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
	950686	A. BUILDING B. WING	09/21/2011

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
KAISER FOUNDATION HOSPITAL, RIVERSIDE	10800 Magnolia Ave, Riverside, CA 92505-3043 RIVERSIDE COUNTY

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE

The following reflects the findings of the Department of Public Health during an inspection visit

Complaint Intake Number
CA00268068 - Substantiated

Representing the Department of Public Health
Surveyor ID # 28294, 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

Abbreviations used in this document

Decon - decontamination
Qty - Quantity
RIV - Riverside
RN - Registered Nurse
SPLT - Sterile Processing Lead Technician
VCARE
Vaginal-Cervical-Ahluwalia's-Retractor-Elevator
x - times
" - inches

Health and Safety Code Section 1279.1
(b) For purposes of this section, "adverse event" includes any of the following

acceptable PoC 8/2/14 [signature] DA

Event ID:MH3U11 5/7/2014 2:02:08PM

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE — TITLE — (X8) DATE
[signature], Director of Accreditation, Regulation & Licensing 7/22/14

By signing this document, I am acknowledging receipt of the entire citation packet Page(s): 1 thru 8

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

State-2567

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(1) Surgical events including the following:
(D) Retention of a foreign object in a patient after surgery or other procedure, excluding objects intentionally implanted as part of a planned intervention and objects present prior to surgery that are intentionally retained.

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."

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.

Title 22, California Code of Regulations, section70223 (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.

Based on observation, interview, and record review, the facility failed to ensure that a surgical

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	050656	A. BUILDING _____ B. WING _____	09/21/2011

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instrument was not left in Patient 1's vaginal cavity following a surgical procedure performed on [redacted] 2009, which resulted in the patient experiencing pain and bleeding for one and a half years, and had the potential to cause infection and trauma to the vaginal cavity.

Findings:

On May 18, 2011, the record for Patient 1 was reviewed. Patient 1 was admitted to the facility on [redacted] 2009 for a "Hysterectomy Supracervical Laparoscopic" (surgical procedure for the removal of the uterus through a scope placed in the abdomen).

The intraoperative record dated [redacted] 2009, indicated:
a. The procedure started at 1:56 p.m., and ended at 6:00 p.m.
b. The "Tray GYN (gynecology) Endoscopic Tenaculum" was one of the instrument trays used in the procedure, and contained the "Koh Vaginal Cup (uterine manipulator)."
c. The surgical counts for sponge, needles/sharps, and "Other" were identified as "Correct - Yes" for the initial, closing, and final counts by both the scrub person and the RN circulator.

Physician 1's Operative Note dated [redacted] 2009, at 5:39 p.m., indicated: "The speculum was placed in the patient's (Patient 1's) vagina and the cervix grasped on the anterior lip with the single tooth tenaculum. The uterine manipulator (Koh, Vaginal Cup, (nondisposable instrument) with a VCARE (Vaginal-Cervical Ahluwalia's Retractor-Elevator)

CORRECTIVE ACTION PLAN
CA00268068

Kaiser Foundation Hospital - Riverside (the "Hospital") is submitting this Plan of Correction as required by state and/or federal regulations. This Plan of Correction documents the actions by the Hospital to address the deficiencies noted. This Plan of Correction constitutes credible evidence of compliance with the cited regulations.

CORRECTIVE ACTIONS

The following immediate actions were taken:

- Affected Patient

The Koh cup was removed immediately upon discovery of its retention. The patient did not require any additional care, as there was no injury and no further effects once the object was removed. [redacted]011

Responsible Party: Treating Physician

- Surgical Instruments Secured Koh Cups

The V-Care Uterine manipulator used in the procedure was disposable, and thus did not include a mechanism by which the Koh cup would attach to it. Over a year before the retained Koh cup was identified, the Hospital had implemented a practice of securing the Koh cups directly to the manipulators with surgical sutures. That practice is still in effect. 01/2010

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	050555		09/21/2011

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was placed atraumatically. The tenaculum and speculum were removed." The record further indicated: "The instruments were removed" that Patient 1 "was returned to the dorsal supine position." and that, "Sponge, instrument and needle counts were correct x (times) 2." Further, that, "Sponge, needle and instrument counts were reported to be correct."

The postoperative record, dated [redacted] 2009, indicated Patient 1 was discharged home from the facility at 9:12 p.m., on [redacted] 2009.

The "Endoscopic Tenaculum Tray" count sheet indicated one "Delineator, Koh, Vaginal Cup, Small" with a product number of "KCS-30" was included on the tray.

On [redacted] 2011, Patient 1 presented to the clinic with painful intercourse. Patient 1 also complained of having bleeding after intercourse for the last one and a half years, and sometimes painful sex. The physician removed a circular piece of metal which was attached to Patient 1's cervix.

On [redacted] 2011, a physician familiar with Patient 1's case confirmed that the metal foreign body removed from Patient 1's vagina on [redacted] 2011, was a "Koh, Vaginal Cup, Small."

On [redacted] 2011, at 9:10 a.m. an observation of the "Koh, Vaginal Cup, Small" was done. The "Koh, Vaginal Cup, Small" was made of a metal alloy, fitted over the cervix with a diameter of 1 1/4", was 1 5/16" in length, and tapered down to a diameter of

Cont'd.

Responsible Party: OB GYN Chief of Service

- Count Procedure

The "Count Procedure" policy was revised to include the Koh cup in the instrument count, separate from the uterine manipulator. — 06-2011

Responsible Party: Director of the Perioperative Services

- Staff Education: Count Procedure

The Operating Room staff was immediately re-educated regarding the policy for counting surgical instruments, and was educated again once the policy was revised. Such training is re-conducted periodically. — 05/2011, 06/2011, 01/2012, 06/2012, 07/2012, 04/2013

Responsible Party: Director of Perioperative Services

- Surgical Procedure: Red Rule Patient Safety Alert

A mandatory requirement "Red Rule Patient Safety Alert" was prepared to ensure that: — 05/2011

o all foreign objects placed in the vaginal cavity have a "tail" that is visible from the outside.

o all items placed in the vaginal cavity are announced by the surgeon and entered on the count whiteboard by the circulator.

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	050685	A. BUILDING _____ B. WING _____	09/21/2011

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14/16" which then attached to the VCARE Standard allowing manipulation of the cervix during the surgical procedure.

The facility Missing Instrument History dated [redacted] through [redacted] 2009, indicated " 'Day Lost' - [redacted] 2009; 'Instrument - Delineator Koh Vaginal Cup, Small; Set - Endoscopic Tenaculum Tray Site - RIV (Riverside), Index - 01, Qty (Quantity) - 1, Comment - (blank)."

On August 23, 2011 at 9:50 a.m., an interview was conducted with Physician 1. Physician 1 stated she did not remember the "Koh Vaginal Cup" being left in the vagina following the close of the surgical case, and cavity searches at the close of the surgical case were not done in [redacted] 2009. In addition, Physician 1 stated she was never informed on [redacted] 2009, that an instrument was missing after the surgical case by the nursing staff or the sterile processing staff.

The facility policy and procedure entitled, "Counts, Surgical," revised on April 2009 with the purpose "to prevent patient injury as a result of an unintentional retained surgical foreign body" indicated the following, "Closing counts. Sponges and other miscellaneous items must be counted on all procedures except when no significant risk for retention exists, e.g. Burn Debridements, Ophthalmology (eye) procedures and Urology (urinary system) procedures."

A review of the Policy and Procedure entitled "Perioperative Services-Sterile Processing-

o all items removed from the vaginal cavity are announced by the surgeon and are documented in the electronic health record

o the surgeon conducts a vaginal exam at the end of the procedure

o appropriate post-case debriefing is conducted and the circulating nurse documents in the Op Time Log Report "Vaginal cavity checked and object removed by Surgeon".

Responsible Party: Director of Perioperative Services

• Staff Education: Red Rule Patient Safety Alert

o All surgeons in the OB-GYN department were educated on the Red Rule Patient Safety Alert, and it was reinforced that routine cavity checks must be performed at the end of all procedures involving the vaginal cavity.

06-2011
07-2011
08-2011

Responsible Party: OB_GYN Chief of Service

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	050606	A. BUILDING _____ B. WING _____	09/21/2011

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Operational/standards" and "Orientation of New Employees" revised June 2008 the following language is set forth under the subtitle "Sterilization of Instruments" "3. Missing items should be searched for right away. -Search other trays that were used on that case for the item. Ask Decon if they have the item. -Call the Charge Nurse immediately to talk with the circulator. The item may still be in the room where it was used."

There was no documentation reviewed that the charge nurse, circulating nurse or surgical staff were notified of the missing instrument pursuant to the facility's policy and procedure.

On August 23, 2011, at 10:10 a.m. an interview was conducted with RN 1. She stated in May 2009, the facility counted instruments but they did not count "Koh Vaginal Cups." RN 1 stated if sterile processing identified there was a missing instrument from a surgical case sterile processing would notify the surgery charge nurse who would notify the circulating nurse, scrub technician, and surgeon. RN 1 stated she was not informed an instrument was missing from Patient 1's surgical case on [redacted] 2009.

On August 23, 2011 at 10:25 a.m. an interview was conducted with the Sterile Processing Lead Technician (SPLT) 1. She stated the process of notifying surgery of a missing instrument was discussed during orientation of sterile processing employees. In addition, the SPLT 1 stated there was no documentation that the surgery charge nurse, circulating nurse, scrub technician, or

o The OR staff were trained on the Red Rule Patient Safety Alert, and it was reinforced that verbal communication is required between the surgeon, scrub staff, and circulator when instruments are inserted and removed from the vaginal cavity. Such training is re-conducted periodically. — 09/2011

o The Red Rule Patient Safety Alert is conspicuously posted in each OR and OR bulletin board so as to make it visible to all personnel and surgeons. — 09/2011

Responsible Party: Director of Perioperative Services

- Missing Instruments Procedure

A new policy and procedure on "Missing Instruments/Parts, Procedure for Locating" was developed. This policy contains a process for tracking missing or broken instruments. As part of the policy, the "Missing Instrument Log" was created and implemented. It is available electronically. — 06-2011

Responsible Party: Director of Perioperative Services

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	050650	A. BUILDING _____ B. WING _____	09/21/2011

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surgeons were notified of the missing instrument on [redacted] 2009.

On August 23, 2011, at 1:05 p.m., an interview was conducted with RN 2. She stated in May 2009, the facility did not include "Koh, Vaginal Cups" in the surgical instrument counts, and she was not informed on [redacted] 2009, that an instrument was missing from a surgical case where she was the circulating nurse.

On August 23, 2011, at 3:29 p.m., an interview was conducted with RN 3. She stated she was the surgery charge nurse on [redacted] 2009 and she was not informed by sterile processing that an instrument was missing from the surgical case performed on Patient 1.

On August 23, 2011, at 1:15 p.m. an interview was conducted with Physician 2. She stated she was not informed on [redacted] 2009, that an instrument was missing from the surgical case performed on Patient 1. She stated that during that time, a count of the vaginal instrument tray was not being conducted during the procedure. In addition, Physician 2 stated whomever removed the introducer/manipulator for the "Koh Vaginal Cup" should have also made sure that the "Koh, Vaginal Cup" was also removed. She also stated that now, during the procedure physicians suture the Kocup to the introducer and conduct a cavity search fowing closure and surgical staff also conduct a surgical count of the vaginal instrument tray after closure.

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- Staff Education: Missing Instruments

o The Operating Room staff were educated regarding the policy for "Missing Instruments/Parts Procedure for Locating", which included education on the Missing Instrument Log. Such education is re-conducted periodically	06/2011 01/2012 06/2012 07/2012 04/2013
o The SPD staff were educated regarding the policy for "Missing Instruments/Parts Procedure for Locating", which included education on the Missing Instrument Log. Such education is re-conducted periodically.	06-2011 06-2012 06-2013 02-2014

Responsible Party: Director of Perioperative Services

MONITORING

- Staff Competency

o A new competency validation tool was developed for the Sterile Processing Department, which includes competency for accurate instrument tray assembly by employees responsible for such assembly. This competency validation is conducted annually by the SPD manager	08-2011 and On-going
o A Surgical Counts Competency for the Operating Room staff is conducted annually by the OR Manager, in collaboration with the OR Educator.	06-2011 and On-going

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	The facility's failure to ensure that a surgical instrument was not left in Patient 1's vaginal cavity following a surgical procedure 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 Health and Safety Code section 1280.1. 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)		Monitoring continued The competency validation tool includes: 1. The method to systematically and accurately account for the items placed on the surgical field 2. No items used in surgical procedure are lost or left in the patient • Koh Cup Audit A Koh cup audit was conducted for the period November 2011 to June 2012. Koh cup counts were monitored for all laparoscopic hysterectomy cases. A 100% compliance rate was attained. The results were reported monthly to the Accreditation, Regulation and Licensing Committee, and quarterly to the Performance Improvement Committee and Medical Executive Committee. The auditing is ongoing and the facility continues to attain 100% compliance. Responsible Party: Director of Perioperative Services	11-2011 to 06-2012 and On-going