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 _____	08/11/2017

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: Complaint Intake Number: CA00479796 - Substantiated Representing the Department of Public Health: Surveyor ID # 2895, 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. 1279.1 (b)(1)(D) 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. California Codes Health & 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 was made. The CDPH verified that the facility informed the			

Accepted 8/30/17 KA Ghenes

CA DEPT OF PUBLIC HEALTH
2017 AUG 24 PM 6:27
LICENSING & CERTIFICATION
VENTURA DISTRICT OFFICE

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE K Cahill TITLE President & CEO (X6) DATE 8/24/17

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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	patient or the party responsible for the patient of the adverse event by the time the report was made. 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 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 and record review, the facility failed to ensure surgical counts for sponges were performed according to professional standards of practice and the facility's policies and procedures. This failure resulted in leaving a surgical sponge inside one patient (Patient A), during open heart surgery. On 3/9/16, an entity reported event (ERI) was submitted by the facility to the CDPH Licensing and Certification indicating retention of a foreign object was discovered inside Patient A's chest. According to the facility, Patient A was recently hospitalized for unrelated chronic issues, a chest x-ray was performed and the foreign body was identified on the chest x-ray dated 2/13/16.	70223 (b)(2)	*Accountability:* *Chief Nurse Executive Officer* *Immediate Action:* 1. Implemented concurrent observations and auditing, performed by the Director of Surgical Services and leadership team to verify the "Prevention of Retained Surgical Items "policy was fully implemented. The concurrent audit process included a review of documentation in the patient record to verify all required counts were recorded. During the month of March, 100% of cases were observed and verified the tasks and requirements of the policy were completed as required. 2. A site visit was conducted on 3/10/16 by the Dignity Health surgeon expert/ consultant, responsible for the "No Thing Left Behind" project. The surgeon observed procedures and conducted an independent evaluation of key processes. During the site visit, the consultant met with surgeons, surgical staff, administrative and physician leaders and provided on-site education regarding "Prevention of Retained Surgical Items" Dignity Health policy and standardization of safety processes as outlined in policy expectations. Recommendations were made and immediately implemented following the site visit. 3. Additional sponge holders were ordered and placed in all procedure rooms. Verification of the use of sponge holders in all operating rooms was completed.	3/9/16 – 3/31/16 3/10/16 – 3/11/16 3/18/16

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	According to the Association of Perl-Operative Registered Nurses (2014) standards and best practices for prevention of retained surgical items (RSI), "The final count should not be considered complete until ALL of the sharps, broken parts, sponges, equipment....used in the surgical procedure are returned to the scrub person. A multidisciplinary system approach should be used so that all team members can verify that all items are accounted for and be sure that a surgical item is not left in the patient at the end of a procedure. Team members need to use standardized and reliable counting practices that ensure all surgical items are accounted for or are reconciled at the end of the procedure." Burlingame, B. et al. "Guideline Summary: Prevention of Retained Surgical Items." AORN Journal 104.1 (2016): 49-53. A review of the facility's policy and procedure entitled, "Prevention of Retained Surgical Items," undated, indicated the purpose of the policy is: (A) To provide safety rules for perioperative registered nurses and surgical technologist in the performance of sponge...counts; (B) To provide safety rules for surgeons in the performance of a methodical wound exam and actions to prevent unintentional retention of surgical items; ... (F) To assists in accounting for all surgical items... According to the same policy, the facility uses the, "Sponge Accounting System" (SAS), a standardized, transparent manual accounting system that requires visible verification of the free surgical sponges used in an operation. Using the	70223 (b)(2)	***Systemic Action:*** 1. A sponge management competency is mandatory for all Circulators and Scrub Technicians. The competency includes the following elements: a. Viewing of a 21 minute video demonstration of the Sponge Accounting process. Demonstration of knowledge and understanding of the safety process is verified with a Test and requires a passing grade of 100%. b. All Circulator and Scrub Technicians (existing and newly onboarded) are required to read, agree and sign an attestation/commitment to follow the safety processes outlined in the "Prevention of Retained Surgical Items" policy. c. 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.	3/25/16 and On-going

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	SAS, all of the used and unused sponges during a surgical procedure must be in the sponge holders at the end of the case (surgery) to have a correct final count and to be able to perform a team verification step (show me). Further review of the policy, specifically under subpart (VI) (A), entitled "Surgery Count," the policy provisions indicate that during a surgery there are "IN Counts." "In Counts," according to the policy, are counts performed of surgical sponges to establish the baseline number of items (sponges) being used during the case. Additionally, the policy also provides for, "OUT Counts," which consist of the following: * Cavity count- performed before closure of a cavity within a cavity; and * Closing count- performed before wound closure begins; and * FINAL Count- performed after skin closure, when surgical items are no longer in use and ALL are passed off the field. Section 111. (C) of the policy indicates the following: "Surgical counts must be performed in procedures in which an incision is made or a wound is created and surgical items are used." Section V. (A) of the policy indicates the following: "A registered nurse is responsible for medical documentation. Section (C) sets forth: "Counts and other required information should be entered concurrently with an occurrence or at the end of the case. Documentation in the medical record serves	70223 (b)(2)	2. An ongoing monitoring system was implemented including observation and verification by the Director of Surgical Services and the Surgical Services leadership team. Documentation in the patient record of surgical counts is observed and evaluated. The immediate action taken, ongoing monitoring of the safety system was presented and accepted by the Surgical Services Committee, Quality Improvement Committee, Patient Safety Committee, Medical Executive Committee and Governing Board. There have been no retained surgical item events identified since the occurrence in March, 2016. CA DEPT OF PUBLIC HEALTH 2017 AUG 24 PM 6:27 LICENSING & CERTIFICATION VENTURA DISTRICT OFFICE	

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	as legal evidence of what practices were performed." In section V1. B (2) (e) (13), the policy sets forth: "At the time of the final count, ALL sponges (used and unused sponges) MUST be in the sponge holders and two people viewing the sponge holders must make the final verification. The preference is to have the clinician who closes the skin verify with the circulating nurse that the number of sponges in the holders agrees with the number of sponges documented on the dry erase board. If this not possible, the anesthesiologist, a charge nurse or RN who was not involved in the case may substitute. The requirement is to have "new eyes" look at the holders and the dry erase board to minimize confirmation bias between the scrub person who counted in the sponges and the circulating nurse." During a review of the clinical record for Patient A, the "Operative Report," dated 7/7/15 at 12:06 p.m., revealed Patient A had an Aortic (largest artery in the body) Root replacement with an aortic valve and tube graft using the Cabrol technique (tension-free re-implantation of the coronary arteries) on 7/7/15. During an interview with MD 1, on 4/14/16 at 10:56 a.m., he explained that toward the end of the surgery, Patient A started bleeding from the surgical holes. MD 1 stated, "I packed the bleeding area with thrombin (facilitates blood clotting), gel foam (absorbable foam to aid in clotting) and a Ray-Tec (X-ray detectable) sponge behind his Aorta and applied pressure to achieve hemostasis (blood clotting)."			

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	A review of Patient A's "Surgical Document Final Report," dated 7/7/15 at 11:20 a.m., revealed the initial count (IN Count) was performed by registered nurse (RN 1) and (RN 2) at approximately 7:52 a.m. There was no other documentation of any of the OUT counts (cavity, closing or final). During an interview with the registered nurse (RN 1), on 3/23/16 at 3:05 p.m., he reviewed the "Surgical Document Final Report," dated 7/7/15 at 11:20 a.m., to locate Patient A's sponge counts. RN 1 acknowledged the closing and final sponge counts were not documented on the final report. Furthermore RN 1 acknowledged that if the closing and final count were not documented on the surgical final report that meant, "The closing and final sponge counts were not done." During an interview with registered nurse (RN 2), on 4/1/16 at 9:00 a.m., she explained and recalled performing the initial sponge count during Patient A's surgical procedure with RN 1, but did not acknowledge or explain any other counts during Patient A's surgical procedure. According to RN 2, the Ray-Tec sponge was under all the items and used to produce clotting. During an interview with the scrub technician (SCT 1), on 3/23/16 at 4:05 p.m., he explained he did not do any sponge counts during Patient A's surgical procedure. A review of the document entitled, "Responsibilities: Circulating Nurse (RN) and Scrub Person," revised 5/15, sets forth under Section 111. B the following: "During surgery, the circulating RN will be			

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	responsible for managing and coordinating all aspects of patient care." In part B (1) of the policy, the following is set forth: "The Circulating Registered Nurse (RN) is responsible for documenting all nursing care in the electronic medical record, in Surginet/Perioperative Doc/Operating Room Intraoperative Nursing Record." In part D of the policy, the following is set forth: "The circulating RN and scrub person share accountability for sponge, sharp and instrument counts as well as patient safety and infection control." In section 1V. A. 1 (j) of the policy, a circulating nurse responsibilities is documented to include the following: "Perform sponge, sharp and instrument counts with scrub person per policy." A review of Patient A's Computed Tomography CT chest (serial of X-rays), dated 3/4/16 at 4:55 p.m., revealed: "Small tangle of wires, approximately 2.5 cm (centimeters) of the mediastinum just above and anterior to the right pulmonary artery." The surgeon (MD 1) was interviewed on (4/14/16 at 10:56 a.m.) MD 1 stated the two X rays of the chest taken before Patient A's discharge were underpenetrated and the sponge was not seen at that time. After reviewing the CT, the surgeon shared the sponge was isolated between the graft and the patients old aorta.			

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	During an interview with the administrator (Adm 1), on 3/23/16 at 2:05 p.m., she explained that when Patient A was bleeding, the Ray-Tec sponge was used to apply pressure to the bleeding site. Adm. 1 stated the Ray-Tec sponge is reactive and cannot be left inside the patient's [Patient A] chest, as it may cause an inflammatory response, an abscess (pus within the tissue), and/or a fistula (abnormal connection between two hollow spaces such e.g. blood vessels). According to Adm 1, these types of sponges are not meant to be retained inside the patient's body. Furthermore, Adm 1 explained that during [Patient A] incident, it was concluded that the surgical staff did not follow the [Prevention of Retained Surgical Items] policy and the SAS which were in place at the time of [Patient A] incident to account for the sponge counting. During an interview with the surgeon (MD 1) on 4/14/16 at 10:56 a.m., he shared he felt Patient A would probably not survive the surgery to remove the sponge and stated the surgery would be "too risky." According to MD 1, the patient was going to be evaluated for a heart transplant and at that point they could remove the sponge.The failure of the surgeon and the OR staff to follow the facility's policies and procedures, as it pertained to counting any and all items entering the patient and ensuring the items came back out of the patient, during a surgical procedure, resulted in the retention of a Ray-Tec surgical sponge in Patient A. The facility's failure to implement surgical care and services in compliance with section 70223 (b) (2) for Patient A with a retained foreign object is a deficient practice that has caused, or is likely to cause, serious injury			

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	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).			

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