POLICY
NoThing Left Behind®:
Prevention of Retained Surgical Items Multi-Stakeholder Policy

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NoThing Left Behind® is a National Surgical Patient Safety Project to Prevent Retained Surgical Items 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 using the Sponge ACCOUNTing System, one of the deliverables of the NLB project. Soon to be 10 years, we work primarily with hospitals and interested healthcare entities to prevent patient harm from inadvertent retention of surgical materiel. 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 tools.

For the prevention of retained surgical sponges the essential change for surgeons is to perform a methodical wound exam before closing every wound and that includes the vagina after a birth. For nurses, the essential change is to not just “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 behavior change to actually use these safe practices will prevent patient harm. Our work continues in the study of best practices for the prevention of retained small miscellaneous items and device fragments, sharps/needles and instruments.

This policy represents the best, safest, rational and most reasonable set of current practices ever assembled. 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, 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 is a result of reading many OR policies from around the country as well as focused reviews, root cause analyses and studying clinical cases where there have been retained surgical items. Additional information has been obtained from talking with OR personnel and observing hundreds of cases during the work NoThing Left Behind® has been engaged in since this project began. This document was sent out and reviewed by many, is being used in many hospitals and represents what I think, can be ideal and 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 first 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 have been some wording changes for clarification throughout the document and conceptual changes discovered through watching practice which have lead to enhanced policy directives. These include significant changes to the sections on:
- Therapeutic packing of soft goods
- Instrument counts
- The Missing Surgical Item (MSI) imaging primer for safe intraoperative x-rays
- Monitoring and Education with emphasis on sharing knowledge and information through in-services, newsletters and meetings held and disseminated on a regular basis throughout an organization. Shared learnings (we call it Collective Wisdom) are important when dealing with rare
events so people can learn quickly from the experiences of other. In this way each individual doesn’t have to have an event “happen to them” before they will move to change unsafe behavior.

If this is your first view of this policy - what’s different? To name but a few things:
- Multi-stakeholder safety rules for all content experts in surgical item management - nurses and surgical technologists, surgeons, radiologists and radiology technologists, anesthesiologists
- Clearly defined collaborative actions for these content experts to follow
- Clear definitions of what the IN and OUT counts (Closing versus Final count) are, a frequent source of communication failure. These are fully consistent with AORN definitions
- The Sponge ACCOUNTing practice incorporated into the body of the policy – as an example of how a specific practice (process steps that people follow) should be incorporated in policy so there is a standardized process used by everyone the same way. The intent is to remove variation in practice so you can see defects in the process as it’s being used and prevent harm or if error does occur analyze when and how the mistake or slip occurred.
- Sponge ACCOUNTing for Labor and Delivery and Non-OR areas (e.g. cardiology suites)
- Methodical Wound Exam guidelines
- A sample Incorrect Final Count report
- Electronic medical record translator
- Definition of when a surgical item is considered retained and therefore a reportable event
- State and regulatory reporting rules
- Needle count practice with X-ray exclusions
- Miscellaneous small item and device fragment safety rules
- Protocols for use of New Technology sponge tracking devices
- Ten “Points of Discussion” to enhance understanding and implementation

While the entire policy is more than 50 pages it is designed to be flexible for individual site use. The intent is to have a powerful resource of all the necessary information in one place. It is strongly discouraged to pick and chose within Parts I-X individual things that a site might like because there is tightly linked internal consistency and the policy and safety rules represent best practices when considered all together. There are parts (Attachment G) which require individual site-definitions be developed. In the points of discussion section the tone is anecdotal. This information is from front-line communications and represents one kind of evidence. It is worthwhile to remember that there is experimental evidence but experiential evidence is also important and valid.

This policy resides in the OR but is beyond a “counts” policy which directs the actions of hospital nursing and surgical technologist activities. It is multi-stakeholder 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 engagement is required. The means of policy approval will have to be determined by each facility.

I hope you find this document useful and that it will help your organization provide a safe operative experience for all patients so we can make sure there is……. “NoThing Left Behind”.

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PREVENTION OF RETAINED SURGICAL ITEMS POLICY

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SAFETY RULES, PRACTICES AND POLICY DIRECTIVE

I. PURPOSE:

A. To provide safety rules for perioperative registered nurses and surgical technologists in the performance of sponge, sharp, instrument and miscellaneous item counts.
B. To provide safety rules for surgeons in the performance of a methodical wound exam and actions to prevent unintentional retention of surgical items.
C. To provide safety rules for radiology technologists and radiologists in the performance of intra-operative x-ray examination and information to aid interpretation and readback of intra-operative x-rays.
D. To provide safety rules for anesthesiologists and anesthesia personnel in preventing unintentional retention of surgical items.
E. To encourage and support all efforts to improve OR teamwork.
F. To assist in accounting for all surgical items and minimize inventory loss.

II. BACKGROUND:

Good 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 sponges, needles, instruments or other miscellaneous items inside of patients (retained surgical items - RSI) is a preventable event. An RSI is a surgical patient safety problem. These events occur because of problems in communication between medical personnel and faulty OR and procedural practices. To prevent RSI it is important to implement policies that change practice with an understanding of human error and human fallibility in perception and risk assessment. This policy 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 – matériel (supplies, devices, equipment) used in and around a surgical incision or wound, to aid in the performance of the operation or procedure, to provide exposure and to absorb blood and other body fluids.

There are four (4) classes of surgical items:

1. Soft Goods are cotton, disposable cloth or gauze items of various sizes used as dressings (note: packs are considered dressings), drapes and adjuncts to an operative procedure. Within the category of soft goods are surgical sponges and surgical towels (16”x26”), which are white soft goods which contain a radiopaque marker and are used within the surgical wound. These include but are not limited to: laparotomy pads (18”x18”), mini laps (12”x12”), baby laps (4”x18”), raytex (acronym for radiopaque textile) 4”x4” or 4”x8”, tonsils/rondics, peanuts/kittners, cottonoids/patties.
Blue, green or natural colored 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 counted.

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

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, needle holders, malleable/ribbon retractors, scissors.

4. Small miscellaneous items 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 may include but are not limited to: bovie scratch pads, vessel loops, rubber shods, suture booties, umbilical tapes, laparoscopic trocars, disposable instrument inserts, cotton-tip applicators, marking pens, suture reels, screws, nails, safety pins, ligaclip bars, bulldogs, vascular inserts, nuts and bolts. This category also includes device fragments and separable parts of surgical tools (e.g. drill bits) which may become retained.

**B. RETAINED SURGICAL ITEM** – an item that was not intended to remain in the patient, is found in any part of the patient’s body, after the operation, vaginal birth or procedure ends. The operation ends after all incisions or procedural access routes have been closed in their entirety, devices have been removed, final surgical counts have concluded and the patient has been taken from the operating/procedure room. A vaginal birth ends when the mother is in the immediate recovery period (1-2 hours post birth). A procedure ends when all materiel have been removed from the patient regardless of setting (e.g. post anesthesia recovery unit, cath lab, radiology suite, surgical suite, endoscopy unit). [A retained surgical item is considered a “never event”, is generally considered to be preventable and is a reportable adverse event. 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”). 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. The surgical count is performed to identify any packaging errors and to monitor the number of items used during the operation or procedure.

**D. MEDICAL RECORD** – The permanent paper or electronic record of an operation or procedure

**E. EXTREME EMERGENCY CONDITION** – 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 and this must be documented in the medical record by the circulating nurse.

**IV. SCOPE AND APPLICABILITY:**

This policy 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 spontaneous vaginal birth see Attachment C) and surgical items are used in or on a patient (see Attachment D).

**V. DOCUMENTATION AND COLLECTIVE WISDOM:**

A. A registered nurse is responsible for medical record documentation.
B. Specific terminology for sponge, sharp, instrument and small miscellaneous item counts will be used in the medical record depending on the vendor or format of the operation or procedure report as outlined in Attachment A.
C. Counts and other required information should be entered 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.
D. If any count is not performed according to policy the rationale must be documented and primary decision-maker identified e.g. surgeon declared case an extreme emergency condition and no final count was performed.
E. The final count can only be recorded as CORRECT or INCORRECT.
F. In the instance of an INCORRECT final count the circulating nurse will speak to the charge nurse immediately at the end of the case and an INCORRECT FINAL COUNT REPORT will be written in the Event Reporting System (ERS) or as a paper addendum to the electronic ERS. The report will outline all the action steps that were taken as outlined in Attachment B.
G. If a package of any surgical item is found to be defective when opened (e.g. wrong number, damaged, contaminated) the package and its contents will be removed immediately from the field, placed in a plastic bag, labeled and taken from the operating room. The charge nurse should be notified and the packaging error documented. The inventory information should be given to supply purchasing for notification of the distributor and staff should be told about the packaging error at staff educational meetings. It is important to share information about these “bad packs” to inform personnel about the frequency of these events which may alter their perceptions that bad packs are rare. Bad packs 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.
H. 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. The charge nurse should be notified and the device or equipment malfunction documented and reported through manufacturer and regulatory reporting systems.
VI. NURSING and SURGICAL TECHNOLOGIST PROCEDURES and SAFETY RULES:

A. THE SURGICAL COUNT:

1. The IN Counts are
   a. Initial baseline count conducted before the case begins
   b. Count conducted whenever new items are added into the field

2. The IN 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

3. Whenever possible the initial IN counts will be performed before the patient enters the OR. Initial counts must be completed before the Time Out is performed or the incision is made

4. The OUT Counts are
   a. Interim Count:
      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 to close a space is considered a cavity count
      02. CLOSING Count – count performed before wound closure begins
      03. RELIEF Count – count performed at the time of permanent relief of either the scrub person or circulating nurse.
      04. ANYTIME Count – count performed at the discretion of any member of the OR team.
   b. The Final Count:
      FINAL Count – count performed after skin closure, 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.

5. The OUT counts will be performed in the following sequence each time:
   a. Surgical site
   b. Sterile field
   c. Mayo stand
   d. Back table
   e. Kick buckets or ring stands or containers which hold discarded items
   f. Holders or counter boxes
   g. Safe repository where dropped or contaminated items have been placed

6. If a discrepancy occurs at the final count and the item is never found this is an INCORRECT final count and documentation of an INCORRECT final count must be followed (Attachment B).

7. If a discrepancy in a count occurs at an interim count and this discrepancy is reconciled this is a MISCOUNT.

8. 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 E). [Miscounts are “close calls” and can provide learning opportunities. See Point of Discussion #2]

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

10. Separate counts should be maintained for separate procedures. A separate procedure is one in which there is a separate case number. A single case could have multiple parts or
multiple incisions but if coded as one case it should have one set of final counts for the case [For clarification see Point of Discussion #3]

11. 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 operation ends.

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

13. Instrument counts will be recorded on the preprinted instrument count sheets.

14. Personnel handling soiled items should always wear adequate personal protective apparel and utilize safe handling techniques.

15. All trash receptacles and sharps containers will remain in the OR until the conclusion of the case.

B. SOFT GOODS (SPONGE AND RADIOPAQUE TOWEL) COUNTS

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. [See Point of Discussion #4 for additional information about red biohazard bag use.]
   b. All cotton gauze disposables placed in the patient will be white surgical sponges or white radiopaque towels and may contain a separate identifiable label or tag. [See Point of Discussion #5 for additional information about why white?]
   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 increasing complexity. Cutting off the radiopaque marker or tails negates the safety adjuncts put on the sponges to prevent loss or retention.
   d. Effort should be made to minimize the number of different types of surgical sponges used during a procedure.
   e. Small surgical sponges e.g. peanuts, cottonoids should be passed to the surgical field on an instrument.
   f. A standard practice should be used to account for the small surgical sponges.
   g. Blue, green or beige drape towels should only be used on the field to drape the surgical incision. These towels are drapes and should not be counted.
   h. White radiopaque cotton surgical towels (ROTs) should be available if a towel is to be used intra-corporally or as a background during suturing on the field. These white ROTs must be counted in the unit of issue, the count written on the dry erase board and all the white ROTs accounted for at the final count. They are not placed in the hanging blue-backed plastic sponge holders (HBBPSH).
   i. White ROTs should not be used as drapes because if an xray becomes necessary at some time during the case the radiopaque markers in the surgical towels may confound the radiographic interpretation
   j. White ROTS should not be used for prolonged periods of time as a background for suturing because 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.
   k. A surgical sponge that is passed between the scrubperson 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; 4x4’s, 4x8’s, lap pads, mini laps or baby laps.

l. Free surgical sponges should be managed with the Sponge ACCOUNTing System.

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

n. Whenever possible, vaginal dressings (packs) and gauze dressings should not be on the back table. If part of custom packs they should not be opened until needed to insert or cover the incision. Having non-surgical sponges opened during a case is an unsafe practice, as these sponges may get mixed up with the surgical sponges and inadvertently end up in the patient.

2. SPONGE ACCOUNTING SYSTEM (SAS) FOR FREE SPONGES

a. Conceptual Framework

01. SAS 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 case in order to account for them.

03. Free surgical sponges are to be added to the field ONLY in multiples of ten and a two person “see, separate and say” IN count of the sponges must occur.

04. The most important step is to SEPARATE the sponges during the IN count.

05. Sponges are collected throughout the case, separated and put in HBBPSH.

06. All the sponges – the used and unused sponges - must be in the sponge holders at the end of the case to have a correct final count and be able to perform a team verification step (“show me”)

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 me” 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 holder does not agree with the number on the dry erase board.

c. Equipment and Supplies:

01. All ORs or procedure rooms will have a dry erase board someplace in each room where the 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 specific information.

02. Dry erase pens and erasers
03. Boxes of HBBPSH (not to be called “counters” – they don’t count or “bags” - the pocketed holders aren’t bags). Each holder contains 5 pouches. Each pouch has a thin center-divider that separates each pouch into 2 pockets. One sponge is placed in each pocket so one holder can hold 10 sponges.

04. 2-prong IV pole with adjustable height and movable wheels with a securely attached sponge holder rack and a sign “put sponges here”. The rack has a space for the box of sponge holders and has hooks on both sides of the rack on which to hang the sponge holders. One rack can usually accommodate 10 holders. The curved prongs on the top of the back of the sponge holder rack should go over the top of the IV pole (so 4 prong IV poles cannot be used) and the back clamps screwed tightly to the pole. This is to provide stability at four points to prevent sliding and wobble of the rack on the pole. Rack-holding poles should be used solely for racks and not used to hang IV bags.

d. Safety Rules for Use of Dry Erase Boards

01. The dry erase board is a communication tool.
02. Surgical items (other than instruments) used on the sterile field are recorded on the board in the designated areas.
03. Sponge counts for free sponges are always in multiples of 10.
04. The counts should be easily visible and legibly written in a horizontal superscript running total format \((10^{10} 20^{10} 30)\) or a vertical summation line running total format 10
   
   \[
   \begin{array}{c}
   10 \\
   20 \\
   10 \\
   30 \\
   \end{array}
   \]

No extraneous markings in the running total should be made (e.g. + signs, slashes, X’s, circles, initials). All ORs 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.
06. The process is standardized throughout all operating/procedure/birthing rooms to provide consistency in all types of cases.

e. Practice for Use of HBBPSH

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 special racks attached to designated poles. 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 pads, one for raytex.
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 and then fold it up into an oval. Put the first sponge in the last pocket in the bottom of the holder. Load the holder horizontally from the bottom row to the top row, filling
first the bottom two pockets and continuing upwards (“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.

07. Place the folded sponge inside the pocket with the blue tag or blue stripe visible. The blue stripe must be visible because this is what differentiates a sponge with a radiographic marker (a surgical sponge) from a dressing sponge.

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.

10. Place one (1) sponge per pocket; two (2) sponges per pouch; ten (10) sponges per holder.

11. 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.

12. 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 above the holder which is full.

13. At the time of the final count, ALL sponges (used and unused sponges) MUST be in the sponge holders and two people viewing the sponge holders must make the final verification. The preference is to have the clinician who closes the skin verify with the circulating nurse 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 RN who was not involved in the case may substitute. The requirement is to have “new eyes” look at the holders and the dry erase board to minimize confirmation bias between the scrub person who counted in the sponges and the circulating nurse.

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 at the end of the case. 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 in their racks from the IV poles throughout the case. Poles will accommodate multiple holders per side. If a rack becomes full an additional IV pole and rack should be obtained. DO NOT take down the holders from the rack during a case. DO NOT roll them up, put in plastic bags or initial them. The final count must have visual confirmation of all sponges in the holders to ensure that each holder is fully loaded with 10 sponges.

17. Place all the sponge holders in a plastic bag for disposal 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 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 surgeon and nurse can then visually verify that all sponges have been accounted for and none remain in the patient. [See Point of Discussion #6 on the “Pauze for the Gauze” and the “Show Me” steps]
3. SAFETY RULES FOR THERAPEUTIC PACKING:

a. 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 a reportable retained surgical sponge.

b. The number and type of surgical sponges intentionally left within the patient should be documented in the medical record if known. There will be empty pockets in the sponge holders so the final sponge count should be marked as incorrect and an incorrect final count report completed (see Attachment B).

c. The number and type of surgical sponges used for therapeutic packing should be included in the information transmitted at the transfer of care if known.

d. At the subsequent procedure(s) when the therapeutic packs are removed the sponges (usually lap pads) should be placed in a separate sponge holder.

e. At the takeback procedure the number of surgical sponges removed can be reconciled with the documentation from the original procedure count (if known).

f. At the last procedure when no further packing will be performed and wound closure is planned, intra-operative x-rays of the complete surgical wound (see MSI guidelines Attachment F) should be performed at the closing count (before wound closure) to confirm that all surgical sponges have been removed.

g. If the intra-operative x-rays are negative after review by a radiologist and all the surgical sponges from the last operation have been accounted for, the final sponge count for the case should be documented in the medical record as correct.
C. SHARPS AND NEEDLE COUNTS

1. COUNTING SHARPS
   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. Whenever possible, sharps must be handed to and from the surgeon on an exchange basis using a “Neutral Zone” or “Hands Free” technique to minimize needlestick injuries.
   c. Management of all sharps on the sterile field is continually maintained by the surgical scrubperson.
   d. Sharps must be counted on all procedures.
   e. Sharps counts must be taken:
      01. at the INITIAL count
      02. at the CAVITY count,
      03. at the CLOSING count,
      04. at the RELIEF count and
      05. at the FINAL COUNT.
   f. When additional sharps are added to the field, they are recorded on the count board. A running total format is used throughout the procedure.
   g. 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 scrubperson 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.
   h. Sharps broken during a procedure must be accounted for in their entirety.
   i. At the end of the case sharps must be contained in puncture resistant containers to ensure safe disposal.

2. COUNTING NEEDLES
   a. Suture needles must be counted according to the number marked on the outer package and verified by the surgical scrubperson and circulating nurse when the outer package is opened.
   b. A disposable puncture-resistant needle counter should be used for containment of used needles and sharps. Used needles should be put in these 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 box which is designed to aid in the organization and correct counting of the needles e.g. a full 20 slot needle box should not have more than 20 needles in it.
   c. Use 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.
   d. 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 scrubperson 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.
   e. 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 on one side of the needle box and small needles on the other side.

f. Refer to needles by the size of the needle, not the size of the suture the needle is swedged on to.

g. If a needle <15mm is missing in a large cavity case, after a thorough search of the wound and sterile field an x-ray is not required. The final count for sharps and needles will be recorded as incorrect and the procedures outlined in this policy for an incorrect final count followed. (see Attachment B)[see Point of Discussion #7 for the rationale of this needle size cutoff]

h. The needle packages should remain in a small 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.
D. INSTRUMENT COUNTS

1. COUNTING INSTRUMENTS
   a. Instrument counts will be performed on:
      01. All abdominal/pelvic cases.
      02. All chest cases.
      03. All cases where an incision is made that is greater than the size of any instrument used
   b. 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 or has an incision made which is greater than the size of any instrument used, should have complete instruments counts performed.
   c. Only two instrument counts are required; 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 the beginning of wound closure and must be completed before the patient leaves the OR or procedure room. [see Point of Discussion #8]
   d. The initial count will be documented on the preprinted count sheets to verify that what is on the instrument trays as assembled by sterile processing agrees with what is present in the sets at the start of the case.
   e. Like instruments should be consolidated prior to counting.
   f. Any additional instruments opened during the procedure will be counted and added to the preprinted count sheet or written on the dry erase board.
   g. All counted instruments must remain in the room so they can be accounted for at the end of the case.
   h. If an instrument is contaminated it should be shown to the surgical scrubperson and if not needed, secured and remain in the room.
   i. If instruments have multiple parts, all pieces must be accounted for.
   j. If the surgical scrubperson receives an instrument back missing a part or is broken, the surgical scrubperson must speak up and tell the team to look for missing pieces

2. MANDATORY X-RAY IN LIEU OF AN INSTRUMENT COUNT:
   a. In specified cases (See Attachment G) 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, 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-ray 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 should be obtained.

h. The x-rays must include the full surgical field.

i. A radiologist must review the image and provide immediate readback before the patient can leave the OR.

D. SMALL MISCELLANEOUS ITEMS AND DEVICE FRAGMENTS

1. SMALL MISCELLANEOUS ITEMS

   a. Small miscellaneous items should be accounted for on all procedures.

   b. Organization of all non-radiopaque small items on the sterile field should be continually maintained by the surgical scrubperson.

   c. These items are not instruments and counts should be performed as for needles/sharps. Small miscellaneous item counts should be documented on the dry erase board. Examples of small miscellaneous items are outlined in III.A.4.

   d. 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 scrubperson and circulating nurse. If the item is not found an x-ray is not indicated. An incorrect count report must be completed (see Attachment B) and 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. DEVICE FRAGMENTS

   a. Sharps, needles, instruments and small miscellaneous items that are broken or damaged during a procedure must be accounted for in their entirety.

   b. The surgical scrubperson 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. The surgical scrubperson should speak up if a missing part is discovered.

   d. Effort should be made to retrieve any device fragments or parts if possible.

   e. X-rays should be obtained to document the whereabouts of the items and to have knowledge about their composition, size and number.

   f. In the event a device fragment cannot be retrieved it is a clinical decision by the surgeon that it should be left in the wound. This is a retained surgical item. There should be an incorrect final count recorded in the small miscellaneous item category. An incorrect count report must be completed. (see Attachment B)

   g. 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. Appropriate RSI reporting should be conducted as required.
F. MONITORING AND AUDITS
1. PERIODIC SPONGE ACCOUNTING AUDITS:  
   Annual observational audits of each nurse and surgical technologist while engaged in the practice of performing surgical counts should be conducted using the Sponge ACCOUNTing 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:  
   Miscounts of any surgical items should be reported on a miscount report (see Attachment E). Any time an x-ray is obtained to find a missing item a miscount report should be filed. The reports should be collected by the Charge Nurse and reviewed and discussed monthly at OR committee or nursing in-service meetings.[see Point of Discussion #2]

G. EDUCATION AND TRAINING
1. COMPETENCY ASSESSMENT:  
   a. All staff will receive annual training, policy review, skills and cognitive knowledge assessments. Successful completion of review will include satisfactory demonstration of all skills and 80% or better 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 RN's and Surgical Technologist personnel will complete the training and skills assessment modules. In addition to this, they will read this Prevention of Retained Surgical Item policy, review the Sponge ACCOUNTing video and module and demonstrate competency with their assigned preceptor. This will be documented on their orientation competency checklist.
VII. SURGEON PROCEDURES AND SAFETY RULES

A. DETERMINATION OF AN EXTREME EMERGENCY CONDITION:

1. In consultation with anesthesia personnel, the surgeon must determine and verbally declare if a case is an extreme emergency condition. By so doing, the MD is acknowledging that “counts” may be aborted and a mandatory x-ray 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 aborted and 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.

4. Even if the MD has designated the case to be an extreme emergency condition if at all possible initial sponge counts should be performed. Even if initial counts were not performed the SAS should be used throughout the procedure. The circulating RN should still 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 xray to determine if all sponges have been accounted for.

B. PERFORMANCE OF A METHODICAL WOUND EXAMINATION:

1. GENERAL CONSIDERATIONS FOR ALL WOUNDS

a. A methodical exploration of the operative wound must be conducted prior to closure in every operation and at any time the surgeon is informed of a missing item.

b. 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).

c. Surgeons should strive to see and touch during the exploration whenever possible; reliance on only one element of sensory perception is usually insufficient.

d. The surgeon should visually and manually make every effort to assure that no unintended surgical items have been left in body cavities.

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

2. ABDOMEN AND PELVIS

Unless clinically contraindicated for a specific patient, the following steps should be taken 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 #9]

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 (if present) 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.

C. ACTIONS TO RECONCILE AN INCORRECT COUNT:
   1. If the surgeon is informed of a missing object by the circulating nurse, while the OR staff are looking for the surgical item, the surgeon should stop closing the wound and repeat the methodical wound examination. This is a Missing Surgical Item (MSI).
   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 4x4.
   7. Help the radiology technologist obtain x-rays of entire region of interest (side to side, top to bottom; this may require more than one film) (see Attachment F).
   8. Have the radiology technologist obtain two views (AP and oblique/lateral) (see Attachment F).
   9. The scrub 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, or with a newborn taken to the nursery.
   12. Wait for radiologist readback 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 Incorrect FINAL count in the medical record and complete Attachment B – Incorrect 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.
D. CLINICAL DECISION TO LEAVE A SURGICAL ITEM IN THE PATIENT:
   1. 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 will or can be removed.
   2. 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). A disclosure must be made to the patient.
   3. This event should be reported as a retained surgical item because at the beginning of the case this item was not one that was intended to remain in the patient and the act of retention was a consequence of error in surgical practice. (see Point of Discussion #10)

E. 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.
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) (see Point of Discussion #11).

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 (see Attachment F – MSI Exams)
   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 F)

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

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 BETWEEN OR AND RADIOLOGY 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.
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. Be careful when adding or removing items from surgical field or tables.
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 that there are no empty pockets in any of the holders.
11. Make sure that throat packs, bite blocks, and other such devices are removed from the oropharynx at the appropriate time.

B. 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. REPORTING
A. REQUIRED REGULATORY REPORTING:
   1. When a retained surgical item is discovered risk management should be notified and a report in the Events Reporting System (ERS) should be completed. The risk manager is responsible for the timely reporting of the event to the State Department of Public Health according to the State reporting requirements.
   2. Many states follow the definition from the National Quality Forum (NQF) for 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. Specific state reporting requirements are included as Attachment I.
XI. POINTS OF DISCUSSION

This section is intended to provide rationale and 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 where the stated actions were causal. Consider this section part of a shared learning – Collective Wisdom.

1. III. B. Retained Surgical Item – The issue of when an item is considered retained varies among state and regulatory agencies. 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.

   It is important that personnel in each healthcare system know the rules of engagement and report when and if required. There may be disparities between written state regulations and those of regulatory and reporting agencies. The Joint Commission (TJC) currently has a different interpretation of when an item is considered retained and when surgery ends. In the October 2013 Sentinel Event alert from TJC there is no explicit definition of when an item is retained. The document references back to TJC requirements EP 7: The leaders define “sentinel event” and communicate this definition throughout the organization.

   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 but the State of New York still considers retention to correspond with wound closure. What is important is that personnel in each healthcare system must know the rules of engagement and must adhere to the policies and report when and if required. This is an open area of contention since there is obvious disparity between written state regulations and those of regulatory and reporting agencies. If the wording in a rule is “after surgery” use the definition in this policy that after surgery is out of OR not wound closure.

2. VI.A.8. - MIScounts - 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 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 followup x-rays were ordered, nothing happened ……. until the patient returned to the OR days later after a routine post/op x-ray showed the 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 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) MISStaken 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 MISStaken 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 E). 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.

3. VI.A.10. Separate Procedures – 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. 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. These circumstances are also called concurrent cases.

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 one set of counts kept for the entire operation with the expectation that at the end of the day there will be 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.
4. VI.B.1.a. Red Biohazard Bags – 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 so to make it easier 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.

5. VI.B.1.b. Why white? The intent here is to have a unified approach to managing what is safe to go into a patient. If we say and 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 scrubperson organize the back table and make it easier for everyone to account for sponges. 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. They are intended to be used as drapes. There are also unbleached drape towels which are beige or a “natural” color, these are not bleached and are of a coarser grade of cotton and intended to be used as drapes. White ROTs usually are supplied in packs of 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.

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 can be 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). Additionally having white ROTs that are safe to put in patients will help the surgical scrubperson 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 and counted out.
White ROTs should NOT be used as drape towels or draped for long periods of time around the wound when surgeons are sutureing. The operative words here are “long period of time”. Cardiac surgeons often use white towels to cover the wound retractors while sutureing. 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. 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 confound the radiographic interpretation.

6. VI.B.2.e.18 The “Pauze for the Gauze and the “Show Me” Steps are team based activities. They are part of the Sponge ACCOUNTing practice. Of note here is that 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 scrubperson 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 again, 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 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 Show Me step is a final team 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 thereby proving that all the sponges have been accounted for since there should be “no empty pockets”. All other items are similarly demonstrated to have been accounted for. These activities take very little time and help everyone do their part to make sure there is “NoThing Left Behind”.

7. VI.C.2.f. In this policy a needle less than 15mm in size is considered to be 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 all needles of any size 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.

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 xray. If there is any doubt it is always better to get the xrays. 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.

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

8. VI.D.1.c. 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 IN or 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. The count
sheet provided by sterile processing is usually used for this purpose. During an operation if an
additional instrument is added singly it can be written on the dry erase board or if more trays are
brought in they are counted using the accompanying count sheet. Complete instrument counts at the
interim counts (CAVITY, PERMANENT RELIEF, ANYTIME, CLOSING) are not feasible. What
is feasible and should be encouraged is rather than counting the instruments, the surgical
scrubperson at the time of a CAVITY closure 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, 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 time of the CLOSING count the
instrument count is started and will continue onto the end of the operation to be completed at the
FINAL count. This is documented as the FINAL count not as the CLOSING count. Practices are
also outlined for alternative means to determine and document that no instruments
inadvertently been left inside the patient by use of an intraoperative x-ray. Additional alternatives
consist of having pre-set instrument trays with defined slots for instruments such that if an slot is
empty the team has a means to identify that an instrument is missing and can find it. Additional
improvement efforts can be directed to reducing the total number of 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.

9. VII.B.2. It has been 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 (a missing surgical item – MSI) 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.

10. VII.D.3. If the surgeon makes a clinical decision to leave a surgical item in a patient this does not make it a non-reportable event. 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 unexpected patient injury.

11. VIII.A.1. 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 involves 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 they know what is being looked for 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 called for actually different techniques, different films and a different approach may be required. 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 films. Surgeons are often the ones who do a first pass but surgeons aren’t radiologists. We have outlined here a number of new practices to improve the chances that intraoperative film(s) 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 a 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 and an oblique, or lateral is needed primarily to move an item off the midline or to provide an alternative projection. These are standard principles in the radiology world that need to be shared with the OR world to help us get it right.
XII. REFERENCES

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


7. OR Policies from >50 facilities around the country (thank you for sharing!)
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 Sponge ACCOUNTing 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:

Initial Count  [next space in field takes user to a pull down menu to select type of count]
  - Instrument
  - Sponge
  - Blades
  - Needles
  - Other

Initial Count Correct  [next space in field takes user to a pull down menu to select details]
  - Yes
  - No
  - Physician Notified
  - X-ray
  - Other

Clicking on “other” opens a free text box to enter information.

It is possible to click on more than one bullet to complete the response

The other type of counts each have the same pull down fields as above:

- Cavity Closed Count
- Cavity Closed Count Correct
- Peritoneal Closed Count
- Peritoneal Closed Count Correct
- Skin Closed Count
- Skin Closed Count Correct
- Other Count
- Other Count Correct
- Physician Notified Date/Time
- X-ray Results

The designation of these Cerner hard-coded fields with the Sponge ACCOUNTing nomenclature is:

IN count = Initial Count
CLOSING count = Peritoneal Closed Count
FINAL count = Skin Closed Count

The “Cavity Closed Count” field would be used if there was closure of a cavity within a cavity. The “Other Count” field would be used if there was a count performed at a permanent change of relief or at other times as determined any member of the OR team.
Action Taken Drop Down Values

Incorrect Sponge Count Action Taken:

Search Area
Inform Provider, Repeat Methodical Wound Exam, Search Area
Inform Provider, Repeat Methodical Wound Exam, Search Area, XRay Taken
Inform Provider, Repeat Methodical Wound Exam, Search Area, XRay Taken, Radiologist Read As Negative

Incorrect Misc Item Count Action Taken:

Search Area
Inform Provider, Repeat Methodical Wound Exam, Search Area
Inform Provider, Repeat Methodical Wound Exam, Search Area, XRay Taken
Inform Provider, Repeat Methodical Wound Exam, Search Area, XRay Taken, Radiologist Read As Negative

Incorrect Sharp Count Action Taken:

Search Area
Inform Provider, Repeat Methodical Wound Exam, Search Area
Inform Provider, Repeat Methodical Wound Exam, Search Area, XRay Taken
Inform Provider, Repeat Methodical Wound Exam, Search Area, XRay Taken, Radiologist Read As Negative

Incorrect Instrument Count Action Taken:

Search Area
Inform Provider, Repeat Methodical Wound Exam, Search Area
Inform Provider, Repeat Methodical Wound Exam, Search Area, XRay Taken
Inform Provider, Repeat Methodical Wound Exam, Search Area, XRay Taken, Radiologist Read As Negative
**B. Meditech EMR count fields**

Nursing Interventions

<table>
<thead>
<tr>
<th>Count Type</th>
<th>Staff 1</th>
<th>Staff 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>1st Count</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2nd Count</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3rd Count</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4th 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:**

<table>
<thead>
<tr>
<th>IN count</th>
<th>CLOSING count</th>
<th>FINAL count</th>
</tr>
</thead>
<tbody>
<tr>
<td>1st Count</td>
<td>2nd Count</td>
<td>3rd Count</td>
</tr>
</tbody>
</table>

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. McKesson HMS EMR count fields

The Procedure Counts screen:
Count Type has 5 choices
INITIAL
1 COUNT
2 COUNT
FINAL
PERMREL

There are only 3 categories for each count type: Sponges, Sharps and Instruments. Each count type is in a box and by clicking the ADD button you can continue to add more counts after the first 3 count types are completed. There is a check box for X-ray taken and Physician Notified and a free text field for “Counts Comment”.

The designation of these existing McKesson hard-coded fields with the Sponge ACCOUNTing nomenclature is:

IN count = INITIAL
CLOSING count = 2 COUNT
FINAL count = FINAL

The 1 COUNT would be used if there was closure of a cavity within a cavity or for additional counts that may be performed. The PERMREL would be used if there was a count performed at a permanent change of shift. The user interface will allow any number of additional counts to be added.

For counts of Miscellaneous Small Items the “Counts Comment” box should be used for free text entry of any problems or wording: Small Miscellaneous Items counts correct.

D. Paper intraoperative records should specify the primary counts as:
IN
CLOSING
FINAL
And additional counts as:
Cavity
Relief
Anytime
These counts should be included for each type of surgical item e.g. sponge, sharps and needle, instrument, miscellaneous small 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 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 if needed
- Radiology readback verification of results for specific item
- Clinical decision by surgeon not to retrieve device fragment or item
- Therapeutic Packing Performed –
  - o _______ (type of sponge) is in the patient
  - o _______ (number of sponges) are in the patient (if known… don’t guess!)
- Additional X-rays to be ordered at next level of care
- Event reported through Event Reporting System
- Risk manager notified
- Patient disclosure rules reviewed
- Counts and actions documented in medical record

**Follow-up Required:** ____________________________________________________________

______________________________________________________________________________

______________________________________________________________________________

e.g. Nurse Manager will follow-up on documentation
    Risk Manager will report to regulatory agencies
    Patient disclosure discussion by surgeon documented in medical record
    Next level of care X-rays were 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**

**SPONGE ACCOUNTING FOR LABOR AND DELIVERY:**

1. X-ray detectable 4”x8” sponges, baby laps (4”x18”) or lap pads are recommended for use as sponges during vaginal deliveries. [see comments below]
2. There should be a movable pole to hang the rack and a box of hanging blue-backed plastic sponge holders (HBBPSH) in each labor room and the pole should remain in the room at all times. The pole 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 delivery 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. The sponges should not be opened on the delivery table until the delivery is activated.
5. Once the delivery has started the sponges are opened, separated and two people count them (“see, separate and say”). The number of sponges is documented on the dry-erase board
   - 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.
6. As soon as the obstetrician or nurse midwife can, sponges should be removed from the vagina and deposited:
   - to the end of the delivery table or
   - into a container on the delivery table or
   - into a clear plastic bag in a ring-stand
   - directly into the hanging blue-backed sponge holder
7. The circulating RN is responsible for ensuring that all of the used and unused sponges are placed in the HBBPSH. The sponges are added to the holders as they are used 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 or delivery table area into the holder.
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, the obstetrician and/or second staff person must verify with the circulating RN 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 delivery sponges have been accounted for, 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.
PREVENTION OF A RETAINED VAGINAL PACK

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 making sure the pack is removed.

COMMENTS

Labor and Delivery Practices
Consider using sponges in the vagina other than raytex 4x4’s. Small 4”x4”’s can be difficult 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”) are a nice option as they are narrow and not too large and 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 after thought or passive action.
Attachment D

SPONGE ACCOUNTING FOR NON-OR AREAS

1. X-ray detectable 4”x4” surgical sponges (raytex) are usually 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 E**

**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. ___________________________
3. ___________________________  4. ___________________________

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

Sharp/Needle (specify size) ___________________________ Instrument ___________________________

Number of missing item recorded on board: ___________________________

Number of missing item at the interim count: ___________________________

**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 □ 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 F**

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><em>MSI Cranium</em></td>
<td>AP &amp; Lateral (2V)</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><em>MSI Chest</em></td>
<td>AP &amp; Oblique/lateral (2V)</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><em>MSI Abdomen/Pelvis</em></td>
<td>AP &amp; Inlet (2V)</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><em>MSI Vagina</em></td>
<td>AP &amp; Inlet (2V)</td>
<td>Inferior gluteus to above crest and bilateral skin borders. Inlet must show the pelvic ring.</td>
<td>Inlet: Place 14x17 vertical with 25 degree caudal angulation. Special attention needed to avoid grid cut-off</td>
</tr>
<tr>
<td><em>MSI Extremity</em></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.
Attachment G

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

e.g. Total Hip Arthroplasty
Attachment H

A. 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 where the surgical site is distal to the wrist/ankle, endoscopic cases that do not go open or patients with pacemakers or ICDs because the RF wand will interfere with the working of the pacemaker or ICD.
4. Prior to the end of the procedure before the wound is completely closed the circulator will calibrate the wand. The wand will be placed in a sterile plastic sheath and handed to the surgeon and slowly and carefully passed over the incision site in the anterior and lateral planes per manufacturers operating instructions. Include manufacturers instruction HERE.
5. The RF wand does not replace the Sponge ACCOUNTing 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 HB Quat 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. (see Attachment F). 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 was used.
B. RADIOFREQUENCY IDENTIFICATION SYSTEM USAGE PROTOCOL

To use the device most efficiently and effectively, participation and cooperation from all stakeholders in the OR is required. The primary responsibility for the accounting of all surgical sponges will reside with the circulating RN. The fundamental basis of the design of this protocol is that the SmartBucket system, hereafter referred to as the “ecount” is the uncertain methodology, the reliability of which is being assessed. The protocol is designed to take advantage of two of the greatest strengths (advantages) of the smart bucket – the ability to count multiple different types of sponges simultaneously and the ability to bulk count sponges so the circulating RN minimizes the handling of bloody sponges. This protocol is also designed to minimally alter current practices between the surgeon and scrub tech or disturb existing flow patterns of materiel around the OR table. All steps in this protocol are designed with these basic assumptions. Even though we know that manual counting practices have their own degree of uncertainty, for the purposes of this protocol, in all instances, the actions have been designed to use a transparent manual process (“see, separate and say” individual sponges during the IN counts or hanging blue-backed plastic sponge holders (HBBPSH) for the OUT counts) to determine the accuracy of the ecount. Lastly, once the reliability of the Smartbucket and the personnel who use it has been determined to the satisfaction of ALL hospital staff, the manual process at the OUT count can be abandoned without any need to change any other elements in the process allowing for a smooth transition to a fully optimized system for sponge management.

The bucket will be positioned in a part of the OR to allow the circulating nurse easy access to the bucket preferably near the wall mounted dry erase board but not in close association with the OR table or field. This is to discourage the direct placement of used sponges into the bucket. All sponges should come off the field into clear plastic bag-lined kick buckets or ring stands whichever is the current standardized practice in place in the institution. The intent here is not to change the existing practice of how used sponges are passed off the surgical field to minimize disturbances or variation in existing practice while implementing a new counting system. In addition, the bucket is pretty big and will be difficult in every room, to position it close enough to the OR table to allow sponges to be directly put into the bucket. Ideally you would like the bucket to be “handled” the same way in all rooms. The lip of the bucket is high (eventhough it is cantilevered) and there is a natural tendency because of its height to “toss” the sponges in. Wet, bloody sponges shouldn’t be “tossed”. In addition, in order to remove the sponges to obtain a manual count to confirm the ecount, the bucket will have to be repeatedly moved back and forth from the OR table. This is not optimal for the activities around the OR table causing possible distractions and difficulty for the circulating nurse. For these reasons, it is best to have the bucket strategically placed away from the OR table so the circulating nurse can easily observe the electronic screen, have access to the bucket, write on the dry erase board and have a rack of HBBPSH nearby.

For each case a new smart tag has to be placed on the OR table as close as possible to the patient’s body without touching the patient’s skin. It has to be placed in the same area as the surgical wound and should have no more than a draw sheet between the tag and the patient. Who (OR assistants when they clean the room and make the bed place a fresh tag? Scrub tech places a fresh tag during table set up? Circulating RN places a fresh tag before testing wand?) should be responsible for the correct placement of the tag needs to be determined ahead of time and be part of policy. The wand
on the bucket must be tested by the circulating RN to insure proper functioning for each case before the patient is brought into the room. It is not sufficient to test the wand once a day. It should be tested for each case because each patient is different and can vary in the body size and habitus and expected operation and each case has a new tag which needs to be checked.

Since it can’t be determined ahead of time when the wand will need to be used, it must be ascertained before it is needed that the wand is functioning properly.

Kick buckets in the room beside the OR table should be lined with multiple clear plastic bags (>5 at least).

Used sponges will be passed off the table and dropped into the kick buckets throughout the case. At varying intervals the circulating nurse will pick up a plastic bag of the sponges in the kick bucket and drop the bag into the bucket. There needs to be more than one plastic bag lining the kick bucket to allow for multiple “drops” during the case. Having the sponges in clear plastic bags minimizes the handling of bloody sponges by the circulating nurse. They have to be clear so the sponges can be easily seen. No red bags for the kick buckets. The sponges are not being disposed of so there isn’t a biohazard precaution for disposal. Since you don’t know how many bags will be used you can’t even have the “last” bag as a red bag because you don’t know which bag will be the last, and because all the other bags are clear, one red bag makes all the bags appear to be red when you are looking down at the sponges in the kick bucket.

No unpackaged sponges should be in the custom packs. Unwrapped packages of sponges can be packaged with the custom packs but no opened chipped sponges should be within the materials that compose the packs.

The intent here is to have each package of sponges only have the potential of having manufacturer error rather than distributor and manufacturer error. In addition, by having unopened packages of sponges, the scrub and circulator will have to “see, separate and say” together upon opening each package of chipped sponges during the IN counts.

At the initiation of the case during the back table set up, unopened packages of sponges are scanned in on the IN count panel by the circulating nurse. The number of sponges as read out on the readout screen is noted and if the number agrees with the expected number of sponges for that type of sponge and if a “bad pack” error message is not detected, the package is opened.

This is to determine the number of sponges in the pack and to assess that each sponge has a functioning chip. This is the IN ecound.

The sterile sponges are separated by the scrub tech and the sponges within the package are manually counted by the scrub tech separating each sponge and the circulating nurse looking at each sponge to determine that each sponge has a radiopaque marker, a chip and the expected number of sponges exists for that type of sponge.

This is the IN manual count. The process uses standard “see, separate and say” practice to confirm the ecound and make sure the sponges don’t contain manufacturer errors (e.g. radiopaque tags aren’t missing, correct number, chips are there – one would expect the chips to be there because the ecound wouldn’t have given a number of sponges if a sponge didn’t have a chip, but there could be defects in the way the chips are attached to the sponges which would only be detectable by human visual assessment)
The number of sponges are entered on the wall mounted dry erase board.

This is necessary in the event that there is a failure of the electronic readout screen. Even though the expected ability of the bucket to function without power or on a battery system for at least 2 hours with memory retention, the readout panel cannot be seen by everyone in the room while the white board can so the readout panel is not really transparent.

At the “time out” team awareness is discussed that the ecount/manual count system will be in use for the case and that the wand has been tested and is functioning properly. The case begins and progresses.

During the case, used sponges are passed off the field into the plastic lined kick buckets as usual. Aliquots of the used sponges in the plastic bags at varying times during the case are removed from the kick buckets and dropped into the smart bucket. The number of each type of sponge should appear on the readout panel. This is an OUT ecount.

It doesn’t matter how many of the sponges are collected at one time or what type of sponge is in the plastic bag. They can be mixed together. This examines and challenges the bucket to do what it is supposed to do best…. count multiple sponges simultaneously.

After the sponges have been “ecounted” they are taken out of the Smartbucket and placed in individual pockets of HBBPSH positioned in close proximity to the Smartbucket. There should be a separate holder for each type of sponge being used. The holders should remain hanging on the racks throughout the case. The number of sponges put in the holders should agree with the number of sponges obtained with the ecount EVERY TIME. This is the manual count confirming the ecount.

At varying times the sponges should be put in the Smartbucket, ecounted and then put in the sponge holders. Removing the used sponges from the Smartbucket at frequent intervals will also keep the total number of sponges in the Smartbucket to <50 which is the maximal number to be in the Smartbucket at any one time. At >50 chipped sponges the device will issue warning signals to remove sponges. The used, bloody clear plastic bags can remain inside the bucket and do not have to be removed.

Any discrepancies between the ecount and the manual count should be immediately reported by verbally notifying the scrub tech and the surgeon that there has been an error and the case move to a full manual process until the cause of the ecount error can be determined.

It is probably not a good idea to continue a clinical case with a patient on the OR table with a problematic device because OR personnel’s attention may be diverted trying to sort out the device problem rather than staying focused on the conduct of the operation.

At the closing count the surgeon should perform a methodical wound exam to try to remove all the sponges from the wound before receiving closing suture. The scrub tech and the circulating nurse should reconcile the number of sponges on the field, back table and in the hanging holders with the numbers on the readout screen of the Smartbucket and the numbers on the dry erase board. Any discrepancy should be verbally called out to the OR team so the problem can be assessed. If there are no discrepancies the case should proceed through closing. If there is a discrepancy and there is a sponge(s) missing, the wand should be placed in the sterile plastic sheath and the wound scanned to see if the sponge is within the patient. All other potential sites in the OR should also be scanned until the discrepancy is resolved.
If a missing sponge is found by the wand, that sponge MUST be placed in the Smartbucket to be counted. The wand can only identify the presence of the sponge, it does not add it to the existing count.

At the final count, ALL sponges (used and unused) MUST be placed in the Smartbucket. In order to zero the fields on the Smartbucket field, ALL sponges must be placed in the Smartbucket. Those last sponges must be removed from the Smartbucket and placed in the hanging sponge holders to verify that all sponges have been properly accounted for.
C. 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.
Attachment I

STATE REQUIRED REPORTING STATUTE

[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, 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 (f) 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 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 J

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 x-rays 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.