PREVENTION OF UNINTENDED RETAINED FOREIGN ITEMS IN THE OPERATING ROOM

1. SUMMARY OF MAJOR CHANGES: This Veterans Health Administration (VHA) directive:

a. Updates responsibilities for the Department of Veterans Affairs (VA) medical facility Director and VA medical facility Chief of Surgery (see paragraph 2).

b. Adds new responsibilities for the Under Secretary for Health; Assistant Under Secretary for Health for Patient Care Services/Chief Nursing Officer; Assistant Under Secretary for Health for Clinical Services; Assistant Under Secretary for Health for Operations; Director, National Surgery Office (NSO); Veterans Integrated Service Network (VISN) Director; VISN Chief Surgical Consultant; VA medical facility Chief of Staff; VA medical facility Associate Director for Patient Care Services; VA medical facility Operating Room Nursing Leadership; and VA medical facility surgical team (see paragraph 2).

c. Updates definitions to include foreign items, invasive procedure, operating room, sharps, soft goods, miscellaneous items, instruments and surgical suite (see paragraph 7).

d. Moves detailed processes to appendices (see Appendices A - D).

e. Adds the requirement to perform one of two options for additional management of implant components (see Appendix B).

2. RELATED ISSUES: VHA Directive 1004.08, Disclosure of Adverse Events to Patients, dated October 31, 2018; VHA Directive 1039(3), Ensuring Correct Surgery and Invasive Procedures In and Out of the Operating Room, dated November 28, 2018; VHA Directive 1050.01, VHA Quality and Patient Safety Programs, dated March 24, 2023.

3. POLICY OWNER: The National Surgery Office (11SURG) in the Office of the Assistant Under Secretary for Health for Clinical Services is responsible for the content of this directive. Questions may be directed to the Director, NSO at vhaco.national.surgery.office@va.gov.

4. RESCISSIONS: VHA Directive 1103(1), Prevention of Retained Surgical Items, dated March 5, 2016, is rescinded.

5. RECERTIFICATION: This VHA directive is scheduled for recertification on or before the last working day of April 2028. This VHA directive will continue to serve as national VHA policy until it is recertified or rescinded.

6. IMPLEMENTATION SCHEDULE: This directive is effective upon publication.

BY DIRECTION OF THE OFFICE OF THE UNDER SECRETARY FOR HEALTH:

/s/ Erica M. Scavella, MD, FACP, FACHE
Assistant Under Secretary for Health
for Clinical Services/CMO

NOTE: *All references herein to VA and VHA documents incorporate by reference subsequent VA and VHA documents on the same or similar subject matter.*

DISTRIBUTION: Emailed to the VHA Publications Distribution List on April 27, 2023.

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PREVENTION OF UNINTENDED RETAINED FOREIGN ITEMS IN THE OPERATING ROOM

1. POLICY

It is Veterans Health Administration (VHA) policy that the Department of Veterans Affairs (VA) medical facility surgical team must apply a standard approach for the prevention of unintended retained foreign items for Operating Room (OR) surgical and invasive procedures. Occurrence of unintended retained foreign items during OR procedures is a sentinel event and must be investigated and reported using the Critical Incident Tracking Notification (CITN). **AUTHORITY:** 38 U.S.C. § 7301(b).

2. RESPONSIBILITIES

a. **Under Secretary for Health.** The Under Secretary for Health is responsible for ensuring overall VHA compliance with this directive.

b. **Assistant Under Secretary for Health for Clinical Services.** The Assistant Under Secretary for Health for Clinical Services is responsible for supporting the National Surgery Office (NSO) with implementation and oversight of this directive.

c. **Assistant Under Secretary for Health for Operations.** The Assistant Under Secretary for Health for Operations is responsible for:

(1) Communicating the contents of this directive to each of the Veterans Integrated Services Networks (VISNs).

(2) Assisting VISN Directors to resolve implementation and compliance challenges in all VA medical facilities within that VISN.

(3) Providing oversight of VISNs to ensure compliance with this directive and its effectiveness.

d. **Assistant Under Secretary for Health for Patient Care Services/Chief Nursing Officer.** The Assistant Under Secretary for Health for Patient Care Services/Chief Nursing Officer is responsible for communication of the requirements of this directive and providing any necessary oversight and support to relevant Patient Care Services personnel.

e. **Director, National Surgery Office.** The Director, NSO is responsible for:

(1) Providing oversight for the VISN and VA medical facility compliance with this directive and ensuring corrective action is taken when non-compliance is identified.

(2) Reviewing unintended retained foreign items data submitted by the Director, National Center for Patient Safety (NCPS). ***NOTE:*** *CITN is a required reporting system for occurrence of unintended retained foreign items. The Director, NCPS provides the Joint Patient Safety Reporting System surgical data to NSO to review submissions to*

ensure unintended retained foreign item data occurrences are completely captured in the CITN process. See paragraph 6.c. for additional reporting requirements information.

(3) Ensuring unintended retained foreign item CITN aggregate data is dispersed to appropriate VISN Chief Surgical Consultants on a routine basis. ***NOTE:*** *For more information, see VHA Directive 1102.01(2), National Surgery Office, dated April 24, 2019.*

f. **Veterans Integrated Service Network Director.** The VISN Director is responsible for ensuring that all VA medical facilities within the VISN comply with this directive and informing leadership when barriers to compliance are identified.

g. **Veterans Integrated Service Network Chief Surgical Consultant.** The VISN Chief Surgical Consultant is responsible for:

(1) Ensuring that current surgical practice for prevention of unintended retained foreign items across the VISN is compliant with VHA surgical policy.

(2) Reviewing unintended retained foreign item CITN aggregate data from the Director, NSO.

(3) Communicating lessons learned from unintended retained foreign item CITN aggregate data and providing quality oversight to surgical programs within the VISN.

h. **VA Medical Facility Director.** The VA medical facility Director is responsible for:

(1) Ensuring overall VA medical facility compliance with this directive and appropriate corrective action is taken if non-compliance is identified.

(2) Ensuring that all instances of unintended retained foreign items from OR procedures are disclosed to patients as outlined in VHA Directive 1004.08, Disclosure of Adverse Events to Patients, dated October 31, 2018, and reported as a CITN, in accordance with the CITN Memorandum and CITN incident definitions found on the NSO intranet site: https://dvagov.sharepoint.com/sites/VHANSO. ***NOTE:*** *This is an internal VA website that is not available to the public.*

i. **VA Medical Facility Chief of Staff and Associate Director for Patient Care Services.** The VA medical facility Chief of Staff (CoS) and VA medical facility Associate Director for Patient Care Services (ADPCS) are responsible for:

(1) Ensuring compliance with this directive in applicable clinical care areas.

(2) Using CITN to report unintended retained foreign items from OR procedures in accordance with the CITN Memorandum and CITN incident definitions found on the NSO intranet site, https://dvagov.sharepoint.com/sites/VHANSO. ***NOTE:*** *This is an internal VA website that is not available to the public.*

j. **VA Medical Facility Chief of Surgery and Operating Room Nursing Leadership.** The VA medical facility Chief of Surgery and Operating Room Nursing Leadership, who oversees operative care area, are responsible for ensuring that the VA medical facility surgical team performing an OR procedure adheres to the foreign item prevention requirements outlined in paragraph 3 of this directive.

k. **VA Medical Facility Surgical Team.** ***NOTE:*** *For purposes of this directive, the VA medical facility surgical team core members consist of, at minimum, a surgeon, a registered nurse (RN) circulator and a scrub person.* The VA medical facility surgical team is responsible for adhering to the foreign item prevention requirements outlined in paragraph 3 of this directive when performing OR procedures.

(1) **Surgeon.** The surgeon is responsible for:

(a) Maintaining integrity of counted soft goods. This includes leaving counted soft goods in original configuration, not cut or altered in any way or used for dressings. ***NOTE:*** *If other non-soft goods need to be cut (e.g., mesh), ensure cut pieces are counted and removed from wound.*

(b) Providing the RN circulator and scrub person with sufficient time to perform foreign items counts.

(c) Performing complete methodical wound explorations before closing the surgical wound in every OR procedure to ensure that all unintended retained foreign items are extracted in accordance with Appendix A.

(d) Using intraoperative radiography in accordance with Appendix C.

(2) **Registered Nurse Circulator.** The RN circulator is responsible for:

(a) Performing a complete count of all foreign items in collaboration with the scrub person for every OR procedure in accordance with Appendix B.

(b) Informing the surgeon immediately of an incorrect count.

(c) Supporting use of intraoperative radiography in accordance with Appendix C.

(d) Documenting when soft goods are used as therapeutic packing in accordance with Appendix B.

(e) Documenting when foam pads are placed with negative-pressure wound therapy (NPWT) devices in accordance with Appendix B.

(3) **Scrub Person.** The scrub person is responsible for:

(a) Performing mandatory inspections of all foreign items for breakage and fragmentation before placement in the surgical wound and immediately after removal from the surgical wound.

(b) Performing a complete count of all foreign items in collaboration with the RN circulator in accordance with Appendix B.

(c) Supporting use of intraoperative radiography in accordance with Appendix C.

(d) Notifying the RN circulator when soft goods are used as therapeutic packing in accordance with Appendix B

(e) Notifying the RN circulator when foam pads are placed with NPWT devices in accordance with Appendix B.

3. FOREIGN ITEM PREVENTION REQUIREMENTS

As part of complete OR procedure care, the VA medical facility surgical team must adhere to the follow standards regarding foreign items:

a. **Soft Goods.** All soft goods that are placed in the surgical field must be left in their original configuration and must not be cut or altered in any way or used for dressings. ***NOTE:*** *If other non-soft goods need to be cut (e.g., mesh), ensure cut pieces are counted and removed from wound.*

b. **Radiopaque Foreign Items.** Foreign items intended for placement in the surgical wound or on the sterile field which have the potential to be placed or transferred into the surgical wound must be radiopaque (detectable by a radiograph) when a radiopaque option is available.

c. **Non-Radiopaque Anesthesia and Surgical Prep Items.** Non-radiopaque anesthesia and surgical prep items that are used in the OR (e.g., sponges used during intravenous line insertion) must be isolated and disposed of in a separate waste receptacle away from the counted surgical sterile field foreign items.

d. **Methodical Wound Exploration.** A methodical wound exploration must be performed before closing the surgical wound in every case to ensure that all unintended retained foreign items are extracted in accordance with Appendix A.

e. **Count of Foreign Items.** All sterile foreign items, including radiopaque foreign items and non-radiopaque items, must be counted in every case, in accordance with Appendix B.

f. **Foreign Item Integrity Inspection.** All foreign items must be inspected for breakage or fragmentation prior to insertion into surgical wound and immediately after removal from the surgical wound.

g. **Required Use of Intraoperative Radiography.** Intraoperative radiography is required when:

(1) Surgical counts are inaccurate and a potential unintended retained foreign item exists, in accordance with Appendix C.

(2) The surgical team unanimously agrees that the number of surgical instruments utilized during the OR procedure prohibits an expeditious count, in accordance with Appendix C. ***NOTE:*** *A methodical wound exploration and count of all sharps, soft goods and miscellaneous items, must still be performed in addition to inspection of instrument integrity throughout the procedure.*

(3) Clinical circumstances dictate that a patient requires emergency care without time to count foreign items in accordance with Appendix C.

(4) Any member of the surgical team considers the OR procedure to be at higher than usual risk for an unintended retained foreign item in accordance with Appendix C.

4. TRAINING

There are no formal training requirements associated with this directive.

5. RECORDS MANAGEMENT

All records regardless of format (e.g., paper, electronic, electronic systems) created by this directive must be managed as required by the National Archives and Records Administration (NARA) approved records schedules found in VHA Records Control Schedule 10-1. Questions regarding any aspect of records management should be addressed to the appropriate Records Officer.

6. BACKGROUND

a. In 2013, The Joint Commission published Sentinel Event Alert 51, which identified unintended retained foreign items as a sentinel event and provided recommended strategies for reducing unintended retained foreign items (http://www.jointcommission.org/sea_issue_51/).

b. NSO collects data for unintended retained foreign items. For fiscal years 2020-2022, the VHA incidence of unintended retained foreign items was calculated at approximately one in 22,000 surgical procedures. This rate compares favorably to the national incidence of one in every 5,500 procedures of unintended retained foreign items. ***NOTE:*** *For more information on retained foreign items trends, see https://pubmed.ncbi.nlm.nih.gov/18589366/.*

c. The occurrence of an unintentionally retained foreign item is considered a sentinel event and must be reported to NCPS through the Joint Patient Safety Reporting system, in addition to CITN submission and root cause analysis (RCA). ***NOTE:*** *VHA Directive 1050.01, VHA Quality and Patient Safety Programs, dated March 24, 2023, and VHA Directive 1004.08 provide further guidance regarding sentinel event reporting and requirements for patient disclosure*.

d. The CITN process has been established to notify key VA medical facility, VISN, NCPS and NSO personnel of unintended retained foreign item events using a secure web-based intranet tool. On a quarterly basis, NSO reconciles these CITNs to ensure a

complete capture and notification of all events. For more information on CITN, see https://dvagov.sharepoint.com/sites/VHANSO. ***NOTE:*** *This is an internal VA website that is not available to the public.*

e. The American College of Surgeons (ACS) Committee and the Association of periOperative Registered Nurses (AORN) have published guidance regarding unintended retained foreign items that VA health care providers reference for invasive and OR procedures. ***NOTE:*** *For guidance by the ACS Committee and AORN see, https://bulletin.facs.org/2016/10/revised-statement-on-the-prevention-of-unintentionally-retained-surgical-items-after-surgery/ and https://aornguidelines.org/guidelines/content?sectionid=173723395&view=book#173723395 respectively.*

7. DEFINITIONS

a. **Electronic Health Record.** EHR is the digital collection of patient health information resulting from clinical patient care, medical testing and other care-related activities. Authorized VA health care providers may access EHR to facilitate and document medical care. EHR comprises existing and forthcoming VA software including Computerized Patient Record System (CPRS), Veterans Information Systems and Technology Architecture (VistA) and Cerner platforms. ***NOTE:*** *The purpose of this definition is to adopt a short, general term (EHR) to use in VHA national policy in place of software-specific terms while VA transitions platforms.*

b. **Foreign Items.** Foreign items are instruments, sharps, soft goods, drains, guidewires or any miscellaneous items or materials used by the VA medical facility surgical team to perform an OR procedure that are not intended to remain, in part or in whole, in the patient's body after the patient leaves the OR.

c. **Instruments.** Instruments are reusable, disposable or reposable surgical tools or devices used by clinicians for the performance of surgical actions.

d. **Invasive Procedure.** An invasive procedure is the puncture or incision of the skin, insertion of an instrument or insertion of foreign material into the body for diagnostic or treatment-related purposes.

e. **Miscellaneous Items.** Miscellaneous items are foreign items utilized during an OR procedure which are not defined as instrumentation, sharps or soft goods and which are anticipated to touch the wound or sterile patient drape. These include but are not limited to: scratch pads, syringes, vessel loops, sterile wecks, cotton applicators, marking pen with caps, staple loads, electrosurgery pencils and tips, specimen cups, rulers, implant sizers, implant trials, defogging applicator, Penrose drains, cottonoids, suction tips, trocars.

f. **Operating Room.** An OR is a room in the surgical suite that meets the requirements of a restricted area and is designated and equipped for performing invasive procedures in accordance with the Facility Guidelines Institute (FGI). For the purposes of this directive, an OR does not include minor procedure rooms or procedure

rooms located outside of the surgical suite, even if FGI's OR design guidelines are met. ***NOTE:*** *FGI Guidelines for Design and Construction can be found at https://fgiguidelines.org/guidelines/2018-fgi-guidelines/. Registration is required to access a read-only copy.*

g. **Operating Room Procedure.** An OR procedure is any surgical or invasive procedure performed in a VA OR within the surgical suite.

h. **Sharps.** Sharps are surgical needles, aspirating needles, blunt needles, scalpel blades or any items with a sharp or pointed edge that pose a risk for skin puncture by members of the VA medical facility surgical team.

i. **Soft Goods.** Soft goods are cotton gauze sponges of various sizes, laparotomy pads, surgical towels or any non-implantable absorbent materials.

j. **Surgical Suite.** A surgical suite is a group of rooms designed to provide procedure-related surgical services to patients. The surgical suite encompasses all areas associated with surgery including surgical procedure rooms, staff changing rooms and bathrooms, scrub bays and lounges, as well as areas for preparation and anesthesia of patients, equipment storage and post-anesthesia care areas.

8. REFERENCES

a. 38 U.S.C. § 7301.

b. VHA Directive 1004.08, Disclosure of Adverse Events to Patients, dated October 31, 2018.

c. VHA Directive 1039(3), Ensuring Correct Surgery and Invasive Procedures In and Out of the Operating Room, dated November 28, 2018.

d. VHA Directive 1050.01, VHA Quality and Patient Safety Programs, dated March 24, 2023.

e. VHA Directive 1102.01(2), National Surgery Office, dated April 24, 2019.

f. NSO SharePoint. https://dvagov.sharepoint.com/sites/VHANSO. ***NOTE:*** *This is an internal VA website that is not available to the public.*

g. American College of Surgeons Committee. Revised Statement on the Prevention of Unintentionally Retained Surgical Items After Surgery. 2016: https://bulletin.facs.org/2016/10/revised-statement-on-the-prevention-of-unintentionally-retained-surgical-items-after-surgery/.

h. Association of periOperative Registered Nurses. The Guideline for Prevention of Unintentionally Retained Surgical Items. 2022. https://aornguidelines.org/guidelines/content?sectionid=173723395&view=book#173723395.

i. FGI. Guidelines for Design and Construction. https://fgiguidelines.org/guidelines/2018-fgi-guidelines/.

j. Journal of the American College of Surgeons. Incidence and characteristics of potential and actual retained foreign object events in surgical patients. 2008. https://pubmed.ncbi.nlm.nih.gov/18589366/.

k. The Joint Commission. Sentinel Event Alert 51: Preventing unintended retained foreign objects. 2013: http://www.jointcommission.org/sea_issue_51/.

METHODICAL WOUND EXPLORATION

1. A methodical wound exploration must be performed before closing the surgical wound in every operating room procedure to ensure that all unintended retained foreign items are extracted.

2. The space to be closed must be carefully examined. Special focus must be given to closure of a cavity within a cavity (e.g., heart, major vessel, stomach, bladder, uterus and vagina).

3. The surgeon must visually and manually explore the operative field, making every effort to remove all unintended retained foreign items within a body cavity.

4. A methodical visual inspection of the body cavity is required when performing a minimally invasive laparoscopic, thoracoscopic or arthroscopic procedure.

5. A methodical visual wound examination is required for procedures utilizing the microscope (e.g., ophthalmological, otolaryngological).

6. If at any time during wound closure the surgeon is informed of a missing portion of a foreign item or an inaccurate count of foreign items, the surgeon must stop closing the wound and perform a repeat methodical wound examination while the Department of Veterans Affairs medical facility surgical team continues to look for the missing foreign item. It is imperative that a reasonable and appropriate search of the operative field and surrounding area be undertaken to recover the foreign item in question and resolve the discrepancy.

COUNT OF FOREIGN ITEMS

1. FOREIGN ITEM INTEGRITY INSPECTION

All foreign items must be inspected for breakage or fragmentation prior to insertion into surgical wound and immediately after removal from the surgical wound.

2. Foreign items must be counted in every operating room (OR) case. This includes a mandatory count of all sharps, soft goods, instruments (in accordance with Appendix D) and miscellaneous items.

a. All miscellaneous items which could potentially touch the wound or sterile patient drape must also be counted.

b. During implantation procedures, all associated components not intended for permanent implantation (e.g., sizers, trials, protectors, packaging) must be accounted for using one of following methods, even when intraoperative radiographs are utilized in lieu of counting:

(1) **Option One.** Implementing an implantation time-out where the VA medical facility surgical team performs a methodical wound sweep and accounts for all associated components utilized prior to the permanent implantation (e.g., sizers, trials, protectors, packaging). ***NOTE:*** *This is in addition to the pre-implantation read-back required in VHA Directive 1039(3), Ensuring Correct Surgery and Invasive Procedures In and Out of the Operating Room, dated November 28, 2018.*

(2) **Option Two.** Counting all associated components (e.g., sizers, trials, protectors, packaging) as miscellaneous items. ***NOTE:*** *For procedures with a large implant system, it is acceptable to sequester associated implant components (e.g., sizers, trials, protectors, packaging) and add them to the count of all components utilized.*

c. The following items are exceptions and are not required to be counted:

(1) Gowns, gloves and draping sheets which touch the wound or sterile patient drape.

(2) Miscellaneous items on the sterile field which will not touch the wound or sterile patient drape such as, but not limited to, basins, instrument stringers, instrument baskets, etc.

3. A count of all foreign items (sharps, soft goods, instruments and required miscellaneous foreign items) must occur:

a. Before the procedure has begun or the incision is made to establish a baseline count. The baseline count must be increased to account for components added to the sterile field throughout the intraoperative procedure, when:

(1) Additional foreign items are added to the field.

(2) Utilizing Option Two for implant procedures (counting all associated implant components as miscellaneous items).

(3) A drain or other miscellaneous foreign item is cut (e.g., mesh), including accounting for and counting all cut pieces.

b. Before the closure of a cavity within a cavity.

c. Before wound closure begins.

d. At skin closure or end of procedure.

e. At the time of permanent relief of either the scrub person or the registered nurse (RN) circulator.

f. At any time a count discrepancy is suspected.

4. The RN circulator and scrub person must be allowed sufficient time to perform a count of all foreign items. ***NOTE:*** *Sufficient time is based on the number of items (e.g., instruments, soft goods, sharps, miscellaneous items) needed for the invasive procedure and is at the discretion of the VA medical facility surgical team.*

5. When the surgical team unanimously agrees that the number of surgical instruments utilized or the number of radiopaque implants (e.g., screws, plates) during the OR procedure prohibits an expeditious count, an intraoperative radiography may be used in lieu of the instrument count in accordance with Appendix C. ***NOTE:*** *In cases where intraoperative radiography is used in lieu of counting, the non-instrument counts (sharps, soft goods, and miscellaneous items) must still be performed.*

6. All foreign item counts are performed using a standard two-person practice: the foreign items are counted audibly and viewed concurrently by the scrub person and RN circulator.

7. Any time there is a question by any member of the VA medical facility surgical team regarding the count, an additional count must be performed.

8. Perioperative personnel must never assume that the count on prepackaged sterilized items is accurate. The contents of each package must be counted individually by the scrub person and RN circulator using the standard two-person practice. If the package has an incorrect standard number of items and the procedure has not begun, the entire package must be removed from the OR. If the procedure has begun, the package must be bagged, properly labeled and isolated from the other counted foreign items. ***NOTE:*** *In the case of custom pack usage, if a package has an incorrect standard number of items (e.g., there were four lap sponges in the normal five count lap package), only the incorrect items (e.g., lap package) are to be removed/isolated, not the entire custom pack contents.*

9. Counts must be performed in the same sequence each time. The count needs to begin at the surgical site and the immediate surrounding area, proceed to the instrument stand and back table and finally to the counted items (e.g., soft goods, sharps, miscellaneous items, or instruments) that have been discarded from the field. ***NOTE:*** *The use of assistive technologies, including radiofrequency tags to detect technology-enabled soft goods and radio frequency identification systems, are adjunct technologies to supplement the manual counting process but do not replace the requirement to perform a count of foreign items in every surgical case.*

10. When soft goods are used as therapeutic packing and the patient leaves the OR with packing in place, the number and types of items placed must be documented in the EHR in the intraoperative nursing documentation. ***NOTE:*** *The soft goods count is considered correct if all of the sponges are accounted for.* If the patient returns to the OR for a subsequent procedure including the removal of the therapeutic packing, the number and type of radiopaque soft goods must be similarly documented and excluded from subsequent counts of foreign items.

11. When a negative-pressure wound therapy device involves placement of foam pieces in the wound, the number of foam pieces must be documented in the electronic health record (EHR) in the intraoperative nursing documentation. If the patient returns to the OR for a subsequent procedure including the removal of the foam pieces, the number removed must be similarly documented in the EHR.

12. All relief personnel must be documented in the EHR in intraoperative nursing documentation.

USE OF INTRAOPERATIVE RADIOGRAPHY

1. Intraoperative radiography for the purposes described below must be an intraoperative radiograph of the entire surgical field which has a saved digital image or physical radiograph. The request for radiography must contain the clinical indication (e.g., incorrect count with known missing item, high-risk patient with correct count, count not feasible due to high number of surgical instruments, count not feasible due to emergency status).

2. Intraoperative radiography of the surgical field is not required if a methodical wound exploration is performed and a count of all required foreign items is correct at the completion of the procedure.

3. Intraoperative radiography of the entire surgical field to rule out unintended retained foreign items must be performed prior to the patient's transfer from the operating room (OR), in the following circumstances:

a. When the foreign item count is incorrect (e.g., the preoperative foreign item count plus foreign items added during the procedure is greater or less than the postoperative foreign item count) and the foreign item in question is not recovered following a methodical wound exploration.

b. When the missing foreign item cannot be found in the surgical field or in the OR by the surgical team, a radiologist must interpret the intraoperative radiograph and notify the surgical team of their findings. If an unintended foreign item is identified on the intraoperative radiograph, the radiologist must verbally notify the attending surgeon. The radiologist's report must be made available to the VA medical facility surgical team in a timely fashion, recommended to be less than 30 minutes from the time the radiograph was requested. Consideration should be given to obtaining additional views (e.g., an oblique view of the operative site when initial radiographs do not reveal the missing foreign item and the foreign item still has not been found). ***NOTE:*** *The surgeon has the discretion to close the surgical wound prior to receiving a report from the radiologist regarding a missing foreign item if delaying wound closure would substantially increase risk for the patient.*

(1) The attending surgeon may interpret intraoperative radiographs to facilitate the patient leaving the OR prior to radiology concurrence when the attending surgeon determines that it would be detrimental to the patient to wait for radiologist interpretation.

(2) There is no requirement for a radiologist to interpret the intraoperative radiography if the VA medical facility surgical team subsequently finds the missing object, thereby establishing the foreign count as correct.

(3) When the surgical wound does not involve a body cavity and the entirety of the wound is visible to the surgical team, if the surgical team unanimously agrees that an

intraoperative radiograph is not necessary for finding the inaccurate count item, as the surgical wound is not able to retain the missing foreign item, then intraoperative radiography may be waived. The attending surgeon must document the circumstances and reason for not obtaining intraoperative radiography in the patient's electronic health record (EHR) (e.g., circumcision, skin graft and that there was unanimous agreement for a missing item).

(4) If the surgical team unanimously agrees that intraoperative radiography is not needed because the missing foreign item is too small for radiography detection or if the procedure is limited to ocular surgery. The attending surgeon must document the circumstances and reason for not obtaining intraoperative radiography in the patient's EHR.

c. When the surgeon, scrub person and registered nurse (RN) circulator unanimously agree that the number of surgical instruments/radiopaque implants utilized during the OR procedure prohibits an expeditious count. In such cases (e.g., major joint replacement, spine procedures), intraoperative radiography of the entire surgical field, is required as an effective substitute for counting of instrumentation. ***NOTE****: A methodical wound exploration and count of all sharps, soft goods and miscellaneous items must still be performed in addition to inspection of instrument integrity throughout the procedure, even though intraoperative radiography is substituted for the surgical instrument count in such circumstances. Radiography must include sufficient views to assess the entire surgical field, especially when radiopaque implants may limit detection of a potential unintended retained foreign items. Intraoperative radiographs must be interpreted by either an attending surgeon or radiologist prior to the patient leaving the OR.*

d. When the clinical circumstances dictate a patient requires emergency care without counting of foreign items. This divergence or omission from standard protocol (i.e., methodical wound exploration and complete foreign item count) must be documented in the intraoperative documentation in the following manner:

(1) The surgeon must include a statement in the EHR operative report describing the emergent nature of the procedure, the clinical condition of the patient and the reasons for divergence from or omission of standard protocol.

(2) The RN circulator must describe in the intraoperative nursing documentation the emergent nature of the OR procedure, the clinical condition of the patient and the aspects in which standard protocol was omitted or modified.

(3) In such cases, radiography must be obtained in the OR, Post-Anesthesia Recovery Unit or Intensive Care Unit depending on the patient's clinical condition and interpreted by a radiologist to rule out an unintended retained foreign item unless contraindicated by the patient's clinical condition.

e. When the OR procedure being performed is one determined by any member of the VA medical facility surgical team to be at higher than usual risk for unintended

retained foreign items, even though a methodical wound exploration has been performed and the foreign item count is correct. ***NOTE:*** *OR procedures that are potentially higher than usual risk for unintentional retained foreign items include, but are not limited to, emergency procedures involving a body cavity, unexpected change in the conduct or scope of the OR procedure, OR procedures involving more than one surgical team, OR procedures of considerable duration particularly those that require a nursing staff shift change, unexpected blood loss with transfusions of greater than four units of packed red blood cells and high patient body mass index.*

INSTRUMENT COUNT PROCESS ALTERNATIVE

1. An instrument count must occur for every case, unless performing intraoperative radiography in lieu of counting. VA medical facility surgical teams have the option of performing a complete instrument count at every layer of closing or may perform the following alternative instrument count process:

a. A complete instrument count before the procedure has begun or the incision is made to establish a baseline count. ***NOTE:*** *The baseline count must be increased accordingly throughout the intraoperative procedure when additional instruments are added to the sterile field.*

b. A complete instrument count before the closure of a cavity within a cavity. Intracavity instruments may be sequestered away from the patient's wound, draped patient and Mayo stand after the cavity count is confirmed as correct. These intracavity instruments are not required to be included in future closing counts if not utilized for the rest of the procedure.

c. A reduced instrument count before wound closure begins. Wound closure instruments may be sequestered away from the patient's wound, draped patient and mayo stand after the wound closure count is confirmed as correct. These wound closure instruments are not required to be included in future closing counts if not utilized for the rest of the procedure.

d. A reduced instrument count at skin closure or end of procedure. Skin forceps, skin needle drivers, towel clips and any additional instrumentation utilized between closure of the wound and closure of the skin.

e. A full instrument count at the time of permanent relief of either the scrub person or the registered nurse circulator.

f. A full instrument count at any time an instrument count discrepancy is suspected or when the above sequester processes were not followed.

2. The instrument counting processes (either a complete count at every closing layer or the alternative reduced counting process) is for all OR cases except emergency cases where counting instruments would negatively impact patient condition or when the surgical team unanimously decided to use intraoperative radiography in lieu of instrument counting due to large volume of instrumentation.