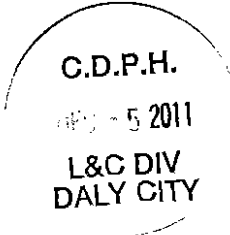


CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY  
DEPARTMENT OF PUBLIC HEALTH

| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION          | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:<br><br>050457  | (X2) MULTIPLE CONSTRUCTION<br>A BUILDING _____<br>B WING _____  | (X3) DATE SURVEY COMPLETED<br><br>03/03/2011  |                    |
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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:<br/>CA00259468 - Substantiated</p> <p>Representing the Department of Public Health:<br/>Surveyor ID # 25732, 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</p> <p>70223(b)(2) Surgical Service General Requirements</p> <p>(b) A committee of the medical staff shall be assigned responsibility for:</p> <p>(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> |   |                             |                    |

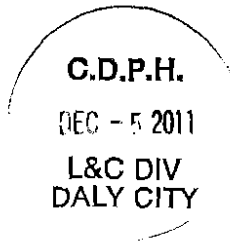
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LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE *Heather O'Hara RN MSN* TITLE Accreditation + Regulatory Manager (X6) DATE 12/1/11

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12/27/11 Accepted POC Jordan acting HFE

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|  | <p><b>Continued From page 1</b></p> <p>This regulation was not met as evidenced by:</p> <p>Based on interview and record review the hospital failed to implement their instrument count policy and procedure when during surgery on [REDACTED] 09, a stiffener stylet (a guide wire) from a Power Port Brand Groshong catheter ( a medication delivery device placed inside a large vein in the body) was placed in Patient A in the OR (operating room). The stiffener stylet was retained and was not accounted for during the final instrument count. The retention of this stiffener stylet required Patient A to under go a second invasive procedure on [REDACTED] 11 to remove the retained stiffener stylet and replace it with a new catheter.</p> <p>Findings:</p> <p>Record review of an Operative Report dated [REDACTED] /09, indicated Patient A was taken to surgery and had a Power Port Brand Groshong catheter placed in her left superior vena cava (large diameter vein in the chest that carries blood to the heart) by Surgeon 1.</p> <p>Review of Patient A's Intraoperative Documentation Note dated [REDACTED] /09, indicated: "Count type: Final count, [X] Sponges [X] Sharps, [ ] Instruments, Count Correct: Yes" The box for indicating that all instruments were accounted was blank.</p> <p>Record review of Patient A's Interventional Radiology Report by Radiologist 1, dated [REDACTED] 11 indicated: "Contrast injection under fluoroscopy ( a kind of x-ray study) to check integrity and function</p> |  | <div style="text-align: center;">  </div> <p><b>St. Mary's Medical Center requests an informal conference with the District Administrator to discuss the merits of the deficiency.</b></p> <p><b>We respectfully disagree with the factual content of statements in the CA00259080 findings document. We request an informal conference with the District Administrator to discuss, clarify, and possibly amend the document to more accurately reflect the facts of our investigation.</b></p> <p><b>T22 §70223 Surgical Services</b><br/>The regulation was not met as evidenced by: Based on interview and record review, the hospital failed to implement their instrument count policy and procedure when during surgery a stiffener stylet from a power port Groshong catheter was placed in the OR. The stiffener stylet was retained and was not accounted for during the final instrument count. The retention of this stiffener stylet required the patient to undergo a second invasive procedure to remove the retained stiffener stylet and replace it with a new catheter.</p> |

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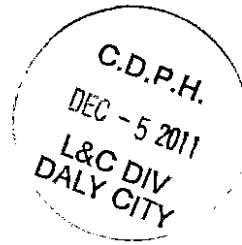
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|  | <p><b>Continued From page 2</b></p> <p>of an indwelling Power Point central venous access system...Difficulty in withdrawing blood and infusing through the indwelling port. Liquid leaking from the skin site after chemotherapy infusion...The tip of the catheter appeared abnormally deviated and a radiopaque linear structure appeared to extend outside the tip of the catheter....this has the appearance of a retained wire fragment...the patient's port is not to be utilized further and the plan is to replace this port and catheter with a new port access system. Impression....Linear structure retained within the catheter and extending out the tip of the catheter which appears to be a retained wire fragment."</p> <p>In an interview on 3/2/11 at 10:20 A.M., Radiologist 1 was asked how he had discovered the retained foreign object in Patient A. Radiologist 1 said, "I was asked by Patient A's chemotherapy physician to check under x-ray why Patient A's Groshong catheter was not working properly. When I injected contrast dye (fluid that shows up on x-ray) under fluoroscopy I noticed there was a needle guide wire sticking outside of the side slit of the catheter. That wire is not supposed to be there. The surgeon takes that wire out after he inserts the catheter in the vein. That guide wire has to come out. Then a new catheter will be put in."</p> <p>In an interview on, 3/2/11 at 1 P.M., Surgeon 1 was asked when he placed the Groshong catheter in Patient A on [REDACTED]/09 did he remember pulling the guide wire out of the catheter. Surgeon 1 said, "After reviewing my Operative Note on Patient A, this does not follow my routine. I can't remember if</p> |  | <p><u>What/How the correction will be accomplished, both temporarily and permanently.</u></p> <ol style="list-style-type: none"> <li>Product change even if minimal requires orientation by vendor. In-service education for surgeons and front line staff on any new or modified product. Representative needs to outline change, differences in product. 3/2/11 &amp; ongoing</li> <li>The Sponge, Instrument, and Needle Count policy (OR 6-D) was clear and available to staff. The policy is consistent with AORN and CHW standards. 8/2010</li> <li>Staff education regarding required elements of Sponge, Instrument, and Needle Count Policy, (OR 6-D). 8/2010 &amp; ongoing</li> <li>Instrument counts will be taken and recorded by nursing personnel at the following times: <ul style="list-style-type: none"> <li>Before incision is made</li> <li>Upon closure of any cavity.</li> <li>Upon closure of the skin</li> </ul> 8/2010 &amp; ongoing</li> <li>Staff education addresses high risk and problem prone procedures 3/2/11 &amp; ongoing</li> <li>Manufacturer notified that internal stylet in <u>Port a Catheter</u> not indicated on package product components. 2/16/11</li> </ol> |   |



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|  | <p><b>Continued From page 3</b></p> <p>I pulled the wire out or just cut across it?"</p> <p>In an interview on, 3/2/11 at 1:15 P.M. the Circulating Nurse (RN 1) and Scrub Technician (ST 1) who were present during Patient A's original surgery were asked if they routinely "count" (method were surgical instruments are accounted for so they do not remain in the body as a foreign object during and after surgery) the guide wire used in this case. Circulating Nurse-1 (Circulating Nurse is a registered nurse who makes preparations for an operation and continually monitors the patient and staff during its course, who works in the operating room outside the sterile field in which the operation takes place, and who records the progress of the operation, accounts for the instruments, and handles specimens) said, "I get that wire when the surgeon pulls it out of the catheter and I put it in a bag. We don't count it like we do needles, sponges and knife blades." The Scrub Technician (Scrub Technician is an unlicensed assistive personnel who work under the supervision of a surgeon or a registered nurse and handle supplies and equipment necessary during the surgical procedure) said, "No we don't count those guide wires that come in the package."</p> <p>Review of the hospital's 11/4/10 Policy and Procedure titled: Sponge, Instrument Count and Needle Count No. ORD 6-D pg. 1 and pg. 5 indicated: " The Operating Room Staff will adhere to the standardized systematic method of accounting (i.e. "counting") for sponges, needles and specific</p> |   | <p><u>Description of the monitoring process to prevent recurrence of the deficiency.</u></p> <ol style="list-style-type: none"> <li>1. Surgical Services Product Evaluation Committee meets monthly to evaluate new and revised products for efficiency and safety including manufacturer's changes to existing products. <span style="float: right;">Sept 2011 &amp; ongoing monthly</span></li> <li>2. Discrepancies in count require: <ul style="list-style-type: none"> <li>• A thorough examination of the wound. <span style="float: right;">3/2/11 &amp; ongoing</span></li> <li>• X-ray if item not located</li> <li>• Report to surgical services director</li> </ul> </li> <li>3. Event reports for retained foreign body incidents are communicated to and trended by the Patient Safety Officer. <span style="float: right;">3/2/11 &amp; ongoing</span></li> </ol> <p><u>Responsible Parties:</u><br/>Director Peri-operative Services<br/>Manager Surgery<br/>Patient Safety Officer</p>  |  |

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|                    | <p><b>Continued From page 4</b></p> <p>small items used during a surgical procedure and for documenting accountability for said count..Instruments: Instruments should be counted on all procedures in which the likelihood exists that an instrument could be retained."</p> <p>Review of a Post Procedure Interventional Radiology Note dated [REDACTED]/11 indicated: "Past Surgical History...Patient with history of breast cancer, undergoing chemotherapy, found to have a leaking central venous access port (Power Port) and retained guidewire...Planned Procedure: Replacement of Power Port due to leaking port with retained wire...Post Procedure Radiologic Findings: Retained stylet fragment found in the previous catheter."</p> <p>During an interview with the Risk Manager on 10/6/11 at 10:30 AM, she stated that a picture dated [REDACTED]/11 of the stiffener stylet that was recovered showed it was less than or equal to 60 centimeters.</p> <p>According to AORN (Association of periOperative Registered Nurses) Perioperative Standards and Recommended 2011 Edition, pages 263-270, Recommended Practices for Prevention of Retained Surgical Items: Recommendation III, "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... III.b.1. Miscellaneous items that should be accounted for include but are not limited</p> |               |                              |                    |

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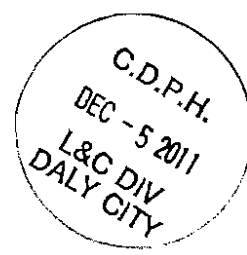
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|  | <p><b>Continued From page 5</b></p> <p>to...vascular inserts, vessel clip bars and vessel loops. III.c. Sharps and miscellaneous items should be counted audibly and viewed concurrently by two individuals, one of whom should be an RN circulator."</p> <p>The facility's failure to implement their instrument count policy resulted in the retention of this stiffener stylet that required Patient A to under go a second invasive procedure to remove the retained stiffener stylet and replace it with a new catheter. This is a deficiency that has caused, or is likely to cause, serious injury or death to Patient A, and therefore constitutes an immediate jeopardy within the meaning of Health and Safety Code, Section 1280.1</p> <p>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).</p> |  |  |  |
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