Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	55C0001059	02/01/2019
Name of Provider or Supplier	**Street Address, City, State**	
Fort Sutter Surgery Center, A Ca Limited Partnership	2801 K Street, Suite 525, Sacramento, CA	

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

(X4) ID Prefix Tag	**Summary Statement of Deficiencies** (Each deficiency should be preceded by full regulatory or LSC identifying information)
Q0242	INFECTION CONTROL PROGRAM CFR(s): 416.51(b) The ASC must maintain an ongoing program designed to prevent, control, and investigate infections and communicable diseases. In addition, the infection control and prevent program must include documentation that the ASC has considered, selected, and implemented nationally recognized infection control guidelines. This STANDARD is not met as evidenced by: Based on observation, interview and document review, the Ambulatory Surgery Center (ASC) failed to operationalize infection prevention policies when 1) Unsterile or unsuitable surgical instruments were found to be available for use, and 2) Three of eight physician health records lacked documentation of compliance with immunization requirements. These failures had the potential to cause surgery-related infections and to expose patients to communicable diseases. Findings: 1A. During the surgical instrument sterilization process, indicators and integrators are used to verify that conditions necessary for sterilization (i.e.- time and temperature)

have been achieved. For example, in steam sterilization the indicators or integrators turn a different color (in this case black) to indicate sterilization has occurred. Single instruments are placed into peel pouches which are made of plastic and paper which is permeable to sterilization (steam) and are durable and protective for instrument storage.

During an observational tour on 1/29/19 at 11:00 a.m. with the Director of Nursing (DON) and the Regional Clinical Director (RCD), many instruments were noted in a storage area adjacent to the operating rooms. One pair of scissors was examined and the following was noted:

a) The scissors were positioned in an instrument protector card which had an indicator on it. This indicator had not turned black from its original color.

b) The scissors were placed into a double peel pouch packaging. Both indicators on the sequential pouches did not change color.

c)An integrator was placed in the first peel pouch at the instrument level. The integrator did not change color to the desired black to indicate the contents were sterilized.

During a concurrent interview, the DON and the RCD agreed the indicators appeared unchanged.

In an interview at approximately 11:30 a.m. on 1/29/19, the DON and the Sterile Processing Technician (SPT) stated the instrument was not sterilized and was erroneously placed with other sterile instruments and available for use.

A review of the ASC policy, IC [Infection Control]- Sterilization Standards: Preparation of Instruments and Supplies for Sterilization, last revised 8/18/11, directed, "Instruments ... reprossessed by the facility will be prepared in a manner to assure maintenance of sterility and promote delivery to the sterile field in an aseptic manner ...VI. Chemical Indicators/integrators will be placed inside each package and an external chemical indicator will be affixed outside each package to be processed ..."

The above policy references AORN (Association of periOperative Registered Nurses)

Standards.

The AORN Guidelines for Sterilization, effective 2018, included, "X.b. Chemical, physical, and biological indicators should be used to monitor sterilization processes. X. c. External and internal chemical indicators (CIs) specific for the sterilization method should be used with each package. X.d. Physical monitors (eg, time, temperature, pressure, humidity, sterilant concentration) should be reviewed at the end of each cycle. The sterilizer operator should verify that all sterilization parameters were met for every cycle and every sterilization method ... X.g. Process monitoring specific to steam sterilizers should be performed.

1B. During a 10:15 a.m., 2/1/19 inspection of the sterile processing area, an engraved tympano tray microforceps (an instrument used during ear surgery) was observed on the supplemental instruments peg board.

In a concurrent interview, the Sterile Processing Technician (SPT) stated, "everything on the [supplemental instruments peg board], we would use," for a procedure.

During a 3:03 p.m., 2/1/19 re-inspection of the sterile processing area, the engraved tympano tray microforceps was observed still on the supplemental instruments peg board.

In a concurrent interview, the SPT stated that the reason the instrument remained on the board was that she was "waiting to take the [identification] number off of it. Then I will reorder it [a replacement]" and discard the engraved forceps.

Review of Association of periOperative Registered Nurses (AORN): Instrument Cleaning section IX.e.4, indicated, "Damage to the finish of the instrument [such as engraving] can create surface imperfections that can harbor microorganisms and debris."

During a 3:10 p.m., 1/29/19 interview, the designated Infection Preventionist, Nurse Manager 2 (NM 2), stated the ASC adhered to AORN standards for infection prevention.

1C. During a 4:01 p.m., 1/29/19 inspection, an unpackaged laryngoscope blade (equipment used to place an airway) was observed in the anesthesia cart of Operating

Room 5. In a concurrent interview, the Nurse Manager of the Operating Rooms (NM 2) acknowledged that the equipment was not sterile.

During a 4:03, 1/29/19 inspection in Operating Room 4, a laryngoscope was observed in an anesthesia cart in packaging which had a tear in it. In a concurrent interview, NM2 acknowledged that the peel pack was torn and indicated that laryngoscope blades needed to be kept in sterile packaging.

Review of the ASC's 4/26/17 "Processing of Anesthesia Intubation [placement of a breathing tube] Equipment" policy reflected, "The laryngoscope blades will be cleaned, disinfected and sterilized between each use."

2. Review of the ASC's 1/2/18 "Post-Offer/Pre-Placement Medical Assessment Policy" reflected, "Proof of immunity to...varicella (chickenpox) and pertussis is a requirement of employment in an HCP [health care personnel] position...The individual will be asked to present immunization record(s) for the varicella (chickenpox) and pertussis as well as any documentation of previous laboratory titers for...chickenpox...If the individual is unable to provide acceptable proof indicating immunity for...varicella, serological tests [laboratory testing to determine immunity] are performed...When the results of the serological tests indicate no immunity...or the individual is unable to provide proof of immunity to pertussis, the individual shall be... offered recommended vaccinations...which include the Varicella (Chickenpox) Vaccine and the...Pertussis Vaccine...Non-immune individuals must be adequately immunized within 90 days of the start of their employment for...varicella and pertussis...."

The policy defined health care personnel as "Employee who provides direct and indirect patient care...including but not limited to physician medical offices...who has the potential for exposure to patients...."

During a review of eight physician health records provided by the Vice President, Clinical Operations (VPCO), immunization or documentation of immunity to pertussis (whooping cough, an easily-spread and potentially deadly communicable disease preventable with vaccination) was not found for Medical Doctors 1 and 3 (MDs 1 and 3). Evidence of immunization for or immunity to varicella (a highly contagious disease) was not found for MD 4.

In a 1:07 p.m., 2/1/19 interview, the VPCO was requested to provide documentation of the missing health information. None was able to be provided by the end of the survey.

	In a 1:31 p.m., 2/1/19 interview, the VPCO stated that the ASC did not have a separate policy for physician immunizations. The 1/22/19 "Medical Staff Bylaws" indicated, "Qualifications of Medical Staff Membership...Annual confirmation of...other appropriate immunizations as required by the facility...."