII. RADIOGRAPHIC PROVIDER PRACTICES AND SAFETY RULES 34-35
   A. INTRAOPERATIVE RADIOGRAPHIC EXAMINATIONS
   B. COMMUNICATION AND ENGAGEMENT WITH OR PROVIDERS
   C. PREVENTION OF RETAINED GUIDEWIRES AFTER CVC INSERTION
   D. CRITICAL FINDING CALL-BACK POLICY

IX. ANESTHESIA PROVIDER PRACTICES AND SAFETY RULES 36
   A. ANESTHESIA EQUIPMENT AND SOFT GOODS MANAGEMENT
   B. PREVENTION OF RETAINED GUIDEWIRES AFTER CVC INSERTION
   C. COMMUNICATION AND ENGAGEMENT WITH OR PROVIDERS

X. ALL STAKEHOLDERS 37-38
   A. ACTIONS TO RECONCILE AN INCORRECT COUNT
   B. ACTIONS TO TAKE IN AN EXTREME EMERGENCY PROCEDURE

XI. PREVENTION OF RSI IN THE EMERGENCY DEPARTMENT 39-42

XII. REPORTING 42

XIII. REFERENCES 42-43
XIV. POINTS OF DISCUSSION (POD) 44-53
1. Retained Surgical Item Definition or When is it After Surgery?
2. Issues with the Surgical Counts
3. Miscounts are Near Miss/Close Call Learning Opportunities
4. When is it a Separate Procedure?
5. Why No Red Biohazard Bags in the Kick Buckets
6. Why white radiopaque OR towels?
7. Putting 10 Lap Sponges in the Holder Pockets Complies with Manufacturer IFUs
8. The “Pauze for the Gauze” and “Show Us” Steps are Team Based Activities
9. Suture Needles Have to be Sorted by Size if a No X-Ray Policy is Used
10. Alternative Ways to Manage Instruments to Prevent Retention
11. The Methodical Wound Exam Isn’t Sweeping
12. UDF and Devices Still Require Patient Disclosure if not Reporting
13. Radiology Personnel are Team Members to Help Prevent Harm from a RSI

XV. ATTACHMENTS: 54-78
Attachment A - Electronic Medical Record Surgical Counts Translator
Attachment B - Incorrect Final Count Report
Attachment C - Miscount Report
Attachment D - Actions Plans for SMIs, Devices and UDFs
Attachment E - Nursing Protocol for Use of Sponge Holders in the SAS
Attachment F - Doctor Guidelines for Performance of a Methodical Wound Exam
Attachment G - Radiology Missing Surgical Item (MSI) Radiographic Guidelines
Attachment H - Sponge ACCOUNTing in Non-OR Areas
Attachment I - Sponge ACCOUNTing for Vaginal Births
Attachment J - Orifice Packing Guidelines
Attachment K - Surgical Towel Management
Attachment L - Electronic Device Sponge Management Protocols
Attachment M - Cases that Allow an Alternate Process in Lieu of an Instrument Count
Attachment N - Incorrect Count OR Checklist
Attachment O - Safety Rules for Therapeutic Packing
Attachment P - State Required Health Service Retained Item Reporting Statue
Attachment Q - What to do with a Retrieved RSI
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, scalpels 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.
VI. NURSING and SURGICAL TECHNOLOGIST PRACTICES and SAFETY RULES:

A. THE SURGICAL COUNT:
A defined process performed by two people, one of whom must be a registered nurse, to account for the four classes of surgical items. Use the names of the six required surgical counts: INITIAL, CAVITY, CLOSING, PERMANENT RELIEF, ANYTIME, FINAL

1. The IN Counts are
   a. Initial baseline count of surgical items from the distributor packs and case carts, conducted before the case begins
   b. Initial count conducted of new items when they are added onto the back table.

2. Two people use the “see, separate and say – 3S’s”; they look at the items together, one person manually separates each item and they audibly count the number of items.

3. The counts are performed to establish the baseline number of items, detect packaging error and provide knowledge on how many items are being used during the case

4. Whenever possible the initial baseline counts will be performed before the patient enters the OR. These initial counts must be completed before the Time Out is performed or the incision is made

5. The OUT Counts are
   a. Interim Counts:
      01. CAVITY Count – count performed before closure of a cavity within a cavity (e.g. uterus, bladder, stomach, peritoneum). A count performed before placement of mesh or bone graft to close a space is considered a cavity count
      02. CLOSING Count – count performed before wound closure begins
      03. PERMANENT RELIEF Count – count performed at the time of permanent relief of either the scrub person or circulating nurse.
      04. ANYTIME Count – count performed anytime at the discretion of any member of the OR team.
   b. The Final Count:
      FINAL Count – count performed when surgical items are no longer in use and all are passed off the field. The final count can only be recorded as correct or incorrect.

6. The OUT counts will be performed in either an IN to OUT or OUT to IN sequence each time. One way or the other has to be established as the methodology used in all cases throughout the OR. There are advantages and disadvantages to either way, with some centers choosing IN to OUT while others prefer OUT to IN. The danger with IN to OUT, especially at the final count, is that an item that is still in use is often “counted” as “out”. With OUT to IN, at the final count, if the item is not on the back table it can’t be “counted” out (because it is not physically present).

IN to OUT
   a. Surgical site
   b. Sterile field
   c. Mayo Stand
   d. Back table
   e. Kick buckets or containers which hold discarded items
   f. Holders or counter boxes
   g. Safe repository where dropped or contaminated items have been placed
versus

OUT to IN
a. Safe repository where dropped or contaminated items have been placed
b. Holders or counter boxes
c. Kick buckets or containers which hold discarded items
d. Back table
e. Mayo Stand
f. Sterile field
g. Surgical site

The OUT to IN sequence is what this policy recommends. [This sequence is favored as explained in Point of Discussion #2]

7. If a discrepancy occurs at the final count and the item is never found this is 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)

8. If a discrepancy in a count occurs and this discrepancy is reconciled this is a miscount

9. Miscounts should be internally reported especially if an x-ray is obtained to find the item. Miscounts should be reported on a miscount report (Attachment C). [Miscounts are “close calls” and can provide learning opportunities. See Point of Discussion #3]

10. At the time of a change in permanent relief, the surgical count of sponges, sharps and small miscellaneous small items shall be conducted between the out-going scrub and the in-coming circulator or vice-versa.

11. Separate counts should be maintained for separate procedures. A separate operation is one in which there is a separate case number. A single case can have multiple parts or multiple incisions or multiple disciplines participating in the operation but if the operation is scheduled or coded as one case it should have only one set of final counts for the case [For clarification see Point of Discussion #4]

12. Sponge, needle and small miscellaneous item counts will be documented on a wall mounted, easily visible dry erase board. Information added to the board cannot be erased until the patient has left the operating or procedure room.

13. The same standardized format for recording information on the boards will be used throughout all operating rooms.

14. Instrument counts will be recorded on the preprinted instrument count sheets that accompany the instrument trays. Instruments should be counted first in SPD when trays are assembled and the instrument counts recorded on the instrument count sheets. The initial count of the instruments in the OR will then use these pre-populated instrument count sheets which must accompany each tray. The count sheets can be placed separately from the instruments in a paper bag and put on the first inner wrapping. When single instruments are added to the case during an operation, those instruments are also recorded on the instrument count sheet. This is to maintain and keep all information about the status of instruments in one place.

15. Personnel handling soiled items should always wear adequate personal protective apparel and utilize safe handling techniques.
16. All trash receptacles and sharps containers will remain in the OR until the conclusion of the case.

**B. SOFT GOODS (SURGICAL SPONGES AND SURGICAL TOWELS)**

1. **GENERAL RULES FOR SPONGE MANAGEMENT**

   a. Kick buckets and sponge receptacles shall be lined with clear plastic bags. Red biohazard bags make it difficult to see bloody used sponges and white bags make it difficult to see unused sponges.
   
   [For additional information about red biohazard bag use see Point of Discussion #5.]

   b. All cotton gauze disposables placed in the patient will be white surgical sponges (cotton gauze sponges that contain a radiopaque marker) or white radiopaque towels and may contain a separate identifiable tag, chip or barcode needed by electronic counting and detection systems.
   
   [For additional information about why white see Point of Discussion #6]

   c. Surgical sponges will not be cut or altered but will remain in their original configuration. Cutting sponges creates additional parts that have to be reconciled. Cutting off the radiopaque marker negates the safety adjunct put on the sponges to aid in retrieval should they be retained in the patient. Note that the tail or loop found on some types of surgical sponges is NOT the radiopaque marker; the radiopaque marker is sewn into the end or woven within the interstices of the gauze sponge.

   d. Effort should be made to minimize the number of different types of surgical sponges used during a procedure. This reduces complexity for the scrub person to track and manage.

   e. During the initial count of a package of surgical sponges the master band must be broken and the sponges manually separated to check for packaging and manufacturing error. Fanning the sponges is an unsafe practice and should not be used. Use the “see, separate and say – 3S’s”; look at the sponges, one person manually separates each sponge and then audibly counts the number of sponges. It is important to touch the white part of each sponge and count the white sponge not just count the blue tails or bands.

   f. A surgical sponge that is passed between the scrub person and the surgeon unattached to an instrument is considered a free surgical sponge. These are usually placed on the field or handed to the surgeon directly. These sponges include, but are not limited to; raytex 4”x4”, raytex 4”x8”, lap pads 18”x18”, mini laps 12”x12” or baby laps 4”x18”. Free surgical sponges should be managed with the Sponge ACCOUNTing System.

   g. Small surgical sponges e.g. peanuts, cottonoids, should be passed to the surgical field on an instrument. A standard practice should be used to account for the small surgical sponges. Prepackaged holders or trays are available and should be used whenever possible. Some centers count the larger cottonoids in multiples of ten and put them in the pockets of the plastic sponge holders also.

   h. Supersize or trauma lap sponges (17”x26”; 18”x36”; 36”x36”) are usually used for hemorrhage control and are managed in the unit of issue. In centers where emergency thoracotomy is performed in the ED, these sponges can be stocked there and since they are very large, when the patient moves up to the OR they can be visualized, removed and put in a sponge holder pouch to separate them.
from the sponges used in the OR. In these circumstances these trauma sponges have not been “counted” in the ED which presents a risk, but having a distinctly different sized sponge for the ED case, provides a prominent recognition factor for OR staff that there is a different type of lap pad in the OR, which must not be confused with the standard laps being used during the operation.

i. If the “super-size” trauma sponges are used in the OR, when opened they are counted in the unit of issue, the count written on the dry erase board and all must be accounted for at the final count. They are not managed in multiples of ten. These sponges can be put in a hanging sponge holder pouch (separated center divider) in the unit of issue and put up on the dispenser racks for a visual verification at the final count to show that all have been accounted for or another suitable means to separate and account for them in the unit of issue established.

j. In the instance of an incorrect count and a surgical sponge is missing use the actions outlined on the Incorrect Count OR Checklist to aid in finding the sponge. The checklist should be on the wall in each OR to facilitate use (Attachment N)

k. Surgical sponges should not be used as dressings. The sponge final count may be incorrect if surgical sponges have been used as dressings or if x-rays are taken, these sponges may appear to be falsely within the patient.

l. Radiopaque vaginal packs and gauze dressings should not be on the back table until use. Dressings should not be part of custom packs. Having non-surgical sponges opened during a case is an unsafe practice. No matter how hard a scrub person may try to hide them or sequester them on the back table, these sponges provide an unnecessary risk. They may get mixed up with the surgical sponges and confound the count or even inadvertently end up in the patient.

m. Dressings should only be opened when needed. Dressings and orifice packing gauze can be cut to fit in the wounds or to cover incisions. If special or complex dressings need to be constructed before use, a separate sterile work area can be established for the dressings, covered until they are needed and then the dressings passed onto the back table or sterile field and used immediately.

n. Dressings are not part of the surgical count. Their presence is documented in the designated part of the nursing intraoperative record and information about them shared at the patient handoff to the next level of care.
2. SPONGE ACCOUNTING SYSTEM (SAS) PRACTICE FOR FREE SPONGES

a. Conceptual Framework
   01. The SAS practice is a standardized, transparent manual accounting system that requires visible verification of the free surgical sponges used in an operation.
   02. It is insufficient for OR personnel to just count the sponges. They must separate them and have them all in one place at the end of the operation in order to account for them.
   03. Surgical sponges are to be added to the field in multiples of ten
   04. Surgical sponges are counted using the 3S’s during all In and Out counts
   05. Surgical sponges are placed in the pockets of hanging blue-backed plastic sponge holders by the circulating nurse, in multiples of ten, following a defined practice. (Attachment E)
   06. Doctors must perform a methodical wound exam at the closing count in every case (Attachment F)
   07. All the sponges (used and unused) must be in the sponge holders at the end of the case to have a correct final count
   08. After the final sponge count, the circulating nurse must perform a “Show Us” step with another person to see that there are “no empty pockets” and all sponges have been accounted for.

b. The Final Count for Free Sponges Using the Sponge Holders
   01. CORRECT FINAL COUNT: The skin is closed and all of the sponges (used and unused) are placed in the pockets of the sponge holders. There is a team verification (“show us” step) that the number of sponges documented on the dry erase board agrees with the number of sponges in the sponge holders.
02. INCORRECT FINAL COUNT: The skin is closed and some sponges (one or more) are missing in the sponge holder or there is an extra sponge(s). There may be empty pockets. The number of sponges in the sponge holders does not agree with the number on the dry erase board. By definition, the presence of an empty pocket at the final count is an incorrect final count and should be documented as such.

c. Equipment and Supplies:
01. All ORs or procedure rooms will have a dry erase board mounted someplace in each room where the surgical counts are visible to personnel in the room. The dry erase boards will be marked in a standardized format to designate the specific areas on the board for the documentation of soft goods, sharps and small miscellaneous items.
02. Dry erase pens and erasers
03. Boxes of hanging blue-backed plastic sponge holders. The holders are not to be called “counters” – they don’t count or “bags” - the pocketed holders aren’t bags. Each holder contains 5 rows of 2 pockets = 10 pockets. There is a thin center-divider that can be broken to convert the holder to have 5 pouches. This center divider should NOT be broken when managing sponges in the SAS practice, so the organization of the holder is always 10 pockets. One sponge is placed in each pocket so one holder can hold 10 sponges no matter if they are lap sponges or raytex sponges. This is IMPORTANT. In the SAS practice holders are used in a 10 pocket format. [This is in compliance with the manufacturer IFUs as covered in Point of Discussion #7]
04. A 2-hook IV stand with stable height adjustment and five (5) movable wheels with a securely attached sponge holder dispenser rack and a rack sign “put sponges here” should be present in each room.
05. The dispenser rack has a basket for the box of sponge holders and has prongs on both sides of the rack on which to hang them. One rack can usually accommodate 10 holders. Dispenser rack IV stands should be used solely for surgical sponge management and not used to hang IV bags. If the racks are properly mounted to the IV stands they won’t be able to be used to hang IV bags anyway. Note: if the IV hooks are visible the dispenser rack is not mounted properly.
06. With the single-facing double-sided racks, the curved prongs on the top of the back of the dispenser rack go over the top of the IV stand (so 4 hook IV stands cannot be used) and the clamps on the back of the rack are screwed tightly to the stand. This is to provide stability at four points to prevent sliding and wobble of the rack on the stand. Multiple distributors provide other dispenser rack configurations and models.

d. Safety Rules for the Use of Dry Erase Boards
01. The dry erase board is a communication tool.
02. Surgical items (other than instruments) used on the sterile field are recorded on the board in the designated areas.
03. Sponge counts for free sponges are always in multiples of 10.
04. The counts should be easily visible and legibly written in a horizontal superscript running total format (10^10 20^10 30) or a vertical summation line running total format 10

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No extraneous markings in the running total should be made (e.g. + signs, slashes, X’s, circles, initials). All rooms within one OR suite must use the same format.

05. The final number in the running total should always be the total number of sponges used in the case. The total number of surgical sponges used will always be a multiple of ten. It will then be easy to find agreement between the total number of sponges and the 1/10 number of sponge holders with one sponge in each pocket at the final count.

06. The process is standardized throughout all operating/procedure/birthing rooms to provide consistency in all types of cases. (Attachment H for Non-OR Areas, Attachment I for Labor and Delivery)

e. Practice for Use of Hanging Blue-Backed Plastic Sponge Holders (Attachment E)

01. Use sponge holders on all cases where free surgical sponges are used.

02. Free sponges should be used only in multiples of ten (10).

03. Hang the holders on the dispenser racks attached to designated IV stands. Each rack should also contain a supply box of new, empty holders. Use a separate holder for each sponge type e.g. one for lap sponges, one for raytex sponges.

04. Used sponges coming from the operative field should be placed into a clear plastic bag-lined receptacle (e.g. kick buckets or ring stands).

05. Only one sponge should be placed in each pocket of the holder.

06. Take one used sponge from the receptacle. Open it up to its full length to make sure there is only one sponge. Put the first sponge in one of the two bottom pockets of the holder. Put the next sponge in the second bottom pocket next to the first. Load the holder horizontally from the bottom row to the top row, filling first the bottom two pockets and continuing upwards (“bottoms up”). This process (going from the bottom to the top) will make visual determination of the filled holder easier to see from the OR table so if there is an empty pocket as the holder is filled it will be clearly visible to all in the room. Top empty pockets are easier to see thus making discovery of error visible.

07. Place the folded sponge inside the pocket with the blue tag or blue stripe facing forward. The blue stripe must be visible because this is what differentiates a sponge with a radiopaque marker (a surgical sponge) from a dressing sponge. This will aid discovery should a dressing sponge be inadvertently placed in a holder pocket.

08. Do not let the blue tag dangle outside of the pocket. If the blue tag dangles from a very wet sponge it will act as a wick and fluid will drip onto the floor.

09. When viewing the holder look for the blue stripe not just the white sponge. Place one (1) sponge per pocket; ten (10) sponges per holder.
10. Periodically throughout the case put the used sponges in the holder. Do not allow sponges to build up or sit in the receptacle used to collect sponges from the field. Keep the kick buckets empty.

11. When one holder has 10 sponges there will be no empty pockets. Visual confirmation between the scrub person and circulating nurse can take place before a new empty holder is hung on the rack in front of the holder which is full.

12. At the time of the final count, all sponges (used and unused sponges) MUST be in the sponge holders. The final count is a thing. It is not the last time the sponges were counted. It is the holders full of sponges. The final count can only be correct or incorrect. If there are no empty pockets this is a correct final count. If there is an empty pocket(s) this is an incorrect final count by definition.

13. After the final count has been completed a “Show Us” step is performed. The circulating nurse and another person must look at the sponge holders to make sure there are no empty pockets. The preference is to have the clinician who closes the skin look at the holders with the circulating nurse and see that the number of sponges in the holders agrees with the number of sponges documented on the dry erase board. If this is not possible, the anesthesiologist, a charge nurse or any other person, who was not involved in the case may substitute. The goal is to have “another set of eyes” participate in the “Show Us” step to minimize confirmation bias that may exist between the same two people who have counted in and managed the sponges throughout the case. It is the responsibility of the circulating nurse to obtain this visual confirmation.

[The Show Us Step is a Team Based Action. see Point of Discussion #8]

14. Keep a running total of the sponges added to the surgical field on the dry erase board using either a horizontal or vertical running total format. The last number should always be the total number of sponges opened during the case. (e.g. $10^{10} 20^{10} 30$ means that 30 sponges are in use and must be accounted for. There should be 3 full holders of sponges – no empty pockets – at the end of the case)

15. At a permanent change of relief, the sponges in the holders should be physically reviewed between personnel changing positions before the relieved person departs the OR. This is to make sure there are no empty pockets in any holder other than the one on top.

16. Sponge holders should remain hanging on the dispenser racks from the IV stands throughout the case. Racks will accommodate multiple holders per side. If a rack becomes full an additional IV stand and rack should be obtained. DO NOT take down the holders from the rack during a case. DO NOT roll them up, put in plastic bags or initial them. The final count must have visual confirmation of all sponges in the holders hanging from the racks to ensure that each holder is fully loaded with 10 sponges.

17. Place all the sponge holders in a plastic bag-lined disposal container at the end of the case. If the sponges are very bloody the holders should be placed in a red biohazard bag. Putting all the holders with all the sponges in one disposal container will ensure that all sponges are removed from the OR or procedure room at the end of the case and prevent a sponge count discrepancy in the next case in the same room.
18. The single most important element in the use of the hanging sponge-holders is to make sure that the final sponge count is taken when ALL the sponges that have been opened during the case (used and unused) have been placed in the holders. The sponges should no longer be in use. The nurse and another person, can then visually verify that all sponges have been accounted for and none remain in the patient.

3. SAFETY RULES FOR THERAPEUTIC PACKING

1. When surgical sponges are intentionally used for therapeutic intra-cavitary packing and the patient leaves the OR with this packing in place, this is NOT an instance of reportable retained surgical sponges.
2. When therapeutic packing of a cavity (usually abdomen or chest) takes place there will be a plan to return to the OR for pack removal. (Attachment O)
3. The Sponge ACCOUNTing System will be used for the management of the sponges throughout the case. Do not abandon the practice.
4. Standard lap pads (18x18”) opened during the operation should be used for packing.
5. Lap pads are easily available and have a well-known radiopaque marker. The number and type of surgical sponges intentionally left within the patient should be documented in the medical record if known. Any hemostatic packing or hemostatic trauma pads inserted should be documented as well.
6. If using lap pads during the case, when some of those lap pads are used for the therapeutic packs, there will be empty pockets in the sponge holders at the final count. The final sponge count should be marked as incorrect. An incorrect final count report must be completed and given to the supervisor/manager who must communicate the information up the chain of command to plan for the takeback procedure and pack removal. (see Attachment B)
7. The number and type of surgical sponges and hemostatic pads used for therapeutic packing should be included in the incorrect final count report and transmitted at the transfer of care if known.
8. At the subsequent takeback procedure(s) when the therapeutic packs are removed these lap pads and trauma pads should be placed in a separate sponge holder.
9. At the takeback procedure, reconcile the number of lap pads and/or hemostatic trauma pads removed with the documentation from the original procedure count (if known).
10. At the last procedure when no further packing will be performed and wound closure is planned, at the closing count, order intra-operative x-rays of the complete surgical wound using the Radiology MSI guidelines (Attachment G). Radiologist read back results of the images to the surgeon in the OR, must be performed to confirm that all pads have been removed. No matter if the number of lap pads used for packing has been reconciled, a mandatory series of x-rays must be obtained. The important point is to prove that all pads have been removed from the patient since therapeutic packing is often performed under uncertain conditions.
11. If the intra-operative x-rays are negative after review by a radiologist and all the surgical sponges from the takeback operation have been accounted for, the final sponge count for the takeback case can be documented in the medical record as correct. The incorrect final sponge count will remain as the documented count for the case in which the therapeutic packs were placed.
4. SAFETY RULES FOR ORIFICE PACKING

1. Intra-operative orifice packing is usually used in the setting of hemorrhage. The most common sites are the vagina and high in the nasopharyngeal sinus, occasionally in the rectum. The packing usually is removed in the post-operative period when the patient has left the OR. These packs are not counted. (Attachment J)

2. Only radiopaque gauze packing material should be used (e.g. vaginal packing). Radiopaque gauze packs must be available in the OR. Whenever possible only one pack should be placed in an orifice (rather than tying together multiple small packs it is better to use just one long one).

3. The safest kind of vaginal packing should have a radiopaque marker running throughout the gauze, rather than just having a marker sewn at one end. This is to ensure that radiopaque material remains in the patient should the packing need to be cut to conform to the site. Remember, packing is considered a dressing (not a surgical sponge) and dressings may need to be fashioned to fit. If the marker is only on one end and that end is cut off, there is no way to detect the presence of the pack should it fail to be removed.

4. After the doctor places the pack, the type, amount and location of the packing will be documented by the circulating nurse on the Packing Hand-Off Communication and Tracking tool (“The Packer Tracker”). (Attachment J) or in the designated nursing post-operative care management plan in an EMR. The paper form is to remain in the patient’s medical record or with the patient and with each handoff the presence of the pack documented on the packer tracker until removal.

5. The circulating nurse will place a packing armband on the patient prior to the patient transferring to the post-operative area. The packing armband is a distinct, facility specific color (that does not compete with all the other armbands being used) and has the words “Packing in Place” on it. The armband will serve as a reminder to the staff at the next level of care and to the patient, that there is packing in place.

6. The circulating nurse must perform a handoff to the post-procedure nurse caring for the patient and include the packing information in that handoff. The post-procedure RN should inform the patient and family of the presence of the packing and the meaning of the armband and then follow the doctor’s orders related to packing removal.

7. The MD provider must write an order providing instruction on the management of the packing and specify when it should be removed.

8. When the packing is removed it must match exactly the description of what was entered on the packer tracker when the packing was inserted. If there is any discrepancy an x-ray must be obtained. When the packing has been successfully removed the armband is cut off.

9. This is a complicated process because care continues over a gap (OR to PACU) and then possibly over multiple handoffs. These situations require strong communication strategies to prevent retained orifice packing.

10. Therapeutic packing, Orifice Packing and Wound Packing are distinct practices sharing the same problem of retained soft goods. It is important to understand the differences between each to utilize the best practices to prevent retention. Here is a table that might be helpful.
5. OR TOWEL MANAGEMENT

1. Within the soft goods category of OR towels there are two types. Surgical towels and drape towels. Surgical towels (16”x26”) are white cotton soft goods which contain a radiopaque marker or a separate identifiable label or tag. The surgical towels are used inside the patient usually to improve exposure. (Attachment K)

2. Drape towels are blue, green, grey or undyed, unbleached soft goods usually made of a coarser grade of cotton and are frequently used as drapes, wipes for wet hands or to dry surgical instruments or covers for the Mayo stand. They are used under retractor blades as a skin protector, as a glove cover when grabbing a light handle, or a stack as a bump for under the knee, or to cover a specimen on its way to pathology. They are a workhorse in the OR and are the responsibility of the scrub person to control. They should not contain radiopaque markers, are not to be placed inside of patients and are not counted.

3. Drape towels should not be used intra-corporally because there is no means to detect the presence of the towel with x-ray should a discrepancy in the count occur. Conversely, white surgical towels should not be used as drapes because if an x-ray becomes necessary at some time during the case the radiopaque markers in the surgical towels may confound the radiographic interpretation. White surgical towels should not be used as drapes or for prolonged periods of time as a background for suturing. The white towels act like mirrors and glare from the OR lights off of the surgical towels can cause eye strain and headaches for surgeons and scrub persons.

4. Using surgical towels that are white will help the surgical scrub person separate the counted white surgical towels from the uncounted blue or green drape towels. In addition, having white surgical towels is in conformance with the use of the other white cotton soft goods that have radiopaque markers and are used inside of patients.

5. Placing towels on the surface of the skin or surface of the surgical field constitutes draping, similarly placing a blue towel under a retractor along a skin edge to protect the
skin is also akin to draping. Using a towel in this way is not putting the towel “in” the patient and it is appropriate to use drape towels. In the patient or intra-corporally connotes intentional placement of the towel in a cavity or within a body part of the patient such as the abdomen or chest. White surgical towels should be used.

6. All of the retained towel cases known to this project, have been the result of intentional placement of a towel usually to provide retraction of viscera or organs and no concurrent management practice to make sure the towel was accounted for at the end of the case. The towels have not “slipped in” the cavity or space nor were they inadvertently placed. They did not “accidentally” end up in the patient.

7. Alternatives for the use of surgical towels include larger lap pads or supersize trauma sponges. A priori there is no prohibition to the use of surgical towels. What is important is that when they are used, they are counted in and there is a standardized means to account for them at the end of the case.

8. Used surgical towels are placed in the kick buckets or ring stands used for the surgical sponges and can be placed in the pouches of a hanging sponge holder or some other visible site, so all can be accounted for at the end of the case. Drape towels frequently are disposed of directly into trash and waste receptacles.

6. ELECTRONIC DEVICES FOR SOFT GOODS MANAGEMENT
There are currently two electronic devices commercially available to assist in the management of surgical sponges and surgical towels. One device counts the soft goods through the use of a matrix label on each item and a matrix reading device. The other device is a detection system that employs a passive electronic tag on each item and a radiofrequency detection system to “see” items that contain the tag. (Attachment L)

C. SHARPS
1. GENERAL RULES FOR SHARPS MANAGEMENT
   a. Sharps must be handled according to OSHA guidelines. Used sharps present a hazard of inflicting injury to and inducing microorganisms in both the patient and personnel.
   b. Disposal puncture-resistant plastic counter boxes should be available for containment of used needles and sharps.
   c. Whenever possible, sharps must be handed to and from the surgeon on an exchange basis using a “Safety Zone” or “Hands Free” technique to minimize injury. A plastic basin or mat is frequently used.
   d. Management of all sharps on the sterile field is continually maintained by the surgical scrub person.
   e. Sharps must be counted on all procedures and the use of counting boxes is encouraged.
   f. Sharps counts must be taken:
      i. at the INITIAL count
      ii. at the CAVITY count,
      iii. at the CLOSING count,
      iv. at the PERM RELIEF count and
      v. at the FINAL COUNT.
   g. When additional sharps are added to the field, they are recorded on the count board. A running total format is used throughout the procedure.
h. All counted sharps must remain within the operating room and/or sterile field during the procedure. If a counted sharp is passed or inadvertently dropped from the sterile field, the circulating nurse must retrieve it, show it to the surgical scrub person and put it in a safe proximate place so any dropped items will be included in the final count and all items will be properly accounted for.

i. Sharps broken during a procedure must be accounted for in their entirety. If broken parts or pieces are discovered and are unable to be removed, the directive related to UDFs are followed.

j. At the end of the case sharps must be contained in puncture resistant containers to ensure safe disposal.

2. NEEDLE MANAGEMENT TO REDUCE NEEDLE MISCOUNTS
   a. Suture needles must be counted according to the number marked on the outer package and verified by the surgical scrub person and circulating nurse when the outer package is opened.

   b. Pass suture needles on a needle holder and have the surgeon return needles back to the scrub person on a needle holder. A plastic pan used as a safety zone which is large enough to contain the needle and needle holder is ideal. The scrub person has to get the pan to the surgeon to facilitate putting the needle in the pan. The goal is to get the needle and the needle holder in the pan. The surgeon should not have to move their eyes from the field if they don’t think it is safe to do so to get the needle and needle holder in the pan. If the needle gets in the pan then team members immediately know where the needle is and the needle can’t be retained.

   c. The scrub person is then responsible for providing the surgeon with an additional suture as requested and then with putting the used needle in a needle counter box.

   d. If a needle holder is returned without a needle or a needle is discovered to be missing the scrub person must speak up immediately at the time of discovery so a search can be quickly taken to find the needle.

   e. A disposable puncture-resistant needle counter box should be used for containment of used needles and sharps. Used needles should be put in needle counting boxes by placing one needle per marked slot in the box. Placing more than one needle in the marked slot defeats the purpose of the needle counter which is designed to aid in the organization and correct counting of the needles e.g. a full 20 slot needle box should have 20 needles in it.

   f. Obtain needle counter boxes that will accommodate 40 or fewer needles so there will be a forcing function to keep the numbers of needles being tracked low.

   g. If there are a large number of needles used during a case, at various times during the case a defined number of needles may be counted by the surgical scrub person and circulating nurse, placed in a counter box and the box labeled, closed and passed off the sterile field. The boxes are to remain in the room and will be included in the final count.

   h. For purposes of this policy:
      Microneedles are smallest size available - 5mm
      Small needles are 6mm - 15mm
      Large needles are 16mm - largest size available

   i. Consideration should be given to sorting needles by size or type in the needle counter boxes so in the event of an incorrect needle count the size of the missing needle will be
known with certainty e.g. place large needles e.g. >15mm, on one side of the needle box and small needles on the other side.

j. The needle packages should remain in a basin or container or in a defined space on the back table until the final count is completed should the packages be needed to aid in reconciliation of a miscount. The needle packages are used in the reconciliation of a needle count, not to count the packages but to have access to the information printed on the packages of how many and what size needles were contained within each pack.

k. During the usual practice of suturing, refer to the size of the suture, but if a needle is lost or missing or communication about a needle is taking place, refer to needles by the size of the needle, not the size of the suture the needle is swedged on to. The needle size is in mm and is printed on each package of suture.

l. If an incorrect needle count occurs, actions outlined on the incorrect count checklist on the wall in each OR should be conducted.

m. If a small needle (<15mm) is missing in a large cavity case, (e.g. chest, abdomen, pelvis), after a thorough search of the wound and sterile field, an x-ray is not required. The final sharps count will be recorded as incorrect and an incorrect final count report must be completed and given to the supervisor/manager who must communicate the information up the chain of command. (see Attachment B) [For the rationale of this needle size cutoff and actions see Point of Discussion #9]

n. If the needle is never found a disclosure discussion with the patient must be held, telling the patient that the needle was lost during the operation. It is suggested to show the patient the small size of the needle and discuss any concerns about risk of injury versus risk of retrieval. If there is any question or concern on the part of the patient, obtain a CT scan of the surgical cavity, which can detect the presence of metal needles.

D. INSTRUMENTS

1. GENERAL RULES FOR INSTRUMENT MANAGEMENT
   a. Instrument counts will be performed on:
      a. All abdominal/pelvic cases.
      b. All chest cases.
      c. All cases where an incision is made that is greater than the size of any instrument used
   b. An initial instrument count should be performed in a case where the incision is greater than the size of any instrument used (especially considering three dimensions of size) because these conditions present the possibility that an instrument could be retained. Wounds in obese patients present a real risk in this regard. Then if the case proceeds such that no instrument was used that was smaller than the wound (having eliminated the risk of retention), a final instrument count would not be required.
   c. An initial instrument count is required on all minimally invasive surgery (MIS) cases since there is always the potential to have to convert the case to open and this cannot be predicted at the start of the case. Any MIS case which converts to open should have complete instruments counts performed. If it remains minimally invasive than a final instrument count would not be required.
   d. Only two instrument counts are required in the OR; an Initial count and a Final count. The Initial count will be taken before the procedure starts and the Final Count will be started at closing and must be completed before the patient leaves the OR or procedure room.
e. The initial count will be documented on the preprinted count sheets which have been composed in the sterile processing department (SPD) when the instruments were counted and put on the instrument trays. The initial count in the OR is to verify that what is on the instrument trays as assembled by SPD agrees with what is present in the sets at the start of the case. Discrepancies between these counts should be reported with a Miscount Report and follow-up conducted with SPD. Errors at this step are the most common source of instrument miscounts. [See Point of Discussion #10]

f. At the start of closing, the instrument count can begin with the instrument count sheet and proceed in the pre-determined direction of counting. An instrument that is in use or one that is still in the patient cannot be counted as “out” therefore has not been accounted for. Stop counting that item or group of instruments and return to it later. This is one reason that starting the instrument count at the back table and proceeding from “out” to “in” will prevent the counting of instruments that are still in use (they won’t be on the back table to count). At the completion of the final count all instruments must be out of the patient for the final count to be called correct.

g. Like instruments should be consolidated prior to counting.

h. Any additional instruments opened during the procedure will be counted and added to the preprinted count sheet. Do not add instruments to the dry erase board. Use the preprinted count sheets for the recording of all instruments so an accounting of all instruments is in one place.

i. All counted instruments must remain in the room so they can be accounted for at the end of the case.

j. If an instrument is contaminated it should be shown to the surgical scrub person and if not needed, secured and remain in the room.

k. If instruments have multiple parts, all parts must be accounted for. If a part is missing a search much be undertaken to find it. X-rays may be required. If the part is not found then an incorrect final count for small miscellaneous items should be documented because only a small part is missing NOT the entire instrument and efforts in reporting and discovery of the missing part are more consistent with conceptual understandings and actions for miscellaneous items. An incorrect final count report must be completed and given to the supervisor/manager who must communicate the information up the chain of command. (see Attachment B)

l. If the surgical scrub person receives an instrument back missing a part or is broken, the surgical scrub person must speak up and tell the team to look for missing pieces.

m. Personnel in SPD must call back to the OR charge nurse or a designated person if missing parts or pieces of instruments are discovered when trays are returned to SPD. There are increased requirements to ensure direct instrument tray to patient accountability. Applicable policies must be developed with SPD to ensure compliance.

n. If device or sales representatives are present in the OR and are providing loaner trays with an inventory maintained by the company, the representative must conduct an inventory of the trays before the trays leave the OR to determine if any parts or pieces are missing. If any deficiencies are identified the representative must notify the OR manager or designated person to ensure the missing parts are found or are proven not to be unintentionally left in the patient. In this role the representatives are not performing instrument counts or replacing or substituting for the responsibility of the scrub person or circulating nurse. They are “content experts” and their expertise should be utilized.
2. MANDATORY X-RAY IN LIEU OF AN INSTRUMENT COUNT:
   a. In specified cases (See Attachment M) usually when a very large number of instruments are used or intra-operative radiography is a usual part of the procedure, a mandatory x-ray can be used in lieu of the final instrument count.
   b. This x-ray examination cannot substitute for sponge, needle or small miscellaneous item surgical counts.
   c. In the specified cases, if fluoroscopy is being used, a fluoroscopic image read by the surgeon may substitute for an x-ray if a permanent copy of the image can be recorded and retained to be subsequently reviewed by a radiologist. This decision must be documented in the OR record.
   d. In the specified cases (Attachment M), intra-operative x-rays must be obtained at the time of the closing count BEFORE the incision is closed.
   e. Table mounted retractors and extraneous equipment which can obstruct or confound the interpretation of the x-rays should be removed from the surgical field.
   f. A sterile non-radiopaque towel or plastic drape should be placed over the wound.
   g. A request for an intra-operative x-ray must state that the film is being taken to review specifically for surgical instruments. An AP film alone may be satisfactory but if there is any questionable density (e.g. the instrument may be positioned “on-end”) two-views must be obtained.
   h. The x-rays must include the full region of interest. Follow the Radiology MSI Guidelines (Attachment G)
   i. A radiologist must review the image specifically looking for the presence of surgical instruments not only for the position of the surgical construct. The radiologist must provide immediate read-back to the surgeon before the patient can leave the OR.
   j. If this review is negative, the final instrument count can be documented as correct.

3. SIMULTANEOUS METHODICAL WOUND EXAM/BACK TABLE REVIEW IN LIEU OF AN INSTRUMENT COUNT: SURGEON/SCRUBPERSON “CHECKOUT”
   a. In specified cases, as determined by each facility, instead of counting all instruments it may be possible to use a team based verification process to ensure that all instruments have been removed from the patient. Instruments are frequently easy to feel if they are specifically looked for. This team based process may be especially useful in orthopedic and neurosurgery cases where radiolucent temporary implants (e.g. trail heads, measuring pins) are used which may not be easily detected by x-ray.
   b. The surgeon, scrub person and circulating nurse must unanimously agree at the beginning of the case that the surgeon/scrub “checkout” will be used “in lieu” of an instrument count so instrument management can be handled throughout the case to facilitate the process.
   c. Vendors will supply instrument trays in a format such that a visual check can easily confirm that all temporary implants and instruments are accounted for and the scrub person throughout the case will maintain an organized standardized back table and return instruments and implants to designated slots or positions on the trays.
   d. At the closing count a hard stop is taken. The surgeon must stop and perform a methodical wound exam to make sure all the instruments and temporary implants are out of the wound before beginning wound closure. This purposeful examination is performed in concert with the scrub person who will also stop and simultaneously perform a back table and field exam. Together these team members are specifically examining the wound and the contents of
trays and organized instrument sets to determine if all tools, instruments and parts have been removed from the patient and trays and instruments are complete. This surgeon/scrub person “checkout” will be assisted by the RN circulator using information on the count sheets and trays.

e. If there are any deviations or concerns that something is missing the team will obtain an x-ray of the surgical field which must be read by a radiologist with knowledge of what is missing with read-back to the surgeon.

f. At the successful completion of this process, when all the instruments are no longer in use and out of the patient, with acknowledgement from the surgeon, the final instrument count can be documented as correct.

E. SMALL MISCELLANEOUS ITEMS

1. GENERAL RULES FOR SMI MANAGEMENT
a. Small miscellaneous items that enter the patient or are on or near the surgical site must be counted. The counts should be written on the dry erase board. These items pose a risk for retention and must be accounted for at the end of the case on all procedures.

b. The intraoperative record must provide a space to document the final SMI count in the same form that counts for sponges, sharps and instruments are documented.

c. Exhaustive lists of all items are not feasible but the most commonly used SMI that enter the patient or are on or near the surgical site for each case can be permanently written on the dry erase board. Staff must manage all SMI and ensure that any which entered the patient have been removed from the patient.

d. Whenever possible all SMI should be radiopaque or contain a radiopaque marker.

e. The back tables should have a standardized format for the surgical items being managed which is maintained by the surgical scrub person.

f. Organization of all non-radiopaque small items on the sterile field should be continually maintained by the surgical scrub person. The scrub person must maintain active engagement with the circulating nurse in the counts of the SMI using the dry erase board.

g. These items are not instruments and counts should be performed as for needles/sharps.

h. The surgical scrub person must maintain active engagement with the surgeon in surgical item management. The scrub person must inspect the surgical items passed to the surgeon and returned from the field to ensure they are complete and intact.

i. In the event of a missing item that does not contain an x-ray marker or is not radiopaque, the surgeon should perform a methodical wound exam and a thorough search of all areas should be conducted by the surgical scrub person and circulating nurse. If the item is not found an x-ray is not indicated.

j. An incorrect final count report must be completed and given to the supervisor/manager who must communicate the information up the chain of command. (Attachment B) A disclosure discussion that the item was lost during the operation should be conducted with the patient. Consideration can be given to obtain a CT scan which may show the object or suggest its presence even though the item itself is not radiopaque.
2. MANAGEMENT OF HEMOSTATIC DRESSINGS AND PADS
   a. Hemostatic dressings are being used in multiple venues. Non-radiopaque versions are available to the public so patients may come into the ED with wounds stuffed with the hemostatic material.
   b. For the OR there are two versions – both have radiopaque markers.
      - a 12”x12” trauma pad, which is smaller than a lap pad. This is used for immediate hemostasis and can also be used in conjunction with therapeutic packing. When used; count in the unit of issue like surgical towels and account for the pads at the end of the case. If used as intra-cavity therapeutic packing enter the information on the incorrect final count report along with the other information
      - a Z-fold dressing which can be cut and put in bleeding wound tracts, used as packing or hemostatic material in a bleeding site. The dressing, if cut and used intra-operatively, should be counted as the unit of use. That is, if cut into 4 pieces, the count for the use of the material would be 4 and four pieces need to be accounted for at the end of the case.
   c. They are mentioned here because the inclination may be to count them as a surgical sponge but actually because of the way they are used it is better to count them as a SMI, especially the Z-fold dressing, and track on the dry erase board with the other SMIs. Especially if using the SAS practice, which manages sponges in multiples of 10, these soft goods are more consistently managed as SMI.
   d. They must be removed either in the OR or in the postoperative period within 24 hours. They do not dissolve.
   e. If used as wound packing then the packing is documented in the nursing intraoperative record and post/op wound care removal orders must be written by the doctor.

F. DEVICES AND UNRETRIEVED DEVICE FRAGMENTS
   a. All surgical devices are not counted but if during the course of a procedure, a missing device or a missing part or piece of a device is discovered, efforts should be made to retrieve it or any fragments or parts. (Attachment D)
   b. The surgical scrub person must maintain an organized field and inspect instruments and devices passed to the surgeon and returned from the field to ensure they are complete and intact.
   c. Instruments and small miscellaneous items that are broken or damaged during a procedure must be accounted for in their entirety. The surgical scrub person should notify the surgical team if a missing part is discovered.
   d. In the event a device fragment cannot be retrieved it is a clinical decision by the surgeon that it should be left in the patient. This is an unretrieved device fragment (UDF). The phrase often used to explain this circumstance is that “the risk of retrieval is greater than the risk of retention”.
   e. Collect all available remaining parts. Sequester the broken device. Do not discard. Obtain lot and serial numbers from any original packaging available. Follow the guidelines as outlined in Actions for Management of SMI, Devices and UDFs. (Attachment D).
   f. Obtain an unbroken device or identical surgical item for comparison with the damaged goods. This will help determine the size of the retained fragment; especially helpful for UDFs that aren’t radiopaque.
g. X-rays should be obtained to document the position of the item and to have knowledge about composition, size and number. If fluoroscopy is being used, save a permanent image to a file.

h. Notify the radiologist what is being looked for so the information will be dictated correctly into the radiology report.

i. An incorrect final count is recorded in the appropriate item category (e.g. broken needle with retained fragment would be an incorrect needle count) and an incorrect final count report must be completed and given to the supervisor/manager who must communicate the information up the chain of command. (see Attachment B)

j. The patient should be informed and a disclosure discussion held. Device fragments may migrate, embolize, cause thrombosis, become infected, heat during MRI or wobble and may cause injury. Future diagnostic testing can’t be predicted so the patient should be informed.

k. Appropriate RSI reporting and FDA MedWatch reporting should be conducted as required.

G. MONITORING AND AUDITS
1. PERIODIC AUDITS OF PRACTICE:
   Annual observational audits of each nurse and surgical technologist while engaged in the practice of performing surgical counts, should be conducted. Auditing of the SAS practice for sponge management can be performed using the SAS practice external audit tool. Results of these audits should be discussed at nursing in-service meetings.

2. INCIDENT REPORTS:
   Any policy violations by any perioperative personnel or incidents of non-compliance should be reported through the ERS to promote remediation and performance improvement.

3. MISCOUNT REPORTS (NEAR MISS REPORTING):
   Miscounts of any surgical items should be reported on a miscount report (Attachment C). At the very least any time an x-ray is obtained to find a missing item a miscount report should be filed. These reports provide opportunities for learning and understanding where practice improvements may be considered. The reports should be collected by the Charge Nurse and reviewed and discussed monthly at OR committee or nursing in-service meetings.

H. EDUCATION AND TRAINING
a. All staff will receive annual training, policy review, skills and cognitive knowledge assessments. Video review and cognitive testing should be performed. Successful completion of review will include satisfactory demonstration of all skills and satisfactory results on written test modules.

b. Unsatisfactory performance will result in mandatory re-training and supervision for a period determined by reviewer. Failure to comply or adhere to practice standards will result in corrective action as defined in Human Resource policies.

c. At unit orientation, all new and registry nurse and surgical technologists, will complete the training and skills assessment modules before working in the OR. In addition, they will review the Sponge ACCOUNTing System practice video and module and demonstrate competency with their assigned preceptor with a teach-back demonstration, if the SAS practice is being used. This will be documented on their orientation competency checklist.
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.
Attachment E

NURSES
USE HANGING BLUE-BACKED PLASTIC SPONGE-HOLDERS FOR LAPS AND RAYTEX

This process involves the use of hanging blue-backed plastic sponge-holders that each contain 5 rows of 2 pockets = 10 pockets. One sponge per pocket means that each holder can accommodate 10 sponges. We recommend that each holder always be set up to hold 10 sponges be they laparotomy packs or raytex. The sponge holders are held on racks mounted to IV poles. The racks have a basket in which to store a box of holders. A wall-mounted dry erase board to record operative information and the IN counts should be easily visible in each room. This process should be standardized for use throughout all operating rooms to provide consistency in all types of operative cases.

The single most important element in the use of the hanging sponge-holders is to make sure that the final count is taken when ALL the sponges that have been opened during the case (used and unused) be placed in the holder. The surgeon and nurse can then visually verify that all sponges have been accounted for and none remain in the patient.

1. Use blue-backed sponge holders on all cases that use surgical sponges. Add laps and raytex in multiples of 10. At the IN count “See, SEPARATE and say” individual sponges within each pack.
2. Hang the holders on the special racks attached to designated IV poles. Use a separate holder for each sponge type e.g. one for laps, one for raytex.
3. Used sponges coming from the operative field should be placed into a CLEAR plastic bag (lined receptacle e.g. kick buckets or ring stands).
4. Take each used sponge from the receptacle. Make sure you have only one sponge. Open it up to its full length and then fold it up into an oval. Place one (1) sponge per pocket; two (2) sponges per row; ten (10) sponges per holder.
5. Put the first sponge in the LAST pocket in the bottom of the holder. Load the holder horizontally from the bottom row to the top row. Filling first the bottom two pockets and continuing upwards. This process (going from the bottom to the top) will make visual determination of the filled holder easier to see from the OR table. Once a holder is full with 10 sponges, visual confirmation with the scrub person should occur before hanging the next empty holder.
6. Place the filled sponge inside the pocket with the blue tag or stripe visible but not dangling out. The blue stripe must be visible because this is what differentiates a sponge with a radiographic marker from a gauze drawing sponge. Place another sponge in the other pocket. Periodically throughout the case, put the used sponges in the holder. Keep the kick buckets empty.
7. At the final count ALL sponges (used and unused) MUST be in the sponge holders. The final count is a thing. It is the holder full of sponges. The final count can only be correct or incorrect. No EMPTY POCKETS = a correct final count. Then a “show US” step is performed and two people view the holders to make sure there are no empty pockets. This is a team-based effort.
8. Keep a running total of the sponges added to the surgical field on the dry erase board using the same format that is used to count needles. The last number should always be the total number of sponges opened during the case.
9. At a permanent change of relief, the number of sponges in the holder should be physically reviewed using visual and audible communication between the circulating nurses changing positions before the relieved nurse departs the OR.
10. Sponge holders should remain hanging in their racks from the IV poles throughout the case, even if there are multiple parts to the procedure. DO NOT take the holders down. At the completion of the case the holders can be disposed of in a red biohazard bag thus removing all the sponges from the case so there will be “nothing left behind” to confound the counts on a subsequent case.

10 LAPS / 10 RAYTEX / 10 POCKETS / 10 STEPS...

Sponge ACCOUNTing System
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