

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTIONS		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: <b>14C0001185</b>		(X2) MULTIPLE CONSTRUCTION A. BUILDING B. WING		(X3) DATE SURVEY COMPLETED <b>06/20/2023</b>	
NAME OF PROVIDER OR SUPPLIER <b>WESTERN DIVERSEY SURGICAL CENTER</b>				STREET ADDRESS, CITY, STATE, ZIP CODE <b>2744 N WESTERN AVE , CHICAGO, Illinois, 60647</b>			
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Q0000	INITIAL COMMENTS		Q0000				
	<p>A post complaint visit (PCV) for Complaint #97108, investigated on 4/5/2023, was conducted on 6/20/2023. An immediate jeopardy (IJ) began on 5/10/2023, due to the Facility's failure ensure that surgical instruments were sterilized and remained sterile before use; and was identified on 6/15/2023 at 42 CFR 416.51, Infection Control. The IJ was announced on 6/15/2023 at 3:30 PM during a meeting with the Facility Administrator and Nurse Manager and was not removed by the survey exit date of 6/20/2023.</p>						
Q0240	<p>INFECTION CONTROL</p> <p>CFR(s): 416.51</p> <p>§416.51 Conditions for Coverage – Infection control. The ASC must maintain an infection control program that seeks to minimize infections and communicable diseases.</p> <p>This CONDITION is NOT MET as evidenced by:</p> <p>Based on document review, observation, and interview, it was determined that the Facility failed to maintain an infection control program that seeks to minimize infections and communicable diseases by ensuring the sterility of surgical instruments. As a result, it was determined that the Condition for Coverage, 42 CFR 416.51 Infection Control, was not in compliance.</p> <p>Findings include:</p> <p>1. The Facility failed to ensure that surgical instruments were sterilized according to manufacturer's instructions and/or nationally recognized infection control guidelines. (Q-242 A)</p> <p>2. The Facility failed to ensure that sterile technique was used to maintain the sterility of instruments used for surgical procedures. (Q-242 B)</p> <p>An immediate jeopardy (IJ) began on 5/10/2023, due to the Facility's failure ensure that surgical instruments were sterilized and remained sterile before use; and</p>		Q0240	<p>Q0240 ALL INSTRUMENTS HAVE BEEN COMPLETED ,FULLY CHECKED AND STERILIZED AS OF 6/19/2023. ALL INSTRUMENTS ARE PEEL PACKED SEPARATELY ,INDIVIDUALLY ONLY 1 INSTRUMENT PER PACK. ALL HINGED INSTRUMENTS HAVE THE SEPARATOR WITH THE FOLD IN PLACE AND ALL INDICATORS HAVE BEEN DOUBLE CHECKED TO ENSURE THE ARE ACCEPTABLE. THIS IS BEING RECORDED ON A LOG SHEET WHICH IS DONE WEEKLY (DAILY SINCE WE ARE OPEN ON WEDNESDAYS)AND SIGNED OFF BY NURSE MANAGER/ADMINISTRATOR AS A SECOND PERSON VERIFYING. THIS IS REPORTED TO THE ADMINISTRATOR AND THE COMMITTEE QUARTERLY. SPOT CHECK WAS PERFORMED TODAY TO ENSURE COMPLIANCE OF STERILIZATION OF INSTRUMENTS. WE ARE USING ONE SOURCE FOR ALL MIFU'S. PROCEDURES WILL RESUME ON 7/5/2023 DEPENDING ON AC.</p>		<p>6/19/2023</p> <p>6/27/2023</p>	

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. (See reverse for further instructions.) Except for nursing homes, the findings stated 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.

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE	TITLE	(X6) DATE
JULIE SWANSON	FACILITY ADMINISTRATOR	6/23/2023

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Q0240	Continued from page 1 was identified on 6/15/2023 at 42 CFR 416.51, Infection Control. The IJ was announced on 6/15/2023 at 3:30 PM during a meeting with the Facility Administrator and Nurse Manager and was not removed by the survey exit date of 6/20/2023.	Q0240					
Q0242	<p><b>INFECTION CONTROL PROGRAM</b></p> <p>CFR(s): 416.51(b)</p> <p>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.</p> <p>This STANDARD is NOT MET as evidenced by:</p> <p>A. Based on document review, observation, and interview, it was determined that the Facility failed to maintain an ongoing program to prevent and control infections by ensuring that surgical instruments were sterilized according to manufacturer's instructions and/or nationally recognized infection control guidelines. This had the potential to affect any patients receiving surgical procedures at the Facility.</p> <p>Findings include:</p> <p>1. The Facility's policy titled, "Sterile Processing" (revised 8/29/2017), was reviewed and required, "The manufacturer's recommendation for use [for]... sterilization will [be] followed..."</p> <p>2. The Steam Sterilizer Manufacturer's Operating Procedures (dated 3/26/98) was reviewed and required, "...Chemical Indicator – Placed in center of pack/package indicate physical conditions of temperature, time, moisture have been reached in that portion of the pack/package."</p> <p>3. The Facility's policy titled, "Packaging Materials, Selection and Use of" (revised 3/1/2008), was reviewed and required, "Materials used for packaging of sterile supplies should permit the sterilization process to take place and should provide delivery of the contents without contamination. Package systems should: ... Allow penetration and removal of sterilant... Resist tears and punctures... Be used in accordance with the manufacturer's written instructions... Proper packaging allows visualization of the item..."</p> <p>4. The CDC (Centers for Disease Control &amp; Prevention)</p>	Q0242	<p>Q0242 A. ALL INSTRUMENTS HAVE BEEN COMPLETED, FULLY CHECKED AND STERILIZED AS OF 6/19/2023. ALL INSTRUMENTS ARE PEEL PACKED SEPARATELY AND INDIVIDUALLY, ALL HINGED INSTRUMENTS HAVE THE SEPARATED PROPERLY AND ALL INDICATORS HAVE BEEN DOUBLE CHECKED TO ENSURE THE ARE ACCEPTABLE. ALL PEEL PACKS WERE CHECKED FOR DATE, INITIALS, INDICATORS. MOISTURE AND HOLES. ALL INSTRUMENTS FROM CART AND CABINET HAVE BEEN RE-PROCESSED. ALL INDICATORS ARE VISIBLE.</p> <p>STERILE PROCESSING STAFF- HAS UNDERGONE OUTSIDE TRAINING AND COMPETENCY AT UNIVERSITY OF CHICAGO HOSP AND CONTRACT COMPANY HAS COME IN TO THE FACILITY TO DO MORE TRAINING AND COMPETENCY FOR STERILIZATION STAFF- WHICH WAS COMPLETED ON 5/2/2023.</p> <p>OUTSIDE AGENCY WAS NOTIFIED OF ERRORS MADE, STERILIZATION STAFF WAS RE-TRAINED ON PEEL PACKS ON 6/19/2023</p> <p>ALL COMPETENCY PAPERWORK IS IN EACH INDIVIDUALS FILE. THEY WILL HAVE ANOTHER OUTSIDE TRAINING AND FOLLOW UP COMPETENCY IN AUGUST FOR QUARTERLY REVIEWS AS WELL AS SPOT CHECKS BEING DONE PRN BY NURSE MANGER FOR IC. THIS INFORMATION WILL BE REPORTED TO NURSE MANAGER, ADMINISTRATOR AND COMMITTEE. WE WILL CONTINUE OUTSIDE TRAINING AND COMPETENCY QUARTERLY X4 THEN SEMI-ANNUALLY.</p>			<p>6/19/2023</p> <p>4/10/2023</p> <p>5/2/2023</p> <p>6/19/2023</p>	

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Q0242	<p>Continued from page 2</p> <p>"Guideline for Disinfection and Sterilization in Healthcare Facilities" (updated May 2019), was reviewed and required, "Packaging: Once items are cleaned, dried, and inspected, those requiring sterilization must be wrapped or placed in rigid containers and should be arranged in instrument trays/baskets according to the guidelines provided by the AAMI and other professional organizations. These guidelines state that hinged instruments should be opened... Loading: All items to be sterilized should be arranged so all surfaces will be directly exposed to the sterilizing agent. Thus, loading procedures must allow for free circulation of steam (or another sterilant) around each item..."</p> <p>5. An observational tour of the Surgical (OR) Area was conducted on 6/14/2023, between approximately 10:00 AM and 12:00 PM. Instruments available for use for procedures were stored in a supply cabinet in OR#2 and on a cart in the hallway outside of OR#2. Staff were observed obtaining instruments for use from both the cabinet and the cart during the tour.</p> <p>- 1 pack on the cart contained a surgical instrument that was dated 6/7/2023 and there was no internal chemical indicator present inside the pack (to indicate whether sterilization criteria were met).</p> <p>- 2 packs of surgical instruments found on the cart, both dated 5/10/2023, had a chemical indicator strip inside; however, the black indicator bar did not pass the ACCEPT line, indicating the contents of the packs did not meet sterilization criteria.</p> <p>- 11 packs observed contained multiple instruments (3-6) contacting one another in one peel-pack which did not allow for free circulation of the sterilant around all surfaces of the instruments.</p> <p>- 17 hinged instruments observed in the packs were not properly held open using an insert to keep the instrument open during the sterilization process to allow for all surfaces of the instrument(s) to make contact with the sterilant.s.</p> <p>6. An interview was conducted with Sterile Processing Technician (E#4) on 6/14/2023, at approximately 10:30 AM. E#4 stated that hinged instruments should be kept open by folding the insert down the middle to prevent it from closing. E#4 confirmed that the chemical indicator was missing in the one pack and that the two others did not pass. E#4 stated that these need to be reprocessed. E#4 stated that the instruments in the cabinet are not used often and have not yet been</p>			Q0242			

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Q0242	<p>Continued from page 3 reprocessed. E#4 stated that if multiple items are placed in the peel-packs, they should not touch each other during the cycle.</p> <p>7. An interview was conducted with the Facility Administrator (E#1) on 6/14/2023, at approximately 12:41 PM. E#1 stated that they did not have a chance to go through all of the instruments in the cabinet yet since they restarted procedures in May 2023 and that staff should be using the instruments on the cart in the hallway first. E#1 stated that Sterile Processing staff should be checking the peel packs every week to ensure they were packed appropriately and that the indicators were present and passed; somehow those 3 packs were missed.</p> <p>B. Based on document review, observation, and interview, it was determined that the Facility failed to maintain an ongoing program to prevent and control infections by ensuring that sterile technique was used to maintain the sterility of instruments used for surgical procedures. This had the potential to affect any patients receiving surgical procedures at the Facility.</p> <p>Findings include:</p> <p>1. The National Abortion Federation 2022 Guidelines included, "All instruments entering the uterus must be sterile."</p> <p>2. The Facility's policy titled, "Basic Aseptic Technique" (dated 3/1/2008) was reviewed and required, "Sterile drapes will be used to establish a sterile field... All items used within a sterile field should be sterile... All items introduced into a sterile field should be dispensed by methods that maintain sterility of the item and integrity of the sterile field."</p> <p>3. An observational tour of the Surgical (OR) Area was conducted on 6/14/2023, between approximately 10:00 AM and 12:00 PM. During the tour, setups for elective abortion procedures were observed in OR#2. The staff (E#5) setting up the instrument field, placed the "sterilized" instruments (such as speculums, dilators, forceps, and curettes) on a non-sterile chuck pad and was using non-sterile gloves to arrange/touch the instruments. Non-sterile supplies (such as gauze and lubricant) were also placed on the field and touched the instruments.</p> <p>4. An interview was conducted with the Medical Assistant (E#5) on 6/14/2023, at approximately 11:45</p>		Q0242	<p>Q242B B. WE AGREE WITH THE FINDING AND ALSO AGREE THAT STERILE FIELD SHOULD HAVE BEEN DONE. STAFF WAS RE-TRAINED ON 6/15/2023 ON SETTING UP AND MAINTAINING A STERILE FIELD. ALL OR STAFF ATTENDED - SURGICAL TECHS, MA's STERILE PROCESSORS AND NURSE PRACTITIONER . A 'CHUCK PAD' SHOULD NOT HAVE BEEN USED FOR INSTRUMENTS. STAFF IS AWARE THAT A STERILE DRAPE, STERILE GLOVES AND INSTRUMENTS VISUALLY INSPECTED FOR INDICATOR PASS, NO HOLES OR MOISTURE BEFORE OPENING PEEL PACK IN THE OR AS A SECOND CHECK POINT FOR INFECTION CONTROL MONITORING. STERILE DRAPEs WERE READILY AVAILABLE LESS THAN 1 FOOT AWAY ON THE CART BEING USED FOR INSTRUMENTS. NURSE MANAGER WILL BE MONITORING DAILY FOR IC/QC AND WILL BE REPORTED TO ADMINISTRATOR AND TO COMMITTEE QUARTERLY AND PRN. MD WAS ALSO REMINDED OF PROPER STERILE FIELD/TECHNIQUE AS WELL. QUALITY CONTROL INFECTION CONTROL LOG WILL CONTINUE TO MONITOR STERILIZATION, PEEL PACK INSPECTION, CLEANING OF AREAS, INDICATORS WEEKLY (DAILY SINCE OPEN ON WEDNESDAYS) WITH THE NURSE MANAGER OR ADMINISTRATOR OVERSEEING AND SIGNING OFF. THIS IS REPORTED TO THE COMMITTEE QUARTERLY AND PRN. THIS WILL HELP WITH IC TRACKING/TRACING.</p>		6/15/2023	

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Q0242	<p>Continued from page 4</p> <p>AM. E#5 was not aware that sterile technique and a sterile field were necessary for elective abortion procedures.</p> <p>5. An interview was conducted with the Obstetric Physician (MD#1) on 6/14/2023, at approximately 11:22 AM. MD#1 stated that the instruments used for abortion procedures should be handled using sterile technique. MD#1 stated that he dons sterile gloves before touching the instruments</p> <p>6. During an interview with the Facility Administrator (E#1) on 6/15/2023, at approximately 9:35 AM, E#1 stated that staff should be placing the instruments on a sterile pad/drape which is individually wrapped and not placing them on chuck pads. E#1 stated that the chuck pads are to be used underneath the patient. E#1 stated that they have sterile gloves and supplies if the staff need to touch or place items on the sterile field.</p>			Q0242			