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
	050107	A. BUILDING ______ B. WING ______	12/17/2015

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
Marian Regional Medical Center	1400 E Church St, Santa Maria, CA 93454-5906 SANTA BARBARA COUNTY

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	The following reflects the findings of the Department of Public Health during an inspection visit:	Accepted January 19, 2016 Ka Chun, RN.	2016 JAN 19 AM 11:25 LICENSING & CERTIFICATION VENTURA DISTRICT OFFICE	CA DEPT OF PUBLIC HEALTH
	Complaint Intake Number: CA00405547 - Substantiated			
	Representing the Department of Public Health: Surveyor ID # 31899, 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: 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 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 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.			

Event ID:EGCF11 12/31/2015 1:18:37PM

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE: [signature] TITLE: PRESIDENT / CEO (X6) DATE: 1/18/16

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 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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	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 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 Section1279.1 (b) For purposes of this section, "adverse event" includes any of the following: Health and Safety Code Section 1279.1 (b) (1) (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, Division 5, Chapter 1, Article 3, Section 70223 (b) (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. Based on interview, record review and policy/procedure review, the facility failed to			

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	implement their policies and procedures to conduct a miscellaneous item count of a Toomey Bulb Syringe (TSB) device, and to do a complete wound sweep during a laparoscopic vaginal hysterectomy (removal of the uterus through the vagina with the use of robotics to assist) which advanced to a vaginal hysterectomy procedure. These failures lead to the retention of a TSB (green plastic bulb at the top of a 60 cc syringe (the bulb size was 2 1/2 inches by 2 1/2 inches). The retention of the TSB resulted in a second surgery on 6/5/14 under general anesthesia (putting a patient to sleep for an operation) to remove the retained TSB. Findings: Patient 1, a 54 year old female, was admitted to the facility on 4/22/14 for surgery due to uterine fibroid tumors [noncancerous growths that develop in or just outside a woman's uterus (womb)], according to her medical record. The scheduled surgical procedure was: Robotically assisted laparoscopic total hysterectomy, possible bilateral salpingo-oophorectomy, with diagnostic cystoscopy (removal of the fibroid tumors, possible removal of the ovaries and fillopian tubes and a test that allows the doctor to look at the inside of the bladder and the urethra using a thin, lighted instrument called a cystoscope). The procedure was scheduled for 7:30 a.m. in the hospital OR room 7 on 4/22/14. According to the surgeon's (Surgeon 1) dictated Operative Report on 4/25/14, the uterus was,			

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	"Grossly enlarged with multiple large fibroids." The surgeon was unable to remove the uterus through the laparoscope, "Due to its size,"according to the operative report. The same operative report indicated the uterus was, "Manually morcellated,(division and removal in small pieces) with the scalpel and scissors vaginally." Additionally, the operative report noted, "A Toomey syringe bulb (TSB) was inserted into the vagina to hold the pneumoperitoneum (the presence of air or gas in the abdominal cavity)." The operative report further indicated, "all instruments were removed from the vagina. Sponge, needle, and instrument counts were noted to be correct x 2." During an interview with Patient 1 on 9/4/14 at 10:30 a.m., Patient 1 indicated she was seen by Surgeon 1 at 2 weeks and at 6 weeks, postoperatively. At the two week visit with the surgeon, Patient 1 stated she had bruising and pain in her abdomen and some vaginal bleeding. According to Patient 1, Surgeon 1 did not perform a pelvic exam and indicated to the patient the bleeding, bruising and pain were "normal" at this point in Patient 1's recovery process. According to Patient 1, at the 6 week visit, Patient 1 continued to have pain, and the bleeding had increased. According to Patient 1, Surgeon 1 performed a pelvic exam at the 6 week visit and the surgeon indicated she thought there was something plastic in the vaginal area. Patient 1 stated, "Surgeon 1 tried to remove the item but was unable to remove it because of my pain." According to Patient 1, Surgeon 1 scheduled an appointment away from the facility at an outpatient ambulatory surgical			

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	center where Patient 1 underwent a second surgical procedure under general anesthesia on 6/5/14 to remove the retained TBS. Patient 1 stated, "The night before the second procedure, (Surgeon 1), called me and told me that the item left in me was a bulb she used during the kind of surgery I had done." The circulating nurse for Patient 1's surgical procedure on 4/22/14 was interviewed on 7/17/14 at 10:00 a.m. CN1 indicated the facility practice in the operating room (OR) was to announce when any item was added to the patient and then the CN1 would repeat the item. CN1 stated that the item would be added to the patient and written on the white board in the operating room. Additionally, according to the CN1, the item would be included in the count of items listed on the white board. CN1 indicated she did not hear Surgeon 1, who performed Patient 1's procedure, announce a TSB had been added to the patient. CN1 confirmed Surgeon 1 had used this item in previous similar procedures on other patients. The Scrub Technician (ST1) present for Patient 1's surgery on 4/22/14 was interviewed on 7/17/14 at 10:50 a.m. ST1 stated it was hospital practice to say out loud what was being added to the patient during a procedure and that someone else was to verbally repeat the item. The assigned CN would also add the item to the white board used for the surgical count. ST1 indicated she had witnessed Surgeon 1 use the TBS on vaginal hysterectomy cases, prior to Patient 1's surgery, in order to hold the pneumoperitoneum until the surgeon finished			

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	suturing. ST1 stated she did not recall Surgeon 1 placing the TSB into Patient 1 at the time the procedure was performed, and ST1 stated she did not hear any announcement from Surgeon 1. During an observation and concurrent interview with ST1 on 7/18/14 at 11 a.m., ST1 also stated, "Placing anything into the patient is out of my scope of practice. The surgeon places all items into the patient, I hold the instruments and hand them to the surgeon as the surgeon needs them." FA 1, part of the surgical team for Patient 1's surgery on 4/22/14 was interviewed on 7/17/14 at 1:30 p.m. FA1 indicated she would have been located at the abdomen of Patient 1 and her view of the vaginal area would have been obstructed by the robotic arm. FA1 indicated the routine was to announce any items added to the patient and the item was then noted on the white board in the operating room. FA1indicated Surgeon 1 would have been between the patient's legs removing the uterus. The intra operative nursing record dated 4/22/14, did not indicate that a Toomey bulb was ever placed, removed, or entered into the surgical count. During an interview with the surgeon on 7/17/14 at 4:15 p.m., Surgeon 1 was asked if she recalled performing a methodical wound sweep and vaginal exploration as per facility policy and procedure. Surgeon 1 stated, "I didn't do one." A review of the facility's policy and procedure		2016 JAN 19 AM 11:25 LICENSING & CERTIFICATION VENTURA DISTRICT OFFICE CA DEPT OF PUBLIC HEALTH	

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	of the two people must be a registered nurse. Surgical counts must be performed in procedures in which an incision is made or a wound is created and surgical items are used. The surgical count is performed to identify any packaging errors and to monitor the number of items used during the operation or procedure." Also, according to the policy: "the surgical technologist must maintain an organized field and inspect instruments and devices passed to the surgeon and returned from the field to ensure they are complete and intact." The policy further indicates: "A methodical exploration of the operative wound must be conducted prior to closure in every operation," and "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 vagina should be examined if it was entered or explored as part of the procedure." The facility failed to implement policy and procedure when hospital's OR staff and surgeon did not account for all miscellaneous items added to Patient 1 during a surgical procedure, did not count all items added to Patient 1 during a surgical procedure, did not inspect all instruments and devices passed to Surgeon 1 and returned from the field, and did not perform a methodical wound sweep at the end of Patient 1's surgical procedure. These failures resulted in the retention of a TSB in		2016 JAN 19 AM 11:25 LICENSING & CERTIFICATION VENTURA DISTRICT OFFICE CA DEPT OF PUBLIC HEALTH Plan of Correction: A. The following corrective action plan was executed: 1. The policy "Prevention of Retained Surgical Items" was reviewed with the Department of Surgical Services including a focused review of the policy and steps required to account for all miscellaneous items added to the patient during a procedure. Review of the safety policy is now completed and documented annually.	

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	Patient 1, and the necessity for a second surgical procedure under general anesthesia to remove the retained TSB. 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 the Health and Safety Code section 1280.3 (g). 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).		2. The policy requirement to perform a "methodical wound sweep" at the end of the procedure was reviewed with the individual surgeon by the Chairman of OB/GYN. 3. The facility met with the patient to review the event, apologize, answer questions, and review actions taken to prevent recurrence. All associated costs were covered by the facility. B. The Director of Surgical Services will be responsible for the corrective action plan and monitoring. The Director of Surgical Services is accountable to the Chief Nurse Executive. 1. "Random audit of 10 cases per month to validate presence of 'miscellaneous items' listed on the OR count board with expectation of 100% compliance." 2. "Random audit of 10 GYN cases per month to validate methodical wound sweep performed with expectation of 100% compliance." C. The corrective action (1 and 2) completed by October 2, 2014. Corrective Action 3 was completed on January 23, 2015.	

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