California Department of Public Health

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	CA040000254	A. BUILDING _____ B. WING _____	C 07/14/2011

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
FRESNO SURGICAL HOSPITAL	6125 NORTH FRESNO ST FRESNO, CA 93710

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A 000	Initial Comments The following reflects the findings of the Department of Public Health during an inspection visit: Complaint Intake number: CA00246867 - Substantiated Representing the Department of Public Health: [redacted], 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. DEFICIENCY CONSTITUTES IMMEDIATE JEOPARDY	A 000	POC ACCEPTABLE YES ☑ NO ☐ Reviewed By: S Campbell Name Facility Notified Name: Jen Ruffner Date: 10/27/11 Time: 9:00 AM Notified By: S Campbell Name	
A 001	Informed Adverse Event Notification Health and 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.	A 001	Informed Adverse Event Notification The facility informed the patient and the family of the adverse event prior to reporting the incident to CDPH per Health and Safety Code Section 1279.1(c).	
E 347	T22 DIV5 CH1 ART3-70223(b)(2) Surgical	E 347		

Licensing and Certification Division

Kristie O'Kossack, CEO TITLE 10-24-11 (X6) DATE

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

OCT 24

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E 347	Continued From page 1 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 the governing body. Procedures shall be approved by the administration and medical staff where such is appropriate. This Statute is not met as evidenced by: Based on staff interview, clinical record, and administrative document review, the facility failed to implement the facility " Counts of Sponges ... " policy and procedures. The facility failed to ensure staff accounted for all sponges after Patient 1 ' s surgery on [redacted]/09. This failure caused Patient 1 to have a second hospitalization for intravenous (IV) antibiotics; a third hospitalization for a second surgery on [redacted]/09 to determine the cause of Patient 1 ' s continued infections. The second surgery identified a retained lap sponge as the source of her infections. On 7/13/11 at 2:15 p.m. during an interview, Patient 1 stated when she came home from the initial surgery on [redacted]/09; she never began to get better during her recovery and continued to inform her physician of her pain, and weakness. Patient 1 stated her physician continued to place her on antibiotics (Cipro, Levaquin) for about 3-4 months making changes of the type of antibiotics until she collapsed at home and was admitted into a hospital for 11 days to be treated with IV antibiotics for infection. Patient I stated 2 days after discharge from the hospital she began to feel terrible again and continued on antibiotics as	E 347	T22 DIV 5 CH1 ART3-70223 (b)(2) Surgical Services General Requirements The Document Management Committee which is chaired by the Chief Nursing Officer is responsible for the development, maintenance and implementation of the written policies and procedures in consultation with administration and other appropriate healthcare professionals. All of the policies and procedures are approved at the Medical Executive Committee and the Board of Managers meeting prior to being implemented. The Operating Room Record was revised in order to provide more accurate documentation of the closing and final count procedure. The form now reflects a place for the nurse to document the closing/second count and the final count for both the sponges and the needles used during the procedure. Education on the revisions to the operating room record has been provided to the OR staff . Both the revised form and the Policy and Procedure, Counts of Sponges, Needles and Instruments (TX 04.013) was reviewed with all OR staff members by the OR Coordinator and is to be completed by October 28th, 2011. Education focused particularly on performing the count audibly and concurrently viewing the sponges as they are separated and counted by two individuals, one being a licensed Registered Nurse. A training video on Patient Safety and Retained Foreign Objects has been made available and is part of the education that is required of all the operating room staff. The CNO in collaboration with the OR coordinator will assure that all OR staff view this training video by October 28th, 2011 in order to educate staff further on identification of risk factors for retained foreign objects and how to prevent the occurrence of retained foreign objects. A post test will be completed by all OR staff members who are required to view the video in order to further measure staff's understanding and ability to reduce risk factors.	

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E 347	Continued From page 2 ordered by her physician and was referred to a different specialist who performed numerous tests and stated she needed to have a second surgical procedure. Patient 1 stated it was after her second surgery that she was told she had a retained sponge. Patient 1 stated she now has a weak bladder and is incontinent of urine and is being currently treated for the incontinence with medication twice a day. Patient 1 stated " I feel like I have been robbed of my life having to live with this. " The clinical record was reviewed on 2/10/11. It showed Patient 1 was admitted on [redacted]/09 for surgery and discharged the following day on [redacted]/09 at 6:00 p.m. The procedure performed was a " Total vaginal hysterectomy and bilateral Salpingo-Oophorectomy, Anterior Posterior Repair, Avulta anterior mesh, Perineoplasty, Suprapubic cystostomy for indwelling catheter On 2/10/11 at 11:34 a.m., during an interview, the Chief Executive Officer (CEO) stated the facility received notice of an allegation that a foreign object was retained as a result of a surgical procedure performed at their facility. The CEO stated that Patient 1 had a second surgery on [redacted]/09 at another hospital as a result of a retained foreign object left from the first surgery of [redacted]/09 (eight months earlier). On 2/24/11 at 3:00 p.m. during an interview, Surgeon 1 stated Patient 1 had been placed on antibiotics post surgery and continued on antibiotics for about 5-6 months to treat infection. Surgeon 1 stated that he spoken to the Surgeon who performed the secondary surgery to remove the retained foreign object from Patient 1. Surgeon 1 stated he was informed by Surgeon 2 " gauze was surgically removed and sent to	E 347	All OR staff are required to view a training video on Patient Safety and Retained Foreign Objects by October 28, 2011 in order to educate staff further on identification of risk factors for retained foreign objects and how to prevent an occurrence of retained foreign objects from occurring. All operating room staff members were educated on the revisions of the operating room record as it pertains to documenting the count procedure, by the OR coordinator. The OR staff are also to be re-educated on the Policy and Procedure, Counts of Sponges, Needles and Instruments (TX 04.013), by October 28, 2011. The Policy and Procedure, Counts of Sponges, Needles and Instruments (TX 04.013), will be in effect for all patients having a surgical procedure performed at FSH. This process will be monitored to assure strict compliance going forward. 30 surgical procedures per month will be monitored concurrently by the OR Coordinator to assure that the Count policy is followed and appropriately documented on the operating room record. Monitoring criteria will include: All sponges, sharps and needles and instruments are counted and recorded when added to the operative field, counts will be audible, all sponges are separated and visualized by both the scrubbed person and the circulating nurse when counting, all sponges on the field are x-ray detectable, and sponges are never cut. The results to the audits will be reported by the OR representative to the Hospital Wide Quality Committee on a quarterly basis. Ongoing concurrent monitoring will continue for a minimum of 6 months, until the quality committee has seen satisfactory compliance with all components of the Sponge, Needle and Instrument Count policy and procedure. 10/28/11 SC/per Lois Ruffin CNO	

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E 347	Continued From page 3 Pathology. " Surgeon 1 stated he was never informed at the time of surgery that the sponge count was incorrect. The Operating Room record dated [redacted]/09 documented Sponge counts were done twice intraoperatively, with both counts being correct, but lacked specific times as per the facility policy and procedure " Counts of Sponges, Needles, and Instruments. " (pre-operative and when closure of vaginal cuff, anterior and posterior repair were completed) There was no indication the count was done audibly as required by the above policy. The Pathology Report from the second surgery dated [redacted]/09 documented the following operative findings: Gauze sponge trapped between mesh and bladder ...Clinical diagnosis: Retained sponge ...The First specimen " one tan-green gauze that measures approximately 15 x 7.5 x 0.8 cm " ... " mucosal tissue that measure up to approximately 1.5 x 1.3 x 0.9 cm " ... " the specimen is putrid " ... The facility policy and procedure titled " Counts of Sponges ... " revision dated 12/24/08 (original date 1/1/92) indicated the Procedure for counting sponges and sharps will be followed for every operative or invasive procedure unless otherwise indicated per policy ...Definitions ...Beginning/Initial Count- indicated the sponge count done prior to incision and conducted by the RN and a scrub person ...Closing Count - indicated when closing any cavity ...Counts are performed ...Prior to start of surgery ...at closure of cavity or hollow organ, ... counts will be performed audibly and viewed concurrently as they are separated and counted by two individuals, on of whom is a registered nurse	E 347		

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E 347	Continued From page 4 ...Sponges must be x-ray detectible and are counted as precise number in package. The facility ' s failure to ensure staff followed the " Counts of Sponges ... " resulted in Patient 1 sustaining the retention of a foreign object (gauze sponge) for eight months. Due to the retention of the foreign object, Patient 1 suffered with pain and weakness since [redacted]/09. She needed an additional hospitalization for antibiotics for 11 days and required a second surgery on [redacted]/09 for removal of the gauze sponge. Patient 1 stated " I feel like I have been robbed of my life having to live with this. " This 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.	E 347		