Pediatric Patient Positioner
INSTRUCTIONS FOR USE

GENERAL INFORMATION:
The Pediatric Patient Positioner is composed of acetal homopolymer (delrin), polyethylene, urethane coated fabric, vinyl, polyurethane, nylon, synthetic rubber, thermoplastics, stainless steel, steel, PPSU (Radel), 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 Pediatric Patient Positioner is compatible with Jackson Table™ Systems designed for spine surgeries such as the Mizhuo OSi TRIOS® and Allen® Jackson Frames. 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 Pediatric Patient Positioner has a maximum weight limit of 400 pounds (181 kg).

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.

Although the Pediatric Patient Positioner is optimized for pediatric patients, the positioner may be used for adult patients at the surgeon's discretion. 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 Pediatric Patient Positioner 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/CAUTIONS/PRECAUTIONS:
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 Pediatric Patient Positioner 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.

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. Confirm all pads are draped with pad covers prior to patient loading.
3. 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.
4. 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, DISINFECTION, AND MAINTENANCE (POSITIONER AND COMPONENTS):

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.

REPROCESSING OF REUSABLE INSTRUMENTS (LATERAL PUSH ARM & T-HANDLE – PN: 551-400 & 551-160):

General Information for all Instruments:

- **Point-of-Use Processing:** To facilitate cleaning, instruments should be cleaned initially directly after use in order to facilitate more effective subsequent cleaning steps. Place instruments in a tray and cover with a wet towel to prevent drying.
- The cleaning process is the first step in effectively reprocessing reusable instruments. Adequate sterilization depends on thoroughness of cleaning. All reusable instruments that have been taken into a sterile surgical field must be decontaminated and cleaned using established hospital methods before sterilization and reintroduction into the sterile surgical field.
- The cleaning and sterilization processes in this IFU have been validated and demonstrate that soil and contaminants have been removed leaving the devices effectively free of viable microorganisms.

- It is recommended that all new relevant clinical practice guidelines be followed as per the CDC guidance, “Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008.”
- It is recommended to rinse the device components with water that meets specifications for *AAMI TIR34 “Water for the reprocessing of medical devices, 2014”* for example, DI/RO water.
- The validated cleaning and sterilization reprocessing steps provided in these instructions are considered recommended guidelines. The user is ultimately responsible for verifying adequate cleanliness of the devices. Any reprocessing methods used aside from those recommended for Alphatec Spine devices should be validated by the user prior to implementation.
- Equipment, materials, and personnel differ between hospitals; therefore, validation and routine monitoring of the process are normally required at a reprocessing facility.

Instrument Preparation and Disassembly:

- Cleaning, inspection, and sterilization must be performed by hospital personnel trained in the general procedures involving contaminant removal.
- Instruments must be cleaned prior to sterilization.

Cleaning of Instruments, Containers, and Trays:

- Instruments provided in a set must be removed from the set and cleaned prior to sterilization. Instrument trays, containers, and lids must be thoroughly cleaned separately until visually clean.
- Cleaning, maintenance, and mechanical inspection must be performed by hospital personnel trained in the general procedures involving contaminant removal.
- Visually inspect each instrument for deterioration such as corrosion and worn components; ensure that the laser markings are legible and verify that all actuating parts move freely. Visual inspection must be performed at each cleaning to determine if an instrument is acceptable for use. If an instrument is not acceptable for use, return to the manufacturer.
- Clean the instruments, trays and inserts using only recommended cleaning solutions. Use of caustic solutions (caustic soda) will damage the instruments.
- All solutions for cleaning must be prepared per the manufacturer’s instructions.
- Use of water with high mineral content should be avoided.
- Complex instruments, such as those with, cannulas, hinges, retractable features, mated surfaces, and textured surface finishes, require special attention during cleaning. Brush tight tolerance areas with an appropriately sized brush and flush using a water jet or syringe where debris could become trapped.
- Ensure instruments are in the fully extended, open position throughout cleaning. Disconnect Quick Connect handles/knobs from the shafted instruments prior to cleaning.
- Ensure all moving parts of instruments are cleaned at both extents of travel. Handle all products with care. Mishandling may lead to damage and possible improper function.

Visually inspect the instrument after each cleaning step to ensure the instrument is clean. If not clean, repeat the step until clean.

Manual Cleaning Steps for Instruments (Required)

Step 1	Rinse devices in ambient temperature tap water to remove visible soil.
Step 2	Prepare enzymatic solution, such as *Prolystica® 2X Concentrate Enzymatic Presoak & Cleaner* or equivalent, per manufacturer’s recommendations and submerge device

	in enzyme solution. Actuate the device while it is submerged and soak for a minimum of 10 minutes.
Step 3	Actuate and scrub the device using an appropriately sized soft bristled brush, such as a *Spectrum Surgical code #M-16* or 45-542 (or equivalent), to brush any lumens for a minimum of 2 minutes. If needed, actuate at several locations to access all surfaces. Use of a syringe (minimum of 50 ml) or water jet is recommended for the hard to reach areas and repeat 3 times.
Step 4	Rinse devices in Deionized / Reverse Osmosis (DI/RO) water for a minimum of 1 minute.
Step 5	Prepare cleaning solution, such as *Prolystica® 2X Concentrate Alkaline Detergent,* per manufacturer's recommendations and submerge and actuate devices in cleaning solution and sonicate for a minimum of 10 minutes.
Step 6	Thoroughly rinse devices with DI/RO water to remove all detergent residues.
Step 7	Dry devices with a clean, lint free cloth or filtered compressed air.

Automatic Washer Cleaning Steps for Instruments

Step 1	Complex instruments, such as those with cannulations, lumens, hinges, retractable features, mated surfaces, and textured surface finishes, require special attention during cleaning. Brush tight tolerance areas with an appropriately sized brush and flush using a water jet or syringe with ambient temperature tap water where debris could become trapped. Place them into the Washer/Disinfector and process through a standard surgical instrument cycle.
Step 2	Prewash with cold tap water for 2 minutes.
Step 3	Enzyme wash using cleaner such as *Prolystica® 2X Concentrate Enzymatic Presoak & Cleaner* or equivalent, per manufacturer's recommendations, hot tap water (66°C/150°F minimum), for a minimum of 1 minute.
Step 4	Detergent wash using detergent such as *Prolystica® 2X Concentrate Alkaline Detergent* or equivalent, per manufacturer's recommendations, hot tap water (66°C/150°F minimum), for a minimum 2 minutes.
Step 5	Rinse 2 times, hot tap water (66°C/150°F minimum), for a minimum 15 seconds.
Step 6	Purified water rinse, hot (66°C/150°F minimum), for a minimum 10 seconds.
Step 7	Hot air dry (115°C/239°F minimum), for a minimum of 10 minutes.

INSPECTION (LATERAL PUSH ARM & T-HANDLE – PN: 551-400 & 551-160):

- Inspect the Lateral Push Arm (PN: 551-400) and T-Handle (PN: 551-160), container, and tray to ensure that all visible contamination has been removed. If contamination is noted, repeat the cleaning/disinfection process.
- Check the action of moving parts (e.g., hinges, box-locks, connectors, sliding parts, etc.) to ensure smooth operation throughout the intended range of motion.
- Check long slender features of the Lateral Push Arm (PN: 551-400) and T-Handle (PN: 551-160) for distortion.
- Inspect the Lateral Push Arm (PN: 551-400) and T-Handle (PN: 551-160) for any other damage, wear, and/or corrosion.
- When necessary, dispose of products in accordance with national regulations and approved hospital practices for surgical instrument disposal.

STERILIZATION AND RESTERILIZATION (LATERAL PUSH ARM & T-HANDLE – PN: 551-400 & 551-160):

- The Lateral Push Arm (PN: 551-400) and T-Handle (PN: 551-160) are provided non-sterile and must be steam sterilized prior to use using validated cycle parameters in the table below. Each facility should ensure its processing system can effectively apply validated cycle parameters such that equivalent sterility assurance levels are achieved. It is the responsibility of the healthcare facility to qualify their sterilizers' maximum load capacity and determine what effect the loading pattern of the sterilizer has on the sterilization of the devices.
- Alphatec perforated trays have been validated to achieve a sterility assurance level (SAL) of 10^{-6} using sterilization accessories (containers and filters). Reusable or paper filters should be used to achieve and maintain sterility after processing.
- Alphatec perforated container/tray configurations have also been validated to a sterility assurance level (SAL) of 10^{-6} using sterilization wraps. Perforated container/tray configurations must be double wrapped to allow steam to penetrate and make direct contact with all surfaces.
- Do not stack trays during sterilization.
- Sets have been validated in standard configurations. No additional items should be added to the set for sterilization.
- Certain devices are packaged non-sterile as a single device to be steam sterilized by the end user. Without stacking, place the device in a container basket or use hospital-provided sterilizers and accessories (e.g., sterilization wraps, sterilization pouches, sterilization trays). Confirm the container basket or sterilizer/accessories are acceptable for use with the ATEC device by referring to the specifications outlined in basket/sterilizer/accessory instructions for use. Verify sterilization can be achieved following the recommended sterilization cycle specifications (time and temperature).
- It is the end user's responsibility to use only sterilizers and accessories (such as sterilization wraps, sterilization pouches, chemical indicators, biological indicators, and sterilization cassettes) that have been approved for the selected sterilization cycle specifications (time and temperature). Recommended sterilization parameters are provided below.

Sterilization Parameters

Set Type	Cycle Type	Temperature	Exposure Time	Minimum Drying Time	Minimum Cool Down Time
Instrument Only Set	Pre-vacuum	132°C (270°F)	4 Minutes	45 Minutes	75 Minutes

Sterilization Notes:

- These parameters are consistent with the appropriate version of ANSI/AAMI ST79 "Comprehensive guide to steam sterilization and sterility assurance in health care facilities."

RETURNING INSTRUMENTS TO ALPHATEC SPINE:

All used products returning to Alphatec Spine must undergo all steps of cleaning, inspection, and terminal sterilization before being returned to Alphatec Spine. Documentation of decontamination should be included.

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, e-mail, 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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