**E 000**

**Initial Comments**

The following reflects the findings of the Department of Public Health during a Complaint visit.

**Complaint Intake Number:**

CA00228605 - Substantiated

Inspection was limited to the specific complaint investigation and does not represent the findings of a full inspection of the facility.

Representing the Department of Public Health:

[Redacted]

RN, HFEN

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.

**T22 DIVS CH1 PART3-70223 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.

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T22 DIVS CH1 ART3-70213(a) Nursing Service Policies and Procedures.

(a) Written policies and procedures for patient

**How the correction will be accomplished, both temporarily and permanently**

4/9/10
The retention of the sponge was reported to us on April 5, 2010. A staff meeting was held with all Surgery Department staff on April 9, 2010 reorienting them to the "Counting Sponges, Sharps and Instruments" policy which states that documentation of all counts on intra-operative nursing records must be initialed by both the scrub person and the circulating nurse.

The surgeon stated on April 9, 2010 that he no longer will place Raytec sponges into incisions to help with pain relief.

The title and position of the person responsible for the correction.

The Surgery Department Manager is responsible for the correction.

Description of the monitoring process to prevent recurrence of this deficiency.

The Surgery Department Manager or designee audits intra-operative records to assure that counts of sponges, sharps and instruments are signed by both the scrub person and the circulating nurse.
Extracted Text:

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<tr>
<td>Record under the section Nursing Error II: Potential for Injury, dated 12:30 p.m., indicated the initial and final sponge counts had been conducted and were correct, however it appeared the counts were completed by one person as evidenced by the style of the script.</td>
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In a letter from the facility sent to the Department dated April 29, 2010, additional information was provided to the Department regarding the report of retention of a foreign object. The letter indicated ACL reconstruction surgery was performed on Patient 1 on April 29, 2010 and the patient returned to the surgeon’s office with concerns of a lump in the knee area on May 12, 2010 (over two months later). A review of the X-ray report dated May 12, 2010, indicated Patient 1 had a retained foreign object (Raytec sponge) in the right knee. The letter further indicated the surgeon subsequently reported that the patient underwent removal of the sponge at a different facility within one week of identifying the retained sponge.

A review of the face sheet from the second general acute care hospital indicated Patient 1 was admitted on May 14, 2010 with diagnoses which included leg pain status post ACL. The face sheet also indicated in the comments section, removal foreign body (sponge), right knee. The Operative Report dated May 14, 2010, from the second general acute care hospital, disclosed Patient 1 had removal of foreign body, irrigation and debridement of right knee. The pre-operative diagnosis was a right knee retained foreign body status post ACL reconstruction. The operative report indicated the old skin incision was opened 3 cm in length which allowed visualization of a Raytec sponge. The sponge...
was removed using tonsil forceps.

During an interview with Employee A (the surgery department manager) on June 3, 2010 at 2:35 p.m., when asked if the Intraoperative Record under the section Nursing Focus II: Potential for Injury, first and final sponge counts were signed/initialed by the same person, she stated yes. Employee A stated the licensed nurse (circulating nurse) signed/initialed the first and final sponge count for herself and the scrub tech. Employee A further stated the count should not have been counted as correct.

A review of the facility’s policy and procedure titled “Counting Sponges, Sharps and Instruments” dated October 2003, indicated count sheets shall be signed and dated by the circulator and scrub person. Employee A stated this policy was in effect during Patient 1’s procedure.

During an interview with Employee A on December 15, 2010 at 10:50 a.m., she stated the sponge count on the Intraoperative Record should be signed/initialed by each individual, the circulating nurse and the scrub tech as indicated by the policy and procedure.

A request was made to observe a Raytec sponge used for Patient 1’s procedure. Employee A revealed a pack of ten of the same type of sponges used in Patient 1’s procedure and each sponge was 10.18 cm x 10.18 cm. When Employee A was asked how the surgeon managed to insert the 10.18 cm sponge into a 3 cm incision, she stated the sponge was saturated with anesthetic and stuffed into the incision.

During a phone interview with the surgeon (Employee B) on December 16, 2010 at 11:30
Continued From page 4

a.m., he stated the sponge was bathed in anesthetic, placed along the edge of the skin and put inside the incision to help with pain relief.

During an interview with the scrub tech (Employee C) on December 17, 2010 at 1:40 p.m., he stated the signatures/initials on the sponge count for Patient 1's surgical procedure dated 12/16/2010, was not initialed by him. Employee C further stated he had never signed the count sheet before, as this was done by the circulating nurse. When Employee C was asked how the surgeon managed to insert the 10.18 cm Raytec sponge into the 3 cm incision, he stated the surgeon "crammed the sponge" into the incision after it was saturated with the anesthetic.

A review of the facility's policy and procedure titled Counting Sponges, Sharps and Instruments dated October 2003 indicated Raytec sponges were not to be utilized as packing or dressing.

The facility's failure to implement its policy and procedure to prevent retention of the Raytec sponge used during a surgical procedure was a deficiency that caused, or was 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.