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
	050082	A. BUILDING _____ B. WING _____	08/09/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
ST JOHNS REGIONAL MEDICAL CENTER	1600 N Rose Ave, Oxnard, CA 93030-3722 VENTURA COUNTY

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	The following reflects the findings of the Department of Public Health during an inspection visit: Complaint Intake Number: CA00450055 - Substantiated Representing the Department of Public Health: Surveyor ID # 1896, 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 1280.3(g): 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. Health and Safety Code Section 1279.1 (a): A health facility licensed pursuant to subdivision (a), (b), or (f) of Section 1250 shall report an adverse event to the department no later than five days after the adverse event has been detected, or, if that event is an ongoing urgent or emergent threat to the welfare, health, or safety of patients, personnel, or visitors, not later than 24 hours after the adverse event has been detected. Disclosure of individually identifiable patient information shall be consistent with applicable law. Health and Safety Code Section 1279.1 (b) (1) (D) For purposes of this section, "adverse event"			

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE TITLE President/CEO (X6) DATE 8/30/18

By signing this document, I am acknowledging receipt of the entire citation packet, Page(s) 1 thru 9

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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	to surgery that are intentionally retained. Health and Safety Code Section 1280.3 (g): 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. This RULE: is not met as evidenced by: Title 22, California Code of Regulations, Division 5, Chapter 1, Article 3, Section 70223 (b)(2), 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. This RULE: is not met as evidenced by: Based on interview and record review, the facility failed to ensure the surgical team members followed the facilities' policies and procedures. This failure resulted in the			

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	retention of a surgical straight suture pacing wire needle inside one patient (Patient A), following open-heart surgery. A review of the facility's policy and procedure entitled, "Accounting-Sponges/Needles/Sharps/Misc. Small Items/Instruments," dated 4/14, set forth the purposes of the policy as follows: "(1) Account for sponges, sharps, miscellaneous small items and instruments used in operative/invasive procedures; (2) To safeguard the surgical patient from retained foreign bodies; and (3) To define surgical materials to be counted, the times counts are done and the documentation required." The policy further set forth the following: "Counts are performed for all sponges, sharps, and miscellaneous small items and instruments to account for all items used during all invasive procedures to ensure that the patient is not harmed by a retained foreign body. Instrument counts are performed on all procedures in which the likelihood exists that an instrument could be retained, with the following exception: open hearts, spines and emergency traumas. Two-view post-operative x-rays anterior-posterior AP (to visualize through the front and back aspect of the chest) and Oblique (to visualize the ribs, sternum and chest at a 45			

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	degree angle) will be taken in the OR (operating room) in lieu of an instrument count for these procedures." The policy also set forth the following: "Any member of the surgical team may initiate a count, but it (is) the responsibility of the RN to ensure the count is performed at designated times;" "Sponges, sharps and miscellaneous items will be counted before the closure of a cavity within a cavity (1st count), before wound closure begins (2nd count), at skin closure or the end of procedure (3rd or Final count);" and "Miscellaneous items will be counted before procedure is concluded ensuring only the device intended for implant was left in the patient." Finally, the following: "The surgeon will account for all parts of sharps broken during the surgical procedure;" "Members of the surgical team will account for instruments broken or disassembled during the surgical procedure;" and, "Immediately prior to the end of the procedure the physician will verify all of the components not meant to be retained in the patient are accounted for." The policy defines "counts" as "audibly and visually" counted. A review of Patient A's medical record indicated that Patient A was admitted on 12/19/14 for open heart surgery to replace the mitral valve (the valve between the two chambers of the left heart preventing blood from flowing back into the top chamber) and the aortic valve (a valve in the heart that prevents the blood from flowing back into the aorta when the heart pumps).			

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	An operative report dated 12/19/14, set forth that Patient A's physician and surgeon, MD 1, placed pacer wires (wires use to improve blood flow in the presence of irregular or abnormal heart beats) to pace the heart externally. During an interview with MD 1, on 7/28/15 at 12 p.m., he stated that during Patient A's surgery, "One of the pacer wire needles broke off." MD 1 explained that a pacer-wire is a long needle that consists of two parts, a breakaway needle and a pacer wire. The breakaway needle section is meant to exit the skin, only the wire section stays inside the chest attached to the heart in order to be able to pace the heart from the outside of the body. MD 1 stated: "One of the pacer wire needles broke off, the needle got lost inside the patient's abdominal tissue, I attempted to retrieve the needle, but I couldn't retrieve it." During the same interview, MD 1 stated: "I forgot about the needle completely, I didn't remember anything about the pacer-wire needle until recently when Quality contacted me to let me know there was a needle inside the patient. At that time, I remembered the incident again." On 7/27/15, at 11:30 a.m., Patient A's clinical record was reviewed and there was no documentation in the patient's clinical record to reflect the broken needle or that it was left inside Patient A. The "Surgical Documents Final Report," dated 12/19/14, noted the surgical count was "correct"			

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	for all three counts during Patient A's surgical procedure. Further review of the same document revealed that no AP and Oblique X-rays were taken on Patient A post operatively (end of surgery) in the OR as required by the facility's policy and procedure for open heart surgery. On 7/28/15 at 1:50 p.m., license nurse (LN 2) was interviewed. LN2 confirmed during the interview she was present and performed the final surgical instruments count during Patient A's surgery, and that she was aware of one needle (pacer-wire needle) being inside the patient at the time that she performed the final procedure count. LN2 stated, "I asked the scrub tech, where's the needle? The scrub tech (SSCT1) pointed to the patient. We both knew where the needle was (in the patient), that's why we accounted for the needle as number 1." LN 2 acknowledged during interview that counting without visualizing the needles was not right nor correct. LN 2 further explained and confirmed that X-rays were not completed for Patient at the end of surgery. On 7/30/15, at 9:35 a.m., the senior scrub tech (SSCT 1) was interviewed. SSCT 1 confirmed she was present and performed the final surgical instruments count during Patient A's surgery. SSCT 1 stated the following during the interview: "When we counted, I mentioned there was a needle inside the patient. Everyone knew one needle was still inside the patient. We started counting by saying, "One needle in the			

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	patient," that was needle number 1, then we continued counting the rest of the needles, the ones outside on the table." SSCT 1 explained during interview that she knew the needle was in the patient's abdomen and that other staff present at the surgery knew the needle was inside the patient. SSCT 1 stated that she did not know why the counts were documented as correct if a needle was still inside the patient. SSCT 1 confirmed that x-rays were not completed for Patient A at the end of the surgery. During an interview with MD 1 on 7/28/15, at 12 p.m., he explained that the nurses told him the counts were correct, that is why there was no need to have X-rays taken on Patient A. MD 1 confirmed X-rays were not taken on Patient A in the OR. An interview on 7/28/15 at 11:50 a.m., was conducted with LN 1. LN1 confirmed she was present and performed the final surgical instruments count documentation during Patient A's surgery. LN 1 explained she was charting (documenting the events) on Patient A's open-heart surgical procedure of 12/19/14. However, she was far away and could not see what was going on or hear the surgical team members. A review of the medical record entitled, "Emergency Department (ED) Physician Notes," dated 7/6/15, revealed Patient A returned to the hospital's emergency room complaining of			

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	abdominal pain. The ED Physician notes indicated the following: "The patient presents with epigastrium (top of stomach) burning for past 15 days, tonight pt. (patient) states she noticed a sharp object protruding from her abdomen when she bent forward, pt. with a hx (history) of heart surgery in December. After obtaining CT (computerized tomography), the object was removed using local anesthetic, without complication. The object appeared to be a surgical straight suture needle." According to the CT scan report there was a "7 cm (2.75 inches) long metallic wire within the upper abdominal wall subcutaneous tissues is stable and probably represents a remnant epicardial (heart) pacing lead. The end of the wire appears to tent if not protrude beyond the skin surface. Correlation with clinical findings and the surgical history recommended." A review of the "Surgical Pathology Report," dated 7/6/15, further revealed a "Silver-like object 7 centimeter (cm) in length, and approximately 1 millimeter (mm) in diameter was the foreign object removed from Patient A's abdomen." The failure of the surgeon and the OR staff to follow the facility's policies and procedures, as it pertained to performing two-view post-operative x-rays while in the OR on patients who had an open heart procedure, accounting for any and all items entering the patient and ensuring the items came back out of the patient, during a			

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	surgical procedure, resulted in the retention of a 2.75 inch pacing wire needle in Patient A, and the necessity of an emergency room visit, a CT scan, and a second surgical procedure under local anesthesia to remove the retained needle. The facility's failure to implement policies and procedures for surgical care and services is an immediate jeopardy in which the facility's noncompliance with one or more requirements of licensure has caused, or is likely to cause, serious injury or death to the patient as defined under Health and Safety Code Section 1280.3 (g).			

CA 00450055

Immediate Corrective Action:

- Case reviewed by departments of surgery and radiology. (5/18/15)
- Reviewed procedure for red tag tracking damaged items in the OR and Sterile Processing Department. (6/12/15)
- Department of Surgery informal rounds were conducted by the Risk Manager reminding staff of the hospital general high risk event reporting, and reporting specifically related to retained surgical items. (6/15/15)
- Case presented to the Quality Improvement Committee by Manager of Quality. (6/17/15

Systematic Corrective Action:

- Broken/Malfunctioning Instrument Policy was created and approved by the Medical Executive Committee. (10/5/16)
- Dignity Health Prevention of Retained Surgical Items was approved by Medical Executive Committee. (10/5/16)
- Communication from the Chief of Staff to all physicians on the importance of confirming the final count as outlined in the approved policy. (10/10/16)
- Daily intraoperative staff huddles include reinforcement of prevention of retained items requirements. (10/10/16)
- Daily staff huddles in procedural departments include reinforcement of prevention of retained surgical item requirements. (10/10/16)
- Education session conducted with procedural departmental leaders to review the revised Broken/Malfunctioning Instrument Policy and Prevention of Retained Surgical Items policies and staff huddles. (10/14/16)
- Written communication disseminated to all procedural departmental leaders by the Interim Manager Perioperative Services to review new Broken/Malfunction Instrument policy and procedure and implementation of broken instrument log. (10/14/16)
- Expert Safety Consultant from Dignity Health is scheduled to conduct education and training to surgeons on the Prevention of Retained Surgical Items. (10/21/16)
- Formal education was rolled out to all operative/procedure clinical staff on 10/10/16 using tools, post-tests, and observation evaluations as directed by Dignity Health based on the Prevention of Retained Surgical Items Policy. (10/27/16)
- Competency assessment for retained surgical items was revised and initiated on 10/03/16 by the Clinical Supervisor for operative/procedural staff with full completion by 10/27/16 or prior to next scheduled shift. (10/27/16)
- Competency assessment was created and initiated on 10/10/16 by the Clinical Supervisor for Broken Equipment through direct observation or verbal response for operative/procedural staff with full completion by 10/27/16 or prior to next scheduled shift. (10/27/16)

Monitor:

20 observation rounds conducted monthly to verify perioperative staff complete all requirements related to the prevention of retained surgical items. Results reported to Surgery Committee, Hospital Quality Committee, Medical Executive Committee (MEC), Quality Improvement Committee (QIC), and Governing Board until 100% compliance sustained for 4 months. (10/10/16)

Responsible Person(s): Manager Perioperative Services