

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  <b>050070</b>	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED  <b>03/30/2011</b>
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NAME OF PROVIDER OR SUPPLIER  <b>KAISER FOUNDATION HOSPITAL - SOUTH SAN FRANCISCO</b>	STREET ADDRESS, CITY, STATE, ZIP CODE <b>1200 EL CAMINO REAL, SOUTH SAN FRANCISCO, CA 94080 SAN MATEO COUNTY</b>
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(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
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The following reflects the findings of the Department of Public Health during an inspection visit:

Complaint Intake Number:  
CA00258737 - Substantiated

Representing the Department of Public Health:  
Surveyor ID # 21155, HFEN

The inspection was limited to the specific facility event investigated and does not represent the findings of a full inspection of the facility.

Health and Safety Code Section 1280.1(c): For purposes of this section "immediate jeopardy" means a situation in which the licensee's noncompliance with one or more requirements of licensure has caused, or is likely to cause, serious injury or death to the patient.

Abbreviations and Glossary:

1) Abscess - An enclosed collection of liquefied tissue, known as pus, somewhere in the body. It is the result of the body's defensive reaction to foreign material.

2) Chordoma - Rare tumor that usually occurs in the spine and base of the skull. It is a malignant tumor.

3) Circulator or Circulating Nurse - Registered Nurse who is responsible for delivering quality nursing care to the patient in the OR

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**Health and Safety Code 1280.1 (c) 2/16/11**  
**Immediate Action RCA:**

- Root Cause Analysis (RCA) was performed to assess contributing factors and to develop a corrective plan of action to prevent further incidents.
  - The RCA was conducted by the Director of Risk Management and the Assistant Physician in Chief for Risk Management.
  - Participants included the Surgeon, Circulating Nurse, and Perioperative Services Director.

*POC approved 6/30/11 by R. Jordan*

Event ID: X00N11	6/14/2011	2:25 18PM
LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE <i>Linda J. Jensen</i>	TITLE <i>SR. VP, Area Manager</i>	(X6) DATE <i>6/24/11</i>

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CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY  
DEPARTMENT OF PUBLIC HEALTH

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(operating room) using the nursing process. This RN makes preparations for an operation and continually monitors the patient and staff during its course, who works in the OR outside the sterile field in which the operation takes place, and who records the progress of the operation, accounts for sponges, instruments, and specimens.

4)Curvilinear Density - A mass of matter appearing as a curve, nonlinear.

5)cm - centimeter

6)Counter Bags (sponge holder bags) - Transparent bags into which sponges are individually inserted by the circulating nurse, after they are counted.

7)CT Scan - Computed Tomography Scan - A computerized x-ray procedure. A CT scan produces cross-sectional images of the body. The images are far more detailed than x-ray films, and can reveal disease or abnormalities in tissue and bone.

8)Diabetes - A group of metabolic diseases in which a person has high blood glucose either because the body does not produce enough insulin, or because cells do not respond to the insulin that is produced.

9)Erector Spinae Muscle - The superficial longitudinal muscle mass on either side of the vertebral column. It arises in a broad, thick

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- The RCA focused on potential human factors which may have resulted in error, possible environmental factors (such as noise, equipment, etc) and potential process failures which may have resulted in the error. Other potential factors explored included staffing level, orientation and training of staff, competency assessment and credentialing, supervision of staff, and communication among staff members.
- A literature review was conducted.
- The findings of the root cause analysis were: 1) the final sponge count from the surgical procedure was correct, and

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6/24/11

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	<p>Continued From page 2</p> <p>tendon from the sacrum, the ileum, and the lumbar vertebrae. It inserts into the ribs and into certain cervical vertebrae. It extends and flexes the vertebral column and the head, draws the ribs downward, and bends the trunk to the side.</p> <p>10)Hairy Cell Leukemia - A rare cancer in which a type of white blood cell called the lymphocyte, present in the blood and bone marrow, becomes malignant and proliferates. It is called hairy cell leukemia because the cells have tiny hair-like projections when viewed under the microscope.</p> <p>11)Kick Buckets - A metal receptacle in the OR used to throw waste.</p> <p>12)Laparotomy Sponge - Also "lap sponge" or "lap tape". An and absorbent pad constructed of gauze and cotton with an embedded radiopaque fiber used to absorb fluids and blood in surgery.</p> <p>13)Mayo Stand - A stand where the sterile tray lays in the OR. On the tray are the instruments that may be immediately needed by the surgeon.</p> <p>14)MRI - Magnetic Resonance Imaging - Diagnostic technique which uses a magnetic field and radio waves to provide computerized images of internal body tissues.</p> <p>15)OR - Operating Room</p>	<p style="writing-mode: vertical-rl; transform: rotate(180deg);">CA DEPT OF PUBLIC HEALTH</p> <p style="writing-mode: vertical-rl; transform: rotate(180deg);">AUG 13 2012</p> <p style="writing-mode: vertical-rl; transform: rotate(180deg);">L&amp;C DIVISION SAN FRANCISCO</p>	<p>documented as such by the Circulating Nurse; and 2) the Medical Center policy for announcing and documenting tucked sponges had not been followed by the Surgeon, Circulating Nurse, and Surgical Technician.</p> <p>The participants in the RCA discussed the possibility that a sponge from a previous case may have been left in one of the kick buckets in the OR, thus contributing to the erroneous correct count.</p> <p><b>Immediate Action Process Changes:</b></p> <ul style="list-style-type: none"> <li>As a practice change, the responsibility for removing the soiled liners from sponge kick buckets at the conclusion of each surgical case was transitioned from Environmental Services to OR clinical staff. Liners are</li> </ul>	2/17/11	

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*6/24/11*

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	16)Paraspinous Muscles - The muscles next to the spine. They support the spine and are the motor for the movement of the spine.		to be removed and discarded by the Surgical Scrub Person (RN or technician) assigned to the case, after the case is completed and the patient has left the Operating Room where the procedure took place.
	17)Pelvis (Pelvic) - The lower portion of the trunk, bounded anteriorly and laterally by the two hip bones and posteriorly by the sacrum and coccyx.		
	18)Radiopaque - An entity that is impenetrable to x-rays or other radiation.		As a practice change, Circulating Nurses were asked to hang sponge holder bags (Counter bags) back-to-back, thus allowing each category of sponge (laparotomy sponges and ray-tecs) to be placed in its own bag, with the front sides of both bags being visible simultaneously. This ensures that both bags can be visualized by all team members (including the surgeon), without the need to "flip" bags back and forth. <span style="float: right;">2/17/11</span>
	19)Ray Tec - A brand name for a 4x4 or 4x8 gauze sponge with an embedded radiopaque fiber. Also referred to as "raytex" sponges.		
	20)RFO - Retained Foreign Object		
	21)RN - Registered Nurse		
	22)Root Cause Analysis (RCA)- A class of problem solving methods aimed at identifying the root cause of problems or events.		
	23)Sacrum - The large heavy bone at the base of the spine. It is roughly triangular in shape and makes up the back wall of the pelvis.		
	24)Sacrectomy - Excision or resection of the sacrum.		<u>Systemic Action:</u> All Perioperative clinical staff (Registered Nurses, Surgical Technicians, Surgical Assistants, and Registered Nurse First Assistants) received re-education on Medical <span style="float: right;">3/11/11</span>
	25)Sinus - A cavity, channel, or recess		
	26)Subcutaneous Tissue - The layer of loose		

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*6/24/11*

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connective tissue directly under the skin.

27) Surgical Scrub Technician - Refers to the surgical technician or RN who is responsible for directly maintaining the sterile field where the operation is taking place, and for delivering the sterile instruments, supplies, and equipment directly to the surgical team.

Title 22

70213(a) Nursing Service Policies and Procedures

(a) Written Policies and procedures for patient care shall be developed, maintained and implemented by the nursing service

This regulation was not met as evidenced by:

Based on interviews and record reviews, the hospital failed to implement their policy and procedure on counting surgical sponges when a Ray-Tec sponge was retained in the left paraspinous muscle of the sacrum of Patient 1. The patient had a prolonged wound recovery from an initial surgery on [REDACTED] 10 from a partial sacrectomy for a sacral chordoma. Due to persistent sacral wound drainage and prolonged healing, Patient 1 underwent a second surgery on [REDACTED] 10 for wound debridement. Patient 1's sacral wound continued to have lack of healing, then, on [REDACTED] 11, a pelvic CT scan revealed a retained surgical sponge. Patient 1 underwent a third

Center Surgical Count Policy which includes the process for announcing and documenting tucked sponges. Staff participation was mandatory. 100% of staff completed required training.

• Kaiser South San Francisco Medical Center conducted a Surgical Safety Summit.

4/5/11

- Course content included review of surgical count process and RFO prevention strategies, including review of medical center policy for surgical counts and process for announcing, documenting, and reconciling tucked sponges.
- Event was attended by 73 clinicians from Surgical Services departments including Surgeons, Anesthesia Providers, Registered Nurses, Registered

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Occupation

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surgery on [redacted] 1 to remove the retained Ray-Tec sponge which was the cause of the persistent non-healing wound for over a six month period.

Findings:

Review of the Discharge Summaries dated [redacted] 10 showed Patient 1 was admitted to the hospital on [redacted] 10 for partial sacrectomy of a sacral chordoma, a rare malignant tumor that usually occurs in the spine or the base of the skull. Additional diagnoses of the patient included diabetes and hairy cell leukemia. The patient tolerated the procedure well and was discharged on [redacted] 0.

Further record review showed Surgeon 1's documentation on the History and Physical Note dated [redacted] 10 that stated, "(The patient) has been recovering slowly but still has two small areas of clear/pinkish drainage. (The patient) denies any fevers, chills, nausea, vomiting. (The patient) has been dealing with bowel and bladder issues and these seem to be improving steadily. Given the persistent drainage, (the patient) is here for evaluation and discussion of wound debridement." Subsequently, Patient 1 underwent a second surgery on [redacted] 10 for an incision and drainage of the sacral wound.

However, the records showed that on [redacted] 11, an MRI of the pelvis was done to further evaluate the area of the ongoing, non-healing

Nurse First Assistants, Surgical Assistants, and Surgical Technologists from the Operating Room; as well as staff from other procedural areas.

- Agenda topics included rationale for surgical counts; responsible parties in process; strategies for minimizing disruptions and errors related to human factors; sequencing of count activities in relation to surgical case flow / events; review of items to be counted; step-by-step instructional review for each category of counted items (sponges / needles / instruments); process for investigation and resolution of discrepancies.
- Highly Reliable Surgical Teams Surgical Safety Summit curriculum materials were widely distributed to physicians and staff

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sacral wound. The findings on the report documented the following, "Left erector spinae muscle 3.6 cm collection with surrounding inflammation, suggestive of an intramuscular abscess." Consequently, a CT scan was advised.

On [REDACTED] 11, the CT scan revealed the following, "Complex thin curvilinear density seen in the area of the expected abnormality of the left erector spinae musculature most suggestive of retained sponge or packing material."

Patient 1 underwent a third surgery on [REDACTED] 11 to remove the retained sponge. Surgeon 1's report dated [REDACTED] 11 documented the following: "The patient was brought in urgently for evaluation. I saw the patient this morning and discussed the situation with (the patient). I advised (the patient) to urgently go to the operating room for removal of this foreign body as this was may be the source of (the patient's) nonhealing wound." In the same report, Surgeon 1 described the removal of the sponge as follows: "A probe was placed into the sinus and after we got into the subcutaneous tissues, we cutdown onto the probe. This probe tracked down into a cavity which was in the left paraspinous muscle directly where a retained Ray-Tec was located. The retained Ray-Tec was in a walled off cavity. This was extracted readily."

working in surgical and procedural areas.

**Monitoring:**

- Perioperative services will monitor compliance with action plan through monthly audits of surgical case sponge counts. 3/7/2011
  - Sample Size: Random Audit 50 cases/ month
  - Required Compliance: 100% compliance with expected process for 4 consecutive months.
  - Perioperative Services Director will submit report to Risk & Safety Committee, Quality Improvement Committee and Medical Executive Committee. July 2011

**Audit Process Indicators include:**

- Adherence to policy for initial and subsequent sponge / needle / instrument counts;

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On a subsequent visit to the hospital beginning [REDACTED] 11, during an interview at 11:36 AM, Circulating Nurse 1, who was present during the [REDACTED] 10 surgery, remembered Patient 1's case very well. Circulating Nurse 1 stated, "(It) was a tumor case...a fairly big case lasting approximately 2 to 3 hours...(the tumor) was deep in the spine... there was a lot of bleeding and a lot of sponges being used... it was not a crisis situation... it was routine but there were more instruments used than usual." When this surveyor asked Circulating Nurse 1 about surgical sponge counting practice, the nurse responded, "The counts are recorded on the count board. There is the initial count, closing count, and final count. The final count is announced to the surgeon." This surveyor asked what Surgeon 1 customarily does when the final count is announced and the nurse responded, "Not sure if he visualizes but he acknowledges the team when the final count is announced." Then, Circulating Nurse 1 was asked if she remembered whether or not Surgeon 1 announced that he did a deep sponge tuck during the [REDACTED] 0 procedure and she stated, "I do remember... Surgeon 1 did not announce a deep tuck sponge. (I remember) there was no tuck recorded on the board. There is a special section on the count board specifically for deep tucks. The practice is that the surgeon announces the deep tuck." Circulating Nurse 1 was confident that the final count was correct. "We did the closing together, we did the bags as a team, and before the patient left the room, I was confident

- Use of sponge count bags to display discarded sponges;
- Circulating Nurse maintenance of the white board with count data;
- Use of approved process for resolution of discrepant counts;
- The Surgeon calls out each and every tucked sponge;
- Circulating Nurse documents tucked sponges on the board in the area identified for tracking tucked sponges;
- Case Conclusion / Final Verification activities, including passing of all sponges off surgical field for verification by the surgeon;
- Removal of all liners from all used kick buckets by the Surgical Scrub

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the count was correct."

In another interview on 3/28/11 at 2:23 PM, Circulating Nurse 2 was also present during the [redacted] 10 surgery but was the relief nurse for lunch break for Circulating Nurse 1 so she was not involved in the final sponge count but she did acknowledge that surgeons customarily announce deep tuck sponges and the circulating nurse would record the deep tuck sponge on the board. Circulating Nurse 2 stated, "Sometimes surgeons don't announce removal of the deep tuck sponges and (when that happens) I ask the surgeon if the tuck sponge was out"

In an interview on 3/29/11 at 12:21 PM, Surgical Scrub Technician 2 (Surgical Scrub Tech 2) was also present during the [redacted] 10 surgery but was the lunch break relief for Surgical Technician 1 so she was not involved in the final sponge count process. She acknowledged that in general, surgeons "tell the scrub (about the deep tuck sponge) and the scrub will communicate this to the circulating nurse...if the tucked sponge was not announced, it will show in the final count."

During an interview on 3/29/11 at 3:35 PM, Surgeon 1 stated that the patient had "wound break down, or a slight opening (at the surgical wound site after the first surgery)." The treatment at that time involved home wound management and close observation but "the wound did not completely heal."

Person (RN or technician).  
Cleaning  
Procedure: In-Depth For OR Suite (Terminal) (Section 4F) has been revised to address specifically how the kick buckets will be handled between cases.

5/26/11

**Responsible Parties:**

- Perioperative Services Director;
- Chief Nursing officer/Chief Operating Officer;
- Assistant Physician-in-Chief of Operating Room;
- Physician OR Director

Event ID X00N11

6/14/2011

2 25 18PM

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

TITLE

DATE

*Log*

6/24/11

any deficiency statement ending with an asterisk (\*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. Except for nursing homes, the findings above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(K1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  050070	(K2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	AUG 13 2012  L&C DIVISION	(K3) DATE SURVEY COMPLETED  03/30/2011
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NAME OF PROVIDER OR SUPPLIER  KAISER FOUNDATION HOSPITAL - SOUTH SAN FRANCISCO	STREET ADDRESS, CITY, STATE, ZIP CODE 1200 EL CAMINO REAL, SOUTH SAN FRANCISCO, CA 94080 SAN MATEO COUNTY SAN FRANCISCO
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(K4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	DATE COMPLETE
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According to Surgeon 1 during the same interview on 3/29/11, the second surgery revealed necrotic tissue which he believed was the cause of the non-healing wound. But, even after the second surgery, Surgeon 1 stated, "the wound broke down again." Surgeon 1 thought the patient's history of diabetes and leukemia might have been contributing factors to the persistent non-healing wound. The surgeon stated, "I consulted with the Infectious Disease physician, treated the patient with antibiotics, and managed (the patient) conservatively."

During the interview conducted on 3/29/11 at 3:35 PM, Surgeon 1 spoke of his analysis of the initial surgery on [redacted] 10. "The wound was deep... there was an increased amount of bleeding so there were lots of sponges used... the retained sponge was in the paraspinous muscle which is an area not very visible... I relied on the count... when the count was stated correctly, I agreed." When this surveyor asked the surgeon regarding deeply tucked sponges during surgery, he replied, "Personally, I don't like to use Ray-Tecs. I like to use lap sponges (laparotomy sponges). In this case, I needed to use the Ray-Tec to move the muscles." When this surveyor asked the surgeon if he could remember whether or not he announced a deep tuck sponge, he replied, "I don't remember if I did". Finally, Surgeon 1 stated that the last time he spoke with Patient 1 was on [redacted] 11. At that time, the wound "was

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6/24/11

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  050070	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED  03/30/2011
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NAME OF PROVIDER OR SUPPLIER  KAISER FOUNDATION HOSPITAL - SOUTH SAN FRANCISCO	STREET ADDRESS CITY STATE ZIP CODE 1200 EL CAMINO REAL, SOUTH SAN FRANCISCO, CA 94080 SAN MATEO COUNTY
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(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
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down to 1 cm and was now healing well."

During a telephone interview on 3/30/11 at 10:30 AM, with Surgical Technician 1, the surveyor asked if he recalled the case that involved Patient 1 on [REDACTED] 10. He said, "I don't remember the case but the name sounds familiar." He also stated, "Surgeons most of the time will announce deep tuck sponges and that the scrub tech will tell the circulating who records on the board." His own personal practice was he made a mark on the mayo stand with a marker when a deep tuck occurred to help him keep track. The surveyor asked what Surgeon 1 customarily did at the final count and he said, " He verbally acknowledges when the team announces the final count is correct and that (Surgeon 1) visualizes the blue count bag."

During an interview on 3/29/11 at 3:10 PM, the Director of Risk Management stated that the facility reviewed the case with Surgeon 1, Circulating Nurse 1, and the Perioperative Service Line Director in [REDACTED] 2011 after the RFO incident was discovered and revealed the following 1)Surgeon 1 did recall the deep sponge tuck and that it was a bloody case. 2)The documentation was correct regarding the sponge counts. 3)The internal investigation could not definitively determine the cause of the RFO.

During the same interview with the the Director of Risk Management on 3/29/11 she stated

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that the facility's RCA formulated possible causes of the RFO: 1)There might have been a sponge left in the kick bucket from a prior procedure. 2)Not all deep tucks were announced by surgeons unless there were cavities involved. Announcement of a deep tuck sponge by surgeons was done mainly with procedures that involved cavities. 3)The blue holder bags overlapped each other when hung on the stand.

The hospital's policy and procedure titled, "Surgical Counts (Sponge, Needle, Instrument), Number PC 19 11, effective date 4/1985, review/revise date 06/2009 documented the following: "page 1 2.4.1 Items which have been tucked into the wound or which cannot be visually accounted for due to their being in use at that time will be verbally accounted for on the count board, and this information reviewed by the incoming and outgoing parties. page 6 4.1 Any item that is tucked or packed into the wound, or cavity, canal, orifice (e.g., throat packing, nasal or vaginal, etc) will be verbally announced by the Scrub Person at the time it is inserted into the patient, and documented on the count board by the Circulating Nurse. Likewise, when an item previously documented as being tucked or packed is removed from the patient, it will be crossed off of the "Tucked Items" count "

The hospital's policy and procedure titled, "Cleaning Procedure -13, In-Depth For or Suite (Terminal), effective date 1/1985.

**Title 22 Nursing Service Policies and Procedures:**

In response to this event Kaiser Foundation Hospital South San Francisco is taking the opportunity to further review our Surgical Count Policy to make changes for further clarity.

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revision date 3/27/2009, documented the following: "page 2 of 2, Procedure -Daily, #4 Operating Rooms, Wash with approved germicidal solution all fixtures, equipment, furniture. Thoroughly wash waste receptacles." The Perioperative Service Line Director stated that this policy addresses the Environmental Services' responsibility with the clean up of the kick buckets when he gave this document to this surveyor on 3/30/11. The document does not address how the kick buckets should be specifically handled between cases.

The hospital failed to implement their policy and procedure for surgical sponge count when a Ray-Tec sponge was retained in the left paraspinous muscle of the sacrum of Patient 1 during surgery on [REDACTED] 10. He underwent a second surgery on [REDACTED] 0 for wound debridement and a third surgery on [REDACTED] 1 for removal of the retained surgical sponge. The sponge was retained for over 6 months and as a result, the patient's wound from the original surgery had delayed healing. Surgeon 1 missed the count during surgery on [REDACTED] 0, then missed the opportunity to discover the RFO at the post-operative visit on [REDACTED] 0 when he determined only adebridement was required. By limiting his examination to diagnosis and treatment of the infection without probing further to determine the cause, Surgeon 1 may have further delayed the discovery of the RFO. Delayed discovery of the cause of the non-healing wound did not occur

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<i>[Signature]</i>		<i>8/24/11</i>		

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until [REDACTED] 11 which suggests that treatment for the infection may have masked the effects of the RFO by preventing a full blown infection despite the presence of the RFO.

This failure is a deficiency that has caused, or is likely to cause, serious injury or death to the patient, and therefore constitutes an immediate jeopardy within the meaning of Health and Safety Code Section 1280.1

This facility failed to prevent the deficiency(ies) as described above that caused, or is likely to cause, serious injury or death to the patient, and therefore constitutes an immediate jeopardy within the meaning of Health and Safety Code Section 1280.1(c)

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*J. Jensen* SR. VP, Area Manager

6/24/11

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