CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY
DEPARTMENT OF PUBLIC HEALTH

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION

(X1) PROVIDER/SUPPLIER/CIA IDENTIFICATION NUMBER:
050360

(X2) MULTIPLE CONSTRUCTION
A. BUILDING
B. WING

(X3) DATE SURVEY COMPLETED
01/10/2014

NAME OF PROVIDER OR SUPPLIER
Marin General Hospital

STREET ADDRESS, CITY, STATE, ZIP CODE
250 Bon Air Rd, Greenbrae, CA 94904-1702 MARIN 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:
CA00367325 - Substantiated

Representing the Department of Public Health:
Surveyor ID # 25962, 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.

Penalty number: 110011046

T22 DIV5 CH1 ART3 - 70223(b) (2) Surgical Services 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.

Immediately upon learning of the retained foreign body the patient was taken to the operating room for removal of the Raney clip on 8/14/2013. There were no apparent sequelae as a result of the retained Raney clip or the surgical removal.

There have not been any further occurrences of retained Raney clips.

All circulating RNs and scrub techs working in the operating room and neurosurgeons were instructed to count Raney clips during neurosurgical procedures effective immediately on 8/14/2013.

The policy entitled Sharp and Sponge Accounting was modified on 9/15/2013 to specify Raney clips in the section of the policy referring to small/other items that require counting.

Circulating RNs and scrub techs also received...
Based on observation, staff interview, record and policy review, the facility failed to ensure a written policy and procedure was implemented to ensure Patient 1 did not have a retained foreign body after a surgical procedure, when a disposable surgical scalp clip used to prevent bleeding was left in during a cranial (head) surgery that resulted in a second surgical procedure to remove the surgical scalp clip and potential for further complications such as bleeding, infection, stroke, death and coma.

Findings:

During an interview and review of the electronic record on 09/20/13 at 11:20 a.m., the Risk Manager stated that Patient 1 was admitted on 08/12/13 and discharged on 08/19/13. On 08/12/13, Patient 1 had cranial surgery and on 08/14/13, Patient 1 had a second surgery to remove a disposable surgical scalp clip from the first surgery. The Risk Manager stated that the surgeon brought Patient 1 back to surgery and placed a "burr" hole (a hole that is drilled into the skull) and removed the surgical clip through the hole.

Patient 1’s operating room electronic record dated 08/12/13 indicated that Patient 1’s preoperative diagnosis indicated Patient 1 had a right side cranial defect with prior craniotomy, and procedures that were performed were a cranioplasty (surgical repair of the deformity of the skull) and wound closure. The operating room record indicated that three counts were done for items used on the surgical field and did not indicate items were subsequent in-service education on 10/16/2013. (See attachment.)

**Responsible Person**

Director, Perioperative Services

**Monitoring**

All craniotomy cases were reviewed for the period 8/12/2013-2/28/2014 for retained foreign objects. There were none noted.

Beginning and ending counts for these craniotomy procedures were correct.

There have been no further incidents of retained Raney clips or other small items reported through the incident reporting system.

Occurrences of retained foreign objects are reported at the Performance Improvement Committee, which meets bimonthly.
The surgeon's electronic note, dated 08/13/13, indicated that on closer inspection of a CT scan, (Computerized Tomography - a computerized x-ray scan procedure), it appeared that there was a retained disposable surgical clip from the scalp. There was no evidence of associated injury; however, "it is a foreign body in epidural space" (outside dura mater or fibrous covering of the brain) that "will potentially limit complete re-expansion of the brain". The note indicated that Patient 1 needed to go back to surgery for partial reopening and removal of the foreign body and that the surgeon wanted to perform the procedure urgently to minimize the risk of problems and to expedite his recovery. The note indicated that Patient 1 was added on to the surgery schedule on 08/14/13. The surgeon's operative record for the 08/14/13 surgery indicated the postoperative diagnosis was retained foreign body.

Review of the surgical pathology report for Patient 1, signed 08/15/13 by the pathologist indicated under clinical data, retrieval of retained foreign object and under gross description was noted "foreign object" consists of green plastic object measuring 1.5 x 1 x 1 cm.

During an interview on 09/20/13 at 1:55 p.m., Operating Room Director stated that they looked at the operating room policy for counting, which did not include to specifically counting disposable surgical scalp clips during the surgery. Operating Room Director stated that it was not their practice.

The Performance Improvement Committee recommends further action as appropriate, including but not limited to the need for ongoing monitoring.
to count disposable surgical scalp clips in the past.

During an interview on 09/20/13 at 2:40 p.m., the Surgical Technician stated that he and the Licensed Surgical Nurse did counts of the needles, bovie scraper, hypo needles, sponges at the beginning and end of the case, but didn't count the disposable surgical scalp clips. The Surgical Technician stated that the surgeon removed the surgical scalp clips as he closed the scalp.

The Facility "Sponge & Sharp Accounting #436.10" policy and procedure, last revised 12/12 indicated that the purpose of the policy was to describe guidelines to account for sponges, sharps, and small or other items used during surgical or invasive procedures. The definition of "Small/Other items include (but not limited to) hydrafajas, Penrose drains, rubber shods, bull-dogs, suture reeis, umbilical tapes, vessel loops, bovie" (cautery)" tips, bovie scratch pads, angiocaths, and fish" (surgical retainer). The policy did not specify the disposable neuro scalp clips in its definition of small items to be counted.

During a telephone interview on 11/26/13 at 7:58 a.m., the Licensed Surgical Nurse stated that she did the initial and final count for Patient 1's surgery and counted everything except for the disposable surgical scalp clips. The Surgical Nurse stated that no one noticed the missing disposable surgical scalp clips and she was not alerted about any missing items in the count. The Surgical Nurse stated that their policy did not specifically say to count the disposable surgical scalp clips and that
she never counted them before at the facility.

The facility failed to develop, maintain, and implement policy and procedure to ensure Patient 1 did not have a retained foreign body when a disposable surgical scalp clip was not counted and left in the patient during neurosurgery of the brain. A second procedure was required to remove the disposable surgical scalp clip and had the potential for further complications of infection, bleeding, stroke, coma and death. This failure was a violation of section 70223(b)(2) of Title 22 of the California Code of Regulations and was a deficiency that caused or was likely to cause a serious injury or death to the patient and therefore constitutes an immediate jeopardy within the meaning of the health and safety code 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).