Lateral Patient Positioning System
INSTRUCTIONS FOR USE

GENERAL INFORMATION:
The Lateral Patient Positioning System is inclusive of the LTP Positioner and is composed of urethane coated fabric, vinyl, polyurethane, nylon, synthetic rubber, thermoplastics, stainless steel, and aluminum. The device is to be used by trained personnel only and is suitable for use by healthcare professionals in hospital and healthcare settings.

The Lateral Patient Positioning System is compatible with Jackson Table™ Systems designed for spine surgeries such as the Mizhuo OSi TRIOS® and Allen® Jackson Frames with a maximum patient weight limit of 650 pounds (295 kg). Jackson tables include carbon-fiber frames and padding with no central table support which allows the table to rotate through 180 degrees. These devices should be used according to the manufacturer's directions and at the direction of the attending physician.

The provided pads must be used with covers or draping that provide a layer of isolation from the device and protection from fluids. The covers should be disposable and composed of non-toxic and non-allergenic materials (such as a polyester, polypropylene, and/or polyethylene) that are suitable for contact with intact skin.

The application techniques outlined in these instructions are the manufacturer's suggested techniques. The final disposition of each patient's care as related to the use of this equipment rests with the attending surgeon.

INTENDED USE:
The Lateral Patient Position Supports are devices intended to maintain the position of an anesthetized patient during surgery on a fixed or mobile surgical table within operating room environments of hospitals and surgical centers.

WARNINGS:
1. Do not use alkaline, acid, or household detergents.
2. Do not pour any liquid directly onto the supports.
3. Do not subject the components to an equipment washing machine.
4. Proper preoperative and intraoperative procedures must be followed to prevent venous stasis and pooling, pressure sore development, neuropathy, improper electrosurgical tissue grounding, hypotension and hyperthermia.

MRI SAFETY INFORMATION:
The Lateral Patient Position Supports are considered 'MR Unsafe'.

'MR Unsafe' items pose unacceptable risks to patient, medical staff, or other persons within the MR environment

PREOPERATIVE MANAGEMENT:

1. Preoperative assessment should include a description of the patient's overall skin condition and identification of patients at risk for pressure ulcers with documentation as needed for continuity from arrival and discharge.
2. PN: 181-717 is “Not made with natural rubber latex”.

INTRAOPERATIVE MANAGEMENT:

1. As outlined in the AORN Recommended Practices for Positioning a Patient in the Perioperative Setting, following the positioning of the patient, an assessment of the patient’s alignment, tissue perfusion, and skin integrity should be completed. All contact points of the patient with the table pads, head and arm support should be monitored during the procedure.
2. Thoracic Positioner to be placed with the Thoracic Anterior Paddle above the breasts on females.
3. Pelvic Positioner to be placed with the patient’s greater trochanter in line with bed rail marking.
4. When using the Paddle, Arm Support (PN: 180-500 & 181-500), do not fully break the Thoracic Bolster.
5. Confirm Pelvic Strap is sufficiently caudal such that it does not obstruct the lateral ALIF access.
6. Confirm all pads are draped with pad covers prior to patient loading.
7. Reassess the patient's body alignment, placement of the safety strap(s), and the placement of all padding after repositioning or any movement of the patient, procedure bed, or any equipment that attaches to the procedure bed to reduce the risk of pressure injury and tissue shearing.
8. Do not translate the patient while an access system is in contact with the patient.

POSTOPERATIVE MANAGEMENT:

1. Postoperative assessment should include a description for injury related to position.

CLEANING, DISINFECTING, AND MAINTENANCE:

Thoroughly clean the support pads with standard disinfectant/decontaminant cleaner (such as CaviCide®) or pre-saturated disposable wipes (such as CaviWipes™ and CaviWipes™ XL) labeled for use in hospitals and health care setting for non-porous surfaces including hospital beds, bed railing, and tables. Always apply cleaner and follow contact times per the manufacturer’s EPA labeling and instructions/directions for use. Wipe dry with a lint-free cloth or towel. DO NOT soak or autoclave the pads.

ATEC performs regular preventive maintenance prior to shipping products to the surgical location. If an item is damaged and/or worn out, parts can be replaced by returning them to ATEC. Please contact Customer Service at Alphatec Spine, Inc. +1 (800) 922-1356 or 760-431-9286 to order replacement parts.

UDI CONSTRUCTION

To compile a unique device identifier (UDI) for reusable, reprocessed devices, the device identifier (GTIN) may be ascertained by searching for the part number in the FDA GUDID at https://accessgudid.nlm.nih.gov/. The production identifier(s) (e.g., lot number, serial number) may be found directly marked on the device.

COMPLAINT HANDLING / REPORTING:

All product complaints relating to safety, efficacy or performance of the product should be reported immediately to Alphatec Spine by telephone, or letter, per contact information below. All complaints should be accompanied by name, part number, and lot numbers. The person formulating the complaint should provide their name, address, and as many details as possible. You may contact Customer Service directly at customerservice@atecspine.com.

For Surgical Technique Guides or additional information regarding the products, please contact your local representative or Alphatec Spine, Inc. Customer Service directly at customerservice@atecspine.com.

CAUTION: Federal law (USA) restricts these devices to sale by or on the order of a physician.

For a listing of Symbols and Explanations, see **atecspine.com/eifu**

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