CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY
DEPARTMENT OF PUBLIC HEALTH

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	050043	A. BUILDING _____ B. WING _____	03/11/2009

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
ALTA BATES SUMMIT MEDICAL CENTER - SUMMIT CAMPUS	350 HAWTHORNE AVENUE, OAKLAND, CA 94609 ALAMEDA COUNTY

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	The following represents the findings of the California Department of Public Health during the investigation of an entity reported incident. Entity Reported Incident Number: CA00173006 Representing the Department: [redacted] The inspection was limited to the investigation of the entity reported incident and does not represent a full inspection of the facility. T22 DIV5 CH1 ART3-70223(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. T22 DIV5 CH1 ART7-70707(b)(2) Patients' Rights (b) A list of these patients' rights shall be posted in both Spanish and English in appropriate places within the hospital so that such rights may be read by patients. This list shall include but not be limited to the patients' rights to: (2) Considerate and respectful care. Based on staff interview and record review, the facility failed to follow its own policy and procedure for "Counts, Instruments, Sponges, Needles and		**Preparation and/or execution of this Plan of Correction does not constitute admission or agreement by the provider of the truth of the facts alleged or conclusions set forth on the Statement of Deficiencies. This Plan of Correction is prepared and/or executed solely because it is required by Health and Safety Code Section 1280** **Plan of Correction:** 1. The Department of Surgical Services implemented a practice change requiring a count of all instruments utilized in port access cases. 100% of cardiac surgery team members were notified of change through team meetings. 2. The agenda for the weekly Surgical Services staff meetings was revised to include a standing agenda item to address compliance with the current "count" policy and procedure and for discussion of proposed revisions. 3a. The Department instituted the Cardiac Team Task Force which focused their efforts on a performance improvement initiative to improve hand-off communication, management of multiple component instrumentation and count process.	**Completed Date:** January 05, 2009 January 05, 2009 April 30, 2009

Event ID:TQ7G11 6/5/2009 8:58:46AM

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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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	Continued From page 1 Unusual Items", and to observe a patient's right for considerate and respectful care while in the surgical department. As a result, a ring/band sizer, used during heart valve repair, was left in Patient M's pericardial sac and a major chest surgery was required to remove it. After the chest surgery, Patient M experienced complications to include acute kidney failure. THIS EVENT CONSTITUTED AN IMMEDIATE JEOPARTY (IJ) WHICH PUT THE HEALTH AND SAFETY OF PATIENT M AT RISK WHEN THE SURGICAL DEPARTMENT STAFF FAILED TO IMPLEMENT THE HOSPITAL WRITTEN POLICY AND PROCEDURE FOR "COUNTS, INSTRUMENTS, SPONGES, NEEDLES AND UNUSUAL ITEMS." THIS FAILURE RESULTED IN A MAJOR CHEST SURGERY FOR PATIENT M. THUS, THESE VIOLATIONS CAUSED OR WERE LIKELY TO CAUSE, SERIOUS INJURY OR DEATH TO THE PATIENT. Findings: On 3/9/09, review of the facility policy and procedure for "Counts, Instruments, Sponges, Needles and Unusual Items", showed that the hospital was to use the AORN (Association of Operating Room Nurses) recommended practices and to maintain a " ...policy of counting all sponges, sharps, instruments and/or other countable items on all procedures except for those where retention of a foreign body is virtually impossible." Review of the facility's copy of the "Perioperative Standards and Recommended		3b. The team developed and in April 2009 began dissemination of a "hand-off badge" to facilitate communication regarding key surgical key processes. In-service training of 100% all staff (including casual relief staff) is part of the implementation plan. 3c. As a reinforcement for the learning process, posters are being developed and will be placed in each OR as a reference for hand-off communication. 4. The Surgical Services staff is receiving in-service education on the Chain of Command Policy and Procedure; this includes staff accountability to report count discrepancies through the chain of command to resolution. Training is being conducted in "face to face" sessions or by "read and sign" of the policy and procedure. 5. The "Counts, Instruments, Sponges, Needles and Unusual Items" policy and procedure has been revised to include instrument counts for all procedures where instruments enter a body cavity and to address the management of multiple component instruments. It is being implemented in DRAFT form (In process of Medical Staff approval). 100% of Surgical Services staff are receiving in-service training regarding revisions.	July 10, 2009 July 10, 2009 July 10, 2009 July 10, 2009

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	Continued From page 2 Practices" per the AORN that was faxed to the Department on 3/17/09, showed that "individual pieces of assembled instruments should be accounted for separately on the count sheet. Removable instrument parts can be purposefully removed or become loose and fall into the wound or onto or off the sterile field." The hospital policy also stated, "The OR Team (operating room team) will take all reasonable measures to protect the patient from retained surgical items, unless such retention is deliberate and planned." According to the same hospital policy, all instruments were to "be counted visually and audibly by the circulator and scrub on all procedures in which the likelihood that an instrument may be retained exists", and additional counts were to be done, "before any cavity within a cavity is closed (e.g. uterus, bladder, and pericardium)". Furthermore, the surgeon was to be informed by the nurse or the operating room technician "when any discrepancy in a count of surgical items is discovered" and an appropriate investigation/action was to be taken. Record review on 3/9/09, showed that Patient M was a 79 year old male who had mitral and tricuspid heart valve repair on 12/11/08. The surgeon had done the operation by making an incision on the right chest and going between the ribs to approach the heart ("port access" surgical procedure). Patient M was put on cardiopulmonary bypass and an incision was made on the right		6. The matter was referred to Medical Staff for review and action as indicated. Since this incident, there have been no reports of incidents of retained foreign bodies. **Monitoring Plan:** 1. Retrospective audits conducted on 100% of port access cases to assure compliance will be conducted through the year 2009. 2. The effectiveness of implementation of hand off communication tools will be evaluated through 10 observation audits each week. 3. Compliance with the Chain of Command Policy and Procedure will be monitored through review of 100% of unusual occurrence reports. 4. Compliance with the revisions to the "Counts, Instruments, Sponges, Needles and Unusual Items" Policy and Procedure will be monitored through observation audits of 70 cases per month. 5. Any deviations by staff will result in disciplinary action. The results of disciplinary action will be used in the annual performance evaluations.	December 31, 2008 Ongoing Weekly Daily Monthly Ongoing/ Annually

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	Continued From page 3 upper heart chamber to gain access to the mitral and tricuspid heart valves and allow for their repair. Review of the interim "Discharge Summary" dated 1/23/09 showed that Patient M "had a very complicated postoperative course" after the initial surgery on 12/11/08. His heart rate was so slow that a pacemaker had to be inserted. Patient M had increasing shortness of breath and a chest x-ray showed accumulation of fluid in his right chest. The 12/18/08 operative report showed Patient M had surgery for the removal of a collection of blood and fluid from the right chest. Patient M continued to have breathing difficulties, and a chest x-ray showed repeated fluid collection in the right chest. The 12/23/08 operative report showed that Patient M had another surgery to remove a large amount of blood clots and fluid from the right chest and 900 milliliters of clear fluid from the left chest and the right chest outer lining was "peeled off". On 12/22/08, Patient M required a CT scan of the chest. It showed a "27 x 7 mm (millimeter) ring like..." retained foreign body. A repeat CT scan on 12/24/08 showed a "disc-like foreign body within the posterior pericardium (heart sac)", that was later identified as the ring sizer used to measure the valve during the surgery performed on 12/11/08. A ring/band sizer is an instrument used to measure the size of the heart valve opening in order to determine the size of the ring/band that is needed to go around a heart valve to maintain it open (valve repair). Further record review showed that on 12/25/08,		6. Peer Review outcomes are reviewed by the Department Chair and are part of the ongoing Medical Staff credentialing and reappointment process. **Responsible Parties:** Director of Surgery Cardiac Team Task Force Members	Ongoing

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	Continued From page 4 Patient M had to undergo general anesthesia and an attempt was done to gain access to the ring sizer in the heart sac through the 12/11/08 chest incision. Patient M had bleeding at the pulmonary artery site and became hypotensive (had low blood pressure) during the attempt to remove the ring sizer through the previous incision. Patient M's sternum (breastbone) was cut open to gain access to his chest. He was put on cardiopulmonary bypass which allowed the surgeon access to the ring/band sizer that measured 26 mm (millimeters) in diameter (slightly bigger than the diameter of a 25 cent coin) and 6 mm in thickness. According to a cardiovascular intensive care physician note dated 12/25/08, Patient M's surgery was "complicated by blood loss & (low) BP (blood pressure)". The Discharge Summary, dated 1/22/09, read, " Postoperatively, he (Patient M) was unable to be weaned from the ventilator, and so on 12/30/08, he had a percutaneous tracheostomy (a surgical opening on the neck that allows direct placement of indwelling tube in the trachea for passage of air) placed. " Patient M went into acute renal failure after "removal of the FB (foreign body) operation". On 3/9/09 at 11:45 a.m., Scrub Tech 1 stated that he was aware of the missing ring/band sizer when he noted that his instrument placement on his tray was not correct; the ring/band sizer handle did not have the ring/band sizer attached to it. Scrub Tech 1 stated the mitral valve ring/band sizer and the handle were not screwed onto each other, the handle "... just pops in". Scrub Tech 1 stated that			

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	Continued From page 5 he had been relieved for lunch by Scrub Nurse 2 and that when he returned from lunch nothing was said to him concerning the sizer, so he "assumed" it had been found. "Everything seemed normal," Scrub Tech 1 said during the interview. The surgical team jeopardized Patient M's safety when it failed to account for the missing ring/band sizer, to implement the "policy to ensure that surgical items are not retained in a patient following surgery", and to do an appropriate search and recovery of the item. During a telephone interview on 3/11/09 at 2:47 p.m., Surgeon A stated he assumed that instruments were counted and accounted for as part of "everything" during intraoperative surgical counts.			

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