CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY
DEPARTMENT OF PUBLIC HEALTH

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	050324	A. BUILDING _____ B. WING _____	05/14/2010

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
SCRIPPS MEMORIAL HOSPITAL - LA JOLLA	9888 GENESEE AVENUE, LA JOLLA, CA 92037 SAN DIEGO COUNTY

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	The following reflects the findings of the Department of Public Health during a complaint/adverse investigation visit: Complaint Intake Number: CA00224687 - Substantiated Representing the Department of Public Health: [redacted], 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. Entity Reported Incident Number: CA00224687 Category: Retention of a foreign object in a patient. The investigation was limited to the specific incident reported and does not represent the findings of a full inspection of the facility. Representing the California Department of Public Health: Marilyn Hutcheson, HFEN. Health and Safety Code Section 1279. 1 (c), "The facility shall inform the patient or the party responsible for the patient of the adverse event by the time the report is made."		RECEIVED CA DEPT OF PUBLIC HEALTH APR 5 1 [illegible] LICENSING & CERTIFICATION SAN DIEGO NORTH DISTRICT OFFICE Background regarding incident: The following circumstances contributed to the retained foreign body: • Surgeon was urgently called to the patient's ICU bedside while intensivist was pumping blood into the patient • Patient's exsanguination • Urgent transfer of the patient to the OR • Simultaneous draping, prepping and intubation of patient • Large volume of lap sponges and towels utilized to pack abdomen and remove blood clots	

Event ID:GYGH11 8/4/2010 9:01:10AM

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE	TITLE	(X6) DATE
[signature]	[signature]	[signature]

Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. Except for nursing homes, the findings above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

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	Continued From page 1 The CDPH verified that the facility informed the patient or the party responsible for the patient of the adverse event by the time the report was made. Health and Safety Code 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 70223 (b) (2) (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. Based on interview and record review, the facility failed to ensure that Operating Room staff implemented the policy and procedure with regard to the use of blue towels for 1 sampled patient, (Patient A) during surgery. The Operating Room staff also failed to implement the policy and complete a count of towels used during Patient A's surgery. As a result, a blue towel was left undetected in Patient A's abdominal cavity for a period of four months, during which time, Patient A was hospitalized three times for treatment related to non-healing post surgery. Patient A subsequently required a second surgery on 4/7/10,		**a. How the correction will be accomplished, both temporarily and permanently.** The policy and procedure: *Counts: Sponge, Needle, Instrument, and Small Items* will be followed by Operating Room staff. The OR Staff was educated immediately regarding the following items in the above policy: • The emergent nature of a procedure or an unexpected change in the condition of the patient may necessitate omission of counts to preserve patient life or limb. In such cases, a count may be omitted on order of the surgeon; however an x-ray must be taken at the end of the case and read by the radiologist to document the absence of retained foreign bodies before the patient leaves the room. • A postoperative radiologic exam will be performed before the patient leaves the room in the following circumstances: ○ A case lasting more than 10 hours ○ When more than two body cavities are entered	

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	Continued From page 2 at which time, the surgeon discovered and removed the blue towel from Patient A's abdomen. Findings: Patient A, an 80-year-old-male, was admitted from a skilled nursing facility on 12/14/09, per the Emergency Record. According to the notes, the Emergency Department (ED) physician assessed the patient and admitted him for a gastroenterology (digestive system) consultation. The ED physician diagnosed the patient with an acute gastrointestinal bleed and hypovolemic (low blood volume) shock. On 12/18/09, Patient A went emergently to the operating room (OR) for an exploratory laparotomy (abdominal surgery) after, "Partially exsanguinating (bleeding out) from uncontrollable bleeding in the intensive care unit." The patient went to surgery with, "a known high-risk of death and complications, and the option of continued non-operative management", per the Operative Report. Patient A had an inflammatory mass which was actively bleeding and had eroded (worn through) into the gastroduodenal artery (a small abdominal artery) and into the peritoneum (abdominal cavity), per the Operative Report. Patient A required a partial gastrectomy (stomach removal); a Roux-en-Y gastrojejunostomy (surgical connection between stomach and part of small intestine, i.e. jejunum) and duodenectomy (a removal of the first part of the small intestine and the formation of a new connection between the middle of the small		○ When three or more permanent scrub reliefs occur ○ When eight or more units of blood or blood products are given (except open heart cases) ○ When a full baseline count was not competed • Only towels with radiopaque markers should be used in the wound. If towels are used in the open wound, they should be included in the count as a miscellaneous item, and should be easily distinguished from other towels. • An additional process change was implemented and the OR staff was educated immediately: ○ Non-radiopque items will not be placed onto the sterile field after a cavity is opened <u>Other Opportunities have been identified and are in the process of implementation</u>: • Larger laparatomy sponges	

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	Continued From page 3 intestine and the remaining portion of the stomach); and a Roux-en-Y choledochojejunosotomy (to reroute the flow of bile). Following the procedures, the surgeon irrigated the abdomen and subcutaneous tissue (the layer directly under the skin) with normal saline and closed the skin. Patient A transferred to the ICU in critical condition. According to the Intraoperative Report, Patient A's surgery began at 9:54 A.M. and concluded at 1:02 P.M. The record reflects that Scrub Technician (ST) 1 and Circulating Nurse (CN) 1 conducted the initial count of sponges, Sharps (needles etc), small items and instruments. ST 2 and CN 2 conducted the two final counts, per the documentation. Patient A underwent numerous radiologic examinations after the surgery to include a biliary scan on 12/24/09 and an MRI (magnetic resonance imaging) of the abdomen and a CT (computerized aided tomography) scan of the abdomen on 12/28/09. Patient A transferred to a skilled nursing facility on 12/30/09. Physician A documented in the Transfer Summary, that Patient A had a significant amount of drainage and the biliary stent (a device placed in the bile duct to keep it open) had migrated into the small intestine. On 1/1/10, Patient A returned to the facility and was admitted for treatment. The patient had peritonitis (inflammation of the tissue that lines the abdominal cavity) secondary to a bile leak and underwent a bile duct drain placement, per the Discharge Summary dated 1/16/10.		• Evaluation of paper drapes as opposed to the use of towels for draping • Evaluation of additional circumstances in which an x-ray needs to be ordered **b. The title or position of the person responsible for the correction.** Administrative Director, Surgical Services **c. A description of the monitoring process to prevent recurrence of deficiency.** Manager of the OR Service Lines will review the practice of counting by OR staff in the operating rooms on a daily basis. Any deviation from the above policy will be brought to the attention of the Administrative Director, Surgical Services for immediate action. These issues will be discussed with the OR Medical Director, OR Leadership and Risk Management in the weekly OR Safety meetings to identify process improvements.	

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	Continued From page 4 On 3/5/10, Patient A's physician referred him to another facility (Facility B) for further tests due to the patient's persistent bile leak. During the hospitalization at Facility B, Patient A had CT scans and an abdominal abscess drained. On 4/1/10, Patient A returned to the ED at the facility, "obviously jaundiced", per the ED report. A CT scan showed the patient had, "what appeared to be an abscess in the abdomen where his drains are." On 4/7/10, Patient A returned to surgery, per the Operative Report. The surgeon documented in the report that the patient developed a bile leak after the surgery performed on 12/18/09. The investigations included, "multiple and extensive CT scans, drains, and treatment with antibiotics." The patient had a persistent bile leak and right upper quadrant abscess and the surgeon elected to perform a second exploratory surgery. According to the Operative Report dated, 4/7/10, Patient A had, "an obvious mass in the infrahepatic (under the liver) area in the right upper quadrant....." The surgeon dissected the bile duct anastomosis (the surgical connection of two body parts), performed on 12/18/09, and, "found a retained sponge at the base of the anastomosis.....". Further surgical procedures performed during the surgery were right upper quadrant debridement, small bowel resection, right hemicolectomy (removal of part of the colon), and a revision of the original choledochojejunostomy.		**d. The date the immediate correction of the deficiency will be accomplished. Normally this will be no more than thirty days (30) from the date of the exit conference.** Education began with staff on April 8, 2010 and is continuing.	Completion Date . April 8, 2010 – On-going

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	Continued From page 5 Physician 1 (the surgeon who performed both surgeries), spoke about Patient A on 4/16/10 at 8:25 A.M. The surgeon stated that on 12/18/09, Patient A was in the ICU, "essentially bleeding to death." Physician 1 stated that the patient received several units of blood at full pressure. The physician took the patient to surgery as an emergency measure. Physician 1 said that when he opened the patient's abdomen there was so much blood that he was, "trying to scoop it out with my hands." The physician stated that in order to locate the source of the bleeding he said to the Scrub Technician (ST 2), "Get me towels." Physician 1 added, "I packed the abdomen full of towels to try to compress the bleeding." Physician 1 said that it took several towels to staunch the flow and added, "Had there been a sterile mop there, I would have used it." According to Physician 1, Patient A had extensive and prolonged surgery. At the conclusion of the surgery, the physician flushed the abdomen and looked for retained foreign objects but did not see any. Physician 1 said that over the course of the next four months, Patient A had extensive tests and treatments to try to determine why the patient was not healing as well as expected. Several CT scans failed to show the retained surgical towel. Physician 1 said that he was reluctant to take the patient back to surgery because of the risks to the patient, but on 4/7/10 decided that a second surgery was required. Physician 1 said that when he found the towel in the patient's abdomen, "The team was devastated."			

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	Continued From page 6 The physician said that all he could say about the first surgery was that, "The patient was dying, it was an, uncontrolled environment", and "we used what was available to save a life." ST 2 said during an interview on 4/16/10 at 9:30 A.M., that as soon as the surgeon opened the patient during the first surgery on 12/18/09, the tone in the room changed. "It was urgent." ST 2 said, "I handed the surgeon a blue towel and said, 'Blue towel in' ", for the Circulating Nurse (CN 1) to record it on the white board for counting later. According to ST 2, blue towels are used in the operating room (OR) for draping the patients and lining the back table on which instruments are placed for use during the surgery. Blue towels are made from a lightweight absorbent cloth and measure 15 x 24 inches. ST 2 said that blue towels were not supposed to be used inside a patient, but said that the surgeon had to stop the bleeding and there were no green towels (radiopaque towels that can be seen with x-ray) immediately available. ST 2 said that although he is certain that he called out, "Blue towel in" for CN 1, she may not have heard because of the activity going on around the patient at the time. ST 2 failed to confirm with CN 1 that she had added the use of a towel to the count board during the surgery. At the conclusion of the surgery, ST 2 counted with CN 2 and documented that the count was correct. ST 2 acknowledged giving Physician 1 at least one towel to use in the patient's abdomen during the surgery, but failed to include the towel(s) in the final count. On 4/16/10 at 10:00 A.M., CN 1 talked about			

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	Continued From page 7 Patient A's surgery. CN 1 said that in 30 years of OR nursing, she had never seen blue towels used in a patient, so they were not routinely counted prior to the start of the procedure. If a surgeon used a green towel during a surgical procedure, the Scrub Tech called out, "Towel in" and the Circulating Nurse repeated what was said and recorded it on the board to be included in the final count at the end of the procedure. CN 1 said that she did not recall ST 2 calling out, "Blue towel in," so she did not record any towels on the white board for the count. CN 1 said that she could not remember if the surgical team used any radiopaque towels during the surgery. CN 1 said that another circulating nurse (CN 2) relieved her during the surgery and CN 2 did the final count at the end of the procedure. During an interview with CN 2 on 5/14/10 at 11:00 A.M., CN 2 stated that she took over from CN 1 during the surgery and was responsible for the final count at the end. CN 2 confirmed that no towels were listed on the count board as being used during the surgery. CN 2 said that blue towels should never be used inside the patient. CN 2 said that had the Scrub Technician called out, "Towel in," the Circulating Nurse should have repeated that information back to the Scrub Technician and marked it on the board for the final count. CN 2 said that accurate and complete communication between the Scrub Technician and the Circulating Nurse was vital to prevent items being left inside a patient at the conclusion of a surgery. CN 2 said, "This should never have happened."			

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	Continued From page 8 The facility's policy and procedure entitled, "Counts: Sponge, Needle, Instrument, And Small Items," effective date January 2009, addressed the procedure for the use of towels during surgery. Under the section, Procedures, 1.7, "Only towels with radiopaque markers should be used in the wound. If towels are used in the open wound, they should be included in the count as a miscellaneous item, and should be easily distinguished from other towels." Patient A had emergency surgery at the facility on 12/18/09 to repair a ruptured abscess that resulted in a massive loss of blood. During the surgical procedure, Physician 1 said that he used, "several towels" in an effort to stop the flow of blood. OR staff did not record the use of any towels on the count board. ST 2 said that he remembered handing Physician 1 a blue towel but did not recall if the surgeon used any more towels. ST 2 also said that he called out, "Towel in" for CN 1, but failed to ensure that CN 1 heard and recorded the use of the towel on the count board. As a result, when CN 2 and ST 2 completed the final count, both said that towels were not included in the count as required in the facility policy. Following the initial surgery, Patient A experienced delayed healing with persistent bile drainage and infection. Patient A required three subsequent admissions to hospital for treatment related to the first surgical procedure. Several X-rays and CT scans failed to identify the retained blue towel in the patient's abdomen because it was not radiopaque. Finally, Patient A returned to surgery			

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	Continued From page 9 on 4/7/10, and underwent a second surgical procedure during which time, Physician 1 discovered the retained blue towel. The facility's failure to ensure that OR staff followed the policy and procedure, firstly by using a non radiopaque towel inside Patient A's abdominal cavity, and secondly by not recording the use of the towel(s) during the surgery on the count board, 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). 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).			

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