VALENCE® ROBOTIC NAVIGATION SYSTEM
INSTRUCTIONS FOR USE

GENERAL INFORMATION:
The Valence Robotic Navigation System is designed to assist surgeons in navigated and robotic assisted procedures. It is validated for placing pedicle screws in the thoracolumbar and sacropelvic spine for (T1-ilium) and placement of interbody devices from T12/L1 through L5/S1.

The system uses optical instrument tracking and registration to an intraoperative 3D scan to navigate patient anatomy across three independent workflows:

- Robotic assisted screw navigation
- Freehand screw navigation
- Freehand disc prep and interbody implant navigation

The system includes:
- A computer workstation with integrated navigation software
- A robotic targeting platform
- A control unit for manual and automatic positioning of the targeting platform
- An optical tracking camera
- Positioning arms and sterile/ non-sterile accessories

The Valence Robotic Navigation System is installed by qualified ATEC personnel only. If you have any questions about your system installation, contact ATEC (see contact information section). There are no recommended settings or configurations for the system interface except the input/output connections described in the Valence Robotic Navigation System Operator Manual LIT-85806.

The intended users for the Valence Robotic Navigation System are the operating room staff during the procedure (including spine surgeons, nurses, and clinical support specialists). The users should be familiar with the clinical procedure. The Valence Robotic Navigation System should be used only by qualified medical professionals who are trained in use of the system.

Select Valence Robotic Navigation Instruments are compatible with Medtronic StealthStation Navigation System. Refer to INS-188 for Instructions for Use related to the StealthStation compatible instruments.

The Valence Robotic Navigation System is also compatible with the De Soutter Medical Osteodrive Power Console (Refer to De Soutter Medical 2467EN_GB), De Soutter Medical Osteodrive Foot Pedal (Refer to De Soutter Medical IFU-TF007-1EN_GB), and Zethon hekaDrill (refer to Zethon IFU TF006-1EN_GB).

INDICATIONS FOR USE:
Valence Robotic Navigation System is indicated for use as an aid for precisely locating anatomical structures and for the spatial positioning and orientation of a tool holder or guide tube to be used by surgeons for navigating and/or guiding compatible surgical instruments in open or percutaneous spinal procedures in reference to rigid patient anatomy and fiducials that can be identified on a 3D imaging scan.

The Valence Robotic Navigation System is indicated for assisting surgeons in spinal procedures, such as:

- Pedicle screw placement
- Interbody device placement

CONTRAINDICATIONS:

The Valence Robotic Navigation System is contraindicated for:

- Use in patients with medical conditions that contraindicate spinal surgery.
- Use with surgical tables other than the Allen Advance, Jackson Table, or equivalent tables when the robotic targeting platform is in use.

WARNINGS/CAUTIONS/PRECAUTIONS:

⚠ WARNING: Risk of patient injury and/or increased surgical time. Ensure each instrument is carefully inspected for signs of wear, bending and visible damage, in particular when verification is not performed.

⚠ WARNING: Risk of increased surgical time. Handle the equipment with care to prevent severe or functional damage to the system.

⚠ WARNING: Risk of patient safety and/or system interference with intra-op steps or prevents usage of intraop steps. The network connections between system elements must ONLY be established directly, without use of any hub, switch, router, or equivalent device, to avoid any impact on performance.

⚠ WARNING: Risk of patient injury and/or new risk analysis required. Do not connect to a non-approved IT network or changing the IT network. The system must only be connected to a compatible 3D imaging system. Log files within the system will be maintained to verify proper setup. The responsibility for the identification, analysis, evaluation, and control of risks associated with connecting the system to a non-approved IT network resides with the individuals performing the connection.

⚠ WARNING: Risk of patient safety and/or system vulnerabilities. Ensure that the hospital network is secure and has the necessary firewalls to prevent unauthorized access.

⚠ WARNING: Risk of patient injury. Ensure the Positioning Arms and Targeting Platform are securely connected and can withstand procedural forces to prevent slippage or instability.

⚠ WARNING: Risk of patient injury and/or increased surgical time. Always consult the Computer Workstation display for current trajectory alignment information. External monitors are for reference only.

⚠ WARNING: Risk of patient injury and/or increased surgical time. If the system appears inaccurate, abort the use of the system.

⚠ WARNING: Risk of patient injury and/or increased surgical time. Do NOT allow collisions between the Guide Tube Assembly and the patient anatomy.

⚠ WARNING: Risk of patient injury. Do NOT leave instruments in the Guide Tube or touching patient anatomy while making automatic or manual movements of the Targeting Platform.

⚠ WARNING: Risk of patient injury and/or increased surgical time. Do NOT use instruments, interfacing devices, or sterile drapes that are not indicated for use with the system.

⚠ WARNING: Risk of patient injury. Patient anatomy may change during interbody placement. Check accuracy between interbody placements and if inaccurate take a new scan.

⚠ WARNING: Risk of delay of surgery and/or patient injury. Do NOT let the Registration Plate, Patient Array, Camera, or patient move during scan or registration process.

⚠ WARNING: Risk of patient injury. Ensure the patient array hardware does NOT move during the scan, registration, or intra-operatively relative to the patient anatomy. Confirm accuracy with anatomical landmark checks, direct visualization, and intraoperative fluoroscopy.

⚠ WARNING: Risk of patient injury and/or increased surgical time. Do NOT move patient or disrupt spinal anatomy during the procedure and confirm accuracy with anatomical landmark checks, direct visualization, and intraoperative fluoroscopy.

⚠ CAUTION: Risk of electric shock. All input/output cables must remain connected and the protective cover for the computer input/output panel must always remain secured in place.

⚠ CAUTION: Risk of increased surgical time. Do NOT connect other non-compatible imaging devices, the hospital PACS, or other network devices. Only connect the 3D imaging system to the isolated network receptacle on the back of the System Cart.

⚠ CAUTION: Risk of electric shock. Do NOT connect other medical devices or non-medical device technologies to unused electronic interfaces found on the device. These interfaces are reserved for ATEC service technicians for maintenance purposes.

⚠ CAUTION: Risk of electric shock. The Valence Robotic Navigation System is not drip or splash proof (ingress level IPX0). The Power and Network Unit, Control Unit, and Strain Relief box are rated for limited protection against dust and protection against water spray from any direction (IP54). The Targeting Platform is only rated for indicating protection against solid objects larger than 12.5 mm and no protection against water (IP20).

⚠ CAUTION: Risk of electric shock. The camera is designed for medium to long-term contact with the patient but is NOT intended for direct cardiac contact (Type BF per IEC 60601-1).

⚠ CAUTION: Risk of electric shock. The Targeting Platform is intended for direct contact with the patient which includes patient connections that are isolated from other parts of the ME Equipment (Class CF).

⚠ CAUTION: Risk of electric shock or burn. The Valence cart should be powered in a standalone isolated ground outlet connected to protective earth labeled "MEDICAL GRADE" or "HOSPITAL GRADE". Do NOT use power strips or extension cords.

⚠ CAUTION: Risk of increased surgical time. Keep ball joints of the Ratcheting Arm clean to prevent seizing of joints.

⚠ CAUTION: Risk of increased surgical time and/or improper system function. Do NOT use the Targeting Platform with a broken housing or broken cover tape.

⚠ CAUTION: Risk of infection. Do NOT drape a Targeting Platform with broken housing or covers.

⚠ CAUTION: Risk of infection. Do NOT exceed the sterile drape coverage area with range of motion for the Targeting Platform.

⚠ CAUTION: Risk of increased surgical time. Transport and store the system per the IFU.

⚠ CAUTION: Risk of increased surgical time. Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30cm to any part of the system, including cables specified by the manufacturer.

⚠ CAUTION: Risk of increased surgical time. The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required), this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or reorienting the equipment.

⚠ CAUTION: Risk of system failure and/or increased surgical time. Do NOT stack equipment. If equipment is stacked, verify equipment is operating normally.

- ⚠ CAUTION: Risk of increased surgical time. Ensure proper gross positioning of the Targeting Platform at the beginning of the surgical procedure to be able to align with the active surgical plan.
- ⚠ CAUTION: Risk of increased surgical time. Do NOT allow collisions between the Targeting Platform cables, and the Positioning Arm. Collisions may inhibit the Targeting Platform from achieving the desired surgical plan.
- ⚠ CAUTION: Risk of increased surgical time. Hold the move enable button for the complete course of movement, once released movements are canceled.
- ⚠ CAUTION: Risk of patient injury. The SingleStep stylet is NOT navigated, therefore the stylet is NOT visually represented.
- ⚠ CAUTION: Risk of patient injury due to improper system operation because of increased electromagnetic emissions or decreased electromagnetic immunity. Only use equipment specified by the manufacturer.
- ⚠ CAUTION: Risk of infection. Only use drapes as described in the OPM and IFU.
- ⚠ CAUTION: Risk of increased surgical time. Do NOT use the equipment if it is damaged or the system components are beyond their useful life of 5 years.
- ⚠ CAUTION: Risk of electrical shock or thermal injuries. Beware of risks when using high frequency (HF) electrosurgery devices under 6kv (peak-to-peak), such as monopolar or bipolar needles or forceps, together with the system. Do NOT use HF electrosurgery devices with maximum output voltages higher than 6 kV (peak-to-peak).
- ⚠ CAUTION: Risk of infection. The system, instruments and components designed for reuse are supplied non-sterile. Clean the system and components per the IFU and sterilize instruments before every use in accordance with the IFU.
- ⚠ CAUTION: Risk of electric shock. Do NOT plug in the power cord in such a way that makes it difficult to disconnect and protect the cable from potential damage.
- ⚠ CAUTION: Risk of electric shock. Do NOT use the equipment with power cords that are not supplied by ATEC.
- ⚠ CAUTION: Risk of thermal injury. Do NOT recharge or disassemble batteries that have been removed from the system.
- ⚠ CAUTION: Risk of increased surgical time. Do NOT allow the Registration Plate to contact the patient skin.
- ⚠ CAUTION: Risk of increased surgical time. Settings to configure the 3D imaging systems for image transfer should be defined based on the settings used by the hospital and only adjusted by the appropriate Radiology Tech or trained ATEC Personnel.
- ⚠ CAUTIION: Risk of increased surgical time. To ensure navigation orientation is correct, correctly enter the patient orientation into the connected imaging device.

MRI SAFETY INFORMATION

Valence Robotic Navigation System has not been evaluated for safety in the MR environment. It has not been tested for heating or unwanted movement in the MR environment. The safety of the Valence Robotic Navigation System in the MR environment is unknown. Do not bring the system into the MR scanner room or within the magnetic fringe field of MRI equipment.

PREOPERATIVE MANAGEMENT

Surgeons should have a complete understanding of the operator manual (LIT-85806), system indications, contraindications, warnings and precautions, safety information, as well as functions and limitations of the implants and instruments.

Careful preoperative planning should include construct strategy, pre-assembly of component parts (if required), and verification of required inventory for the case.
Prior to system use, the patient is brought into the OR, anesthetized, and positioned onto an Allen Advance, Jackson, or equivalent radiolucent OR table.

INTRAOPERATIVE MANAGEMENT

Follow directions for use outlined in Operator Manual (LIT-85806) for intraoperative management.

POSTOPERATIVE MANAGEMENT

- When use of the Targeting Platform and Camera is complete, remove drapes and cables to prepare the system components for cleaning and sterilization.
- Power off the Valence System by pressing and holding the power button on the Control Unit for 2 seconds.
- Clean the undraped Targeting Platform, Camera assembly and accessory equipment.
- Follow the instructions in the section “Reprocessing of Reusable Equipment.”
- Place the cleaned Targeting Platform, Strain Relief Box, Control Unit and Cable, Camera, Positioning Arms, Bed Rail Adapters, and all system cables securely in the drawers of the System Cart.
- Power down the system computer and disconnect the main power cable from the AC outlet. Inspect the cable for any potential damage. Also ensure to disconnect the Ethernet Cable from the 3D imaging system if not previously done.
- Remove the PSIS Pin or Spinous Process Clamp from the patient.
- Disconnect and remove the Targeting Platform and Camera assemblies from the Positioning Arms.
- Remove the High-Speed Bur Console and Foot Pedal if used.

STERILIZATION AND RESTERILIZATION

REPROCESSING OF REUSABLE INSTRUMENTS

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.”*
- It is recommended to rinse the device components with water that meets specifications for *AAMI TIR34 “Water for the reprocessing of medical devices,”* 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.
- If any cement is in the Alignment Guides after cement delivery, use the Alignment Guide Cleaner to remove cement prior to cement setting.
- Certain instruments may be disassembled prior to cleaning per instructions provided below**:**
  1. ***LIF Inserter:*** Press the button at the distal end of the inserter body handle to detach the sleeve from the inserter assembly.

  2. ***PO Inserter :*** Press the rectangular button at the distal end of the inserter body handle to detach the sleeve from the inserter assembly.

  3. ***Shankdriver:*** To disassemble the Shankdriver, press the clean button on the proximal end of the sleeve and remove the inner shaft.

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 unacceptable deterioration such as corrosion, discoloration, pitting, cracked seals, 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

Step 1	Rinse devices in ambient temperature tap water to remove visible soil.
Step 2	Prepare enzymatic solution 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 to brush any lumens for a minimum of 2 minutes. If present, actuate at actuating 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. If needed, actuate at actuating locations to access all surfaces. Use a syringe (minimum of 50 ml) or water jet to flush hard-to-reach areas (e.g., lumens) from each end of the devices. Ensure to flush out lumens, blind holes, cracks, or cavities while rinsing.
Step 5	Prepare pH neutral or alkaline cleaning solution 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. If present, actuate at actuating locations to access all surfaces. Use a syringe (minimum of 50 ml) or water jet to flush hard-to-reach areas (e.g., lumens) from each end of the devices and repeat 3 times. Ensure to flush out lumens, blind holes, cracks, or cavities while rinsing.
Step 7	Dry devices with a clean, lint free cloth or filtered compressed air.

Automatic Washer Cleaning Steps for Instruments

It is recommended based on validations to conduct all manual cleaning steps before automated cleaning steps when using alkaline detergent.

Step 1	Rinse devices in ambient temperature tap water to remove visible soil.
Step 2	Prepare enzymatic solution 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 to brush any lumens for a minimum of 2 minutes. If present, actuate at actuating 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. If needed, actuate at actuating locations to access all surfaces. Use a syringe (minimum of 50 ml) or water jet to flush hard-to-reach areas (e.g., lumens) from each

	end of the devices and repeat 3 times. Ensure to flush out lumens, blind holes, cracks, or cavities while rinsing.
Step 5	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 6	Prewash with cold tap water for 2 minutes.
Step 7	Enzyme wash using cleaner per manufacturer's recommendations, hot tap water (66°C/150°F minimum), for a minimum of 1 minute.
Step 8	Detergent wash using pH neutral or alkaline detergent per manufacturer's recommendations, hot tap water (66°C/150°F minimum), for a minimum 2 minutes.
Step 9	Rinse 2 times, hot tap water (66°C/150°F minimum), for a minimum 2 minutes.
Step 10	Purified water rinse, hot (66°C/150°F minimum), for a minimum 2 minutes.
Step 11	Hot air dry (115°C/239°F minimum), for a minimum of 10 minutes.
Step 12	Dry devices with a clean, lint free cloth or filtered compressed air.

INSPECTION:

- Inspect each instrument, 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 instruments with long slender features (particularly rotating instruments) for distortion.
- Drill bits, reamers, rasps, and other cutting instruments should be inspected after processing.
- Cutting instruments should be inspected after processing with alkaline detergents.
- Visually inspect for unacceptable deterioration such as corrosion, discoloration, pitting, cracked seals, and worn components,
- Ensure that the laser markings are legible and verify that all actuating parts move freely.
- When necessary, dispose of products in accordance with national regulations and approved hospital practices for surgical instrument disposal.
- Check instruments with long slender features (particularly rotating instruments) for distortion.
- Inspect instruments for any other damage, wear, and/or corrosion.

STERILIZATION AND RESTERILIZATION:

- All instruments are provided non-sterile and must be steam sterilized prior to use using validated cycle parameters in the tables 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 FDA cleared sterilization accessories (containers and filters). FDA cleared 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 FDA cleared sterilization wrap. 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.
- Instrument 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 FDA-cleared 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 cleared by the FDA 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."*

Cleaning, Disinfection and Inspection of Reusable Valence System Accessories and Components (Non-Instrument Items)

General Procedure

- Do not allow fluid to enter any system enclosure. Do not spray liquids directly on the system. This can lead to equipment damage. Disconnect from power and allow the system to dry if you suspect fluids may have entered any part of the unit.
- Power down and unplug the system before performing cleaning or disinfection procedures.
- Refer to the table below for compatible disinfectants and recommended chemistries. If a premoistened wipe is not available, use a clean wipe and moisten with the disinfectant.

Do not over-saturate the wipe so much that liquid can enter openings in the parts to be cleaned.

- Wipe the external surfaces with a clean wipe moistened with water or 70% isopropyl alcohol to remove disinfectant residue on the system components. This will help maintain the appearance of the system components.

Disinfectant type	Disinfectant level
Quaternary ammonium germicidal detergent solution	Low level
Isopropyl alcohol (70%)	Low level
Phenolic germicidal detergent solution	Low level
Sodium hypochlorite (5.25% to 6.15%)	Low level

Cleaning of Valence Robotic Navigation System Compatible High Speed Drill(s) and Components

The manual and automatic cleaning for the following instruments are found below:

Part Number	Description	Instructions for Cleaning
525-1060	Valence High Speed Drill	IFU-TF006-1EN_GB for Manual and Automated Cleaning.
103394	S-C15 - 150mm Straight Attachment (2.38mm)	
104569	S-D31 - 310mm Straight Attachment (3.18mm)	
104611	S-D31S - 310mm Straight Attachment-Slimline (3.18mm)	
18050	PC-470 Power Console - Basic	2467EN_GB for Manual Cleaning
18580	FS-270 Foot Pedal - Corded	IFU-TF007-1EN_GB for Manual Cleaning

Cleaning the Targeting Platform, Control Unit, Strain Relief Box, and Camera

Limitations on Reprocessing	Repeated reprocessing has minimal effect on these devices. End of life is normally determined by wear and damage due to use.
INSTRUCTIONS	
Point of Use	Remove excess soil with disposable cloth or paper wipe.
Preparation for Cleaning	Power down, unplug the system, and remove sterile drapes before performing cleaning or disinfection procedures.
Automated Cleaning	Not applicable. Manual cleaning only.

Manual Cleaning	Unmount the Targeting Platform and the Camera from the respective Positioning Arms. Wipe and clean the exterior surfaces of the Targeting Platform, Control Unit, Strain Relief Box, Power and Network Unit, and Camera with a moistened low-level disinfectant wipe with water or 70% isopropyl alcohol to remove disinfectant residue per the manufacturer's instructions. Do not damage the blue tape that seals the opening of the Targeting Platform. If disinfection is desired, make sure that the surface to be disinfected remains in contact with the disinfectant for the specified contact time as directed by the disinfectant manufacturer. The contact time refers to the minimum amount of time the surface needs to remain visibly wet. Use additional wipes, if needed, to maintain continuous contact time with the disinfectant. Examine the surfaces for visible soil. If soil is present, repeat cleaning.
Drying	If necessary, dry the device with a clean, lint-free towel.
Maintenance Inspection Testing	Preventive maintenance is performed by authorized hospital or ATEC personnel only.
Sterilization	Not Applicable.
Storage	See label on the package for storage conditions.

Cleaning the Positioning Arms

- Make sure that the ball joints of the Ratcheting Arm are free from debris.
- Wipe and clean the exterior surfaces of the Positioning Arms with a moistened low-level disinfectant wipe per the wipe manufacturer's instructions.
- If disinfection is desired, make sure that the surface to be disinfected remains in contact with the disinfectant for the specified contact time as directed by the disinfectant manufacturer.
- The contact time refers to the minimum amount of time the surface needs to remain visibly wet.
- Use additional wipes, if needed, to maintain continuous contact time with the disinfectant.
- Examine the surfaces for visible soil. If soil is present, repeat cleaning.

- Wipe the external surfaces with a clean wipe moistened with water or 70% isopropyl alcohol to remove disinfectant residue.

Cleaning the Targeting Platform Cable Set, Control Unit Cable, Power and Network Cable

Limitations on Reprocessing	Repeated reprocessing has minimal effect on these cables. End of life is normally determined by wear and damage due to use.
INSTRUCTIONS	
Point of Use	Remove excess soil with disposable cloth or paper wipe.
Preparation for Cleaning	Power down and unplug the system before performing cleaning or disinfection procedures. Unplug external cables.
Automated Cleaning	Not applicable. Manual cleaning only.
Manual Cleaning	Clean the cable by wrapping a low-level disinfectant wipe completely around the cable starting at one connector. If disinfection is desired, make sure that the surface to be disinfected remains in contact with the disinfectant for the specified contact time as directed by the disinfectant manufacturer. The contact time refers to the minimum amount of time the surface needs to remain visibly wet. Use additional wipes, if needed, to maintain continuous contact time with the disinfectant. Examine the surfaces for visible soil. If soil is present, repeat cleaning. Wipe the external surfaces with a clean wipe moistened with water or 70% isopropyl alcohol to remove disinfectant residue.
Drying	If necessary, dry the cables with a clean, lint-free towel.
Maintenance Inspection Testing	Ensure cable pins are not obstructed by particles that can compromise a proper connection. Other preventive maintenance steps are performed by authorized personnel only.

Sterilization	Not applicable. If necessary, dry the device with a clean, lint-free towel.

Cleaning the Main Power Cord

Limitations on Reprocessing	Repeated processing has minimal effect on this cable. End of life is normally determined by wear and damage due to use.
INSTRUCTIONS	
Point of Use	Remove excess soil with disposable cloth or paper wipe.
Preparation for Cleaning	Power down and unplug the system before performing cleaning or disinfection procedures.
Automated Cleaning	Not applicable. Manual cleaning only.
Manual Cleaning	Clean the power cable by wrapping a low-level disinfectant wipe completely around the cable. Wipe the cable from the plug end toward the back of the System Cart. Ensure contact with the plug, bend relief, and cable. Do not wipe the metal prongs on the plug. If disinfection is desired, make sure that the surface to be disinfected remains in contact with the disinfectant for the specified contact time as directed by the disinfectant manufacturer. The contact time refers to the minimum amount of time the surface needs to remain visibly wet. Use additional wipes, if needed, to maintain continuous contact time with the disinfectant. Examine the surfaces for visible soil. If soil is present, repeat cleaning. Wipe the external surfaces with a clean wipe moistened with water or 70% isopropyl alcohol to remove disinfectant residue.
Drying	If necessary, dry the cable with a clean, lint-free towel.

Maintenance Inspection Testing	Preventive maintenance is performed by authorized personnel only. Inspect the cable for any potential damage.
Sterilization	Not applicable. If necessary, dry the cable with a clean, lint-free towel.

MAINTENANCE

Corrective Maintenance

If the instructions in the Troubleshooting section do not solve the problem, contact ATEC for assistance. Technical service personnel will either assist to solve the problem immediately or inform you about the procedure for replacement of the affected component. No corrective maintenance will be provided during patient treatment.

Recommended Maintenance

The system and its associated components should be inspected and tested annually at a minimum. Inspection and testing should be completed by an authorized and trained service person.

Contact ATEC or train a human resource in your facility to schedule a maintenance and system check appointment.

Software Updates

Software updates and patches will be installed by qualified ATEC service technicians when required. For detailed instructions on security of the device, refer to Valence Operator Manual (LIT-85806).

Disposal

Do not dispose of the system or system components in the unsorted municipal waste stream. Observe local regulations concerning disposal of system components. Device decommissioning is performed by authorized ATEC personnel to ensure secure handling of the system. The device does not store any Protected Health Information (PHI) or Personally Identifiable Information (PII). For guidance on proper disposal or return of the device, please contact ATEC Technical Support.

RETURNING PRODUCTS TO ALPHATEC SPINE:

All used products returning to Alphatec Spine must undergo all steps of cleaning, disinfection, and inspection 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.

℞only 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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