ALPHATEC SPINE NAVIGATION INSTRUMENTS
INSTRUCTIONS FOR USE

GENERAL INFORMATION:
The Alphatec Spine Navigation Instruments are intended for use in surgical procedures. These instruments are non-sterile, re-usable instruments designed to function with the Medtronic® StealthStation® System and NavLock® Tracker. Refer to the Medtronic StealthStation System Manual and/or Navigation Operative Technique for additional details regarding system use.

The Alphatec Spine Navigation Instruments are for use with Alphatec Spine pedicle screw systems, specifically, the Arsenal® Spinal Fixation System, Illico® Posterior Spinal System, Invictus® Spinal Fixation System, and Invictus® OCT Spinal Fixation System. This supplemental Instructions for Use (IFU) contains only information regarding the Navigation Instruments. For pedicle screw system Contraindications, Warnings, Precautions, and Possible Adverse Effects, please refer to the appropriate Alphatec Spine System IFU.

INDICATIONS FOR USE:
Alphatec Spine Navigation Instruments are intended to be used during the preparation and placement of Alphatec screws during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open or minimally invasive procedures. Alphatec Spine Navigation Instruments are specifically designed for use with the Medtronic StealthStation System, which is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as a skull, along bone, or vertebra, can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks for the anatomy.

WARNINGS/CAUTIONS/PRECAUTIONS:
When using SingleStep™, the Stylet is not navigated (i.e., the Navlock tracker does not move with the stylet) but can be represented on the navigation screen with a projection line.

As the stylet is advanced or retracted with the adapter the user must adjust the projection length on the Stealthstation which will not be visible in real-time; however, the screw projection will be visible in real-time when advancing it using the proximal handle since the driver/screw are navigated (i.e., the Navlock tracker moves with the driver/screw and not stylet).

Alphatec Spine Navigation Instruments are provided non-sterile and must be cleaned and sterilized prior to surgery. Invictus OCT navigating drills are disposable devices, designed for single use and should not be reused or reprocessed. Reprocessing of single use instruments may lead to instrument damage and possible improper function.

CONTRAINDICATIONS:
There are no specific contraindications associated with the Alphatec Spine Navigation Instruments.

PREOPERATIVE/INTRAOPERATIVE MANAGEMENT:
1. Inspect all instruments before use. If visibly damaged, do not use the instrument.
2. The Alphatec Spine Navigation Instruments are designed to be used with the Navlock Instrument Set and StealthStation Spine Referencing Set. Other sets and disposables can be utilized at the discretion of the surgeon and should follow the manufacturer's instructions for use accordingly.

3. Instruments designed for use with the StealthStation System have a precise instrument geometry and LED/sphere configuration. The specific geometry of each instrument is stored in a file to which the computer refers to determine where the tip of the instrument is located in relation to the instrument LEDs or spheres. Before beginning navigation, the computer must be told which instrument has been chosen.
4. When selecting the instrument from the list in the application software, the system will expect verification that the chosen instrument is not bent or otherwise damaged. To do this, place the tip of the instrument into a metal divot on the reference frame (e.g., StealthAiR Spine Frame). The camera and computer will then confirm that the instrument in use matches the specifications for the instrument selected in the software.
5. Users must complete verification steps as required per the Medtronic StealthStation System Manual and/or Navigation Operative Technique.
6. To maintain accuracy, the system must continuously track the position of the anatomy during registration and navigation. This is necessary because anatomy or the localizer may accidentally or unavoidably be moved after patient registration or image acquisition. If the system did not track the position of the anatomy via the patient reference frame, any movement of the patient or localizer after registration or image acquisition would result in inaccurate navigation.
7. During surgery, the system tracks the position of specialized surgical instruments in or on the patient anatomy and continuously updates the instrument position on these images.
8. The system continuously re-computes the relative spatial positions of the patient reference frame and instrument in the navigation field and relates this information to the patient registration data in order to identify the location of the instrument on the operative images.
9. The user should assess, before the procedure and repeatedly throughout the procedure, the positioning of the tip of each Navigation instrument on an identifiable anatomical landmark and compare the actual tip location to that displayed by the system. When verifying the accuracy of the Navigation Drivers, the accuracy test should include the screw (of which diameter and length are selected/entered in the software) assembled securely onto the distal end of the driver using the tip of the screw on the selected landmark.
10. Surgical accuracy should be assessed repeatedly throughout a procedure when using a surgical navigation system by positioning the navigated instrument tip on an identifiable anatomical landmark and comparing the actual tip location to that displayed by the system.
11. In the event of a registration failure or suspected inaccuracy, the instrument should not be used with the Navigation System and the instrument should be inspected for damage before continuing with a replacement instrument or non-navigated procedure.

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, 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.
- Certain instruments may be disassembled prior to cleaning.

Shankdriver: To disassemble the Shankdriver for cleaning, press the proximal gold button and remove internal hexalobe shaft from the outer sleeve.

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

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 the lumen 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 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 cannulas, 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, cold tap water, 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, 1 minute.
Step 4	Detergent wash using detergent such as *Prolystica® 2X Concentrate Alkaline Detergent,* per manufacturer's recommendations, hot tap water (66°C/150°F), 2 minutes.
Step 5	Rinse 2 times, hot tap water, 15 seconds.
Step 6	Purified water rinse (66°C/150°F), 10 seconds.
Step 7	Hot air dry (115°C/239°F) for at least 10 minutes.

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.
- Inspect instruments 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:

- All reusable instruments 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 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.
- 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	Pre-vacuum	270°F (132°C)	4 minutes	45 minutes	75 minutes

Sterilization Notes:

- The cycle conditions in the tables above were validated and are considered adequate to achieve a SAL of 10^{-6}.
- 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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