STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTIONS	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 43C0001029	(X2) MULTIPLE CONSTRUCTION A. BUILDING B. WING	(X3) DATE SURVEY COMPLETED 07/31/2024

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
RIVERS EDGE AESTHETIC SURGERY	4201 S MINNESOTA AVE SUITE 111 , SIOUX FALLS, South Dakota, 57105

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED 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) COMPLETION DATE
Q0000	INITIAL COMMENTS A complaint health survey for compliance with 42 CFR Part 416, Subpart C; requirements for Ambulatory Surgery Centers (ASC) was conducted from 7/30/24 through 7/31/24. Areas surveyed included Pharmacy, Infection, and Nursing Services. Rivers Edge Aesthetic Surgery was found not in compliance with the following requirement: Q241.	Q0000		
Q0241	SANITARY ENVIRONMENT CFR(s): 416.51(a) The ASC must provide a functional and sanitary environment for the provision of surgical services by adhering to professionally acceptable standards of practice. This STANDARD is NOT MET as evidenced by: Based on observation, interview, policy review, and manufacturer's instructions for use (IFU) review, the provider failed to ensure: *Nine of sixteen observed surgical instruments contained surgical tape and were free of cracks, rips, tears, and discoloration. *Nine of sixteen observed surgical instruments had surgical tape wrapped greater than 1.5 times around the instrument and were lying flat without gaps per manufacturer's IFU. *Seven of sixteen observed surgical instruments were free of rust. *Proper concentration of enzymatic and water was being measured per manufacturer's IFU. *The water temperature used for pre-cleaning of instruments was being measured per manufacturer's IFU. *One of one air pressure relationships (clean and dirty air) had been maintained by a pass-through window	Q0241	All tape has been removed from all instruments. Staff was educated on this change by the Director of Nursing and the policy ("instrument decontamination and reprocessing") was reviewed and updated to state: Use of instrument labeling tape is strictly prohibited. The DON will monitor that there are no instruments with tape applied in use on a weekly basis by randomly selecting five instruments for inspection. Weekly inspections will continue until compliance reaches 100% and then randomly monitored 2 times per month for the next six months. Results will be reported by the Director of Nursing to the BOG at quarterly meetings. Staff was educated by the DON on the update to the "instrument decontamination and reprocessing" policy that states: Inspect instruments for stains, rust or defects (items with stains, rust or defects must be removed from service until restored or repaired. The DON will monitor that there are no instruments containing rust or stains in use on a weekly basis by randomly selecting five instruments for inspection. Weekly inspections will continue until compliance reaches 100% and then randomly monitor 2 times per month for the next 6 months. Results will be reported by the DON to the BOG at quarterly meetings. A Healthmark Watermark Liquid Crystal Thermometer has been installed by the DON and serves two purposes.	8/23/2024

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
Jodi Pierret Jodi Pierret	Administrator	8/22/2024 8/26/2024

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTIONS	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 43C0001029	(X2) MULTIPLE CONSTRUCTION A. BUILDING B. WING	(X3) DATE SURVEY COMPLETED 07/31/2024

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
RIVERS EDGE AESTHETIC SURGERY	4201 S MINNESOTA AVE SUITE 111 , SIOUX FALLS, South Dakota, 57105

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED 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) COMPLETION DATE
Q0241	Continued from page 1 between a dirty and clean area. Findings include: 1.Observation on 7/30/24 at 10:18 a.m. in the dirty utility room with certified surgical tech (CST) A revealed: *She had put on personal protective equipment (PPE) which included a gown, face shield, and gloves. *She filled up the left side of the sink with water to a mark that was etched into the sink and was difficult to see. *She filled the right side of the sink with clean water. *She added one pump of McKesson Multi-Enzymatic Cleanser (instrument detergent) to the water. *The temperature of the enzymatic solution had not been measured. *She brushed each surgical instrument and placed them in the clean water on the right side of the sink. *She removed all her PPE and performed hand hygiene and put on a new pair of gloves. *She took the instruments from the clean water on the right side of the sink and placed them onto a surgical towel to allow them to air dry. *A pass-through window to the clean storage room had been left open allowing negative (dirty) air to flow into the clean processing room. Interview on 7/30/24 at 10:25 a.m. with CST A revealed: *All surgical instruments had been cleaned with an enzymatic detergent prior to sterilization. *A gallon of water had been measured to the etched line in the sink. *She stated, "There used to be a permanent marker to where we needed to fill it to, but it came off." *They had not measured the water temperature of the enzymatic solution in the sink. *The surgical instruments should have been soaked for two minutes.	Q0241	1. To monitor the water level of the left sink at 2 gallons 2. To monitor the water temperature to be between 68-122 degrees F. The "instrument decontamination and reprocessing" policy has been updated to state: Add McKesson Multi-Enzymatic Cleanser (2 pumps = 2 ounces to 2 gallons of water) per manufacturer IFU, Water temperature must be between 68-122 degrees F and 2 gallons of water must be placed in the left sink to the Water temperaturestrip representing 2 gallons. A minimum soak time of 2 minutes is recommended (refer to enzymatic cleanser IFU). Staff was educated on the changes to the policy by the DON and references have been posted at the point of care. The DON will monitor compliance by direct observation once weekly until compliance reaches 100%, then randomly select 2 days each month for the next 6 months to monitor compliance. The DON will report to the BOG results at quarterly meetings.	

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Q0241	Continued from page 2 *She stated, "The pass-through window to the sterilizers had always been open. We were told at one time to shut it, but weren't cited for it, so we did not change our practice." *She agreed the pass-through window should be closed when not in use to maintain proper airflow. 2. Observation on 7/30/24 at 10:30 a.m. in the clean storage room revealed: *A liposuction cannula contained within a surgical pack had been reprocessed on 7/23/24, was ready for patient use, and had surgical tape residue and rust on it. *A knife handle contained within a surgical pack had been reprocessed on 7/23/24 and was ready for patient use, and had rust around the surgical tape. *Double prong hooks within a surgical pack had surgical tape wrapped more than 1.5 times around and had not been laid flat without gaps per the manufacturer's IFU. Interview on 7/30/24 at 10:35 a.m. in clean storage with CST A regarding the above observations revealed she: *Had been on vacation and did not have the opportunity to inspect those instruments that had been reprocessed. *She agreed the surgical instruments should not have contained rust or surgical tape residue creating an uncleanable surface. *Agreed the surgical tape had been wrapped around the double prong hooks greater than 1.5 times and were laid flat without gaps created the potential of bacteria to remain on surgical instruments. *Would have inspected those instruments prior to using them on a patient. *Agreed the instruments should not have been used for patient's surgical procedures because of the risk of infection to patients. 3. Observation on 7/30/24 at 1:10 p.m. in operating room (OR) 1's clean storage cabinet revealed nine surgical instruments had issues with: *The surgical tape wrapped around the surgical instrument greater than 1.5 times or had been lying flat without gaps.	Q0241	The "instrument decontamination and reprocessing" policy has been updated to state: The pass-through window will remain closed when not in use to maintain proper airflow. The DON educated staff on the new policy and a reminder has been posted on the window. The DON will monitor compliance by direct observation once weekly until 100% compliance has been maintained for 4 weeks. Then the DON will monitor once a month for the next 6 months to maintain compliance. The DON will report results to the BOG at quarterly meetings. The DON has trained all staff on the updated "instrument decontamination and reprocessing" policies regarding 1. removing tape, residue and rust and defects on the instruments prior to putting them into service. 2. Use of the new Healthmark Water-mark Crystal Thermometer to measure 2 gallons of water in the sink along with the appropriate temperature of water. 3. Utilizing 2 pumps of McKesson Multi-use enzymatic cleanser to 2 gallons of water. 4. The pass through window will remain closed at all times, when not in use to maintain proper airflow.	

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Q0241	Continued from page 3 *Surgical tape was cracked, ripped, or discolored. *Rust around the surgical tape and hinges of the surgical instruments. Interview on 7/30/24 at 1:15 p.m. with director of nursing (DON) B revealed she: *Confirmed the instruments had contained surgical tape which was wrapped more than 1.5 times around the surgical instrument. *Confirmed the tape was cracked, ripped, and discolored. *Confirmed the surgical instruments contained rust and needed to be recleaned to prevent surgical infections. *Stated, "I would like to see all the tape gone." *The provider used Association of perioperative Registered Nurses (AORN) and Association for the Advancement of Medical Instrumentation (AAMI) national guidelines to guide their practice and write their policies and procedures. 4. Interview on 7/30/2024 at 2:50 p.m. with registered nurse (RN), co-office manager C revealed: *Instruments that had rust or tape on then should not have been used. *Instruments that had been stained or rusted should have been set aside and been reprocessed. *Inspection of instruments for rips or tears in the packaging had been done monthly and prior to opening for a surgical procedure. *They had inspected the instruments to ensure the hemostats (clamp) and scissors were in the open position. *The provider used AORN standards to guide their practice. 5. Interview on 7/30/24 at 3:24 p.m. with certified nurse practitioner (CNP) D revealed: *Surgical tape on instruments should not be frayed or ripped. *She would have expected the instruments to have been	Q0241		

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Q0241	Continued from page 4 cleaned, sterilized, and free from rust. *Instruments containing rust would not have been used. 6. Interview on 7/30/24 at 3:45 p.m. with DON B revealed she: *Would have expected a visible line in the decontamination sink to ensure the correct concentration of water and enzymatic cleaning solution had been used. *Would have expected the provider to monitor the temperature of the water containing the enzymatic if the manufacture's IFU required it. -Agreed the temperature was not monitored in the decontamination sink and should have been. *Inspected surgical instruments weekly to ensure proper packaging. *Would have expected surgical instruments containing rust to have been recleaned and not used on patients because of the risk of infection. *Stated, "I would like to see the tape gone and it will be gone." *Stated the pass-through window should have been closed. 7. Interview on 7/30/24 at 4:22 p.m. with CST A revealed she: *Inspected all surgical instruments during the washing, packaging, and sterilization process. *Inspected the tape to ensure it was free of rips, tears, or grooves. *Expected rusted surgical instruments to have been put aside or disposed of and not been used on patients. 8. Interview on 7/31/24 at 10:15 a.m. with office manager E revealed: *The provider followed the Association for the Professional in Infection Control and Epidemiology (APIC) and AORN to guide their practices. *She was unfamiliar with AAMI standards. *She would have expected surgical instruments with rust	Q0241		

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Q0241	Continued from page 5 to have been replaced. *She would have expected surgical instruments with tape in poor condition to have been replaced per manufacturer's IFU. 9. Review of the provider's 2/5/24 Instrument Decontamination and Reprocessing policy revealed: *"ASP ENZOL: Add one ounce (1 pump) per gallon of water. *A minimum soak of 1 minute is recommended. *Mechanically clean items with brushes or soft clothes. *Visually inspect wrapped items as they are removed for the autoclave. Items that are wet, torn or compressed should not be used. *Do not use items that have become wet, damaged or opened." *The provider's policy had not addressed the temperature range for the enzymatic cleaning solution. 10. Review of the manufacturer's revised 12/21 McKesson Multi-Enzymatic cleanser directions for use revealed: *Staff were to use one-half to one ounce of McKesson Multi-Enzymatic cleanser per one gallon water. *It recommend a solution temperature range between 68-122 degrees Fahrenheit (F) to be used. *A minimum soak time of 2 minutes was recommended. 11. Review of the manufacture's revised 2024 Key Surgical Identification Tape IFU revealed: *"Wrap tape 1.5 times on a stainless-steel instrument. Tape should lay flat without gaps. *Inspect tape prior to each use. Identification tape is not intended as a permanent mark and will discolor, break, chip, or flake over time. *Replace as soon as these are noticed." 12. Review of AAMI national guidelines ST 79: 2017 page 40 revealed: *"Instruments should be carefully inspected for flaws, damage, debris, detergent residue, and completeness,	Q0241		

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Q0241	Continued from page 6 then dried. *Instrument tape and plastic dipping material, when used properly, are ways of identifying specific instruments. *These types of marking products wear out over time and staff need to inspect them each time the instrument is processed, check them for wear according to the IFU of the product used, and replace them as often as needed."	Q0241		

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	43C0001029	A. BUILDING B. WING	09/04/2024

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Q0000	INITIAL COMMENTS An onsite revisit survey was conducted on 9/4/24 for compliance with 42 CFR Part 416, Subpart C; requirements for Ambulatory Surgery Centers (ASC) for all previous deficiencies cited on 7/31/24. All deficiencies have been corrected and no new non-compliance was found. Rivers Edge Aesthetic Surgery was found in compliance with all regulations surveyed.	Q0000		

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