7/16/10 POC accepted EL

FORM APPROVED

California Department of Health Services

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	CA930000070	A. Building _____ B. Wing _____	C 01/13/2010

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
CITRUS VALLEY MEDICAL CENTER – IC CAMPUS	210 W. SAN BERNARDINO RD. COVINA, CA 91723

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
E 000	Initial Comments The following reflects the findings of the Department of Public Health during a Complaint Investigation. Complaint Intake No. CA00179980 Representing the Department of Public Health: [redacted], RN, HFEN The inspection was limited to the specific complaint investigated and does not represent the findings of a full inspection of the facility. 1280.1(c) Health and Safety Code Section 1280 For purpose of this section, "Immediate Jeopardy" means a situation in which the licensee's noncompliance with one or more requirements of licensure has caused, or likely to cause, serious injury or death to the patient.	E 000		
E 264	T22 DIV5 CH1 ART3-70213(a) Nursing Service Policies and Procedures (a) Written policies and procedures for patient care shall be developed, maintained and implemented by the nursing service. This RULE: is not met as evidenced by: Based on interview and record review, the facility failed to implement their policy and procedure to prevent the retention of a metal portion of a disposable medical device used during Patient A's surgical procedure, which resulted in an Additional surgery/general anesthesia for removal of the foreign object.	E 264		

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE	TITLE	(X6) DATE
Jodi Sallee	CNO/VP Patient Care Services	7-15-2010

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E 264	Continued From Page 1 Findings: On December 7, 2009, an unannounced visit to the facility was conducted to investigate a reported incident of a retained foreign object after open heart surgery on Patient A. During an interview with Employee 1 (Registered Nurse), on December 7, 2009, at 2:30 p.m., he stated, an incident of device failure had been Reported to the FDA (Food and Drug Administration). On August 1, 2008, an eighty Year-old, female (Patient A), had a coronary artery bypass surgery. During the surgery , a Guidant Heart string device (surgical seal device) was utilized. The object was disposable and evidently was not part of the counted items during surgery, as all surgery counts were documented as correct. However, a small metal portion of the medical device was later discovered by x-ray as having been left inside the patient, by the surgeon. The patient required a second surgery with general anesthesia to have it removed. On December 7, 2009, at 3:00 p.m., during an Interview, Employee 2 (Registered Nurse) stated, She had relieved the scrub nursing during the first surgery (open heart) for Patient A. She had Completed the first, second and final counts for The sponges, sharps, and instruments. She also Stated the Heart string device was not Considered part of the count because it was not a "sharps" item. The facility policy and procedure, titled, Counts, Sponges, Sharps, Instruments, and Miscellaneous Items, Policy #: c-111, with a Revised dated of March 19, 2008, stipulated counts were performed to account for miscellaneous items introduced into an open	E 264	Due to our deep concern and serious nature of this unanticipated event that had never previously occurred in our facility, immediate action was taken after its discovery. The following are the steps taken: On August 5, 2008, we voluntarily self-reported the event to CDPH. The manufacturer of the product was notified and immediately removed this type of device from the facility. They replaced these devices with an upgraded model and provided education to the staff (see attached inservice sign in sheet). On August 11, 2008, a root cause analysis was performed to analyze the event, determine all possible contributing factors, and arrive at measures to prevent a recurrence. On August 11, 2008, we voluntarily self-reported this event and the device to Medwatch so that they could determine whether this was a possible defective product. In addition, ECRI recalls were reviewed to determine whether this device may have been recalled.	8/5/08 8/11/08 8/11/08

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E 264	Continued From Page 2 body cavity during a surgical procedure and to ensure that the patient was not injured as a result of a retained foreign body. The policy stipulated that "all items opened onto the surgical field would be included as part of the count. If an item other than a sponge or needle is introduced into an opened body cavity, that item will be entered as a counted item and will follow the Procedure for counting." The medical record for Patient A was reviewed On December 7, 2009, and revealed the following: The History and Physical dated July 7, 2008, Disclosed Patient A was admitted on July 7, 2008, with a chief complaint of chest pain, status Post cardiac arrest. The physician's impression indicated the patient had acute inferior wall myocardial infarction (heart attack). The Operative Report, by Surgeon 1, dated August 1, 2008, indicated the use of a Guidant Heart String Device (surgical seal device) during the surgery. The Intraoperative Nursing Documentation dated August 1, 2008, confirmed the counts for the first surgery were documented as correct. There was no documentation that the Heart string device was part of the count during the surgery. A follow-up chest X-ray for evaluation of possible Small linear density projecting over the right side of the cardiac silhouette, dated August 2, 2008, taken at 12:30 p.m., disclosed the following: "incidental findings was the presence of a linear tube shaped density projecting over the right side of the cardiac silhouette, which measured 2.7 mm (millimeter) x 16.4 mm. The foreign body may represent a piece of a tube or metallic clip	E 264	Surgical Services Policy #C-111, entitled," Counts: Sponges, Sharps, Instruments, and Miscellaneous Items" was reviewed. Upon investigation of this event, it was discovered that the policy was followed appropriately after this patient's surgery, with the exception of this unanticipated event where a component of the device became detached. It was identified that the retained object was a component of the device. As such, it would not have been considered to be a separate miscellaneous item and therefore would not have been noted in the postoperative count. The detachment of this component was not an event that could have been anticipated. To ensure that this event would not recur, Surgical Services Policy #C-111 was revised on 9/5/08 to specify that a postoperative x-ray is required for every open heart surgery procedure before the patient is transferred from the surgery room (please see attached policies); however, if the patient's condition prevents the x-ray from being performed prior to transfer, it shall be performed immediately after transfer to the destination that is conducive to providing safe patient care. The Surgery Department was educated about this event and about the revision to this policy. Two processes have been monitored. First, audits have been performed on 100% of all open heart surgery cases to determine whether x-rays were performed after the procedure (see attached audit form). The dates of the attached audits include open heart surgeries that were performed between 10/1/08 and 3/31/10. Second, audits have been done to assure that documentation reflects the "count performed prior to closure" and that "all items have been accounted for." Ongoing monitors shall be continued.	9/5/08

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E 264	Continued From Page 3 or some other object. This was seen to be present on the chest x-rays of August 1, 2008, at 5:02 p.m., and the film of August 2, 2008, at 6:56 a.m." A CT (computerized tomography) of the chest without contrast dated August 2, 2008, indicated a linear 17 mm long radiopaque foreign body Was seen. It appeared to be in the pericardial area of the right side of the heart, possibly representing a foreign body. The Intraoperative Nursing Documentation, dated August 13, 2008, documented Patient's A surgery procedure for removal of foreign body from the right posterior pericardium (heart). The Operative Report, by Surgeon 1, dated August 3, 2008, documented the surgery Performed was: reopening of sternotomy (chest) incision, exploration of pericardial (heart) cavity, and the removal of the foreign body, which was a metal piece form the heart string device (aka the Guidant Heart String Device; surgical seal Device) used in the patient's previous surgery, the coronary artery bypass. The report further documented that "evidently when the heart string was removed, this piece of metal fell off inadvertently and was not noticed" during the first surgical procedure performed on August 1, 2008. Because Patient A had a retained foreign body that required an additional chest surgery under general anesthesia for its removal, the patient was placed at risk for possible additional complications. The facility's failure to implement its policy/procedure to prevent the retention of a metal portion of a disposable medical device during a surgical procedure is a deficiency that	E 264		

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E 264	Continued Form Page 4 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 264		