CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY
DEPARTMENT OF PUBLIC HEALTH

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	050047	A. BUILDING _____ B. WING _____	08/15/2013

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California Pacific Medical Center – Pacific Campus Hospital	**2333 Buchanan St, San Francisco, CA 94115-1925 SAN FRANCISCO COUNTY**

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	The following reflects the findings of the Department of Public Health during an inspection visit: Complaint Intake Number: CA00358159 - Substantiated Representing the Department of Public Health: Surveyor ID #25732, 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. Health &Safety Code Section 1279.1 (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. T22 DIV5 CH1 ART3-70223 (b)(2) Surgical Service General Requirements (b) A committee of the medical staff shall be assigned responsibility for:		Please note: The following constitutes California Pacific Medical Center (CPMC) - Pacific Campus Hospital's credible evidence of correction of the alleged deficiencies cited by the California Department of Public Health in the Statement of Findings Form 2567 dated 8/15/2013. Preparation and/or execution of this credible evidence submission does not constitute admission or agreement by the provider of the truth of the facts alleged or the conclusions set forth in the Statement of Findings. T22 DIV5 CH1 ART3-70223 (b)(2) Surgical Service General Requirements **Corrective Action:** 1. The CPMC Surgical Counts policy was revised to include a system for tracking all surgical items placed or inserted during procedures. A copy of the revised policy was provided to CDPH on 8/22/13. 2. Standard work was developed to account for items placed, packed or tucked within a surgical cavity. The Surgical Services staff was educated to the policy changes and standard work. 9/5/14 POC accepted.	06/28/13 08/02/13

CADEPT OF PUBLIC HEALTH
SEP - 5 2014
L&C DIVISION
SAN FRANCISCO

Event ID:DS6111 8/26/2014 2:32:24PM

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE George Khabaal RN TITLE Patient Safety Manager (X6) DATE 09/04/14

By signing this document, I am acknowledging receipt of the entire citation packet, Page(s) 1 thru 9

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 stated 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 participation.

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	(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 the administration and medical staff where such is appropriate. This RULE is not met as evidenced by: Based on record review, policy review and staff interviews, the hospital failed to ensure that Surgical Services Staff implemented the policy and procedure titled: "Counts Surgical (Sponges, Sharps, Miscellaneous Items and Instruments)." On 5/30/13 Patient A had a Robotic-assisted total hysterectomy (surgery for removal of the uterus). A Jackson Pratt drain bulb (A soft round squeeze bulb) was placed in Patient A's vagina in the OR (Operating Room). The Jackson Pratt drain bulb was not accounted for during the final surgical count (a method whereby the surgical staff accounts for all instruments, sponges, needles and specific small items to prevent retention and injury to the patient). The retention of this Jackson Pratt drain bulb required Patient A to go to the Emergency Department complaining of abdominal pain and fever The retained • Jackson Pratt Bulb was removed. The patient was given antibiotics then was transferred to the hospital where Patient A had to be admitted for a period of three days for an infection due to retention of the Jackson Pratt drain bulb.		Cont. 2. Standard work was developed to account for items placed, packed or tucked within a surgical cavity. The Surgical Services staff was educated to the policy changes and standard work. 3. Standard work was also developed for completing the sign-out procedure prior to the patient leaving the procedure area. The Surgical Services staff was educated to the standard work process. 4. The OB/GYN physicians identified options for maintaining pneumoperitoneum when the specimen is removed through the vagina. The physicians were informed of these options as well as the changes to the count policy at their department meetings and through written communication.	8/02/13 8/08/13 and 8/09/13 8/02/13 8/08/13 and 8/09/13 7/10/13 7/16/13 and 7/29/13

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	Findings: Record review of an Operative Note dated 5/30/13 indicated: Patient A was taken to surgery and had Robotic –assisted laparoscopic total hysterectomy (surgery to examine and remove pelvic organs using a viewing tool called a laparoscope, carbon dioxide gas is pumped into the abdomen to help the surgeon see the organs more easily). Record review of Patient A's Intra-Operative Case record, dated 5/30/13 indicated: "Sponge / Needle / Other Counts, Needle/Sharps/Miscellaneous Items Initial, Closing and Final Counts were correct." Record review of Patient A's Emergency Department Report, dated 6/5/13 indicated: " Patient A presents to the emergency department with abdominal pain of the left lower quadrant described as constant sharp...symptoms/episode began occurred since surgery on 5/30/13...fever today...Pelvic Exam...Speculum Exam: positive FB (Foreign Body) in vagina, removed, found to be bulb from Jackson Pratt drain... foul smelling..Impression: fever, Infected vaginal foreign body, rule out Intra-abdominal infection..." Record review of a Emergency Room medication order form, dated 6/5/13 at 9:45 P.M., indicated Patient A received Zosyn 3.375 grams (an intra venous antibiotic for skin and soft tissue infections). Record review of Patient A's hospital Discharge		Cont. **Monitoring Plan:** Observational audits were conducted to validate compliance to the policy changes and standard work. Audits results were tracked at 30, 60, 90 and 120 days. Audit results revealed compliance at 100%. The audits results were reported to Senior Leadership at 30 day intervals. **Responsible Person:** Vice President, Surgical Services Department Chair OB/GYN	8/12/13 through 12/16/13

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Summary, dated 7/13/13 indicated: "Date of Admission 6/6/13, Date of Discharge: 6/9/13, Discharge Final Diagnosis: Status post retained device with subsequent vaginal cuff cellulitis (infection of the skin and underlying tissues that can affect any area of the body. It often begins in an area of broken skin, like a cut or scratch. Then bacteria invade and spread, causing inflammation, pain, swelling, warmth, and redness), Reason for hospitalization: Treatment of Vaginal Cellulilitis in the setting of retained medical device..."

Record Review of an Adverse Event Report from the hospital to the California Department of Public Health, dated 6/11/13 indicated: "...Writing to report and incident of a retained foreign object after a robotic assisted laproscopic hysterectomy...Patient A, underwent surgery on 5/30/13 at the Pacific Campus. The retained object is a Jackson –Pratt bulb that was left in the vagina. The object was detected and removed at an outside hospital on 6/5/13. The incident was reported to our office on 6/10/13."

In an interview on, 8/22/13 at 3 P.M. the Circulating Nurses (RN-1 and RN-2) and the Operating Room Technician (ORT) who were present during Patient A's surgery on 5/30/13 were asked in this surgery what was the Jackson Pratt Bulb used for.

RN-1 said," Surgeon-1 is the only surgeon who uses this. It is put in backwards, bulb end first then inflated. It helps keep the CO 2 gas in during the laproscopic surgery. Surgeon 1 uses it less then fifty percent of the time. It all depends on the

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patient's anatomy. We keep it in close proximity to the surgical field. This is only the second time I have seen Surgeon 1 use it. Surgeon 1 is the only one who use it in this kind of procedure."

In the same interview RN-1 was asked if the Jackson-Pratt Bulb was part of the surgical count for this surgery.

RN-1 said, " No, the Jackson-Pratt Bulb was not part of the count."

In the same interview, RN -2 was asked if there was a written record of the surgical count. RN 2 said," When we count we use a white eraser board in the operating room to list what was used in the surgery. The actual count is done on the white board. The count is recorded in the record as correct then the whiteboard is erased for the next case. We have a standard count. We count needles, blades, sponges and small things like penrose drains, clips that have the potential to be left in the patient during surgery. We write those on the white board."

RN 1 and RN-2 were then asked if the Jackson-Pratt Bulb was written on the white board during the surgery.

RN-1 and RN-2 said, "No"

RN-1 was then asked if the Jackson-Pratt Bulb was to remain in the Patient A after the surgery.

RN 1 said, "No."

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RN-1 and RN-2were then asked if according to the hospital's surgical count policy was the Jackson Pratt drain considered to be a miscellaneous item that required counting during surgery.

RN-2 said," No, I consider it a drain. We count small items on the field like surgical clips(a device met to hold thing together in surgery) We count things that are put in the pelvic cavity not things put in the vagina in this case. The surgeon puts the Jackson Pratt Bulb in and the surgeon takes it out."

In the same interview the ORT was asked how Surgeon 1 gets the Jackson Pratt Bulb when it is going to use it for surgery. The ORT said," Surgeon 1 asks for it and we pass it to her."

In an interview on, 9/10/13 at 4 P.M., Surgeon 1 was asked what occurred with the use of the Jackson Pratt Bulb during Patient A's surgery.

Surgeon 1 said," We made a mistake and left the Jackson-Pratt bulb in after the surgery, it happened, it was a change in my own process, I have a habit of sweeping the area (vagina) after the surgery. The other surgeon came in to do a cystoscope (a diagnostic procedure to look at the bladder). I went to the robot console away from the patient. The Jackson Pratt Bulb plugs the hole in the vagina so we can do the surgery. Once we blow it up it is out of view. I don't think the other surgeon knew about it"

In the same interview, Surgeon 1 was asked if she was familiar with surgical counts and if the Jackson

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Pratt Bulb had been part of the surgical count for this particular surgery. Surgeon 1 said," Yes, I am familiar with surgical counts but I don't actually know if we count the Jackson Pratt Bulb in this procedure."

Surgeon 1 was then asked if she was familiar with the hospital policy and procedure on Miscellaneous Item Surgical Counts. Surgeon 1 said," I have not read it."

Review of the hospital's policy and procedure on Counts, Surgical (Sponges, Sharps, Needles, Miscellaneous items) indicates:

"The use of a standardized systematic method of accounting for instruments, sponges, needles and specific items used during a surgical procedure will promote patient safety by helping to prevent retained foreign bodies." (Hospital Policy No. 27.22.1.54, dated 7/2011,pg. 1)

"When counts are performed...as newer items are added to the field....Sharps, needles and miscellaneous items will be added to the white board." (Hospital Policy No. 27.22.1.54, dated 7/2011, paragraph 10, pg. 2)

"Sponge types, free needles, atraumatic needles, sharps and miscellaneous items are recorded separately on the standardized preformatted whiteboard." ((Hospital Policy No. 27.22.1.54, dated 7/2011, paragraph 14, pg. 3)

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" A running total of needles, sharps, and miscellaneous items placed on the boards, work sheets, and instrument count sheets will be done as items are added. The method of documenting additions and totals is standardized." ((Hospital Policy No. 27.22.1.54, dated 7/2011, paragraphs 14, 15, pg. 3)

"Sharps, needles, and miscellaneous items are counted on all procedures...Miscellaneous items include, but are not limited to: liga clips, rubber band, raney clips, cautery cleaner, pads, hernia/ umbilical tapes, vascular clamp inserts, bulldogs, and safety loops.(various items used in surgery) ((Hospital Policy No. 27.22.1.54, dated 7/2011, paragraph C. 1. pg. 7 and line 3 c, page 8)

There was no documented evidence in the surgical count policy and procedure that the Jackson-Pratt drain bulb did not meet the definition of a miscellaneous item that required a count.

Review of a current National Surgical Patient Safety Project to Prevent Retained Surgical Items states:

"Retained Surgical Item: an item that was not intended to remain in the patient, is found in any part of the patient's body, after the operation, vaginal birth or procedure ends..."

" Definitions:...Miscellaneous small items are other objects used during surgical procedures that are often single use, often not radiopaque (seen on X-ray), may be plastic, may be composed of multiple parts...")

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"Miscellaneous small items should be accounted for on all procedures."

See: (Gibbs, Verna C, "No Thing Left Behind: Prevention of Retained Surgical Items Multitaskeholder Policy, February 2011, pgs. 6, 17, available at http://www.nothingleftbehind.org)

The hospital failed to implement it's surgery policy and procedure to account for miscellaneous items post surgery when the Jackson Pratt drain bulb was not removed from Patient A's vagina after the conclusion of the surgery.

The retention of the foreign object, caused Patient A to be treated in the Emergency room for a vaginal infection and abdominal pain, treated with antibiotics, and admitted to the hospital for a period of three days.

The hospital's failure to ensure that the Jackson-Pratt drain bulb was accounted for and removed after Patient A's surgery 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(c).