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
	050567	A. BUILDING _____ B. WING _____	06/29/2010

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
MISSION HOSPITAL REGIONAL MEDICAL CENTER	27700 MEDICAL CENTER ROAD, MISSION VIEJO, CA 92691 ORANGE COUNTY

(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
	The following reflects the findings of the Department of Public Health during an inspection visit: Complaint Intake Number: CA00225145 - Substantiated Representing the Department of Public Health: Surveyor ID # 06793, 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 CONSTITUTING IMMEDIATE JEOPARDY T22 DIV 5 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.		The Occurrence "A 71 year-old female was admitted to Mission Hospital for a surgical removal of an L3-4 interbody graft and implantation of new hardware. The surgical count was correct. On the routine post operative x-ray to ascertain placement, a small retained foreign body was visualized. After further tests, the patient was returned to surgery for removal of a single 8x5 mm metal screw cap which was part of the breakaway portion of the implanted hardware." All this occurred on [redacted] 2010. At that time, the breakaway portions of the hardware were not included in the formal surgical count. However, the surgeon conducted his own count, as per his personal practice, and the two screw caps were counted. It remains unknown how one of the screw caps was retained.	

Event ID:GNY811 3/25/2011 9:32:49AM

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE TITLE (X6) DATE

Director Quality Improvement 4/7/11

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.

OK Received 4-12-11

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
	050567	A. BUILDING _____ B. WING _____	06/29/2010

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
MISSION HOSPITAL REGIONAL MEDICAL CENTER	27700 MEDICAL CENTER ROAD, MISSION VIEJO, CA 92691 ORANGE COUNTY

(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
	Continued From page 1 The above regulation was NOT met as evidenced by: Based on medical record review, staff interview, and review of policies, the facility failed to ensure implementation of policies addressing the counting of miscellaneous items that had a potential for being retained during a surgical procedure. This resulted in a metallic breakaway tab from an implant being retained after surgery on [redacted]/10. The retained implant tab necessitated the patient again undergo the risks and complications of general anesthesia and possible infection when she had to be returned to the operating room the same day for a second surgery to have the retained object removed. Findings: On 6/22/10, medical record review for Patient 1 revealed a discharge summary in which the physician documented Patient 1 underwent back surgery [redacted]/10 without any complications, "accepting that one of the two breakaway tabs for the Cross-link was retained and she underwent a second surgery that night to take out the breakaway tab." On 6/22/10, during interview, the physician stated the breakaway tabs are removed during surgery with a tool that holds the breakaway tabs when they are removed. The physician stated that during the surgery, when he removed the tabs, he shook the tool removing each of the breakaway tabs and counted them with the surgical technician that		The patient was x-rayed in the recovery room to check the placement of the hardware. At that time, the screw cap was seen floating in the epidural space. A confirming MRI was conducted. The surgeon spoke with the patient and the family, and gave them the option to leave the part in or to return to surgery and remove the cap. The surgeon and the family agreed to return to surgery and remove the screw cap. The surgery department did not notify their management staff and did not file an incident report; thus the proper notification to your office did not occur at that time. During a routine review of "unplanned return to surgery" charts, the return to surgery for a retained foreign body was noted. CDPH was immediately notified on April 6, 2010. A. Corrective plans and actions In response to Mission Hospital's investigation of the incident, several corrective actions and changes in policy and procedure were conducted:	

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE TITLE (X6) DATE

Jan Breiner RN PhD Director Quality Improvement 4/7/11

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.

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
	050557	A. BUILDING _____ B. WING _____	06/29/2010

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
MISSION HOSPITAL REGIONAL MEDICAL CENTER	27700 MEDICAL CENTER ROAD, MISSION VIEJO, CA 92691 ORANGE COUNTY

(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
	Continued From page 2 placed them on the Mayo/instrument stand. However, an x-ray taken in the PACU (Post Anesthesia Care Unit) showed a metallic foreign body to the right within the spinal canal and the patient had to be returned to the operating room to remove the metal tab. On 6/22/10, during interview, staff stated these breakaway tabs were not included in the count and there was no policy/procedure in place addressing these breakaway tabs. However, review of the policy addressing the counts to be performed during a surgical procedure revealed the purpose of the counts was to account for all items and to lessen the potential for injury to the patient as a result of a retained foreign body. The "Purpose" also stated "There will be a count performed for all sponges, instruments, sharps, and miscellaneous items on all surgical procedures in which the possibility exists that a sponge, instrument, sharp, or miscellaneous item could be retained." In addition, the policy described "miscellaneous items" as items other than sponges, sharps, or instruments that have the potential for being retained in a surgical incision. In violation of its own policy, the facility failed to follow the protocol to account for the breakaway tabs that had the potential for being retained. Review of the medical record revealed anesthesia reports documenting Patient 1 had undergone general anesthesia for the initial surgery and again for the second surgery to remove the retained object on [redacted]/10.		1. OR and Sterile Processing staff were inserviced about the Medtronic Crosslink Deformity set (tray) (April 12-14, 2010). 2. The instrument tray count sheet for this device was changed. A picture of this break off tool was placed on the count sheet. A reminder was given to SPD staff to inspect and confirm that the device was fully functional and ready for use (April 13, 2010). 3. The Medtronic Crosslink 5.5 titanium deformity set container was labeled to indicate all screws to be counted and added to miscellaneous count (April 13, 2010). 4. The OR documentation system (PICIS) for the surgical counts was revised to include a category for all miscellaneous items such as the break away tabs (May 2010). a. Prior to this revision, the counts had included only those items on the AORN list, such as sponge, needle, and instrument counts.	

Event ID:GNY811 3/25/2011 9:32:49AM

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE TITLE (X6) DATE

Jan Brewer RN PhD Director Quality Improvement 4/7/11

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.

APR 1 1 2011

75

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
	050567	A. BUILDING _____ B. WING _____	06/29/2010

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
MISSION HOSPITAL REGIONAL MEDICAL CENTER	27700 MEDICAL CENTER ROAD, MISSION VIEJO, CA 92691 ORANGE COUNTY

(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
	Continued From page 3 The facility's failure to ensure the implementation of the established policy regarding accounting . for miscellaneous items with the potential for being retained during a surgical procedure 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(c). 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 1280.1(c).		b. At the time of the incident, community standard is that these kinds of miscellaneous items (break away tabs) are not included in the surgical counts. 5. A list of miscellaneous items has been expanded and discussed with staff. These lists were incorporated into a revised count policy. 6. The surgeon did not follow common practice regarding the taking of x-rays to assure placement of hardware in OR prior to close. The surgeon ordered the x-ray for the post operative time. This case was sent to physician peer review (April, 2010). 7. OR policy was revised so that x-rays to determine proper hardware placement will be required before the patient leaves the OR. This policy change was discussed and approved by the Surgical Executive Committee (July 2010), the Medical Executive Committee (July 2010), and the Board of Trustees (July 2010).	

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE	TITLE	(X6) DATE
[signature]	Director Quality Improvement	4/7/11

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.

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
	050567	A. BUILDING _____ B. WING _____	06/29/2010

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
MISSION HOSPITAL REGIONAL MEDICAL CENTER	27700 MEDICAL CENTER ROAD, MISSION VIEJO, CA 92691 ORANGE COUNTY

(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
	Continued From page 3 The facility's failure to ensure the implementation of the established policy regarding accounting for miscellaneous items with the potential for being retained during a surgical procedure 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(c). 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 1280.1(c).		8. OR contacted Medtronics to inquire if there had been any reports or similar occurrences. Medtronics formally replied that there have been no such reports (April, 2010). An FDA report was sent to MedSun related to the tools used to break off the tabs, under the Safe Medical Device Act. (April 2010) B. Responsible Party - Director of Surgical Services/designee C. Monitoring The circulating RN is responsible to document all counts on the intraoperative record. The circulating RN verifies the presence of any miscellaneous items prior to closure and documents on the intraoperative record as appropriate. Any count variation is reported immediately and count policy is followed – including x-rays – prior to close. Monitoring is ongoing and has become part of Standard work. D. Actions were completed by July 28, 2010, or as indicated. Monitoring continues as described.	

Event ID:GNY811 3/28/2011 9:32:49AM

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE	TITLE	(X6) DATE
Jan Drews MD PhD	Director Quality Improvement	4/2/11

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.

575