DEPARTMENT OF THE NAVY
BUREAU OF MEDICINE AND SURGERY
7700 ARLINGTON BOULEVARD
FALLS CHURCH, VA 22042

IN REPLY REFER TO
6460
Ser M3B215UM30205
JAN 1 1 2016

MEMORANDUM FOR COMMANDER, NAVY MEDICINE EAST
COMMANDER, NAVY MEDICINE WEST

Subj: PREVENTION OF RETAINED SURGICAL ITEMS STANDARD OPERATING PROCEDURE

Ref: (a) BUMED Memo 6300 Ser M3/14UM30087 of 30 June 2014 Product Line Implementation
(b) BUMED Memo 6700 Ser M3/AT-0286242 of 07 Oct 2013 Standardization of Medical Equipment and Services across Navy Medicine

Encl: (1) Prevention of Retained Surgical Items Standard Operating Procedure

1. Per references (a) and (b), this memorandum and enclosure (1) provide standard operating procedures for the prevention of retained surgical items for Navy Medical Treatment Facilities (MTFs) and Mission Specific Commands under the control of the Chief, Bureau of Medicine and Surgery (BUMED).

2. The purpose of this memorandum is to provide guidance to perioperative personnel for prevention of unintended retained surgical items during operative or other invasive procedures. Details for the utilization of Radio Frequency Scanning Technology are included in enclosure (1) standard operating procedures. The expected outcome is that the patient will be free from signs and symptoms of injury related to unintended retained surgical items.

3. My point of contact for any questions or concerns is [redacted] Surgical Services Program Manager, who can be reached at (703) 681-9133 or [redacted]

S. A. HARTZELL
Deputy Director, Healthcare Delivery

SUBJECT: **PREVENTION OF RETAINED SURGICAL ITEMS**	REFERENCE
	PAGE 1 of 13
DEPARTMENT: MAIN OPERATING ROOM	EFFECTIVE:
APPROVED BY:	REVISED:

Purpose

To provide guidance to perioperative personnel for preventing retained surgical items (RSIs) during operative or other invasive procedures. The expected outcome is that the patient will be free from signs and symptoms of injury related to retained surgical items.

Standard Operating Procedure

It is the standard operating procedure of **(FACILITY's name)** that:

- All perioperative team members are responsible for the prevention of RSIs.
- Any individual who observes an item dropped from the surgical field will immediately inform the Room Nurse (RN) circulator and other members of the perioperative team.
- Any perioperative team member (e.g., anesthesia professional, float RN) who assists the surgical team by opening sterile items onto the sterile field will:
  - count the items with the scrub person,
  - add the counted items to the count documentation (e.g., count sheet, whiteboard), and
  - promptly inform the RN circulator of what was added.
- All surgical items opened and used during a surgical procedure will be accounted for.
- Manual counts of radiopaque soft goods, sharps, miscellaneous items, and instruments opened onto the sterile field will be performed in all surgical invasive procedures.
- Instrument counts may be waived for surgical invasive procedures in which accurate instrument counts may not be achievable or practical, including:
  - complex procedures involving large numbers of instruments (e.g., anterior-posterior spinal procedures),
  - emergency trauma procedures,
  - procedures that require complex instruments with numerous small parts, and
  - procedures where the width and depth of the incision are too small to retain an instrument.
- When instrument counts are waived, unless the patient's safety is at risk, intraoperative imaging will be performed before the patient is transferred from the Operating Room (OR).
- A count may be initiated by ***any member*** of the ***perioperative team involved in the counting process***.
- All unnecessary activity and distractions will be curtailed during the counting process.
- Counts and events that require a count (e.g., relief of scrub person or RN circulator) will not be performed during critical portions of the operative or other invasive procedure.
- A variance report will be completed for any incorrect count or adverse event (i.e. Patient Safety Report (PSR)).
- A critical investigation will be conducted regarding any adverse event or near miss related to RSIs.
- The RN circulator will:
  - actively participate in safety measures to prevent RSIs during all phases of a surgical invasive procedure and
  - initiate the count, perform count procedures in concert with the perioperative team, document count reconciliation activities, and report any count discrepancy.
  - Ensure complete and detailed communications between OR personnel and radiologic technologists and radiologists should occur when requesting radiological support to prevent RSIs.

- The scrub person will:
  - maintain an organized sterile field according to the standardized sterile setup for the procedure type;
  - confine and contain sharps in the specified area of the sterile field or within a sharps containment device;
  - maintain awareness of the location of soft goods (e.g., radiopaque sponges, towels, textiles), miscellaneous items, and instruments on the sterile field during the course of the surgical invasive procedure;
  - know the character and configuration of soft goods, sharps, instruments, and other items that are used by the surgeons and assistants;
  - verify the integrity and completeness of soft goods when they are counted;
  - ensure that the RN circulator sees surgical items being counted; and
  - confirm that instruments or devices that are returned from the operative site are intact.
- The surgeon and first assistant will:
  - maintain awareness of all soft goods, sharps, instruments, and other items used in the surgical wound during the course of the surgical invasive procedure, and
  - facilitate the count process by:
    - using ***only radiopaque surgical soft goods in the wound***,
    - communicating placement of surgical items in the wound to the perioperative team for notation (e.g., whiteboard),
    - acknowledging awareness of the start of the count process,
    - removing unneeded soft goods and instrumentation from the surgical field at the initiation of the count process,
    - performing a methodical wound exploration when closing counts are initiated,
    - accounting for and communicating about surgical items in the surgical field, and
    - notifying the scrub person and RN circulator of surgical items returned to the surgical field after the count.
- The anesthesia professional will
  - plan anesthetic milestone actions so that these actions do not pressure the perioperative team to perform insufficient accounting practices;
  - not use counted items; and
  - verify that throat packs, bite blocks, and other similar devices are removed from the oropharynx and communicate to the perioperative team when these items are inserted and removed.

Procedure Interventions

General Accounting Practices

- Counts of sponges, sharps, instruments, and other miscellaneous items will be performed in order from **Facility specific preference** (e.g., large to small item size, small to large item size, proximal to distal from the wound, distal to proximal from wound).
- The perioperative RN circulator will retrieve, show the scrub person, isolate, and include in the final count any counted items either passed off or dropped from the sterile field.
- The final count will not be considered complete until all items (e.g., sponges, malleable retractors, needle holders, scissors) used in closing the wound are removed from the wound and returned to the scrub person.

- Counted items and linen or waste containers will not be removed from the OR or procedure room until all counts are completed and reconciled.
- All items accounted for will be removed from the room during end-of-procedure cleaning.

Surgical Soft Goods

- Non-radiopaque sponges used for skin preps will be isolated before beginning the operative or other invasive procedure.
- The seal will be maintained on dressing sponges included in custom packs, and dressing sponges will be isolated until the final count is resolved.
- Dressing sponges will be withheld from the sterile field until the final count is completed.
- The following items will be included in the count:
  - all radiopaque sponges (e.g., 4x4s, 4x8s, laparotomy, cottonoids, kittners),
  - radiopaque towels, and
  - radiopaque textiles.
- Soft goods will be counted:
  - before the procedure (i.e., initial count);
  - when new items are added to the field;
  - before closure of a cavity within a cavity (e.g., uterus);
  - when wound closure begins;
  - at skin closure at the end of the procedure or at the end of the procedure when counted items are no longer in use (i.e., final count); and
  - at the time of permanent relief of either the scrub person or the RN circulator, although direct viewing of all items may not be possible.
- When counting radiopaque sponges,
  - break the band and discard it;
  - separate each sponge;
  - count audibly (e.g., restarting at one with each new package or counting the total of each type of sponge);
  - two individuals, one of whom is the RN circulator, will view the actual sponges during the count process;
  - record each type of sponge separately (e.g., radiopaque 4x4s, laparotomy sponges, large tonsil sponges, small tonsil sponges); and
  - if an incorrect number of radiopaque sponges or a manufacturing defect is discovered in a package upon initial count,
    - remove the items from the sterile field and then bag, label, isolate, and exclude these items from the count, or
    - remove the defective packages from the room if they are discovered before the patient's entry.
- When counting radiopaque sponges used as therapeutic packing,
  - document the location, type, and number of sponges retained after confirming with the surgeon; and
  - during the transfer-of-patient-care information, inform the receiving caregiver of the location, type, and number of sponges retained and the plan for the eventual removal of the surgical sponges, if known.
- During the removal of therapeutic packing with radiopaque sponges,

- document the number and type of radiopaque sponges removed,
- isolate the radiopaque sponges removed from the sponges used during the removal procedure,
- do not include the radiopaque sponges removed from the patient in the soft goods counts for the removal procedure, and
- consult with the surgeon regarding the need for an intraoperative radiograph.

Sharps and Other Miscellaneous Items

- Sharps and miscellaneous items will be counted
  - before the operative or other invasive procedure (i.e., initial count),
  - when new items are added to the field,
  - before closure of a cavity within a cavity (e.g., uterus),
  - when wound closure begins,
  - at skin closure at the end of the procedure or at the end of the procedure when counted items are no longer in use (i.e., final count), and
  - at the time of permanent relief of either the scrub person or the RN circulator.
- When counting sharps and miscellaneous items,
  - count suture needles according to the number marked on the outer package;
  - the scrub person will verify the number when the package is opened;
  - count audibly, counting the total number and types of needles (e.g., hypodermic, suture, spinal);
  - two individuals, one of whom is the RN circulator, will view the actual sharps and miscellaneous items during the count process;
  - record each type of type of needle (e.g., hypodermic, suture, spinal);
  - keep used sharps on the sterile field in a disposable, puncture-resistant container; and
  - if an incorrect number of items or a manufacturing defect is discovered in a package on initial count,
    - remove the package and its contents from the sterile field and label, isolate, and exclude these contents from the count, or
    - remove the package from the room if it is discovered before the patient's entry.
- Include the following items in the count:
  - all needles, regardless of size (e.g., suture, hypodermic, spinal);
  - all sharps (e.g., scalpels); and
  - all miscellaneous items, including:
    - defogger solution bottle, bottle cap, and associated accessories (e.g., wipe, sponge);
    - electrosurgery active electrode blades;
    - electrosurgery scratch pads;
    - endostaple reload cartridges;
    - laparotomy sponge rings;
    - Raney clips;
    - trocar sealing caps;
    - umbilical and hernia tapes;
    - vascular inserts;
    - vessel clip bars; and
    - vessel loops.

Instruments

- Instruments will be counted:
  - before the procedure (i.e., initial count),
  - when new instruments are added to the field,
  - at wound closure or at the end of the procedure when counted items are no longer in use (i.e., final count), and
  - at the time of permanent relief of either the scrub person or the RN circulator.
- Record the counted instruments on the preprinted count sheet.
- When counting instruments,
  - count audibly (e.g., restarting at "one" with each new package or counting the total of each type of sponge) and
  - two individuals, one of whom is the RN circulator, will view the actual instruments during the count process.
- Individual pieces of assembled instruments (e.g., suction tips, wing nuts, blades, sheaths) will be accounted for separately and documented on the count sheet.
- Count and record on the count sheet additional instruments when they are added to the sterile field.
- The scrub person will assess the condition of each item returned from the operative site to verify that the item is intact and immediately notify the OR team when an item may have broken or become separated within the confines of the surgical site.

Count Discrepancy Investigation and Reconciliation

- If a missing item or device fragment is not recovered, perform intraoperative imaging before the final closure of the wound if the patient's condition permits.
  - If the patient's condition is unstable, take a radiograph as soon as possible.
  - Radiographs will not be required for needles less than **Facility specific size preference** (e.g., 10 mm).
- Perioperative team member responsibilities:
  - The perioperative RN circulator will
    - inform and receive active verbal acknowledgment from the surgeon and surgical team;
    - visually inspect the area surrounding the surgical field, including the floor, kick buckets, and linen and trash receptacles;
    - consult with the radiologist for guidance on the most appropriate available radiographic equipment to use; and
    - request radiological support and provide the following information:
      - the room where the procedure is being performed or where the patient is located,
      - the type of radiograph and views needed (e.g., intraoperative imaging coverage area includes the surgical site and any views deemed necessary by the surgeon or radiologist),
      - a description of the missing surgical item,
      - the operation performed, and
      - the surgical site.
  - The surgeon(s) will:
    - suspend closure of the wound if the patient's condition permits,
    - perform a methodical wound examination by actively looking for the missing item,
    - cooperate in the attainment of radiographs or other modalities as indicated to find the missing item, and

    - remain in the OR or procedure room until the item is found or is determined with certainty not to be in the patient.
  - The scrub person will:
    - assist with visual inspection of the area surrounding the sterile field and
    - visually inspect the sterile field.
- In the event of a count discrepancy or a device fragment being retained, the surgeon will notify the patient and/or the patient's significant other or caregiver both of the event and the following:
  - material composition of the item (if known);
  - size of the fragment (if known);
  - location of the fragment;
  - potential mechanisms for injury (e.g., migration, infection);
  - procedures or treatments that should be avoided, such as magnetic resonance imaging (MRI) examinations in the case of ferrous metallic fragments; and
  - risks and benefits of retrieving the item, as opposed to leaving it in the wound.

Waived Counts

- Complete an initial instrument count, though subsequent counts may be waived for **Facility specific procedures** (e.g., laparoscopic procedures in which the patient is not opened).
- In situations when accurate counting of surgical items is not possible, unless the patient's safety is at risk, perform intraoperative imaging before the patient is transferred from the OR.

Documentation

- The RN circulator will document:
  - the types of counts (e.g., radiopaque sponges, sharps, instruments, miscellaneous items);
  - the number of counts;
  - the names and titles of perioperative personnel performing the counts;
  - the results of surgical item counts (e.g., correct, incorrect, initial count is documented as complete);
  - surgeon notification of the count results;
  - any adjunct technology used and associated records;
  - any explanation for any waived counts;
  - the number and location of any instruments intentionally remaining within the patient;
  - details about radiopaque sponges intentionally retained as therapeutic packing, including:
    - the number of sponges,
    - the types of sponge,
    - the locations of sponges,
    - confirmation of the above documented items by the surgeon,
    - correct document count if the number is confirmed by the surgeon and by the counts,
    - incorrect document count if the number is not confirmed by the surgeon or by the counts, and
    - notification of the receiving caregiver;
  - unretrieved device fragments left in the wound, including:
    - material composition,
    - size,
    - location (if known), and
    - manufacturer;

- actions taken if count discrepancies occur, including all measures taken to recover the missing item or device fragment and any communication regarding the outcome;
- a rationale if counts are not performed or completed as prescribed by policy; and
- the outcome of actions taken.

- Document the counted instruments and pieces of assembled instruments (e.g., suction tips, wing nuts, blades, sheaths) separately on the preprinted count sheets.

FOR FACILITIES WITH RFID SCANNING TECHNOLOGY:

Definitions

- **Radio Frequency (RF) Sponge/Surgical Towels:** Radio frequency tag embedded in sponge (laps 18x18, mini pediatric laps 4/18, raytec gauze 4x4) and white surgical towels for RF identification.
- **Wand:** RF Assure hand-held detection device (Blair-Port Wand®).
- **Bed Mat:** RF Assure Detection Mat.
- **Console:** Electronic equipment required for RF detection.
- **Closing Counts:** Conducted when surgical wound closure begins (i.e.-peritoneum, fascia) and closure of a cavity within a cavity (eg, uterus).
- **Final Count:** Conducted at skin closure at the end of the procedure when counted items are no longer in use.
- **Operative Field:** The isolated area where surgery is being performed.

Policy Statements

- The RF Detection System will be used on all procedures requiring a final count in accordance with the MOR Count Policy where there is a cavity in which a RF sponge can be lost.
- A mat and/or wand scan may be conducted at any time during the surgical procedure.
- A mat and/or wand scan **will** be performed when surgical wound closure (i.e.peritoneum, fascia) or closure of a cavity within a cavity (e.g., uterus) begins. All countable items should be removed from the operative field and a RF scan will be conducted.
- A mat and/or wand scan **will** be performed following the final count. All countable items will be removed from the operative field and a RF scan will be conducted.
- An RF scan is not required for procedures in which RF raytec sponges, laparotomy sponges and/or surgical towels are not used in the operative field or the surgical site is so small that a raytec could not possibly fit in the cavity.
- Use of RF Detection System will **NOT** replace the need for routine manual counts in accordance with recommended standards and MOR Policy and Procedures. The RF Detection System will be used as an adjunct to manual closing counts and final sponge/towel count reconciliation.
- The RF Assure Detection Mat will be available in each room and be the primary detection method used for completing a scan. The wand may be preferable in certain cases as determined by the surgeon.

Procedure

- Plug in the power cord and turn back panel switch to the "ON" setting.
- Remove all surgical sponges/towels to a location 36 inches from the operative scanning area.

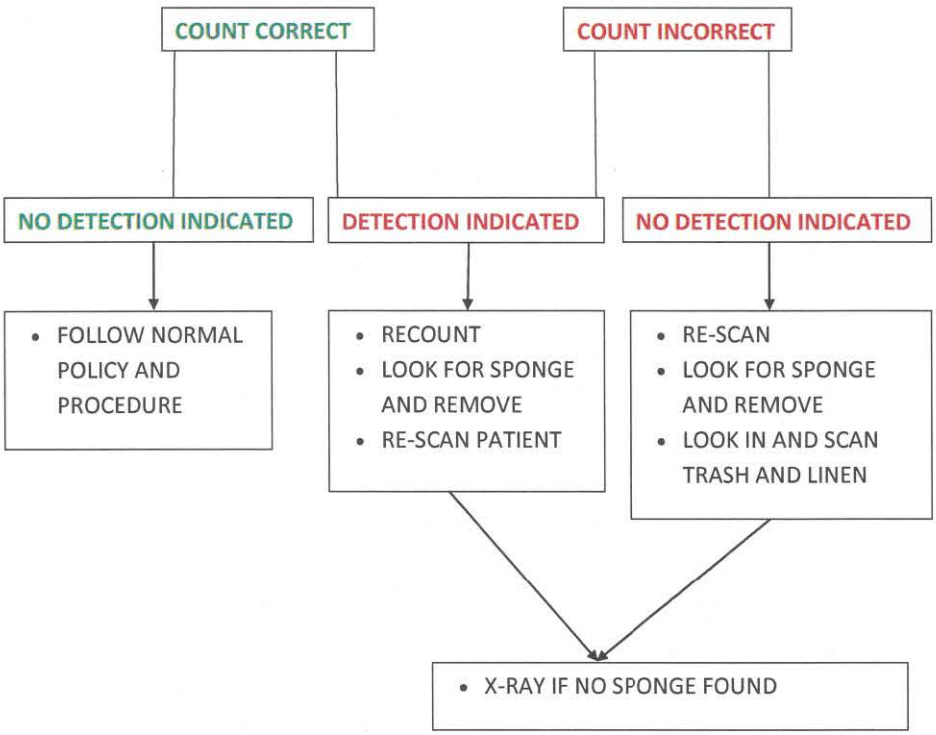
- **Pacemakers/AICDs (Automatic Implantable Cardioverter Defibrilator).** Magnet usage is known to block the tag signal. The following guidelines are suggested for most cardiac rhythm management devices:
    - Temporary cardiac pacemaker rhythm should be observed during the RF scan. Utilize VOO or DOO if indicated and observe the rhythm after RF scan. Notify the EP (Electrophysiology/Pacemaker Technician) service (619-251-6031) if device interrogation is required.
    - For AICDs or pacemakers with a magnet in place during surgery, remove the magnet and resume underlying pacemaker programming before RF scan at the end of the procedure.
    - Notify the EP service if rhythm abnormalities arise for interrogation/reprogramming in PACU or ICU.
    - For AICDs or pacemakers without magnets in place during surgery, observe patient rhythm strip during scan and duration of time in OR after RF scan. Notify EP team if rhythm abnormalities arise for interrogation/reprogramming in Post Anesthesia Care Unit (PACU) or Intensive Care Unit (ICU.
    - For pacemakers placed in asynchronous modes for surgery preoperatively, observe rhythm after RF and notify the EP service (619-251-6031) to reprogram the device postoperatively.

- Use only one device at a time for scanning.
- When the body area that is being scanned extends above or beyond the mat's 16" of effective scanning range, the wand will be used in conjunction with the mat to expand the effective scanning range to 32". A mat scan will be performed first followed by a wand scan.
- **Mat Usage** -Attach the mat cable plug to the connector labeled "RF Mat" on the console front panel. When connected the display icon will illuminate green to indicate a functional mat:
    - Press the RF Assure Mat icon to begin scanning
    - Verify the console is in scan mode by observing the scanning progress bar.
    - RF Mat scanning period can last up to 14 seconds
- **Wand Usage** - Attach wand cable to the connector labeled "RF Wand" on the console front panel. Once connected, the "Blair-Port Wand" icon will illuminate:
    - When the wand is being used it will be covered with the sterile wand drape.
    - Press the Blair-Port Wand icon to begin scanning. This should be done while holding the wand in the air away from the operative field.
    - Verify the console is in scan mode by observing the scanning progress bar.
    - Scan patient by moving wand over the operative site. Move the wand at a steady rate of no more than 6 inches per second. Scan low and slow, close to the patient's body. RF Wand scanning will automatically time out after 4 minutes.
    - To ensure thorough scanning for various tag orientations, the wand must follow a specified scan pattern over the contour of the patient's body (See Appendix A).
- If a tag is detected, the display shows "DETECTION" and a solid tone is audible. Touch the screen to acknowledge and stop alert.
    - When "DETECTION" is observed during scanning, perform an exhaustive search of the surgical wound, body cavities and surrounding areas. When indicated, reopening of peritoneum, fascia and/or body cavity may be required to provide an adequate exploration and location of the tagged item.

- If the item is found, remove the tagged item(s) from the operative field, recount and rescan patient to ensure that all tagged items have been removed.
- If the item is not found, an x-ray will be obtained in accordance with the MOR Count Policy.
- If the item is located on x-ray, remove the tagged item(s) from the operative field, recount and rescan the patient to ensure all tagged items have been removed.
- If the item is not located on x-ray and "DETECTION" continues to be observed, the patient will remain anesthetized, be transferred to a gurney and rescanned to ensure no tagged items remain in the patient.
- Consult Outcomes Algorithm below for additional guidance.

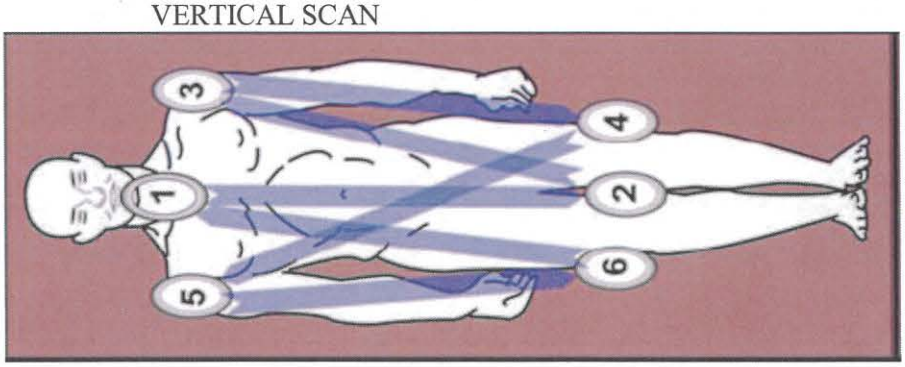
- When finished scanning, press the "STOP" button on the console. Scan stop is indicated by three short beeps.
- Document the scan by checking the "RF Scan Completed" box in the Essentris Intraoperative Note located in the count section of the note.
- To power down the system turn power switch to the off position.
- Following the procedure, the console, wand and mat will be cleaned with a hospital approved germicidal. The wand is not a single use item and may be reused until damaged or not functioning properly.

Outcomes Algorithm:



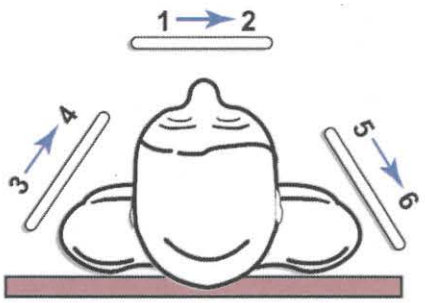
Appendix A: Scanning Recommendations

VERTICAL SCAN

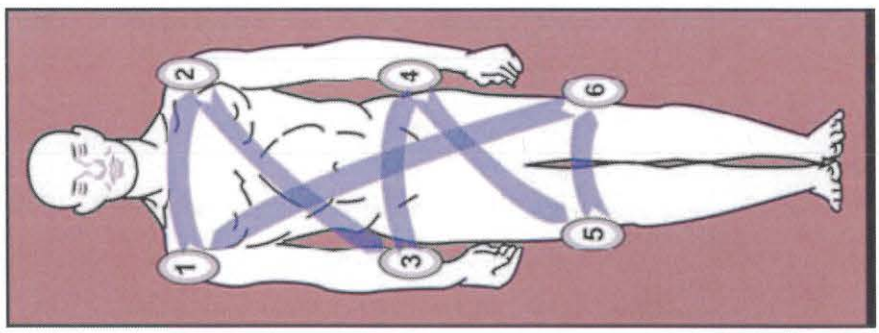


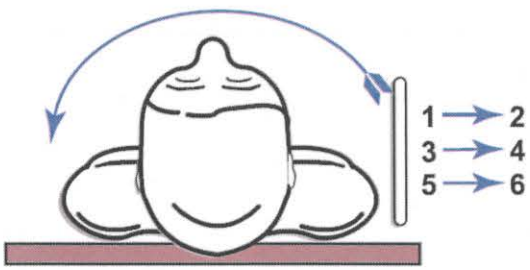
Appendix A

Enclosure (1)



HORIZONAL SCAN





References:

1. RF Surgical Detection System Directions for Use: RF Assure Detection System Model 200
2. RF Assure Quick Start Guide
3. AORN Guidelines for Perioperative Practice, Current Edition

Note: Images courtesy of RF Surgical™ Systems Inc.

Competency

All perioperative personnel will receive education and complete competency validation activities on safe practices for the prevention of RSIs; the risks of injury (e.g., needle sticks) to the patient and to health care personnel; and corrective actions that should be implemented when a process failure occurs, including:

- accounting procedures, equipment, and technology (current and new);
- performance of manual count procedures (e.g., soft goods, instruments, sharps, miscellaneous items);
- use of adjunct technology, following manufacturers' written instructions;
- the roles, responsibilities, and accountability of each perioperative team member;
- measures for reconciliation of count discrepancies; and
- reporting of known or suspected RSIs.

Additional radio frequency scanning education and training will include an initial ONE TIME training:

- [redacted]
- click on the "training" button at the top right of the page
- type in code **navy11**
- register your name
- you will then be required to sign in using your e-mail and password
- select **RF ASSURE MODEL 200** and begin the training
- complete the training and print your certificate for your training file

Personnel will also receive annual RF assure system re-fresher training.

Glossary

Gossypiboma: The unintentional retention of soft goods.

Instruments: Surgical tools or devices designed to perform a specific function, such as cutting, dissecting, grasping, holding, retracting, or suturing.

Miscellaneous items: In relation to items on the sterile field that require counting, this may include vessel clip bars, vessel loops, umbilical and hernia tapes, vascular inserts, electrosurgery scratch pads, trocar sealing caps, and any other small items that have the potential for being retained in a surgical wound.

Sharps: Items with edges or points capable of cutting or puncturing other items. In the context of surgery, items include, but are not limited to, suture needles, scalpel blades, hypodermic needles, electrosurgical needles and blades, instruments with sharp edges or points, and safety pins.

Sponges: Soft goods (e.g., gauze pads, cottonoids, peanuts, dissectors, tonsil/laparotomy sponges) used to absorb fluids, protect tissues, or apply pressure or traction.

Waived count: Surgical procedures in which accurate accounting for sponges, instruments, and miscellaneous items is determined to be unachievable or in situations in which the time required to perform the count may present an unacceptable delay in patient care (eg, trauma procedures, anterior-posterior spinal procedures).

References

Petersen C, ed. *Perioperative Nursing Data Set*. 3rd ed. Denver, CO: AORN, Inc.; 2010.

Recommended practices for prevention of retained surgical items. In: *Perioperative Standards and Recommended Practices*. Denver, CO: AORN, Inc.; 2014:332-350.