The following reflects the findings of the Department of Public Health during an inspection visit:

Complaint Intake Number: CA00584143 - Substantiated

Representing the Department of Public Health:
Surveyor ID # 2494, HFENS

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 1280.3(9): 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.

Health and Safety Code section 1279.1(a)

(a) A health facility licensed pursuant to subdivision (a), (b), or (f) of Section 1250 shall report an adverse event to the department no later than five days after the adverse event has been detected, or, if that event is an ongoing urgent or emergent threat to the welfare, health, or safety of patients, personnel, or visitors, not later than 24 hours after the adverse event has been detected. Disclosure of individually identifiable patient information shall be consistent with applicable law.

Health and Safety Code section 1279.1(b)(1)(D)

(b) For purposes of this section, "adverse event"
includes any of the following:
(1) Surgical events, including the following:
(D) Retention of a foreign object in a patient after surgery or other procedure, excluding objects intentionally implanted as part of a planned intervention and objects present prior to surgery that are intentionally retained.

Health and Safety Code section 1279.1 (c)

(c) The facility shall inform the patient or the party responsible for the patient of the adverse event by the time the report is made.

The CDPH verified that the facility informed the patient, or the party responsible for the patient, of the adverse event by the time the report was made.

70213(d)

(d) Policies and procedures that require consistency and continuity in patient care, incorporating the nursing process and the medical treatment plan, shall be developed and implemented in cooperation with the medical staff.

70223(b)(2)

(b) A committee of the medical staff shall be assigned responsibility for:
(2) Development, maintenance and implementation of written policies and procedures in consultation with other appropriate health professionals and administration. Policies shall be approved by the governing body. Procedures shall be approved by
Based on interview and record review, the facility failed to conduct a surgical instrument count during an Abdominal Hysterectomy (surgical procedure to remove the uterus through an incision in lower abdomen) procedure which resulted in the retention of a Ribbon Retractor (surgical instrument used to separate the edges of a surgical incision or wound, or to hold back underlying organs and tissues so that body parts under the incision may be accessed) inside one patient’s (Patient A) abdomen for twenty days before it was identified and surgically removed. The Ribbon Retractor measured about 33 centimeters (cm) long, five centimeters (cm) wide, and one millimeter (mm) in thickness.

Findings:

During a concurrent interview and chart review with the Quality Resource Nurse (QRN), on 5/2/18, at 9:30 AM, the QRN reviewed Patient A’s clinical records and stated Patient A had an Abdominal Hysterectomy on 4/3/18 by a Resident Physician (RP). The day after Patient A’s surgery, on 4/4/18, the RP was called to visit the patient. In a late entry on 4/5/18 for 4/4/18, the RP documented; “Resident (RP) called to bedside because patient complaining of left sided chest pain radiating to shoulder with ambulation... Patient found [sic] to have positional chest pain on physical exam that was reproducible with palpation and movement.” The RP ordered a chest x-ray and other diagnostic tests. The chest x-ray was done at 5:21 PM on 4/4/18. A
Radiologist (MD 2) read the x-ray film and dictated the findings: "There is new infiltrate in the left lower lobe with small effusion (fluids in the lungs)."

The RP discharged Patient A home on 4/5/18 in stable condition. On 4/23/18, twenty days post-surgery, Patient A returned to the hospital's Emergency Room (ER) complaining of abdominal pain. An ER physician ordered an x-ray of the abdomen, and the film showed "Possible large foreign body." The ED physician compared this film with the one taken on 4/4/18; the ED physician concluded MD 2, who read the first film, failed to recognize the opaque area was a foreign body, not a new infiltrate. Patient A was taken back to the operating room on 4/23/18 for the second surgery to remove the foreign body. The foreign body was then sent to pathology for examination. The pathology report read, in part; "...in a clear plastic bag with the patients [sic] name and labeled "foreign body" is a 160 g (gram, a unit of weight, about 0.16 kilogram), slightly concave/convex silver metallic surgical instrument/retractor measuring 33 x 5 cm x 1 mm in thickness..." The hospital had left the Ribbon Retractor inside Patient A's abdominal cavity from the previous surgery, performed on 4/3/18, for 20 days. This was not detected by MD 2 when he read the x-ray films on 4/4/18.

During a review of the patient's "Intraoperative Nursing Record," dated 4/3/18, signed by a circulating Registered Nurse (RN), indicated the RN and the Surgical Technician (ST) did three surgical counts and all three surgical counts; the initial count, the cavity count, and the closing count were

Responsible Person(s)

Chair of Radiology; Chief Medical Officer, President of Medical Staff

Monitoring:

Chair of Radiology or Radiology Manager will identify cases with an educational opportunity for review at the Radiology Quality Review Meeting. Use of the RADPEER database will continue with findings reported at the Radiology Department Quality meetings, the Quality Management Meeting and the Medical Executive Committee. Further action plans will be developed as needed.
The hospital's policy and procedure on "OPERATIVE/INVASIVE PROCEDURE COUNT FOR THE PREVENTION OF RETAINED SURGICAL ITEMS (RSI)," effective 7/17, was reviewed. It indicated the procedure for surgical counts would be conducted by both the ST and circulating RN on all soft goods, sharps, needles and miscellaneous items. Instrument counts are required when the wound is larger than the smallest piece of instrument. The procedure required the following counts: the initial count—must be completed before the Time Out (before incision is made, every person in the surgical team stops and participate the verification of the patient's name, procedure to be done, verify the procedure and the signature on the consent) is performed and the invasive procedure started. This would give a baseline of countable items. The second count is the "Cavity Count." It is performed before closure of a cavity within a cavity. Patient A had her uterus removed leaving only one cavity count—the abdomen. The third count is the "Closing Count." This is performed before wound closure, such as muscles, begins. The last or the final count is performed after skin closure.

During an interview with the ST, on 5/2/18, at 10:47 AM, about the retention of the retractor, the ST stated the surgeons used a Laparotomy Tray (a tray that contains sterilized instruments for abdominal surgeries). He added; "When surgeons closed the abdomen they asked for a Malleable (Ribbon Retractor). I remember putting it up on the Mayo

B. Plan of Care

1. The Operating Room (OR) staff involved in the case has received one-on-one counseling with disciplinary action as appropriate.
2. The Hospital policy on OPERATIVE/INVASIVE PROCEDURE COUNT FOR THE PREVENTION OF RETAINED SURGICAL ITEMS (RSI), has been reviewed and updated to reflect the current AORN standards and nationally recognized surgical count safety project, "No Thing Left Behind," recommendations. The changes to the policy include:
   1. Clear language identifying when counts are conducted.
   2. "The Final instrument Count will not be considered complete until all instruments, including those used in closing the wound, have been returned to the scrub personnel." Policy 10(i)
3. New communication boards have been ordered for all OR suites with ques to assist with completing appropriate counts.
During an interview with the circulating nurse (RN) in regards to the practice on surgical counts, on 5/2/18, at 11:50 AM, she stated; "I count the same way each time. Use the tray [Instrument Count Sheet] sheet, and do initial [first count at the beginning of the procedure with the ST], another at closing [of the cavity], another at fascia [a thin sheath of tissue under the skin covering organs, muscles, or blood vessels], and another at skin [outer layer of skin]. All counts eyes were on ribbon and instruments [meaning she had her eyes on the retractor during counting]."

During a review of the "Physician Operative Report Dictated," dated 4/3/18, at 4:17 PM, it indicated: "The instrument and sponge counts were correct times two." The documentation indicated the instruments were counted twice and was inconsistent with the "INTRAOPERATIVE NURSING RECORD."

During a review of the hospital's Instrument Count Sheet for Laparotomy Tray, it indicated there should be one one-inch ribbon retractor and one two-inch ribbon retractor in the tray.

During a concurrent interview with Operating Room Manager (ORM) and review of the Instrument Count Sheet for the Laparotomy Tray, on 5/2/18, at 11:30

3. The Hospital has conducted training with Operating Room and Peri-Natal Staff concerning proper count technique. Training was conducted in May 2018 concerning the new Operative and Invasive Procedure count policy. Training included the web-based video, "Surgical Safety Preventing Retained Surgical Items Using the Sponge Accounting System (SAS) Featuring, Verna C Gibbs, M.D. August, 2013." (https://www.youtube.com/watch?v=44SFY_nodrQ)

**Responsible Person(s)**

The Clinical Director of Perioperative Services, Clinical Supervisor of Perioperative Services, Chair of Surgery Department, Chair of OB/GYN Department, Chief Nursing Officer, Chief Medical Officer.
AM, she reviewed the Count Sheet and concluded, “There’s two ribbons (retractors) in the tray (Laparotomy Tray). No final count (the last count after skin was closed) was done (indicating the ST and the RN did not do the final count after skin closure). She (Patient A) came back to surgery because the x-ray (performed on 4/23/18) showed a foreign body (the retractor).”

The “Physician Operative Report Dictated,” dated 4/23/2018, at 12:17 PM, was reviewed. It indicated Patient A was taken back to surgery to remove the retractor. The operative report read: “Findings: Retained malleable (ribbon retractor) in abdominal cavity. Technique... Intra-abdominal survey revealed retained malleable that extended up to the level of the stomach... Specimen: Surgical Malleable.”

The hospital policy and procedure titled “Operative/invasive Procedural Counts for the Prevention of Retained Surgical Items (RSI),” effective date of 7/17, indicated there were four (4) classes of countable items include: Soft Goods (sponges, gauzes) 2. Sharps and Needles, 3. Instruments, and 4. Miscellaneous items. Under “V. Procedure: D. Instrument Counts,” it indicated: “1. Instrument counts will be performed: a. Before the procedure to establish a baseline; b. When additional instrumentation is added to the sterile field; c. Before the closure of a cavity within a cavity; d. When wound closure begins; e. When skin closure begins or at the end of the procedure when counted items are no longer in use.”

**Monitoring:**

The Hospital initiated a direct observation audit for surgical count procedures. Observations were started in May 2018 and are ongoing. The direct observation audit includes:

1. Counts were done;
2. Counts were done at appropriate times;
3. Number of Counts were appropriate for case;
4. Each count was conveyed to the surgeon;
5. Counts were documented correctly;
6. Observed counts matched documented counts; and
7. Counts were correct.

As of January 2019, an additional element was added to the observation: 8. “The Final instrument Count will not be considered complete until all instruments, including those used in closing the wound, have been returned to the scrub personnel.” Policy 10(i).
The 2018 Association of Perioperative Registered Nurses (AORN, a formal recognized national association sets standards for administrative and clinical practice in the operating room), Guideline for Prevention of Retained Surgical Items, indicated: "Recommendation IV: Instruments should be accounted for in all procedures for which the likelihood exists that an instrument could be retained. IV.a. Instruments should be counted for all procedures in which a body cavity is entered. IV.b. Counts of instruments should be performed before the procedure to establish a baseline, when new instruments are added to the field, when wound closure begins or at the end of the procedure when counted items are no longer in use. IV.b.2. The final instrument count should not be considered complete until the instruments used in closing the wound (e.g., malleable retractors . . . ) are removed from the wound and returned to the scrub person."

The hospital staff failed to count surgical instruments used during a surgical procedure consistently had caused the unintended retention of a surgical ribbon retractor inside Patient A's abdomen after an abdominal surgery. This failure resulted in Patient A experiencing severe pain for 20 days and required a return to surgery to undergo another surgical procedure to remove the retractor.

The deficiency 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 1280.3, subdivision (g).

Based on the results of these audits, direct feedback is provided to the staff with disciplinary action as needed.

In addition, as of January 2019, the Clinical Directors and Clinical Supervisors of the Main OR and Perioperative Services, in conjunction with the Quality Department, will complete 10 direct observations of the surgery count procedure per month for the next 90 days to assure compliance with the policy. Feedback will be provided to staff and supervisors, Managers and Directors of Operative service. Results will be reported routinely to the Clinical Quality Management Committee and appropriate action plans developed based on the findings.
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 1280.3(g).