

CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY
DEPARTMENT OF PUBLIC HEALTH

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 050454	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED 04/05/2011
NAME OF PROVIDER OR SUPPLIER UCSF MEDICAL CENTER		STREET ADDRESS, CITY, STATE, ZIP CODE 505 PARNASSUS AVENUE, SAN FRANCISCO, CA 94143 SAN FRANCISCO COUNTY		
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	<p>The following reflects the findings of the Department of Public Health during an inspection visit:</p> <p>Complaint Intake Number: CA00263189 - Substantiated</p> <p>Representing the Department of Public Health: Surveyor ID # 25730, HFEN</p> <p>The inspection was limited to the specific facility event investigated and does not represent the findings of a full inspection of the facility.</p> <p>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.</p> <p>Title 22 70223(b)(2) Surgical Service General Requirements</p> <p>(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.</p> <p>1279.1(b)(1)(D) Retention of Foreign Object in a Patient</p>		<p>The statements made in this Plan of Correction are not an admission and do not constitute agreement with the alleged deficiencies herein.</p> <p>This Plan of Correction constitutes UCSF Medical Center's written credible allegation of compliance for the deficiencies noted.</p> <p>Corrective Action: Beginning on March 28, 2011, in the Moffitt/ Long Operating Room, a process for counting raney clips was successfully piloted with four neurosurgeons for all of their cases in which raney clips are used. The circulating and scrub staff and surgeons in these cases were educated to the new process. Beginning on April 5, 2011 and forward, raney clips are counted in all surgical cases that use them.</p> <p>Beginning on April 1, 2011, the perioperative nursing procedure "Count, Instruments, Sponges, Needles and Small Items" was revised to include counting raney clips in all surgical cases where they are used.</p>	<p>3/28/11</p> <p>4/5/11</p> <p>4/2011</p>

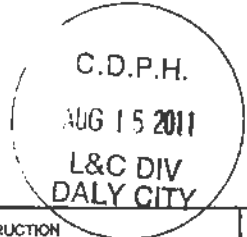
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Event ID: CWSY11 7/20/2011

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE: *Gene Carnagey* TITLE: Director, Regulatory Affairs (X6) DATE: 8/10/11

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C.D.P.H.
AUG 15 2011
L&C DIV
DALY CITY



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	<p>Continued From page 1</p> <p>(b) 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.</p> <p>This Regulation was not met evidenced by:</p> <p>Based on interview and record review, the facility failed to develop and implement a surgical count policy and procedure that specified small items would be accounted for prior to closure after brain surgery resulting in a Raney clip (green plastic clip approximately one inch long and one quarter inch wide) being left inside Patient 1's skull.</p> <p>Findings:</p> <p>Patient 1 was admitted to the hospital on █11 for removal of two melanoma metastases to the right occipital and the right parietal lobes of his brain (Cancer of the skin which spread causing tumors on the right side of the back of Patient 1's brain). On █11 Patient 1 had a craniotomy (surgical operation in which a bone flap was removed [temporarily] from the skull to access that portion of the brain where the tumor was located) with resection (removal) of the tumor in the right occipital area of the brain (right side of the lower back lobe of the brain).</p>		<p>Additionally, the procedure was revised to clarify requirements for counting other small items in accordance with current AORN recommendations. All involved personnel who perform circulating and scrub duties were trained by July 22, 2011.</p> <p>The revised count policy was approved by the OR Committee on April 8, 2011. Beginning in May 2011, competency checklists for circulating and scrub personnel were revised in accordance with the revised count procedure. By July 22, 2011, all affected operating room personnel who were not on a leave of absence were assessed using these revised competency checklists.</p> <p>To ensure systemic change in the organization, by July 20, 2011, the revised procedure for counting small items, including raney clips, was implemented in both Labor and Delivery (L&D) where c-sections are performed and in the Orthopedic Institute (OI) where outpatient orthopedic surgery is performed. L&D and OI personnel were educated in accordance with the procedure.</p>	<p>7/22/11</p> <p>4/8/11</p> <p>7/22/11</p> <p>7/20/11</p>

Event ID: CWBY11

7/20/2011

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	<p>Continued From page 2</p> <p>On [redacted] 11 Patient 1 had a second craniotomy for resection of the tumor in the right parietal lobe of his brain (lobe just above the occipital lobe in the back of Patient 1's brain). The neurosurgeon's Operative Report, dated [redacted] 11, indicated that when closing the skull after this craniotomy, the bone flap was in four pieces and was secured with titanium plates and screws.</p> <p>During both of these operations Raney clips were used to compress the layers of the scalp in order to stop it from bleeding and to keep the scalp out of the surgical area.</p> <p>On 4/5/11, Patient 1's Case Records, dated [redacted] 11 and [redacted] 11, were reviewed and showed that the pre-op and final sponge, needle, and small items counts were documented as correct. The Case Records did not indicate what small items had been counted.</p> <p>Review of the Discharge Summary dated [redacted] 11 indicated Patient 1 had mild left lower extremity weakness after the second surgery. Patient 1 was discharged to a Skilled Nursing Facility (SNF) on [redacted] 11 for acute rehabilitation.</p> <p>Record review of Patient 1's Admission History and Physical dated [redacted] 11 indicated Patient 1 was readmitted to the facility because of a possible infected pseudomeningocele of the operative area. A pseudomeningocele was an abnormal collection of cerebral spinal fluid which formed outside the dura [covering of the brain] causing a pouch-like fluid collection under the scalp in the operative area</p>		<p>Additionally, as of June 28, 2011, personnel in OI completed the competency assessments for counting small items, including raney clips. Beginning July 20, 2011, competency assessment of personnel in L&D began and will be completed by the end of the month.</p> <p>Monitoring: Beginning in April 2011, an audit was conducted of 100% of the neurosurgery cases involved in the pilot testing of the new process for counting raney clips. The compliance rate for a 2-week period was 100%. Results were reported to the Patient Safety Committee on June 1, 2011. At the direction of the members of the Patient Safety Committee, the audit process was revised to include small items in addition to raney clips, to be conducted randomly on a quarterly basis. A report of findings was presented to the Patient Safety Committee at its August 3, 2011 meeting. Compliance with counting both raney clips and other small items for the months of June 2011 and July 2011 was 100%.</p>	<p>6/28/11</p> <p>7/20/11</p> <p>4/1/11</p> <p>6/1/11</p> <p>8/3/11 and ongoing</p>

Event ID: CW9Y11	7/20/2011	2:44:57PM	
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	<p>Continued From page 3</p> <p>where the bone flap had been replaced.</p> <p>Review of the computer assisted tomography (CT) scan performed on [REDACTED] 11 indicated "Tubular shape foreign body in the right occipital resection cavity of uncertain etiology."</p> <p>Review of the Operative Report dated [REDACTED] 11 indicated Patient 1 returned to surgery for a craniotomy and a wound irrigation and drainage with removal of the bone flap. The neurosurgeon's note stated there were signs of infection so he took cultures and then irrigated the wound with two different antibiotic solutions. The neurosurgeon wrote "During the irrigation, we encountered a green Raney clip floating in the irrigant ...and because clips had not been applied to the skin edge during the current wound washout, it was possible that the clip was remnant from the prior operation, and it was removed." A drain was placed in the surgical area to drain cerebral spinal fluid and "residual infection." The neurosurgeon wrote he was not replacing the bone flap because there was a risk of recurrent pseudomeningocele which would require an additional operation to place a shunt and because there was a risk of recurrent infection.</p> <p>Review of the culture report of the subgaleal (under the scalp) fluid, dated [REDACTED] 11 when the specimen was received, indicated the fluid was positive for a moderate amount of staphylococcus aureus.</p> <p>Review of the Inpatient Progress Note dated [REDACTED] 11 indicated the surgeon spoke with the Patient 1 regarding the [REDACTED] 11 surgical findings</p>		<p>At the direction of the Patient Safety Committee at the August 3, 2011 meeting, the monitoring plan going forward in the OR is to audit compliance with counting raney clips and other small items for 5% of cases per month for a 6-month period. In L&D and OI, 10% of cases will be audited due to a lower volume of cases. A report will be given to the Patient Safety Committee in January 2012 when the frequency of continued monitoring will be determined.</p> <p>Responsible Party: Director of Perioperative Services; Chief Nursing Officer</p> <div style="text-align: center;">  </div>	8/3/11 and ongoing

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Yoshida
8/2/11

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	<p>Continued From page 4</p> <p>including the identification and removal of the Raney clip.</p> <p>During a group interview on 4/5/11 at 10:05 AM, the neurosurgeon who had operated on Patient 1 stated he had performed craniotomies with the resection of metastatic tumors on [REDACTED]/11 and [REDACTED] 1. Raney clips were used to stop the scalp bleeding during both operations. The neurosurgeon continued that after the second surgery Patient 1 had weakness of his left lower leg so Patient 1 was discharged to a rehabilitation nursing facility (NF) on [REDACTED] 11. While at the NF Patient 1 developed a pseudomeningocele (an abnormal collection of cerebral spinal fluid [CSF] which leaked through the dura mater [the outer covering of the brain and spinal cord responsible for keeping the CSF contained]). The pseudomeningocele appeared as swelling of Patient 1's scalp over the surgical area. The neurosurgeon stated that during Patient 1's stay at the NF, the pseudomeningocele "ruptured" (began to leak CSF) and he was transferred back to the hospital. The pseudomeningocele appeared infected so another surgery was scheduled to irrigate the wound and drain any infected material. During the irrigation of the wound a Raney clip was identified in the surgical site. The surgeon stated that since he had not used any Raney clips for this irrigation and drainage procedure, the Raney clip was most likely left in the surgical site after the operation of [REDACTED] 11. The neurosurgeon stated he removed the Raney clip, the bone flap, and all of the plates and screws which had been installed during the [REDACTED] 11 operation in order to minimize the chances of a recurrent infection.</p>			



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	<p>Continued From page 5</p> <p>The neurosurgeon stated he spoke with the patient immediately after surgery to disclose the information about finding the Raney clip. The neurosurgeon said he placed multiple calls to Patient 1's son and when they finally spoke, he also informed Patient 1's son about the retained Raney clip.</p> <p>During this interview the neurosurgeon stated Patient 1 required two more operations after the third operation on [REDACTED] 11. The fourth operation was to place a shunt which moved the cerebral spinal fluid away from Patient 1's head to prevent recurrent pseudomeningoceles from developing. The fifth operation was an exploratory craniotomy to determine if another infection had developed. The neurosurgeon said the results of this operation showed only trace amounts of bacteria.</p> <p>Review of the Discharge Summary, dated [REDACTED] 11, indicated that Patient 1 complained of increasing pain after the [REDACTED] 11 surgery and was unable to participate in Physical Therapy. It was thought that the pain was due to a recurring pseudomeningocele and Patient 1 had his fourth surgery on [REDACTED] 1 for placement of a shunt to drain the cerebral spinal fluid from under his scalp to his abdominal cavity. After this surgery the pseudomeningocele problem was solved but Patient 1 still complained of significant pain. Patient 1 was returned to surgery on [REDACTED] 11 for an exploratory craniotomy in order to assess for a reaccumulation of any infected material. There was no purulent material present but cultures did show other rare organisms which</p>			



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	<p>Continued From page 6</p> <p>were treated by the Infectious Disease physicians. Patient 1 was ultimately discharged to acute rehabilitation on [REDACTED] 11.</p> <p>In an interview on 4/5/11 at 11:50 AM, the circulating nurse (RN) stated the Operating Room staff never counted Raney clips before or after neurosurgery cases.</p> <p>In an interview on 4/5/11 at 12:15 PM, the Operating Room Manager (ORM) stated Raney clips were not counted because they were so far away from the surgical area she did not think they could ever fall into the surgical site.</p> <p>In an interview on 4/5/11 at 12:20, the Neuro/Cranio Nurse Manager (NCNM) stated Raney clips were not counted because they were so peripheral that they fell to the floor or into the head collection pouch (a plastic pouch under the patient's head which collected blood, cerebral spinal fluid, bone chips, etc) when they become dislodged. The NCNM stated that when surgery is ending the surgeons and the residents just flip the Raney clips off and toss them anywhere.</p> <p>The facility provided the policy and procedure "Counts: Instruments, Sponges, Needles and Small Items," copyrighted 2009, which stated "Keeping track of the location of items used in and around the sterile field is a shared responsibility between surgeons and nursing personnel. Letting Raney clips just fall to the floor or flipping Raney clips anywhere does not keep track of the location of these small items."</p>			

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	<p>Continued From page 7</p> <p>This policy also stated "Needles, small items, and sharps will be counted manually, audibly and visually by the scrub person and the circulating RN." The policy did not specify what small items would be included and/or excluded from this counting requirement.</p> <p>The Association of periOperative Registered Nurses, or AORN, is an organization with input and liaisons including CDC (Centers for Disease Control), Association for Professionals in Infection Control and Epidemiology, American College of Surgeons, American Society of Anesthesiologists and the American Association of Ambulatory Surgery Centers. The AORN position papers, standards and recommended practices are widely used not only in the perioperative clinical setting but as an authoritative guide to clarify regulatory requirements.</p> <p>According to 2011 AORN Perioperative Standards and Recommended Practices "Retained objects are considered a preventable occurrence, and careful counting and documentation can significantly reduce, if not eliminate, these incidents."</p> <p>AORN Recommended Practices for Sponge, Sharp, and Instrument Counts, Recommendation III stated "Sharps and other miscellaneous items that are opened onto the sterile field should be accounted for during all procedures for which sharps and miscellaneous items are used."</p>			



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	<p>Continued From page 8</p> <p>This Recommendation included III.b.1. "Miscellaneous items that should be accounted for include, but are not limited to, Raney clips."</p> <p>AORN's Recommendation X stated "Policies and procedures for the prevention of RSIs (Retained Surgical Instruments) and unretrieved device fragments should be developed, reviewed periodically, revised as necessary, and readily available in the practice setting."</p> <p>This recommendation included X.a "These policies and procedures should include, but not be limited to, items to be counted..."</p> <p>The facility did not meet the AORN's acceptable Recommended Practices when it failed to require circulating RNs and a scrub person to count Raney clips and when the facility's policy and procedure "Counts: Instruments, Sponges, Needles and Small Items," copyrighted 2009, failed to identify the small items to be counted. These failures resulted in a Raney clip being left in Patient 1's head. The retained Raney clip may have contributed to Patient 1's staphylococcus aureus infection, his left lower leg weakness, his recurring pseudomeningocele due to leaks through the dura in the operative area, and his increased pain levels.</p> <p>The facility's failure to prevent the retention of a foreign body (Raney clip) 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).</p>			

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