The following reflects the findings of the California Department of Public Health during the investigation of a complaint/self-reported event.

Complaint Number: CA00197618

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

Representing the Department of Public Health:

Galen Gattis, RN/HFEN

Health & 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.

Title 22 - 70713 - Use of outside resources:
If a hospital does not employ a qualified professional person to render a specific service to be provided by the hospital, there shall be arrangements for such a service through a written agreement with an outside resource which meets the standards and requirements of these regulations. The responsibilities, functions, objectives and terms of agreement including financial arrangements and charges and of each such outside resource, shall be delineated in writing and signed by an authorized representative of the hospital and the person or the agency providing the service. The agreement shall specify that the hospital retains professional


LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

Catherine Fay Admin Dir

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**LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE**

Catherine Fay

**TITLE**

Admin Dir

**DATE**

2/23/09

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**STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION**

<table>
<thead>
<tr>
<th>(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:</th>
<th>(X2) MULTIPLE CONSTRUCTION</th>
<th>(X3) DATE SURVEY COMPLETED</th>
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</thead>
<tbody>
<tr>
<td>050424</td>
<td></td>
<td>10/15/2009</td>
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</table>

**NAME OF PROVIDER OR SUPPLIER**

SCRIPPS GREEN HOSPITAL

**STREET ADDRESS, CITY, STATE, ZIP CODE**

10665 NORTH TORREY PINES ROAD, LA JOLLA, CA 92037 SAN DIEGO COUNTY

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### Summary Statement of Deficiencies

<table>
<thead>
<tr>
<th>(K4) ID</th>
<th>PREFIX</th>
<th>TAG</th>
<th>PROVIDER'S PLAN OF CORRECTION</th>
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<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Process</td>
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<td>Sterilization of equipment effective immediately</td>
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<td>Review of scheduled OR cases for the next 48 hours and continuing on a rolling 48 hour schedule.</td>
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<td>- Surgical instrumentation of each case will be opened and inspected.</td>
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<td>- Removable components will be disassembled and instruments will go through the complete cleaning and sterilization process.</td>
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<td>Responsible Person</td>
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<td></td>
<td>Admin Director, Surgical Services</td>
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<tr>
<td></td>
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<td>Surgical instrumentation, frequently used for emergency procedures, including add-on orthopedic procedures, will be identified.</td>
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<tr>
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<td>- Surgical instrumentation will be opened and inspected.</td>
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<td>- Removable components will be disassembled and instruments will go through the complete cleaning and sterilization process.</td>
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<td>- Surgical technicians will inspect instrumentation prior to using in the operative field.</td>
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<td>Responsible Person</td>
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<td></td>
<td>Director, SPD/Supply Chain</td>
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<td>Infection control consultation regarding the effectiveness of the sterilization.</td>
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<td>- Notify patients and their physicians of the event</td>
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<td>- Offer blood borne pathogen blood testing to patients</td>
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<td>- Arrange to pay for the blood borne testing by non-Scripps Health laboratory services.</td>
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<td>Responsible Person</td>
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<td>Manager, Epidemiology</td>
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### Findings:

The facility failed to ensure that staff were aware that a specialized surgical instrument, required disassembly before cleaning, processing and prior to use of the instrument. An outside contractor was responsible for training staff regarding use and cleaning of the specialized instrument and was on site at the time the debris was discovered on the specialized instrument. Between 8/11/08 and 7/31/09, twelve (12) patients underwent a surgical procedure where the specialized instrument was either used, or was in the instrument tray set. As a result of the facility's failure to ensure that staff had knowledge that the instrument required disassembly, prior to processing, 11 of the 12 patients were potentially exposed to blood borne pathogens.

On 8/6/09 at 10:15 A.M., the Department was informed that, "What appeared to be red colored-debris/old blood was discovered on a self-retaining screwdriver," that was used during hip/fracture surgery on 7/31/09. Per the Administrative Director, the sheath of the specialized instrument, separated from the

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### Event ID: MLOU11
2/2/2010 9:19:13 AM

**LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE**

Catherine Fay [Signature]

**TITLE**
Admin Dir
Quality/Pl

**DATE**
2/23/09

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**Continued From page 2**

shaft of the instrument while the surgeon was manipulating the instrument and at that point, the, "Surgeon noticed the red colored debris/old blood" on the shaft of the instrument. Per the Administrative Director, OR staff members (surgeon, registered nurses, surgery technicians) and Sterile Processing Department (SPD) staff members all stated they were unaware that the specialized instrument separated into two parts. Per the Administrative Director, a Manufacturer's Representative (MR) was always present in the operating room [OR] whenever the tray with the specialized instrument was used. The MR was present during the 7/31/09 surgical procedure.

On 8/6/09 at 10:40 A.M., the Director of the Sterile Processing Department [SPD] stated the sterile processing staff wash and dry the instruments, and the manufacturer's representative comes in and, "puts the kit together." The SPD Director stated that the sterile processing staff, "Were not aware the sheath came off the screwdriver." The SPD Director stated the manufacturer's representative had not provided a manual or binder related to the instrument tray, and had not provided any in-service education to SPD staff within the past 12 months related to the specialized instrument tray used to repair a traumatic hip/femur fracture.

On 8/10/09 at 9:10 A.M., the OR Manager stated, "No one in OR knew that this specialized instrument came apart until the

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Continued From page 3

incident on 7/31/09, there was no in-service training by the manufacturer's representative until now."

On 8/10/09 at 9:20 A.M., the Manufacturer's Representative (MR 1) who was present when the incident occurred on 7/31/09 stated, "The screwdriver was coated in a black-colored, gel-like material that appeared to be blood, not fresh blood." MR 1 stated, he knew the instrument came apart, but he was not aware that the OR and SPD technicians did not know this specialized instrument came apart. MR 1 stated it was the responsibility of the MR to provide in-service training to OR and SPD staff with regard to proper use and cleaning of instruments supplied by the vendor. MR 1 stated he had not provided the facility with any written procedure manual regarding cleaning the instruments in the specialized tray. MR 1 stated that the instrument should be taken apart in the OR, decontaminated, and sent to SPD for processing. MR 1 stated the instruments should not be reassembled after cleaning, they need to be apart when autoclaved, and then reassembled under sterile conditions when the tray is opened in OR.

Manufacturer's Representative 2 [MR 2] stated, during a phone interview on 8/10/09 at 4:10 P.M., he "Typically gives an in-service presentation one week before or after an instrument tray is brought in." MR 2 stated, "I can't recall the date I gave an in-service to..."
CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY  
DEPARTMENT OF PUBLIC HEALTH  

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION  

(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  
050424  

(X2) MULTIPLE CONSTRUCTION  

A. BUILDING  
B. WING  

(X3) DATE SURVEY COMPLETED  
10/15/2009  

NAME OF PROVIDER OR SUPPLIER: SCRIPPS GREEN HOSPITAL  
STREET ADDRESS, CITY, STATE, ZIP CODE: 10666 NORTH TORREY PINES ROAD, LA JOLLA, CA 92037 SAN DIEGO COUNTY  

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<th>PREFIX</th>
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<th>PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)</th>
<th>(X5) COMPLETE DATE</th>
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Continued from page 4  

facility staff, but I'm sure it took place. I may or may not have demonstrated removal of the sheath on the specialized instrument. I may not have trained every single one on them in SPD. MR 2 stated the instrument sheath is typically separated from the screwdriver and is reassembled when the tray is opened in OR. MR 2 stated it was, "not typical to give OR or SPD a manual (related to a specialized instrument tray); the facility has been asking for these."

MR 1 and MR 2 were unable to provide any documentation or evidence that any in-service training was provided to facility OR and SPD staff related to cleaning and processing of the specialized instrument tray prior to the incident on 7/31/09.

On 8/10/09, the facility provided a listing identifying 12 patients who had surgery that required use of the specialized tool. The listing was reviewed with the Infection Control Nurse (ICN). The ICN stated, on 8/10/09 at 10:10 A.M., that no post-operative infections were identified related to any hip/femur fracture repairs during the previous 12 months. The ICN stated the facility notified 7 of 12 identified patients (the tray was new when used on the first patient, 3 patients had expired, and 1 patient did not have a procedure that required use of the specialized tool) of the risk potential and offered, at no charge, blood borne pathogen testing [HIV, Hepatitis B & C] and follow-up for 1 year.

Event ID: MLOU11  
2/2/2010  
9:19:13AM  

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE  
Catherine Fay  
Quality/PI  
2/23/99  

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### SUMMARY STATEMENT OF DEFICIENCIES

**Continued From page 5**

Review of facility documentation related to OR and SPD staff hire and in-service education dates reflected that 26 of 106 (24.5%) OR staff members were hired after 8/1/08, and 7 of 21 (33%) SPD staff members were hired after 8/1/08. Review of in-service education presentations for OR staff reflected 28 in-services between 8/1/08 through 7/31/09. For SPD, the facility conducted 22 in-service presentations between 8/1/08 through 7/31/09. None of the presentations given to OR and SPD staff were related to the specialized instruments used during a traumatic hip/femur fracture repair.

The facility's failure to ensure that staff had received appropriate training from an outside contracted resource regarding the disassembly and processing of a specialized surgical instrument 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 the Health and Safety Code section 1280.1 (c).

1 of 6

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**Event ID:** ML0U11

**Laboratory Director's or Provider/Supplier Representative's Signature:**

Catherine Fay

**Title:** Admin Dir Quality/PI

**Date:** 2/23/09

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