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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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 RSI.
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.
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 (10⁰ 20¹⁰ 30) or a vertical summation line running total format 10

\[ 10 \]
\[ 20 \]
\[ 10 \]
\[ 30 \]

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 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-corporeally 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.
VII. SURGEON PROCEDURES AND SAFETY RULES

A. PERFORMANCE OF A METHODICAL WOUND EXAMINATION:

1. GENERAL CONSIDERATIONS FOR ALL WOUNDS (Attachment F)
   a. Conduct a methodical exploration of the operative wound, prior to closure in every operation, and at any time the surgeon is informed of a missing item.
   b. Carefully examine the space to be closed. Give special focus before closure of a cavity within a cavity (i.e., heart, major vessel, stomach, bladder, uterus). Placement of mesh or bone graft “closes” a cavity and a wound examination prior to their placement is a recommended practice.
   c. Strive to see and touch during the exploration; reliance on only one element of sensory perception is usually insufficient.
   d. Visually and manually determine that any item that is not intended to remain in the patient, is recognized and removed.
   e. The general process is to look and feel in the recesses of the wound and examine under fatty protuberances and soft-tissue appendages.
   f. If something was inserted or placed in the mouth, nose, rectum or vagina make sure “it” and all of its parts have been accounted for.

2. ABDOMEN AND PELVIS
   Unless clinically contraindicated for a specific patient, take the following steps for procedures performed in the abdomen or pelvis using appropriate retraction to provide adequate visualization. The operative quadrant should not only be explored but all four quadrants of the abdomen examined. [see Point of Discussion #11]
   a. Lift the transverse colon.
   b. Check above/around the liver and above/around the spleen.
   c. Examine within and between loops of bowel.
   d. Inspect anywhere a retractor or retractor blades were placed.
   e. Examine the pelvis.
   f. Look behind the bladder, uterus and around the upper rectum.
   g. The vagina should be examined if it was entered or explored as part of the procedure.

3. CHEST AND MEDIASTINUM
   Unless clinically contraindicated for a specific patient, the following general steps should be taken for procedures performed in the mediastinum or thorax.
   a. In a mediastinal procedure, if the mediastinal pleura were opened, examine the ipsilateral pleural cavity.
   b. In a cardiac procedure, elevate the apex of the heart and examine the retrocardiac space.
   c. Examine the transverse sinus to the right and left of the aorta and pulmonary artery.
   d. In a thoracic procedure, examine the thoracic cavity with attention to the thoracic apex and base of the lungs, paravertebral sulcus, and inferior recesses of the diaphragm.
   e. Place a hand or finger behind the lung and palpate from apex to base.
B. USE OF THE ORIFICE PACKING PROTOCOL

a. Intra-operative orifice packing is usually used in the setting of hemorrhage. This protocol is not intended for intra-cavity therapeutic packing of the abdomen or chest. Separate guidelines are recommended for that. 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. (Attachment J)

b. 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).

c. 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. 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.

d. The MD will determine the packing material to use and place the pack in the orifice.

e. 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)

f. 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.

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

h. 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.

i. If the MD determines that the patient will go home with the packing in place, when the packing is removed in the office, the armband will be cut off.

j. The patient is informed by the handoff RN as soon as clinically possible the meaning of the packing armband and the plans for the removal of the packing.

k. 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.
C. CLINICAL DECISION TO LEAVE A UDF IN THE PATIENT:
   a. During use of devices and supplies in the OR, there is always the possibility of manufacturer error or defects. The user of the device is one of the people who may discover these defects. If something does not look, feel or sound exactly right - STAR (Stop, Think, Act, Review) before proceeding with the use of the device. (Attachment D)
   b. Sharps, needles, instruments and small miscellaneous items that are broken or damaged during a procedure must be accounted for in their entirety. If part of a broken item is retained in the patient and not removed, this is an unretrieved device fragment (UDF).
   c. In the circumstance of an incorrect final count of a known radiopaque item (e.g. small needle or broken device fragment) it is a clinical decision to be made by the surgeon based on best judgment whether or not the item can or will be removed.
   d. Effort should be made to retrieve any device fragments or parts if possible
   e. The decision to leave a surgical item in the patient must be documented in the medical record and an incorrect final count report completed (see Attachment B).
   f. Sequester the broken device. Do not discard it. Obtain lot and serial numbers.
   g. An unbroken device or identical surgical item can be used to measure against the residual part to determine the size of the retained fragment.
   h. Obtain X-rays, if the UDF is radiopaque, to document the position of the item and to have knowledge about composition, size and number.
   i. Inform the patient of the situation and explain any risks. Device fragments may migrate, embolize, cause thrombosis, become infected, heat during MRI or wobble and may cause injury. They may also remain stable and inert and cause no future problems. Future diagnostic testing can’t be predicted so the patient should be informed. Appropriate RSI reporting should be conducted as required. [see Point of Discussion #12]

D. OPERATIVE REPORT DICTATION
   It is good surgical practice to include in the operative dictation of the case the status of the final surgical counts and any actions that were taken during the case to prevent retention of surgical items.

E. PATIENT DISCLOSURE
   1. Upon the discovery of a retained surgical item or UDF a disclosure discussion with the patient should be conducted.
   2. There is no requirement to disclose to the patient the existence of a lost item if it is known with certainty that the item is not in the patient. The difficulty is with the determination, with certainty, that the item isn’t in the patient. Because of the quality and physical characteristics of intra-operative radiography, a negative intra-operative x-ray does not mean “with certainty”. A lot depends on what the surgical item is, but finding the physical item or everyone conclusively agreeing that the surgical item is not in the patient (e.g. because it was known by all to be on the floor or never entered into the patient in the first place) are the two best determinants to use. If an item was lost and never found and there is no agreement on where it is, then a disclosure discussion with the patient should be conducted. This is to discuss options that can be pursued depending on the patient’s best interests. A lost small
suture needle is not an uncommon situation. In that setting, a discussion with the patient can be held, outlining the risks and benefits of getting a CT scan, which will show the presence of metallic suture needles. A CT scan may show a non-radiopaque object or suggest its presence even though the item itself is not radiopaque. If the CT is negative that is the best evidence currently available that the item was not in the patient.

3. Also during disclosure would be a discussion by the surgeon of the risks and benefits of removing the surgical item should it be discovered to be within the patient.

4. If it is decided that the best course of action is to not retrieve the item, the patient should be informed of any risks associated with retention.

5. The best strategy is to develop and implement strong practices to prevent the loss of the items in the first place. This is a team based endeavor and worthy of time and attention.
VIII. RADIOGRAPHIC PROCEDURES AND SAFETY RULES

A. INTRA-OPERATIVE RADIOGRAPHIC EXAMINATIONS
1. If a surgical item is discovered to be missing an intra-operative radiograph is required. This is a Missing Surgical Item (MSI) (Attachment G)
2. A written request for a “STAT intraoperative image” will be generated by the circulating nurse in a specific operating room under the name of the surgeon listed in the operation record. The request will specify:
   a. The name of the surgeon.
   b. The region of interest being requested
   c. The kind or type of surgical item being looked for e.g. Sponge, needle, name of instrument, other item.
   d. If a sponge is the missing item specify the type e.g. lap pad, raytex, towel.
   e. The OR room number and the telephone number for that room.
   f. The name of the circulating nurse or designated person in room to receive call back information.
   g. If the radiograph is being obtained “in lieu of an instrument count” this information should also be conveyed to the radiologist so he or she knows the purpose of this film.
3. The nurse will note on the written request the time the request was submitted.
4. Upon receiving the request a radiology technologist will take radiograph(s) of the appropriate site
5. More than one film may be required to completely cover the surgical field so multiple cassettes should be available.
6. This should be accomplished expeditiously. The technologist will note time request received and time radiograph taken on the request slip.
7. It may be useful to show the radiology technologist a sample of the missing item to give or show to the radiologist as well.
8. The radiology technologist will take radiograph(s) that encompass the entire operative site and region of interest and is expected to meet the standards for each particular region of interest e.g. MSI abdomen/pelvis includes diaphragm to pubis and bilateral skin borders. (see Attachment G)
9. Consideration should be given to obtain two views – usually an AP and an oblique/lateral. If there are any questions about appropriate images or image quality consult immediately with the radiologist [see Point of Discussion #13]
10. The technologist taking the radiograph will call ahead to alert the radiologist on duty that a wet read to rule out “specific item” e.g. “retained lap pad” is needed from a specific OR.

B. COMMUNICATION AND ENGAGEMENT WITH OR PROVIDERS
1. The technologist will notify the radiologist by phone when imaging has been completed and note the time the radiologist was notified that the study is available for viewing. The technologist should remain on the phone with the radiologist in case additional views are required.
2. The technologist will return to the OR if requested to take additional views.
3. The radiologist on duty will review the film or the digital images of the radiographs and will call the specified OR with the results of the examination and information about the quality
and completeness of the image or with a request for additional information or views to be obtained. The radiologist should explicitly state the findings and also address the adequacy of the image in his readback to the surgeon e.g. “there is no raytex identified on these good quality complete MSI abdomen images”

4. This should be accomplished expeditiously. In the event that the radiologist on duty should require additional assistance or consultation to establish a diagnosis, the OR should be notified that such a secondary review is underway.

5. The person who answers the phone in the operating room and receives the results must be a member of the operating team – nurse, surgeon or anesthesiologist. The radiologist should speak directly with the surgeon. The results must have “read back” confirmation and the findings documented in the operative record.

6. The radiologist will dictate the report following verbal transmission of the findings. The name and identifying number of the individual to whom the information was provided must be on the report or if “read back” was provided, indicate as such. The radiologist will note the time the information was transmitted.

7. Performance audits can be conducted to determine if timeliness and image quality guidelines have been met.

C. PREVENTION OF RETAINED GUIDEWIRES AFTER CVC INSERTION

1. X-ray requests for images will be ordered by the MD provider after central line insertion. X-rays are reviewed to confirm catheter position, identify any procedural complications (e.g. pneumothorax, perforation) and rule-out the presence of an inadvertently retained device(s) (e.g. guidewire) or UDF.

D. CRITICAL FINDING CALL-BACK POLICY

Hospital critical lab results and radiology findings that require immediate call back to the ordering physician should include the finding of a newly present or suspicious retained surgical item, retained foreign body or new or indeterminate radiopaque density.
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.
XI. PREVENTION OF RSI IN THE EMERGENCY DEPARTMENT (ED)

1. Any procedure where surgical items are used in or on a patient requires safe practices to prevent an RSI. The following are safety rules for ED providers to prevent the retention of surgical items used during procedures performed in the ED.

2. These guidelines apply to, but are not limited to, the following ED procedures:
   a. Placement of central line
   b. Placement of arterial line
   c. Insertion of a chest tube
   d. Insertion of a temporary pacemaker
   e. Tracheostomy
   f. Lumbar puncture
   g. Wound repair and closure

3. Dressing sponges and wound care products should be used in the ED for wound management. This includes non-radiopaque nasal packing (e.g. iodoform gauze), dressing sponges and devices (e.g. Rhino Rocket). Radiopaque packing and surgical sponges should not generally be available in the ED.

4. In the setting of hemorrhage where radiopaque Quick Clot hemostatic dressings or packs may be placed in the ED before transport to the OR, the number and site of placement must be documented in the ED nursing report and information transmitted at the nursing handoff.

5. A registered nurse is responsible for medical record documentation. Document a post procedure summary in the medical record that includes:
   a. Name of the ED physician completing the procedure
   b. Patient tolerance/response (post-procedure vital signs, aldrete score)
   c. Direct visualization that all surgical items used during the procedure have been accounted for.
   d. 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.
   e. The x-ray is obtained to confirm catheter position, identify any procedural complications (e.g. pneumothorax) and rule-out the presence of inadvertently retained device(s) e.g. guidewires or UDFs.

6. If a package or kit which contains any surgical item is found to be defective when opened (e.g. wrong number, damaged, contaminated) the package and its contents will be removed bagged and labeled.
   a. Obtain a new kit or package.
   b. The charge nurse will be notified (if possible) and the packaging error documented.
   c. The inventory information will be given to supply purchasing for notification of the distributor and staff will be informed about the packaging error at staff educational meetings.

7. If a medical device or instrument breaks or fragments, all effort will be made to retrieve the separated parts.
   a. The device and its parts will be removed from the sterile field or procedure area and sequestered.

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b. The charge nurse will be notified (if possible) and the device or equipment malfunction documented and reported through manufacturer and regulatory reporting systems.

8. Before performing invasive procedures double gloving is a recommended practice. In addition an “indicator glove technique” may be useful where the first glove is a colored glove (can be a colored non-sterile gloves or green sterile indicator gloves) and then a standard sterile non-latex glove is donned over the colored glove. In this way if a break in the outer glove occurs (such as during chest tube insertion or encounters with bony fragments) it will be easily recognized and new gloves donned.

9. The ED provider will perform a methodical wound exam before closure of any wound. At the conclusion of all procedures, the provider will inspect the area and site to ascertain that all items used are intact and those not intended to remain in the patient are on the sterile field.

10. At the end of the procedure, the ED nurse will visually inspect all surgical items used in the procedure to ensure they are intact and all have been accounted for e.g. the guidewire used during central line insertion is back on the sterile field.

11. If a surgical item is discovered to be missing all team members will be informed and a search of the surgical field, the area and the patient will be conducted.

12. If the missing item is radiopaque, X-rays will be obtained to locate the item to aid in its removal. Every effort will be made to retrieve the missing surgical item if possible.

13. In the event the surgical item or device cannot be retrieved (e.g. a small needle) it is a clinical decision by the ED provider in consultation with an appropriate surgeon that it will be left in the patient. This is considered a retained surgical item. The patient will be informed, a disclosure discussion held and appropriate event reporting conducted which includes immediate entry into the Event Reporting System and discussion with the supervisor/manager.

14. If the item does not contain a radiopaque marker and is not found, the ED provider must hold a disclosure discussion with the patient to determine if other diagnostic modalities will be pursued to find the missing item e.g. CT scan, videoscopic examination.

15. In the event a device breaks or fractures and the device fragment cannot be retrieved, it is a clinical decision by the ED provider in consultation with an appropriate surgeon that it will be left in the patient. This is considered an unretrieved device fragment. The patient will be informed, a disclosure discussion held and appropriate event reporting conducted which includes immediate entry into the Event Reporting System and discussion with the supervisor/manager.

16. Radiographic Examinations
   a. 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.
   b. Standard radiographic requests for images (e.g. chest or pelvis x-ray) will be ordered by the provider and obtained as appropriate for the clinical situation.
   c. X-ray requests for images will be ordered by the MD provider after central line insertion. X-rays are reviewed to confirm catheter position, identify any procedural complications (e.g. pneumothorax, perforation) and rule-out the presence of an inadvertently retained device(s) (e.g. guidewire) or UDF.
d. If a surgical item that contains a radiopaque marker is discovered to be missing, a radiograph of the area is required. If at all possible it is preferable to send the patient to the X-ray department to obtain an image rather than use portable radiography in an emergency room.

e. A verbal order for a “STAT image” will be generated by the primary Emergency Department nurse under the name of the ED provider listed in the record. The request will specify:

1. The name of the ED provider.
2. The image being requested e.g. chest, abdomen, using the Missing Surgical Item (MSI) Radiology guidelines (Addendum K)
3. The kind or type of surgical item being looked for e.g. surgical sponge, needle (specify the size in mm of the needle), device, name of instrument, other item.
4. The ED room number and call back information.
5. The name of the primary doctor, nurse or charge nurse to receive call back information.
6. The nurse will document the time the request was submitted.
7. Upon receiving the request a radiology technologist will take radiograph(s) of the appropriate site(s).
8. This will be accomplished expeditiously. The technologist will note time request received and time radiograph taken on the request slip.
9. It may be useful to show the radiology technologist a sample of the missing item to give or show to the radiologist.
10. The radiology technologist will take radiograph(s) using the MSI Radiology guidelines (Addendum K).

11. The technologist taking the radiograph will call ahead to alert the radiologist on duty that a wet read to rule out “specific item” e.g. “retained 17mm needle” is needed from the emergency department.

17. Communication between Emergency Department and Radiology

1. The technologist will notify the radiologist by phone when imaging has been completed and note the time the radiologist was notified that the study is available for viewing. The technologist will remain on the phone with the radiologist in case additional views are required.
2. The technologist will return to the ED if requested to take additional views.
3. The radiologist on duty will review the film or the digital images of the radiographs and will call the specified OR with the results of the examination or with a request for additional information or views to be obtained.
4. This will be accomplished expeditiously. In the event that the radiologist on duty will require additional assistance or consultation to establish a diagnosis, the ED will be notified that such a secondary review is underway.
5. The person who answers the phone in the Emergency Department and receives the results must be a member of the Emergency Department team – ED nurse or ED physician. The radiologist must speak directly with the ED physician. The results must have “repeat back” confirmation and the findings documented in the medical record.
6. The radiologist will dictate the report following verbal transmission of the findings. The name and identifying number of the individual to whom the information was
provided must be on the report or if “read back” was provided, indicate as such. The radiologist will note the time the information was transmitted.

18. Education and Training:
   1. All staff will receive annual training, policy review, skills and cognitive knowledge assessments.
   2. 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.
   3. At unit orientation, all new ED providers, ED RN's and ED technicians will read this Prevention of Retained Surgical Items in the Emergency Department policy. This will be documented on their orientation checklist.

XII. REPORTING

1. When a retained surgical item is discovered specific hospital reporting guidelines should be followed. Usually risk management is notified and a report in an Events Reporting System (ERS) is completed. The risk manager is responsible for the timely reporting of the event to state, local and voluntary reporting agencies.
2. Most states follow the National Quality Forum (NQF) definition for never event reporting of a Serious Reportable Event (SRE) that reads: “Unintended retention of a foreign object in a patient after surgery or other procedure is a serious reportable event.”
3. What individual states require to meet this never event reporting requirement vary.
4. No matter the reporting requirements, upon the discovery of a retained surgical item, a disclosure discussion must be held with the patient. This may be conducted in concert with hospital patient safety personnel following specific hospital disclosure rules.

XIII. REFERENCES

Below are some useful sources some of which have large bibliographies (>100 references) available for review.

   https://aornguidelines.org/guidelines/content?sectionid=173723395&view=book


3. National Quality Forum - Serious Reportable Events in Healthcare 2011:
   http://www.jointcommission.org/sea_issue_51/


6. FDA Medical Device Safety Reporting System – MedWatch
   https://www.fda.gov/MedicalDevices/Safety/default.htm

7. The Joint Commission. Sentinel event policies and procedures. 2017
   https://www.jointcommission.org/assets/1/6/CAMH_SE_0717.pdf

8. OR Policies and Event Reviews from >50 facilities around the country (thank you for sharing!)
XIV. POINTS OF DISCUSSION

This section is intended to provide additional information about specific safety rules. It is acknowledged that some of the comments have an anecdotal quality to them but ALL of the discussion points have been developed because ACTUAL cases of a retained item have occurred where the stated actions were causal. Consider this section part of a Collective Wisdom.

1. RETAINED SURGICAL ITEM DEFINITION OR WHEN IS IT AFTER SURGERY?

The issue of when an item is considered retained varies among state and regulatory agencies. All agree that an item is considered to be retained if found in a patient “after surgery”. The dispute resides with when is it “after surgery”?

The National Quality Forum provides consensus definitions of serious reportable events (SREs). Retained surgical items (the NQF refers to them as retained foreign bodies) is one of the SREs. The definition here conforms to the NQF 2011 revised consensus statement on when an item is considered to be retained and when surgery ends. (See references)

The Joint Commission (TJC) has a different interpretation of when surgery ends and reports that after surgery is any time after completion of the skin closure, even if the patient is still in the operating room under anesthesia. To most the operation is not over under these circumstances and indeed most healthcare facilities and the agencies use the NQF definition. TJC references back requirements EP 7: The leaders define “sentinel event” and communicate this definition throughout the organization, so each healthcare entity can define a RSI sentinel event using the NQF definition and only report those cases where there was a RSI discovered when the patient was out of the OR.

There may be disparities between written state regulations and those of regulatory and reporting agencies. Hospitals should know the state reporting rules in the states in which they operate and put in their policies the rules for retention they are going to follow. For example the Minnesota Hospital Association has adopted rules of retention that conform to what we have published here. The American College of Surgeons and the Coding Definitions follow the NQF. What is important is that personnel in each healthcare system know the rules of engagement and adhere to the policies and report when and if required. If the wording in a rule is “after surgery” use the definition in this policy (which follows the NQF recommendation) that it’s retained after surgery if the patient is out of the OR not when the wound is closed.

2. ISSUES WITH THE SURGICAL COUNTS

In spite of longstanding nursing practice related to the “counting” of surgical items there are confusing guidelines and poor communication strategies in existence. This confusion has been contributory to causing retained surgical sponges. In the implementation of the Sponge ACCOUNTing System practice these sources of conflict have repeatedly emerged and the policy rules promulgated here are direct actions to try to resolve these conflicts. AORN has also been trying to remedy these issues, but these are longstanding practices and difficult to change.

There are three main problems:

1) Referring to the counts with ordinal numbers rather than using a name for the type of count

Effective communication is the exchange of knowledge and information. When the scrub and circulating RN are exchanging information they have to share a common language. If hospital staff use an ordinal number to speak about a count, there is an opportunity for mis-understanding.
What one person thinks is a 1st count is someone else’s initial count. The closing count to some is the 2nd count or maybe the 3rd count to others. When the circulating RN says the 2nd count is correct, which count is that? The one at closing or when a cavity within a cavity was closed or the second time they counted the sponges? This confusion can be eliminated by NOT using numbers to describe a surgical count. The six AORN counts are the Initial, Cavity, Closing, Permanent Relief, Anytime and Final Counts. In this policy the names of each count must be used and each count has a name which describes when and what action to take during that count. So the Cavity count is different from the Closing count or the Anytime Count.

2) Understanding the difference between a closing count and a final count and the AORN directive on the 4th surgical count

The closing count is performed at wound closure which, depending on where the wound is, may involve the closing of layers. For example, in the abdomen the closing of the fascia is the hallmark of the beginning of wound closure. Surgeons usually use different types of suture for closing and there is a shift or change in the flow of an operation before closing. This is called a “natural pause point” and is when the MWE is performed. For the scrub person and circulating nurse the closing count is begun after the surgeon performs the MWE.

The final count has been poorly defined and hence there is frequent confusion between the closing count, skin closure and the final count. In the AORN guidelines the counts are worded:

- Before the procedure to establish a baseline (ie, initial count)
- When new items are added to the field
- Before closure of a cavity within a cavity (eg, the uterus)
- When wound closure begins
- **When skin closure begins or (emphasis mine) at the end of the procedure when counted items are no longer in use (ie, final count)
- At the time of permanent relief of either the scrub person or the RN circulator, although direct visualization of all items may not be possible and
- Any time a discrepancy is suspected

It is the wording of the **count that is problematic because it has an “or” which reflects a choice. Do a count when skin closure begins or do a final count. It would be clearer if AORN separated this sentence into two separate statements or abandon the skin closure count as a separate count and just have a final count. The SAS is clear and defines what a final count is. It is when all the sponges are in the hanging blue backed sponge holders. This document defines what a final count is. It is when all surgical items are no longer in use and off the field. If staff chose to perform a count when skin closure begins that would be considered an anytime count. An anytime count is a count performed anytime a team member wants to call for a count, not necessarily only when a discrepancy is suspected.

3) Establishing the direction in which counts should be performed

This process actually works either from back table to incision or vice versa. The reason for the recommendation in this policy results from the review of malleable retractor cases. Instrument retention cases are very rare but of all instruments that could be retained, the most commonly retained instrument is the malleable retractor or fish retainer. This event arises from the same practice problem. That is, the scrub and circulating RN start at the incision and “count” the retractor
while it is still in use as out. Therefore it was “counted” but not accounted for (that is out of the patient and on the back table). In one case the retractor had been “counted” while being used and then there was a distraction which diverted the surgeon’s attention and the retractor slipped out of view and the wound was closed over the unseen instrument. In the other case the retractor was being used and the scrub “counted” the retractor and said to the surgeon “ok, now don’t forget to take that out” and then a change in shift happened and the next shift received word that the “count” was correct. Needless to say this retractor was also retained. The point here is that the instrument can’t be counted out unless it is physically out of the patient and on the back table. It must be on the back table in order to be accounted for. Starting at the back table if the instrument isn’t there it can’t be counted and checked off the count sheet. This is also the direction that is recommended for counting the sponges using the SAS, as we recommend the count begins at the dry erase board and goes to the holders and then to the table and then to the field. To be consistent and safe the same process is recommended for all the surgical item counts.

3. MISCOUNTS ARE NEAR MISS/CLOSE CALL LEARNING OPPORTUNITIES

If a discrepancy in the count occurs at an interim count and this discrepancy is reconciled this is a miscount. A miscount is a form of an incorrect count but the major difference is that a miscount is an incorrect count that gets reconciled. If the incorrect count occurs at the Final Count and the item is never found it is an incorrect final count not a miscount and the rules for the documentation of an incorrect final count must be followed.

This distinction is emphasized because documentation errors have occurred because nursing personnel did not clearly understand the difference between these two types of incorrect counts. Retained sponge cases have been reviewed where there was an incorrect final sponge count where nursing personnel knew that a sponge was missing but they assumed that the sponge was probably in the trash as was usually the case for many miscounts that regularly occurred. Because it was treated as a miscount no further action was taken after the case. The nurse managers weren’t notified, no follow-up x-rays were ordered, nothing happened …… until the patient returned to the OR days later after a routine post/op x-ray showed the retained sponge. Upon record review it was seen that there had been a missing sponge, there had been x-rays taken that had been read in the OR as negative and the sponge was never found, yet nothing was done about this. It is important to make sure all staff understand the difference between a miscount…. when the count is reconciled…and an incorrect final sponge count…. when something is still wrong and the patient is not out of harms way.

There are usually two kinds of MIScounts that have been recognized through practice observations:

1) MIStaken count – a mistake is made in the counting of the sponges. There may be more or less than the expected number. Upon examination (perhaps two had stuck together, or there were two in one pocket) the error is identified and the count is reconciled.

2) MISSing item – when the count identifies that the number of sponges in use is less than the number recorded on the dry erase board. A sponge is missing. Usually a search is undertaken, x-rays may be obtained and after finding the sponge, a recount is performed and the count is reconciled.

Both of these types of miscounts should be internally reported and discussed, however there is usually a lot of pushback from nursing that the MIStaken count happens so frequently that they would always be filling out reports (isn’t that a problem?) but the second type, the MISSing item
should most certainly be discussed, especially if an x-ray has been ordered. We refer to these events as Missing Surgical Items (MSI) and have outlined radiology actions to improve detection.

Miscounts are “close calls” and can provide learning opportunities. They can be signs of a vigorous process or they can be signs of practice problems. When miscounts occur frequently in an OR these are practice problems. Miscounts should be reported on a miscount report (see Attachment C). At a minimum, any time an x-ray is obtained to find a missing item a miscount report should be completed and provided to the OR nursing director. The miscount reports are for internal quality improvement use to review with staff to help improve performance.

4. WHEN IS IT A SEPARATE PROCEDURE?

Individual hospital ORs handle the issue of separate procedures differently. This variation often provides a source of confusion. It is important for each facility to specify what it considers a separate procedure.

Some facilities consider procedures as separate if they have different surgeons and different instrument sets brought into the same OR for one period of time even though there is one patient and one anesthetic administration. An example of this would be a patient who had a mastectomy and a reconstructive mammoplasty during one operation. The first procedure would be performed by the general surgeons while the second procedure would be performed by plastic surgeons. In this circumstance the hospital’s policy considers these 2 separate procedures and expects the counts for the first procedure to be completed, closed and finalized before starting the second procedure. Often the general surgeon from the first procedure will insist that the counts be finalized for the first procedure. They often assign these cases with two case numbers and expect to see two separate dictations in the medical record – one from the general surgeons and one from the plastic surgeons.

In other facilities this exact same set of circumstances would be considered and treated as one case even though there were two different sets of surgeons and sets of instruments because the operation was conducted on one patient under one anesthetic and had one case number. In this facility there would be only individual counts kept for the entire operation with the expectation that at the end of the day there will be only one set of final counts. It is important that all personnel are clear on what the facility’s definition is.

Finally, as a point of clarification, when different incisions are performed during one operation – say during a bypass graft with saphenous vein harvesting this is one procedure. There are two incisions but only one operation and only one set of final counts would be expected at the conclusion of the operation.

5. WHY NO RED BIOHAZARD BAGS IN THE KICK BUCKETS

Here is a perfect example of how the system sets us up for failure and why preventing retained sponges is a system problem. The requirement to have the kick buckets lined with clear plastic bags is so the circulating nurse can easily see the sponges in the receptacles. If the kick buckets are lined with red biohazard bags it is very hard to see bloody sponges and if they are lined with white plastic bags it is easy to miss unused sponges thrown in the kick buckets. To make it easy to see the sponges and move them out of the kick buckets into the sponge holders, the kick buckets should be lined with clear plastic bags. Miscounts have frequently occurred because an unused surgical sponge was mistakenly thrown in the trash when it wasn’t seen within a white plastic bag which lined the kick bucket, similarly red bloody sponges have been “lost” within the folds of a red biohazard bag.
But then there is the environmental and waste management inspector dictating that biohazard waste must be disposed of in conspicuously labeled red biohazard bags. What’s the right thing to do? The important point here is to understand that the sponges that are placed in the kick buckets are not being disposed of but merely are placed there as a temporary repository. Since they are not being disposed of there is no requirement that there be a red biohazard bag in the kick bucket and a clear bag is just fine.

What is important and makes the practice even safer is that when the case is over, if there are really bloody sponges that are now in the sponge holders, all the sponge holders can be placed in a red biohazard bag for disposal. This serves two purposes, it complies with biohazard waste disposal regulations and it ensures that all the sponges from one case have been removed from the OR so they won’t be around to possibly confound the counts in a subsequent case.

Hospitals pay for biohazard waste disposal and it is clear that some of the regulations with regards to this type of waste are being changed. It is important to make sure the OR personnel understand whether or not the full holders should be placed in trash or red biohazard bags but it is clear that the kick buckets or ring stands that are there to momentarily hold the used sponges should be lined with clear plastic bags.

6. WHY WHITE RADIOPAQUE OR TOWELS?

The intent here is to have a unified approach to managing what is safe to go into a patient. If we practice that all the soft goods that are safe to go inside a patient are white or will be white and have a radiopaque marker (a radiopaque towel - ROT) this may help the surgical scrub person organize the back table and make it easier for everyone to account for soft goods. White cotton soft goods have been bleached and are of a finer grade of cotton. Blue and green drape towels have been dyed and are manufactured to a different standard than sponges. There are also unbleached drape towels which are beige and are of a coarser grade of cotton. These types OR towels are intended to be used as drapes. White ROTs usually are supplied in packs of 2, 4 or 6. So if it’s a white ROT it’s safe and okay to go in a patient. If it’s blue or green or beige it should be used only as a drape, wipe or cover. It is worthwhile to note that trying to “ban” OR towels from use is a failure mode. Drape towels are a workhorse in the OR. They are used on the field as drapes, on the Mayo stand as a cover, under retractor blades as a skin protector, on the back table to separate instruments, as a roll to rest devices on, they travel with specimens, wipe off wet hands and dry surgical instruments. It is a safer strategy to establish a safe practice for the use of white ROTs.

Hospitals should purchase white ROTs for use by surgeons that use towels inside of patients to aid in visceral retraction. These white ROTs should be counted, the category “Radiopaque towel” added to the dry erase board and the number of ROTs written on the board after the ROTs have been counted in. They are counted in the unit of issue (in that they don’t have to be part of the “rule of 10” as they don’t fit in the pockets of the sponge holders. They could be placed in a pouch of the holder after separating the divider however). Having white ROTs that are safe to put in patients will help the surgical scrub person separate the counted white ROTs from the uncounted blue or green drape towels. At the closing count all the white ROTs should be removed from the patient.

White ROTs should NOT be used as drape towels or draped for long periods of time around the wound when surgeons are suturing. The operative words here are “long period of time”. Cardiac surgeons often use white towels to cover the wound retractors while suturing. The white background provides a nice contrast to the fine blue suture they often use. However, white towels reflect the bright OR lights and will cause eye strain and headaches so they shouldn’t be used for long periods of time. If white ROTs are used as a vascular background, they must be counted and
accounted for at the closing count since their purpose will be complete at the time of wound closure. Lastly, you don’t want to use white ROTs for wound draping because if an x-ray becomes necessary at some time during the case the radiopaque markers in the towels will be confusing and may confound the radiographic interpretation.

7. PUTTING 10 STANDARD LAP SPONGES IN THE SPONGE HOLDERS IN A 10 POCKET PATTERN COMPLIES WITH MANUFACTURER IFUs

Manufacturers provide products and devices to aid in the provision of healthcare. They do not provide healthcare services directly and it is up to the hospitals to determine what services they will provide and what products they use. There are at least 10 distributors or manufacturers that provide blue-backed plastic sponge holders. They are also called sponge counter bags, sponge counters and sponge bags but the preferred terminology is a sponge holder because all they do is hold the sponges in one place so everyone can see them. They don’t “count” the sponges. That being said, all the manufacturers have essentially similar wording related to the use of the holders.

For example:

IFU#
1. Place carton into dispenser rack
2. Remove bag from dispenser and unfold
3. With pocket openings facing you, hang bag from wire hooks at bottom of dispenser rack
4. As each bag is filled, hang new bag in front
5. For additional space use hooks on back of dispenser rack
6. 10 soiled sponges may be placed in each bag – 2 in each of the 5 divided pockets
7. For lap sponges, gently separate the seal between each pocket – 5 sponges per bag

IFU#6 provides guidance that the sponge counter bags MAY be used as 10 sponges per bag with 2 in each of the 5 divided pockets. IFU#7 provides an option to separate the pocket and use the device as 5 lap sponges per bag. Both IFU #6 and #7 are equally valid for the use of surgical sponges. Lap sponges are just another type of sponge and come in many different sizes. The options in IFU#6 and IFU#7 are to provide end-user flexibility in the use of the plastic holders depending on how the sponges are counted. The manufacturers are not dictating that the pockets MUST be used only one way or the other but that they MAY be used in these two configurations. A 10 sponge configuration or a 5 sponge configuration will work with the design of the plastic holders. The manufacturers are providing these instructions to follow the recommendation to count in the unit of issue not on any intrinsic properties of the plastic holders. They will not burst or break. Put the sponges in the 10 sponge configuration if you’re counting in 10’s, put them in the 5 sponge configuration if you’re counting in 5’s or in the unit or issue with a large sponge. It is up to the end user to determine the best way in which to use this plastic product. In the SAS practice it is clearly stated to manage the lap sponges in multiples of 10.

The holder pockets easily accommodate standard lap sponges (18”x18”) but if larger sponges are used or towels are being managed, they won’t fit in the pockets of the holders, so a pouch can be created by separating the seal between each pocket. In that setting the towels or trauma sponges would still be placed in the holders in the unit of issue.
8. THE “PAUZE FOR THE GAUZE” AND THE “SHOW US” STEPS ARE TEAM BASED

These steps are part of the Sponge ACCOUNTing System practice. Of note, the “Pauze for the Gauze” which is performed at the closing count, is not a Time Out. It is not a hard stop but a moment which occurs at a natural pause point in most operations. Before the surgeon asks for closing suture, it is a natural time to perform the methodical wound exam and for the circulating nurse and scrub person to perform the closing count activities. After the surgeon has done the MWE, suture can be passed while the nursing team completes their closing count and calls out to the surgeon the status of the count. Actions can then proceed depending on the situation. If something is missing everyone starts looking, if everything seems to be present the case continues to close.

It is important to realize that the closing count is a NON-verifiable count because items are still in use. It is only ever a “best guess” of the situation at the time. The final sponge count however is truly verifiable. Everything should be out of the patient (that isn’t intended to remain in the patient) and should be accounted for. The final count is when all the sponges, the used and unused sponges, are in the pocket of the holders. The final count does not mean the final time the sponges have been counted.

After the final count has been completed (all the sponges are in the holders), the Show US step is performed, which is a team-based verification. It is performed during the debriefing or if that is not part of the surgical practice in the OR then before the surgeon or whomever has been designated to perform wound closure, leaves the OR. The circulating nurse “shows” the surgeon the full sponge holders or the surgeon says “show us” the sponge holders and together they look at them, thereby proving that all the sponges have been accounted for since there should be “no empty pockets”. If the surgeon or designee doesn’t do this as a regular part of the practice, it doesn’t matter, the circulating nurse MUST have “another set of eyes” look at the holders to see that there are no empty pockets. Another member of the OR staff, a nurse manager, anesthesiologist, another human being has to look at the holders. No empty pockets is the real meaning of a correct final sponge count. These activities take very little time and help everyone do their part to make sure there is “NoThing Left Behind”.

9. SUTURE NEEDLES HAVE TO BE SORTED BY SIZE IF A NO X-RAY POLICY IS USED

In this policy needles, 6mm – 15mm in size, are considered small. This is a somewhat arbitrary cut-off, as all of the published evidence related to needle size presents uncertainty as to what exactly is the ideal. Clearly needles less than 10mm are difficult to see on plain radiography however needles of any size >4mm can be seen on CT scans, so a cut-off decision just based on the ability to see on plain x-ray seems insufficient. We have found no reports of needles that are ≤15 mm in size lost in large body cavities (chest, mediastinum, abdomen, pelvis) causing injury. Needles which have caused symptoms (albeit subjective e.g. pain) have been larger than 15mm. It seems to surgeons that spending the extra time taking x-rays for small needles which they won’t remove or have no evidence of causing harm is time poorly spent. So to reach a compromise and still guide good and safe practice a 15mm cutoff has been selected here.

This is not to say that needles should be left in patients with abandon. Far from that. There still have to be safe practices in place to account for needles. If a needle is found missing it must be known with certainty what the size of the missing needle is before bypassing an intraoperative x-ray. This is why the placement of the suture needle and needle holder in a safety zone/plastic pan is advocated. If the surgeon can merely get the needle in the pan, then the needle can’t be in the
patient, even if the scrub person loses control of the needle on the back table or somewhere between the pan and the needle counter. What is important is that the team is certain that the needle was in the pan and therefore couldn’t be retained in the patient. If there is any doubt it is always better to get the x-rays but with intra-operative x-rays small needles are frequently not seen and even if they are seen, most surgeons do not remove them if lost in large cavities.

If the case ends with an incorrect needle count and the needle is never found the patient should be told. There is always the option to obtain a CT scan which will reveal needles of all sizes, however it is still a clinical decision which has to be discussed between the surgeon and the patient whether or not it is possible and safe to try to remove the needle even if it can be seen on the CT scan. Patient disclosure does not have to take place for lost needles if it is known with certainty that the needle is not retained. Circumstances where the lost needle never entered the patient or was removed but lost subsequent to removal from the patient would be examples where disclosure is not required.

In the final analysis all efforts should be directed to having a safe needle management practice in place that will reduce needle miscounts and prevent the loss of the needles in the first place. Such a process is outlined in this policy.

10. ALTERNATIVE WAYS TO MANAGE INSTRUMENTS TO PREVENT RETENTION

There is a lot of consternation about the necessity to perform instrument counts. Counting in and of itself is not required. What is required is a reliable system to account for all instruments used during the operation and a process to make certain that none have been left inside the patient.

This policy recommends that the actual practice of individually counting each instrument take place at two times during an operation. Before the patient is brought into the room as the initial count, which is to be performed with the instrument sheet supplied from sterile processing, to determine what instruments are present at the beginning of the operation. During an operation if an additional instrument is added singly, document it on the instrument count sheet (not on the dry erase board) so all instruments are tracked in one place. If more trays are brought in during the case they are counted using the accompanying count sheet. Complete instrument counts at the interim counts (cavity, permanent relief, anytime, closing) are not feasible nor required. What is feasible and should be encouraged is rather than counting the instruments, the surgical scrub person at the time of a cavity closure (when a cavity count would be performed) should speak up and ask the surgeon to perform a wound exam to make sure there is no instrument left within the cavity before closing it. That is before closing the stomach, uterus, or bladder, the simple act of speaking up to ask to look and feel that there is no instrument inside the cavity can be a useful practice rather than counting all the instruments and hoping to detect one that is missing.

At the beginning of wound closure the instrument count is started and will continue on to the end of the operation, to be completed at the final count. This is documented as the final count not as a closing count. Practices are also outlined for alternative means to determine and document that no instruments have inadvertently been left inside the patient by use of an intraoperative x-ray.

Another useful practice is rather than counting the instruments on cases that have multiple trays and hundreds of instruments, is to implement a hard stop at the closing count for the surgeon to perform a methodical wound exam and the scrub person to look at the instruments on the back table and on the trays in a coordinated manner to determine if all instruments have been removed from the patient. This cooperative effort is worthy of application and use in lieu of counting instruments.
Additional alternatives consist of having pre-set instrument trays with defined slots for instruments such that if a slot is empty the team has a means to identify that an instrument is missing and can find it. Improvement efforts can be directed to reducing the total number of instruments on instrument trays. These reviews should be done with surgeon engagement to determine what instruments are actually used during operations versus ones that are there “because they have always been there” rather than are there because they are needed and used.

It is worth remembering that hundreds of instruments are used during operations but retained instruments are very unusual. The most common retained instrument is a malleable or ribbon retractor. These points speak to the importance of understanding that the way in which an instrument is used rather than the number of instruments used, is a determinant of retention.

**11. THE METHODICAL WOUND EXAM ISN’T SWEEPING**

It has been a surgeon practice to perform a “sweep” of the operative site but a “sweep” is inadequate because “sweeping” or “swishing” has not identified surgical items that have been left inside of patients. There is no experimental evidence to my knowledge about the superiority of a methodical wound exam over a sweep but there is experiential evidence from cases of retained sponges where a “sweep” was reportedly performed yet a sponge in a wound was still missed. Hence the need to perform a methodical wound exam (MWE). Surgeons usually wait until they have been told there is something missing before they perform a MWE but this is also an unsafe practice. The MWE has to be performed at the closing count BEFORE asking for closing suture in order to get the surgical items out so the nurses can perform a closing count. So the surgeon action actually must take place BEFORE the nursing action of counting.

Surgeons should use two sensory modalities, seeing and touching, to increase their chances of finding anything that the surgeon does not intend to remain inside of the patient. Looking requires active thought, visualization of the item being sought and focused attention. None of these are characteristics of “a sweep”. The MWE should be performed on every case in which there is a wound to examine and the areas to be examined should not just be in the operative quadrant. Sponges especially are used to enhance retraction and get moved and pushed into areas outside of the operative site. If the surgeon just looks in the operative site these sponges used for retraction or placed under retractors will be (and have been) missed.

Lastly, the MWE is performed at a natural pause point in the operation, a natural time after the body of the operation has concluded and closing activities begin. It is not an additional step or an add-on, in most operations the closing activity is well recognized and defined. The MWE occurs at the natural pause, with sponges we say take a “pauze for the gauze”. This is not a time-out but a time to examine the wound, get all the items out so the nurses can do their part to make sure there is NoThing Left Behind.

**12. UNRETRIEVED DEVICES AND FRAGMENTS STILL REQUIRE PATIENT DISCLOSURE EVEN IF REPORTING IS NOT REQUIRED**

If the surgeon makes a clinical decision to leave a UDF in a patient or a small needle, while this may be a non-reportable event, it is still necessary to disclose to the patient. The act of retention was still inadvertent and the patient should be told that there is something left inside that he or she would otherwise not expect to be there. This is especially important with metallic objects and fragments that may be discovered on CT scans or MRI examinations. Objects may migrate, wobble or heat up depending on their position and constitution and may cause work their way out and...
provide unexpected discovery. That the disclosure discussion was held should be documented in the medical record.

13. RADIOLOGY PERSONNEL ARE TEAM MEMBERS TO HELP PREVENT RETENTION OR MITIGATE HARM

Radiologists and radiology technologists are team members in making sure surgical items are not inadvertently left inside of patients. The usual problems with the radiological interface involve communication problems between radiologists and surgeons; and radiology technologist practice problems with the actual taking of high quality intraoperative x-rays. The problems with the films themselves often involve a mis-perception between the surgeon and the technologist, that the surgeon knows what is being looked for and where it is and that the standard procedures for intraoperative films in the OR would obtain. However, when a MSI film of a region of interest (ROI) is requested, different techniques, different films and a different approach may be required. The reason the image is being obtained is because no one knows where the item is.

The problem of “anatomical clipping” is frequent with intraoperative films as well as misreads and misinterpretation of images and objects on the part of the radiologist. Suffice it to say, radiologists are the content experts on image interpretation and they should be the ones to read the images. Surgeons are often the ones who do a first pass but surgeons aren’t radiologists. We have outlined here a number of practices to improve the chances that intraoperative images will be correctly read. Importantly, the radiologist must know exactly what is being looked for, the radiology technologist must take complete region of interest films (top to bottom, side to side) and in general a film shouldn’t be called negative unless two views (AP and oblique/lateral) have been obtained.

In the OR sometimes it is difficult to get lateral views because of the positioning of the patient on the table or padding on the table so what is really wanted is an orthogonal view to the AP. An oblique or lateral view is needed primarily to move an item off the midline or to provide an alternative projection. Fluoroscopy might be an option with image capture. These are standard principles in the radiology world that need to be shared with the OR world to help us get it right.

The Incorrect Count Checklist (Attachment N) outlines a few radiology pitfalls and has suggestions for optimizing the communication strategies between the surgeon and the radiologist to find a missing item. A raytex sponge in the mediastinum is frequently missed if it is in a posterior position and intra-operative x-rays are notoriously difficult to provide clear images. If the intra-operative images are negative and of sub-optimal quality and the sponge is not found, it’s best to get better postoperative images in the radiology department when the patient is stable or get a CT scan. The Radiologist can provide the best advice for alternative projections or techniques to assist in finding MSI. Last, the most common radiologist error is to call what turns out to be a retained lap pad, “a drain”. It’s a characteristic of what the lap pad marker looks like. Best practice is to get two views and see if the radiopaque density crosses a skin fold. A drain will always cross a skin fold, but the marker of a lap pad will be the signal that there is a retained sponge. Big difference.
Attachment A

ELECTRONIC MEDICAL RECORD TRANSLATOR

Many different Electronic Medical Record (EMR) systems have hardwired the Surgery Operative Reports with non-adjustable fields into which circulating nurses have to enter the Surgical Counts. This “translator” is a guide to help OR personnel use their existing EMR fields in a consistent way which is compatible with the Sponge ACCOUNTing System terminology as discussed in this policy. These are just a few examples but serve to show that each facility will have to look at the EMR Count fields and make it clear to all OR personnel what each hardwired count field is asking.

A. Cerner EMR count fields:
Here are two screen shots of a well designed Cerner Count Field and Drop Down Menu which shows the 6 counts and the 4 classes of surgical items to count equally represented.
If there is an Incorrect Count, this is indicated by selecting “NO” to the Statement “XXXX Count Correct” then these are the Drop Down Menus:

### Action Taken Drop Down Values

<table>
<thead>
<tr>
<th>Incorrect Sponge Count Action Taken:</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Search Area</strong></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Incorrect Small Misc Item Count Action Taken:</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Search Area</strong></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Incorrect Sharp Count Action Taken:</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Search Area</strong></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Incorrect Instrument Count Action Taken:</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Search Area</strong></td>
</tr>
</tbody>
</table>

### B. Meditech EMR count fields

#### Nursing Interventions

<table>
<thead>
<tr>
<th>Count</th>
<th>Staff 1</th>
<th>Staff 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>1&lt;sup&gt;st&lt;/sup&gt; Count</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2&lt;sup&gt;nd&lt;/sup&gt; Count</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3&lt;sup&gt;rd&lt;/sup&gt; Count</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4&lt;sup&gt;th&lt;/sup&gt; Count</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- Surgeon Notified of Count: ◯ Yes ◯ No ◯ Not Applicable
- X-ray Taken: ◯ Yes ◯ No ◯ Not Applicable
- Operative CDS 1: Before pt leaves procedure room
- Operative CDS 2: OR TEXT
- Dressings
The designation of these existing Meditech hard-coded fields with the Sponge ACCOUNTing nomenclature is:
INITIAL count = 1st Count
CLOSING count = 2nd Count
FINAL count = 3rd Count
The 4th Count would be used if there was closure of a cavity within a cavity or if there was a count performed at a permanent change of shift or at other times as determined by the OR team.

C. Paper intraoperative records should specify the primary counts as:
INITIAL
CLOSING
FINAL
And additional counts as:
Cavity
Permanent Relief
Anytime
These counts should be included for each type of surgical item e.g. sponge, sharps, instrument, small miscellaneous item.
Attachment B
INCORRECT FINAL COUNT REPORT

Pt Name ______________________ Mr# _____________________ Date ____________

Complete an electronic ERS report and this paper report and submit to Nurse Manager. Have the
forms in the OR or in an electronic format that can be readily obtained.
(check all those that apply):

– Surgeon present in the OR
– Nurse manager present in the OR
– Count repeated
– Sponge holders checked to make sure only ONE sponge per pocket
– Surgical scrub person checked all sterile areas
– Circulator searched linen, drapes, floor, trash and room
– Visitors contacted
– Pathology specimens, newborn to nursery verified there is no included item
– Small needle (<15mm) in large cavity, needle not found
– Non-radiopaque surgical item not found
– Intraoperative x-rays obtained
– Type of missing item specified on x-ray request
– Full extent of wound included on x-rays
– Two views (AP and oblique/lateral) obtained
– Radiology readback verification of results for specific item
– Clinical decision by surgeon not to retrieve device fragment or item
– Extreme Emergency Condition and counts aborted
– Therapeutic Packing Performed –
  o _________ (type of sponge) is in the patient
  o _________ (number of sponges) are in the patient (if known… don’t guess!)
  o _________ (when) patient will be brought back to OR (if known)
– Additional X-rays to be ordered at next level of care (e.g. CT scan)
– Surgeon verbally notified that surgical item (e.g. sponge, needle, SMI) never found
– Event reported through Event Reporting System
– Risk manager notified
– Patient disclosure rules reviewed
– Counts and actions taken documented in medical record

Follow-up Required: ____________________________________________________________
____________________________________________________________________________
____________________________________________________________________________

e.g. Nurse Manager will follow-up on when return to OR is expected
Surgeon will dictate events in Operative Report
Risk Manager will report to regulatory agencies
Patient disclosure discussion by surgeon will be held
Next level of care X-rays will be ordered, obtained and read by a radiologist
Surgeon verbally notified of X-ray results
Staff discussion of case to be held at next educational session
Attachment C

MISCOUNT REPORT
(Print on one two-sided page)

A miscount is a type of an incorrect count. The hallmark of a miscount is that the count is reconciled and whatever situation was present (too many or too few) the problem is resolved. This situation is also present with the identification of “bad packs” or device defects that are resolved. If the item is never found then this is an incorrect final count, not a miscount.

Use this report for miscounts.

There are usually two kinds of MIScounts that have been recognized through practice observations:

- MIStaken count – a mistake is made in the counting of the sponges. There may be more or less than the expected number. Upon examination (perhaps two had stuck together, or there were two in one pocket, or there was a bad pack of sponges) the error is identified and the count is reconciled.

- MISsing item – when the count identifies that the number of sponges in use is less than the number recorded on the dry erase board. A sponge is missing. Usually a search is undertaken, x-rays may be obtained and after finding the sponge, a recount is performed and the count is reconciled.

Both of these types of miscounts should be internally reported and discussed, however there is usually a lot of pushback from nursing that the MIStaken count happens so frequently that they would always be filling out reports (isn’t that a problem?) but the second type, the MISsing item should most certainly be discussed, especially if an x-ray has been ordered. We refer to these second types of events as Missing Surgical Items (MSI) and have outlined radiology actions to improve detection (Attachment G). Also we want teams to use the Incorrect Count Checklist (Attachment N) which should be on the wall in every OR to help follow best practices to find the missing item.

Miscounts are “close calls” and can provide learning opportunities. They can be signs of a vigorous process or they can be signs of practice problems. When miscounts occur frequently in an OR these are practice problems. Frequent miscounts can lead to the expectation that miscounts become the norm, since they “happen all the time”. This may lead to normalization of deviance and is a contributing factor to retained surgical sponge occurrences. At a minimum, any time an x-ray is obtained to find a missing item a miscount report should be completed and provided to the nurse supervisor/manager.
MISCOUNT REPORT
(For OR quality improvement use only. Complete after every case with a discrepancy/missing item in surgical counts especially if an x-ray was taken. Review with nurse manager on day of event)

Patient Name: ___________________________________ MR# _________________________________
Date: __________________________ OR#: __________
Operation: __________________________________________________________________________

Surgical Team Members: __________________________________________________________________

Scrub/Circulating Team (specify relief):
1. ___________________________________ 2. ___________________________________

MISSING/MISCOUNTED ITEM:
Sponge (type e.g. lap, raytex, cherry, tonsil, etc.) ______________________________

Sharp/Needle (specify needle size in mm) ___________ Instrument ___________________

Number of the item(s) recorded on board at IN count: ________________

Number of item(s) at the count when found missing (or extra): ________________

ACTION:
Areas Checked:
Sponge Holders ☐ Yes ☐ No
Sterile Field ☐ Yes ☐ No
Floor ☐ Yes ☐ No
Garbage ☐ Yes ☐ No
Laundry ☐ Yes ☐ No
Other places: __________________________________________________

X-rays taken? ☐ Yes How many views? _____ ☐ No (why not?) ____________________
Methodical Wound Exam performed? ☐ Yes ☐ No (why not?) ____________________
Why did this happen?
_______________________________________________________________________________________
_______________________________________________________________________________________
_______________________________________________________________________________________

What can be done to improve practice so it doesn’t happen again?
________________________________________________
________________________________________________
________________________________________________
Attachment D

Action Plans Concerning:
Small Miscellaneous Items (SMIs), Devices & Unretrieved Device Fragments (UDFs)

PRIMARY STRATEGIES TO PREVENT RETENTION
SCRUBPERSON:
- Standardize the back table
- Maintain active engagement in surgical item management
- Manage the SMI count with the circulating RN using the wall mounted dry erase board
- Check the condition of all items passed to and returned from the incision onto the field
- Speak up and question if something is amiss

DOCTOR:
- If something does not look, feel or sound exactly right with an instrument or device, S.T.A.R. (stop, think, act, review) before proceeding with the use of the device
- In every operation, BEFORE closing the incision or wound, perform a Methodical Wound Exmination (MWE).

WHEN A DEVICE (e.g. guidewire, stent, introducer) IS RETAINED OR IF A BROKEN PART OR PIECE OF A DEVICE OR SURGICAL ITEM IS RETAINED (i.e. an UDF); IF THE DOCTOR WILL NOT REMOVE IT BECAUSE THE RISK OF RETRIEVAL > THE RISK OF REMOVAL THEN -

SECONDARY ACTIONS TO MITIGATE HARM:
SCRUBPERSON/CIRCULATING NURSE:
INCIDENT REPORTING
- Collect all available parts of the broken item
- Sequester them, do NOT throw them away
- Get an x-ray of the site (to document the UDF’s position); if fluoroscopy is used save a permanent image to the file
- Notify the radiologist what is being looked for so the information will be dictated into the radiology report
- Save the original packaging with information about the item (e.g. model, lot, serial #’s)
- Obtain an unbroken item for comparison with the damaged goods (this will help determine the size of the retained fragment; especially helpful for UDF’s that won’t show up with x-ray)
- Complete an incident report and move the information up the chain of command
- Report to the FDA/Med Sun system if related to device malfunction

DOCTOR:

PATIENT DISCLOSURE
- Advise the patient of the existence and nature of the UDF (consider showing them what the item looks like)
- Include the following information:
  - material composition of the UDF,
  - the measurement/size of the fragment,
  - where it is in the patient’s body/locaton,
  - x-ray findings with interpretation
- Discuss the potential for injury e.g. migration, infection, embolization, thrombosis
- Discuss any procedures or treatments that should be avoided or should be obtained
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 preserve 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) have been placed in the holders. 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 (fixed 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 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 folded 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 holders full of sponges. The final count can only be correct if 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 all 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. As a permanent change of relief, the number of sponges in the holders 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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Attachment F

DOCTORS CLOSING COUNT

Don’t Just “Swish or Sweep”, perform a Methodical Wound Examination (MWE) in Every Case

The goal is to get all the sponges OUT so they can be accounted for

1. A methodical exploration of the operative wound must be conducted prior to closure in every operation. The space to be closed must be carefully examined. Special focus should be given to closure of a cavity within a cavity (i.e., heart, major vessel, stomach, bladder, uterus, and vagina). Surgeons should strive to SEE and TOUCH during the exploration whenever possible; reliance on only one element of sensory perception is usually insufficient. Before closing, the surgeon should first make a best effort to remove all sponges, then the nurse and scrub person will count them and feedback to the surgeon if all have been accounted for. If told later that there is a missing sponge, always repeat the MWE before obtaining x-rays.

In MIS cases a methodical visual inspection of the operative cavity is required before camera removal. In eye cases a MWE is performed using the operative microscope.

The general process is to look and feel in the recesses of the wound and examine under fatty protuberances and soft tissue appendages.

Unless clinically contraindicated for a specific patient, the following steps should be taken for procedures performed in the abdomen or pelvis.

a. Examine all four quadrants of the abdomen with attention to:
   i. Lifting the transverse colon
   ii. Checking above/around the liver and above/around the spleen
   iii. Examining within and between loops of bowel
   iv. Inspecting anywhere a retractor or retractor blades were placed
b. Examine the pelvis
   i. Look behind the bladder, uterus (if present) and around the upper rectum.
   ii. The vagina should be examined if it was entered or explored as part of the procedure.

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

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

b. In a cardiac procedure, elevate the apex of the heart and examine the retrocardiac space.

Examine the transverse sinus to the right and left of the aorta and pulmonary artery.

c. In a thoracic procedure, examine the thoracic cavity with attention to the thoracic apex and base of the lungs, paravertebral sulcus, and inferior recesses of the clavicles. Place a hand or finger behind the lung and palpate from apex to base.

FINAL COUNT

At the final count the doctor or designer should look at the holders with the nurse to see that there are no empty pockets (2 person confirmation). If all the sponges are in the holders then there can’t be any left in the patient. This is the true meaning of a “correct” count.

Sponge ACCOUNTing System

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MISSING SURGICAL ITEM (MSI) – Radiographic Exams

Upon identification of a missing surgical item, the Surgeon or Nurse will order a specific STAT X-Ray Exam e.g. MSI Chest, which will include the specific region of interest (ROI) as listed below.

<table>
<thead>
<tr>
<th>Exam</th>
<th>Views</th>
<th>ROI</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>MSI Cranium</td>
<td>AP &amp; Lateral</td>
<td>Top of skull to below mandible and bilateral skin borders.</td>
<td>Include Face and Neck if ENT surgery</td>
</tr>
<tr>
<td>MSI Chest</td>
<td>AP &amp; Oblique/lateral</td>
<td>Apices to costophrenic angles (CPA) and bilateral skin borders.</td>
<td>This may require more than one film for the AP projection. The Oblique may be a single 14x17 of the ROI</td>
</tr>
<tr>
<td>MSI Abdomen/Pelvis</td>
<td>AP &amp; Oblique/lateral</td>
<td>Diaphragm to pubis and bilateral skin borders.</td>
<td>This may require more than one film for the AP projection. The Oblique may be a single 14x17 of the ROI</td>
</tr>
<tr>
<td>MSI Vagina</td>
<td>AP &amp; Inlet</td>
<td>Inferior gluteus to above iliac crest and bilateral skin borders.</td>
<td>Inlet: Place 14x17 vertical with 25 degree caudal angulation. Special attention needed to avoid grid cut-off</td>
</tr>
<tr>
<td>MSI Extremity</td>
<td>AP &amp; Lateral</td>
<td>Include above and below ROI and bilateral skin borders.</td>
<td>Use large films. Order must be specific to ROI: LUE or LLE RUE or RLE</td>
</tr>
</tbody>
</table>

Most portable units have a maximum kVp of 90 – 120 and maximum mAs of 320. The xray source must be set at the safest distance to preserve the sterile field. Because of these limitations adequate images may be impossible to obtain in the morbidly obese patient. Image quality should be discussed with a radiologist. Two views must be obtained before an image can be called negative.
Attachment H

SPONGE ACCOUNTING FOR NON-OR AREAS

1. X-ray detectable raytex 4”x4” surgical sponges are used.
2. There should be a movable pole to hang the rack and a box of hanging blue-backed plastic sponge holders in each room. The pole should remain in the room at all times. The pole should not contain rungs for IV bags to hang from.
3. An easily visible small dry-erase board should be mounted in each procedure room.
4. Sponges are always opened and used in groups of ten.
5. The sponges are steriley opened on the procedure table when the procedure starts. The sponges in each package should be separated and counted by two people (“see, separate and say”). The number of sponges is documented on the dry-erase board.
6. As sponges are used they should be deposited back on the procedure table.
7. The procedural RN is responsible for ensuring that all of the used and unused sponges are placed in the hanging plastic blue-backed sponge holders at the end of the procedure. Even if only a few of the 10 sponges in the package are used, ALL of the sponges must go into the holders at the end of the procedure.
8. The pockets in the holder should be filled horizontally from the bottom pockets to the top “bottoms up”. This is so an empty pocket will be easy to see in the top of the holder.
9. At the end of the procedure, the proceduralist and/or second staff person must verify with the RN that all pockets are filled and the number of sponges in the holder agrees with the number of sponges documented on the dry-erase board. There should be “no empty pockets”.
10. Open a package of dressing sponges to cover the wound. Do not use surgical sponges as dressings because the radiopaque markers in the sponge may confound any subsequent post-procedure x-rays.
11. The full sponge holder should be taken down at the end of every case, discarded in a red biohazard bag and a new sponge holder put up for the next procedure.
Attachment I

SPONGE MANAGEMENT IN VAGINAL BIRTHS

1. X-ray detectable 4”x8” sponges, baby laps (4”x18”) or lap pads are recommended for use as sponges during vaginal births. Sponges are managed in multiples of ten. [see comments below]

2. There should be a movable IV stand to hang the dispenser rack and a box of hanging blue-backed plastic sponge holders in each labor room and the IV stand should remain in the room at all times. The stand does not have to be high nor contain rungs for IV bags to hang from. It can be discreetly placed near the foot of the bed.

3. An easily visible small dry-erase board should be wall-mounted in each delivery room.

4. Sponges are always opened and used in groups of ten.

5. Once the delivery has started the sponges are opened, separated and two people count them (“see, S-E-P-A-R-A-T-E and say”). The number of sponges is documented on the dry-erase board

   1. An alternative is to have the sponges added to the delivery table and counted by two people at the time the delivery table is set up. If the sponges are placed on the delivery table at the time of set up, this should occur in the delivery room. The table is covered with a sterile drape until needed. The number of sponges must be documented on the dry-erase board and the delivery table must not be moved from the original delivery room. The cart may remain covered no more than 2 hours.

6. As soon as the obstetrician or nurse midwife can, sponges should be removed from the vagina and deposited:

   i. into a container on the delivery table or
   ii. into a clear plastic bag in a ring-stand or
   iii. directly into the hanging blue-backed sponge holder

   Which of these options will be used must be determined by each facility and implemented as the standardized process used in all births.

7. The circulating RN is responsible for ensuring that all of the used and unused sponges are placed in the sponge holders. The sponges are added to the holders as they are used (not after all are “counted”) and it is better not to wait until the end of the birth but to continuously move the sponges out of the kick bucket or container into the holder. (Attachment E)

8. The pockets in the holder should be filled horizontally from the bottom pockets to the top “bottoms up”. This is so an empty pocket will be easy to see in the top of the holder.

9. At the final count, all the sponges must be in the pockets of the holders. Then the obstetrician and/or second staff person with the circulating RN, “shows us” that all pockets in the HBBPSH are filled and the number of sponges in the holder agrees with the number of sponges documented on the dry-erase board.

10. The full sponge holder(s) can be discarded in a red biohazard bag.

11. If there is evidence of bleeding after the birth, a vaginal pack with a radiopaque marker should be opened and used in the vagina as a pack or dressing. Follow the instructions below for guidance in prevention of a retained vaginal pack.

Here are two video links which demonstrate the practice and answer some FAQs:
Sponge ACCOUNTing for Labor and Delivery (Program)
http://trinityhealth.healthstreamvideo.com/medias/subbpva6bi
Sponge ACCOUNTing for Labor and Delivery (Frequently Asked Questions)
http://trinityhealth.healthstreamvideo.com/medias/wz1lh3hs0n
Attachment J

SAFETY RULES FOR ORIFICE (VAGINA) PACKING

1. A vaginal pack is considered a dressing and just like other dressings it is not to be included with the surgical sponges.
2. Use a cotton gauze vaginal pack that contains a radiopaque marker. Keep an unopened pack in the delivery area.
3. If the obstetrician determines that a vaginal pack is needed, the circulating nurse should open a package and give to the physician an x-ray detectable vaginal pack.
4. The obstetrician should place the pack and then must write an order in the medical record that vaginal packing was placed and when it is to be removed.
5. The L&D nurses should perform a verbal handoff to subsequent caregivers involved in the postpartum care documenting that a pack has been placed in the vagina and when it is expected to be removed.
6. The new mother is told that she has a pack in her vagina and that it will be taken out sometime before she leaves the hospital. The patient should be actively engaged in helping staff to make sure the pack is removed.
7. Use the attached Orifice Packing Hand-off Communication and Tracking Tool

COMMENTS

Labor and Delivery Practices
Consider using sponges in the vagina other than raytex 4x4’s. Small 4x4’s can be difficult for the MD to feel within a post-gravid vagina as they often ball up once they become saturated with blood. They have been extricated from the uterus since the cervix is open and because of their small size the new mother often doesn’t have good discrimination that something remains within the vaginal vault. Baby laps also called T-laps (4”x18”lap pads) are a nice option as they are narrow and the length of a standard lap pad. If needed during a perineal repair, the blue marker can be hung outside of the introitus making it easy to see the sponge and then to remove it.

Vaginal Pack Practice
Various institutions have rules on who can remove vaginal packing. If nurses are to remove the pack there must be a physicians order to do so. Often in retained vaginal sponge cases at the end of the delivery if there is some bleeding, the obstetrician has used a sponge from the delivery table and put it in the vagina without any specific order for how the sponge is to be removed. The obstetrician mentions to the nurse “don’t forget to take this out” but doesn’t write an order. There is no transmittal of the information to the next level of care by the nurses and the patient goes home with the sponge retained and returns later to the ER or office with a fever and foul discharge. This is a common scenario and the process outlined here makes the insertion of a vaginal pack an active, intentional action that requires two people rather than an afterthought or passive action.
Orifice Pack or Dressing Hand-off Communication and Tracking Tool

Packing is considered a dressing and requires instruction on safe management and timely removal. The goal of these instructions is to establish a clinical practice to ensure that orifice packing is removed as intended. The placement and presence of procedural packing must be communicated at each transition of care through removal or to discharge of the patient if packing is to remain in place. The patient or responsible family member should be informed of the presence of packing material and the plan for removal.

1. After placement of a pack the Physician will write an order in the medical record providing instruction on the management of the packing and specify when it should be removed.
2. The type, amount and location of the packing will be documented by the Circulating Nurse on the Packing Hand-off Communication and Tracking form on the reverse side of these instructions. This tool is to remain in the patient’s medical record.
3. The RN caring for the patient, in the area where the packing is first inserted will place a packing armband on the patient prior to the patient transferring to another area. The packing armband is a cranberry color with the words “Packing in Place”. The band will serve as a reminder to staff and to the patient that there is packing in place.
4. The patient and/or family must be informed of the presence of the packing and the intended disposition of the packing. The RN caring for the patient post procedure should provide education to the patient as to the care of the packing while it is in place. Both the MD and the RN should keep the patient informed as to the intended duration of the packing as the patient’s care progresses.
5. The packing armband is to remain on the arm until the packing is removed or the decision is made to discharge the patient with packing in place. The person removing the packing should also remove the armband.
6. When the packing is removed it should match exactly the description of the packing that was originally placed. If there is a discrepancy an x-ray of the area (using the MSI guidelines) should be obtained.
7. If packing is to remain in place at discharge then the MD must write an order and a progress note or discharge note with patient instructions for the plan of removal.
Orifice Packing Hand-off Communication and Tracking Tool

[ ] Physician order written for packing, who (MD or RN) will remove and when

<table>
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<th>Placement of Packing Material</th>
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<td>Unit of Packing Placement</td>
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Placement of Cranberry armband on patient and instructions given about packing

Date / Time Patient and/or Family Informed | Signature of Staff

Hand-off Communication (Tracking) at Transfer of Care

<table>
<thead>
<tr>
<th>Unit / Shift</th>
<th>Assessment/Status of Packing</th>
<th>Date/Time</th>
<th>Signature of Staff receiving the handoff</th>
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Removal of Dressing/Packing Material

<table>
<thead>
<tr>
<th>Date / Time</th>
<th>Location Dressing/Packing</th>
<th>Notes</th>
<th>Signature of Staff removing Packing</th>
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</thead>
<tbody>
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<td>[ ] Packing Removed – must match exactly what was placed – any discrepancy obtain an x-ray</td>
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<tr>
<td></td>
<td></td>
<td>[ ] Packing armband removed</td>
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</tr>
</tbody>
</table>

[ ] Physician order written to discharge patient with packing in place. Packing and removal instructions provided to patient:

Date / Time Patient and/or Family Informed | Signature of Staff
Here is a suggestion for optimization of use of this rather difficult process.

Make a “kit” for the OR. Bundle together vaginal packing of choice, the packer tracker and the armband so when a doctor orders orifice packing (usually it is for the vagina, but can also be for high nasopharyngeal packing), the circulating nurse doesn’t have to run all over the place to find each component individually. Have them in a bin in the OR or in the sterile core (how about right next to the other surgical sponges). When needed, the circulating RN gives the doctor the packing, documents information on the packer tracker and puts the armband on the patient. Then he/she enters comment in the nursing intraoperative record and perform a handoff to the next nurse in the PACU. The packer tracker moves with the patient. The paper packer tracker can be pinned to the patient’s gown or fold it up and pin to the armband so it stays with the patient. Not using paper anymore? This is a difficult process to get all the pieces right in the EMR but we have a number of systems that have executed this in Cerner. Reach back to me and I can share.
Attachment K

SURGICAL TOWEL MANAGEMENT

1. Whenever possible if white surgical towels will be used during a case they should be opened at the initial count performed before the patient enters the OR. If it is not known if a particular surgeon uses surgical towels, packages of sterile surgical towels should be available in the OR.

2. The white surgical towel count will be documented on the dry erase board. The white surgical towels will be counted and documented in the unit of issue which is usually 2, 4 or 6.

3. A distinct name is recommended for a white surgical towel so when written on the board they will not be confused with drape towels. It is not advised to just write “towels” on the board. Names which could be used are:
   - surgical towel
   - radiopaque towel (abbreviated ROT)
   - white surgical towel

4. Surgical towels will be counted at each of the IN and OUT counts when sponge counts are performed.

5. At the closing count all the surgical towels should be removed from the patient and counted out. At the final count all the surgical towels should be on the back table or in an appropriate receptacle.

6. Surgical towels will not be cut or altered but will remain in their original configuration.

7. Surgical towels should not be used inside of patients for therapeutic packing, lap pads should be used. The x-ray markers of lap pads are well known and larger than the markers in radiopaque towels.
Attachment L

ELECTRONIC DEVICES FOR SOFT GOODS MANAGEMENT

2D MATRIX LABEL SPONGE COUNTING SYSTEM PROTOCOL

Verify that a back-up battery is present in every charger in every OR and that the battery is charged or charging at the beginning of the day. If the battery runs low, replace with a charged battery.

The scanner can be removed from the holder on the IV pole to scan the patient ID band only. The scanner must be remounted on the IV pole and remain in the IV pole holder throughout the procedure. All sponge material tags and towels must be scanned in and out with the scanner on the IV pole. The object to be scanned must be brought to the scanner NOT the scanner brought to the object.

Count IN:
During the baseline count, the sponge’s master tag is scanned in by the scrub person. The master tag is then removed. Do not remove the master tag from the sponge material before scanning. Any soft goods that do not have a master tag (e.g. towels) must be scanned in individually.
Perform a manual count of the items.
When sponges are added after the baseline count, the master tag is scanned in by the RN circulator. The RN circulator performs this aseptically by opening the outer wrapper exposing the sterile contents and scanning the master tag. The sterile sponge material is then presented to the scrub person. If there is no master tag the scrub person scans the individual tag.

Count OUT:
A manual count is performed of sponges in the unit of issue.
The RN will scan out the sponge’s individual data matrix tag in the unit of issue. Only sponge materials that have been removed from the sterile field and manually counted first are scanned out. Put scanned sponge material in appropriate groups in hanging sponge holders before counting the next group of sponge material.
All sponges need to be scanned-out prior to procedure completion time or application of the sterile dressing
RADIOFREQUENCY (RF) WAND/MAT USAGE PROTOCOL

The following represents an RF wand process:
1. Remove all non-RF tagged sponges from every OR and surgical pack.
2. RF tagged sponges must be used on all cases.
3. The RF wand is used for all cases except in patients with pacemakers or ICDs because the RF wand may interfere with the working of the pacemaker or ICD.
4. Prior to the end of the procedure at the CLOSING count, before closing suture is passed, the circulator will calibrate the wand. The wand will be placed in a sterile plastic sheath and handed to the surgeon who will slowly and carefully pass over the incision site in the anterior and lateral planes per manufacturers operating instructions. This is a so-called e-MWE.
5. The RF wand does not replace the Sponge ACCOUNTing System process. All sponge counts will be performed per policy.
6. If the RF mat is on the OR table, the mat will be activated at the FINAL count of every case and it’s use documented in the medical record.
7. If the wand is used on more than one patient, it is to be cleaned between uses according to departmental policy with disinfectant wipe.
8. In the event an interim sponge count is incorrect and the sponge has not been found, the patient will be scanned and the RF wand will be used by the circulating nurse on all trash bags and peripheral locations until the sponge is located.
9. If the sponge is NOT located portable x-rays will be obtained of the operative wound using the MSI Radiology guidelines. (Attachment G). If the sponge is still not located the final count will be recorded as incorrect and incorrect final count procedures will be followed (see Attachment B).
10. The circulating RN will document in the intra-operative record when the RF wand is used.
Attachment M

CASES WITH AN ALTERNATIVE PROCESS IN LIEU OF AN INSTRUMENT COUNT

Include here a list of cases where an intra-operative x-ray will be obtained before the wound is closed and will substitute for an instrument count and/or include here cases where a Methodical Wound Exam/Back Table Review Protocol will be used

e.g. Total Hip Arthroplasty
Attachment N

YIELD
AND TAKE TIME TO RECONCILE AN INCORRECT COUNT

USE THIS INCORRECT COUNT CHECKLIST

SURGEONS

☐ Tell surgeon what type of sponge is missing

☐ Ask surgeon to repeat methodical wound exam

☐ Repeat the methodical wound examination, in a heart case check behind heart in posterior mediastinum

☐ Actively look and feel for missing sponge

☐ Repeat count

☐ Check holders to make sure only one sponge per pocket

☐ Search trash, linens

ADDITIONAL HELP

☐ Consider getting “another set of hands” to feel

☐ Call for personnel to search, call nurse manager

☐ Cover the wound with towel or plastic drape

☐ Scrub person search field and drapes

☐ Call for X-rays, get an AP and oblique view

☐ Call for X-rays, include call back info on requisition

☐ Tell radiologist what type of sponge is missing and in a heart case, to look in the posterior mediastinum

☐ Check sponge “departure” opportunities (e.g. went with newborn, around a specimen, anesthesia trash, morgue, around GI scope)

☐ A radiologist should review the film before it is called negative especially if sponge not found

☐ Contact visitors who may have left the room

☐ Check sponge “departure” opportunities (e.g. went with newborn, around a specimen, anesthesia trash, morgue, around GI scope)

☐ Contact visitors who may have left the room

IF SPONGE NOT FOUND:
• RECORD COUNT AS INCORRECT
• TELL THE SURGEON
• REPORT TO ADMINISTRATION
• DISCLOSE TO THE PATIENT

Sponge ACCOUNTING System

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SAFETY RULES FOR THERAPEUTIC PACKING

I. When surgical sponges are intentionally used for therapeutic intra-cavitory packing and the patient leaves the OR with this packing in place, this is NOT an instance of reportable retained surgical sponges.

II. 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.

III. The Sponge ACCOUNTing System will be used for the management of the sponges throughout the case. Do not abandon the practice.

IV. Standard lap pads (18x18”) opened during the operation should be used for packing. 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 (e.g. Quick Clot) inserted should be documented as well.

V. 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)

VI. 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.

VII. 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.

VIII. 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).

IX. 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 I). 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.

X. 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.
Attachment P

STATE REQUIRED REPORTING STATUE

[This is for the state of California, but insert the statute or “regulatory rules” here for your facility]

California Health Service Code 1279.1
Department of Health Services: Reporting and Inspection Requirements
General Acute Care Hospitals, Psychiatric Hospitals or Specialty Hospitals

Legislation enacted 2005-2006 Session

Effective January 1, 2007 SB 1301, Chapter 647 is an act to add Section 1279.1, 1279.2, 1279.3 and 1280.4 to the Health and Safety Code relating to health facilities.
The act among other provisions, would require the Department of Health Services to ensure that periodic inspection of health facilities are not announced, and inspected for compliance with state laws and regulations, no less that once every three years. If an inspection is conducted jointly with another entity that provides notification in advance, the Department will be required to conduct additional inspection that is not announced to the health facility.

The act, in addition requires a general acute care hospital, psychiatric hospital, or special hospital to report to the Department any adverse event within 5 days of its discovery.
If the adverse event is an urgent threat to the welfare, safety or health of patients, personnel, or visitors, the event must be reported to the Department within 24 hours of its discovery.
It requires DHS to conduct an onsite inspection or investigation within 48 hours of 2 business days of a complaint involving the threat of imminent danger of death or serious bodily harm.
The outcomes of the inspections would be required to be posted on the Department’s Internet Web Site.
It would also authorize the Department to assess civil penalties against a license for failure to report an adverse event.
The act adds Section 1279.1, 1279.2, 1279.2 and 1280.4, to the Health and Safety Code:

SECTION 1. Section 1279.1 is added to the Health and Safety Code, to read:
(a) A health facility licensed pursuant to subdivision (a), (b), or (l) of Section 1250 shall report an adverse event to the department no later than five days after the adverse event has been detected, or, if that event is an ongoing urgent or emergent threat to the welfare, health, or safety of patients, personnel, or visitors, not later than 24 hours after the adverse event has been detected. Disclosure of individually identifiable patient information shall be consistent with applicable law.
(b) For purposes of this section, "adverse event" includes any of the following:
   (1) Surgical events, including the following:
      (A) Surgery performed on a wrong body part that is inconsistent with the documented informed consent for that patient. A reportable event under this subparagraph does not include a situation requiring prompt action that occurs in the course of surgery or course of surgery or a situation that is so urgent as to preclude obtaining informed consent.
      (B) Surgery performed on the wrong patient.
(C) The wrong surgical procedure performed on a patient, which is a surgical procedure performed on a patient that is inconsistent with the documented informed consent for that patient. A reportable event under this subparagraph does not include a situation requiring prompt action that occurs in the course of surgery, or a situation that is so urgent as to preclude the obtaining of informed consent.

(D) Retention of a foreign object in a patient after surgery or other procedure, excluding objects intentionally implanted as part of a planned intervention and objects present prior to surgery that are intentionally retained.

(E) Death during or up to 24 hours after induction of anesthesia after surgery of a normal, healthy patient who has no organic, physiologic, biochemical, or psychiatric disturbance and for whom the pathologic processes for which the operation is to be performed are localized and do not entail a systemic disturbance.

Position Statement: Adverse Events Which Include Retained Foreign Objects – Retained Fragments From A Broken Needle Or Screw
From Kathleen Billingsley, Deputy Director, Center for Health Care Quality, California Department of Public Health, Position Statement, March 30, 2010:
Adverse events which include retained foreign objects are defined in the Health and Safety Code (HSC). Specifically, HSC Section 1279.1 (b) (1) (D) states, “Retention of a foreign object in a patient after surgery or other procedure, excluding objects intentionally implanted as part of a planned intervention and objects present prior to surgery that are intentionally retained.”

In some surgical procedures, fragments from a broken needle or screw may be retained within the patient. The physician makes a clinical judgment at the time of surgery to leave the fragment within the patient as the relative risks outweigh the removal of the foreign object. CDPH requires facilities to report even these types of retained objects wherein the physician makes a clinical decision to retain the object; however, the CDPH may not issue a deficient practice relative to an adverse event.
Billingsley, Kathleen (CDPH-L&C)
Attachment Q

WHAT TO DO WITH A RETRIEVED RSI

On occasion an OR team may have to remove an RSI that was left at a previous operation. Once the item has been retrieved the best practice is to submit the specimen or retained item to pathology. If it is just the retained surgical item label it for “gross only”. The pathologists should dictate a description of the item, measure it and describe any findings and document this information in the patient’s medical record in a pathology report.

The patient should not be charged for the pathology interpretation if the operation in which the item was retained occurred at the same hospital. Many hospitals have a separate billing code for these circumstances and the code is also used for the billing of intraoperative xrays taken to find missing items during OR cases.

The reason to send the item to pathology is primarily for documentation of the exact retained item by an outside objective party should reporting, epidemiological or legal action be pursued. On occasion patients have walked into the ER carrying objects that have fallen out of them or they have discovered within them. Additionally physicians have removed retained surgical items in other non-OR settings and they often don’t know what to do with the object. Discarding the item without some form of documentation or specification of the item is a disservice to the patient and hospital and can compound the initial injury.