STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTIONS	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 15C0001019	(X2) MULTIPLE CONSTRUCTION A. BUILDING B. WING	(X3) DATE SURVEY COMPLETED 07/16/2024

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
INDIANA HAND TO SHOULDER BELTWAY SURGERY CENTER	8501 HARCOURT RD , INDIANAPOLIS, Indiana, 46260

(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 This visit was for an investigation of a Federal Licensure Ambulatory Surgery Center complaint. Complaint number: 107776 - Deficiency related to allegations cited at Q0242 and Q0244. Survey date: 07/16/2024 Facility ID: 15C0001019 QA: 7/25/2024	Q0000		
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 document review and interview, the facility failed to ensure that surgical instruments were cleaned properly prior to use for 11 of 11 incident reports reviewed. Findings include: a. Facility policy titled, “Instrument Sterilization Process”, publication date 09/29/2023, under V. Policy Statements, B. Prior to sterilization, each item must be thoroughly cleaned by methods which meet the manufactures’ recommended standards; under VI. Procedures, B. Thorough cleaning of all items intended for sterilization is required. b. Review of Incident Reports from 03/27/2024 through 05/14/2024 indicated issues with sterilized surgical instruments. Incident reports indicated the following:	Q0242		

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

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Q0242	Continued from page 1 IR: 00241035, 03/27/24 indicated bone found in rongeur, it was removed from sterile field, sent for processing, and MD aware. IR: 00231672, 04/01/24 indicated after set-up was completed the tip of the bipolar was noted for having bioburden inside. IR: 00231674, 04/01/24 indicated bone was discovered sitting on top of heavy needle holder. IR: 00231936, 04/03/24 indicated a drill bit had bioburden left on it while pulling instruments out from Acutrak 2 tray. The bit did not come in contact with the patient, it was removed from the field. IR: 00233141, 04/11/24 indicated bioburden and kwire found in wrapped equipment before use on patient. IR: 00233142, 04/11/24 indicated pin collett and kwire driver handle left attached, not taken apart, and processed together. Power set not taken apart per procedure, not checked prior to wrapping for processing, and then the tray was wrapped. IR: 00233561, 04/15/24 indicated operating room (OR) set was being counted and water droplets noted on the bottom layer on the osteotomes under the mallet. Verified with 2 staff in the room water is present. Rigid bottom dry. A new set-up took place. IR: 00235110, 04/24/24 indicated while setting up OR, it was discovered that a set of hemostats had bioburden left in ridges. They did not come in contact with any other instruments, they were removed from the field. IR: 00236832, 05/06/24 indicated bioburden discovered on instrument prior to start of case. Contaminated tray removed and new tray placed. IR: 00236834, 05/06/24 indicated while surgeon was operating drill bit to insert kwire, debris from collet of drill fell into open wound of patient. Precautions taken; entire drill set removed from sterile field. Betadine wash applied to open wound. A new drill set opened and placed in the field for use. IR: 00238174, 05/14/24 indicated osteotomes were wet in sterilized tray. It was identified before the patient was in the OR, removed from the field, and a new set obtained before the start of surgery.	Q0242		

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Q0242	Continued from page 2 c. Interview with A1, Clinical Manager, on 07/16/2024 at approximately 2:00 pm, confirmed the above incident reports were related to sterilization of surgical instruments.	Q0242		
Q0244	INFECTION CONTROL PROGRAM - QAPI CFR(s): 416.51(b)(2) [The program is -] An integral part of the ASC's quality assessment and performance improvement program This STANDARD is NOT MET as evidenced by: Based on document review and interview, the facility lacked documentation of the Process Improvement Plan related to issues with surgical instrument sterilization and failed to report incidents to Quality Assurance and Performance Improvement (QAPI) Committee and Infection Control Committee for review in Quarter 4 of 2023 and Quarter 1 of 2024. Findings include: a. Facility policy titled, “Quality Management/Improvement Program”, Publication Date: 03/31/2024, under V. Policy Statements, A. The Quality Management/Performance Improvement Program applies to areas of operation within the ASC. It addresses clinical, administrative, cost-of-care performance issues and actual patient outcomes, such as results of care and patient safety. The program may include the following activities: 15. Quality Studies, using the 10-step process.; under V. Policy Statements, B. 4. Implementation of corrective actions when problems or opportunities for improvement are identified.; under VI. Procedures, A. Board of Managers, 1. Quality Committee and Operations Team, c. Ensures medical staff leadership and involvement in quality improvement initiatives; and 5. Monitoring Corrective Actions and Process Improvement, a. Appropriate reports, minutes, graphs, etc. shall be shared and reviewed by facility staff, medical staff, administration, and the Board of Managers. Facility failed to review issues with sterile processing of surgical instruments during it's QAPI (Quality Assurance and Performance Improvement) meeting. b. Interview with A5, Medical Doctor/Medical Director, on 07/16/2024 at approximately 3:35 pm, confirmed they were not aware of any issues or incident reports	Q0244		

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Q0244	Continued from page 3 related to issues with sterile processing of surgical instruments. They indicated these issues should have been discussed in the Quality Assurance and Performance Improvement (QAPI) committee meeting and then taken to the Board of Managers (BOM) meeting for further discussion and review. c. Interview with A1, Clinical Manager, on 07/16/2024 at approximately 4:10 pm, confirmed the following: 1. Facility failed to document their Process/Improvement Plan and the current 10 Step Studies related to recent surgical instrument issues. 2. Failed to document coaching and/or disciplinary action of A4, Central Service Technician, A6, Certified Registered Central Service Technician, and A7, Certified Registered Central Service Technician, related to surgical instrument issues identified. 3. Failed to report incidents to QAPI committee and Infection Control committee related to surgical instrument contamination.	Q0244		