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	050232	A. BUILDING ____ B. WING ____	08/29/2017

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FRENCH HOSPITAL MEDICAL CENTER	1911 Johnson Ave, San Luis Obispo, CA 93401-4131 SAN LUIS OBISPO COUNTY

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	The following reflects the findings of the Department of Public Health during an inspection visit: Complaint Intake Number: CA00433908 - Substantiated Representing the Department of Public Health: Surveyor ID # 2595, 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 1280.3(g): 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 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 and Safety Code Section 1279.1(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	9/11/17 Accepted PoC KeChu...	***Accountability:*** ***Chief Nurse Executive Officer*** ***Immediate Action:*** 1. Director of Peri-operative Services, with the leadership team, implemented concurrent observations and auditing, to verify full compliance with the *"Prevention of Retained Surgical Items"* policy. This included: 1) In count(s)- packaging error checks; 2) Closing count- including surgeon methodical wound exam, 3) Final count- all sponges in holders and 4) Actions to reconcile an incorrect count. In March 2015, all cases observed complied with tasks and requirements of the policy. 2. The Chief Medical Officer, and the Department of Surgery Chair, sent a letter to medical staff members performing surgical procedures outlining their responsibilities (steps required) to reduce the probability of retained sponge events. 3. A sponge management competency was mandatory for all current Circulators and Scrub Technicians. This competency was also made mandatory for any new staff working in procedure areas following the identification of this event. The competency includes the following elements: a. Viewing a video demonstration of the Sponge Accounting process. Demonstration of knowledge and understanding of the safety process is verified with a written test and requires a passing grade of 100%. b. The Just Culture policy, process and accountability for safety in the Surgical Services Department will be followed as routine expectation and part of operational processes. "Just Culture" (human error, at risk and reckless behavior) will be utilized for potential and actual breaches in implementation of the *"Prevention of Retained Surgical Items"* policy.	3/9/15 - 3/31/15 3/25/15 Initiated 3/31/15 and Ongoing

Event ID:C7SF11 8/29/2017 11:05:35AM

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE: [signature], MSN, RN
TITLE: COO/CNE
(X6) DATE: 9-7-17

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

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	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. Title 22, California Code of Regulations, Division 5, Chapter 1, Article 3, Section 70223 (b)(2): Surgical Service General Requirements: (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		***Systemic Action:*** 1. A site visit was conducted on 5/7/15 by the Dignity Health surgeon expert / consultant, responsible for the "No Thing Left Behind" project. The consultant met with surgical staff, and provided on-site education (including practical demonstrations) regarding Dignity Health "*Prevention of Retained Surgical Items*" policy, and standardization of safety processes (as outlined in policy expectations). 2. In October and November, 2015, a mandatory Safety Summit was conducted for all nursing staff. As part of this Safety Summit, a module outlining key components of the *"Prevention of Retained Surgical Items"* policy and hands on return demonstration of the sponge accounting process was required for all procedural staff. ***Monitoring System:*** 1. An ongoing monitoring system was implemented, to include observation and verification by the Director of Peri-Operative Services and the Surgical Services leadership team. Documentation in the patient record of surgical counts was evaluated. At least 30 cases were included in this review process monthly which covered all types of procedures and included all staff. The immediate action, ongoing monitoring of the safety system and results demonstrating no further sponge events, was presented and accepted by Surgery Department, Quality Council, Medical Executive Committee and the Community Board.	5/7/15 11/2015 3/9/15 and Ongoing

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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 interview, record review and policy/procedure review, the facility failed to implement their policies and procedures to conduct a sponge count during a right inguinal hernia repair and failed to account for all sponges used during the procedure. These failures lead to the retention of a sponge in Patient 1 for three years and 5 months, caused increased groin pain, prolonged healing, a scrotal abscess, extra antibiotics and for Patient 1 to undergo a second surgery under general anesthesia to remove the retained sponge.

Findings:

A review of the facility's policy and procedure entitled, "Prevention of Retained Surgical Items Policy," undated, revealed the following provisions:

Under the Heading , "THE SURGICAL COUNT," the policy set forth the following:

* "The IN counts are
a. Initial baseline count conducted before the case begins
b. Count conducted whenever new items are added the field (surgical field)."

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	The policy further indicated as follows: * "The In Counts are performed to establish the baseline number of items, detect packaging error and provide knowledge on how many items are being used during the case. * "Whenever possible the In counts will be performed before the patient enters the OR (operating room)." * "Sponge, needle and small miscellaneous items will be documented on a wall mounted dry erase board. Information added to the board cannot be erased until the operation ends." Under the heading, "GENERAL RULES FOR SPONGE MANAGEMENT," the policy indicated: * "All cotton gauze disposables placed in the patient will be white surgical sponges." * "A standardized practice should be used to account for the small surgical sponges." * "Free surgical sponges should be managed with the sponge ACCOUNTing system." Under the heading entitled, "SPONGE ACCOUNTING SYSTEM (SAS) FOR FREE SPONGES," the policy set forth the following additional provisions: * "SAS is a transparent manual accounting system that requires visible verification of the			

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	free sponges used in an operation." * "It is insufficient for OR (Operating Room) personnel to just count the sponges. They must also account for them." * "Free surgical sponges are to be added to the field in multiples of ten and a two person "See, separate and say" IN count of the sponges must occur." * "All the sponges - the used and unused sponges - must be in the blue sponge holders at the end of the case to perform the final count." * "A methodical exploration of the operative wound must be conducted prior to closure in every operation." * "Special focus should be given to closure of a cavity within a cavity (i.e.., heart, major vessel, stomach, bladder, uterus, and vagina)." * "Surgeons should strive to see and touch during the exploration whenever possible; reliance on only one element of sensory perception is usually insufficient. The surgeon should visually and manually make every effort to assure that no unintended surgical items have been left in body cavities." * "The general process is to look and feel in the recesses of the wound and examine under fatty protuberances and soft-tissue appendages. "			

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	A review of Patient 1's medical record revealed Patient 1 was admitted on (9/01/2011,) with a history of symptomatic right inguinal hernia. Patient 1 was scheduled to undergo a repair of a symptomatic indirect inguinal hernia repair with mesh. According to the surgeon's dictated note on 9/1/11, there was "minimal blood loss" and the surgical procedure was "tolerated well" by Patient 1. During an interview with the circulating nurse (CN) for Patient 1's surgery on 9/1/2011, on 3/13/15 at 9:30 a.m., the CN stated she remembered a case with a missing sponge. She remembered notifying the surgeon that a sponge was missing. She does not recall if the sponge was ever located. The CN verified Patient 1's medical record did not contain any documentation of the missing sponge. She indicated surgical counts were done with a nurse and the surgical technician. Items added to the surgical field were written on a white board in the room. Surgical counts were conducted at the beginning, just before closure of the wound and at the end of the case before the patient is taken to recovery. If the count was correct then the box on the "Surgical Safety Checklist" was marked indicating the counts were done. If there was any problem with the count the physician was notified. CN1 was unable to explain why there was no note indicating the missing sponge for Patient 1's surgery on 9/1/2011. During an interview with the Surgical Services			

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	Director (SSD), on 3/13/15 at 11 a.m., the SSD indicated there was a new policy for surgical counts put into effect between 2009 and 2010. He also indicated there was no wound sweep policy in effect at the time the sponge in Patient 1 was retained from the (9/1/2011) surgery. He further indicated if the facility did have a wound sweep policy it was not being followed. He indicated the facility practice was to put 10 Raytech sponges on a surgical field at a time with the maximum number of Raytech sponges being 20 at a time on the surgical field. The record would have a checkoff done indicating the counts had been completed. A review of Patient 1's intraoperative report of 9/1/11 indicated all sponge counts were correct. There were no notes in the physician's operative report of a missing sponge. The CN did not follow the facility's policy procedure regarding surgical counts when she failed to document an incorrect surgical count, failed to notify the charge nurse, and did not "fill out an INCORRECT FINAL COUNT REPORT form" which should have given the staff guidance on the steps to take when there is an incorrect final count. [According to the History and Physical (H&P) dated 2/23/15, Patient 1 was seen in the hospital. The H&P set forth the following notations of Physician 2 (P2) the surgeon for the second procedure: "Surgical evaluation of a possible infected right inguinal hernia repair mesh...first noticed in 2014..in the context of a bulge and then drainage from right inguinal area...he appears to have had a retained			

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	Ray-Tec (blue ink gauze seen on X-Ray) sponge in the groin. In retrospect, the wife stated that she thought she was told that they could not find a sponge at the time of surgery...It looked like a 4-inch gauze packing for a scrotal abscess. However, the patient and his wife are very clear that no one opened or packed this abscess, it was spontaneously draining. Therefore, it appears that it could have been a retained sponge from his operation in 2011. I removed part of it, with gentle traction but I think there is more retained deeper which will require an operation to remove." A review of the "Surgical Pathology Report", dated 2/27/2015 of the right inguinal removal of foreign object on 2/27/15 indicated the following: "...Inked blue...reveals a cavity containing a 30 mm hemorrhagic ball of apparent gauze..." During an interview with Patient 1's wife (PW), on 6/14/16, at 7:39 a.m., the PW stated, "I knew there was something there from the very beginning following the first surgery. There was a lump where the surgery was done. They (the recovery room nurses) all told me it was normal and it would go away. The doctor told me the surgery took so long because there was a missing sponge. My husband had never had any other surgeries prior to the hernia repair. Eventually the sponge migrated down and the skin split open and you could see the sponge trying to come out. They took my husband back			

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	into surgery to remove the sponge. He had to have antibiotics after the second surgery to remove the sponge." The failure of the surgeon and the OR staff to follow the facility's policies and procedures, as it pertained to adding and counting any and all items entering the patient during a surgical procedure, resulted in the retention of a surgical sponge in Patient 1 and the necessity of a second surgical procedure under general anesthesia to remove the retained sponge. This deficiency has caused or is likely to cause serious injury or death to the patient. 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).			