



## **Alphatec Spine Instruments**

### **INSTRUCTIONS FOR USE - ENGLISH**

#### **GENERAL INFORMATION:**

This *Instruction for Use* applies only to the specific Alphatec instrument sets that it accompanies.

This *Instruction for Use* also applies to all Alphatec Spine instruments when individually processed outside of a set. If an individual instrument is intended to replenish an Alphatec Spine set, the *Instruction for Use* for that set should be used instead.

#### **WARNINGS/PRECAUTIONS:**

1. **It is important to read the entire *Instructions for Use* prior to instrument operation.**
2. Handle and store all products with care. This includes not placing heavy instruments on top of delicate instruments. Mishandling may lead to damage and possible improper functioning.
3. Metal brushes or scouring pads must not be used during cleaning. These materials will damage the surface and finish of instruments. Soft-bristled, nylon brushes and pipe cleaners should be used.
4. Avoid allowing contamination, such as blood, body fluid, bone and tissue debris, saline, or disinfectant, to dry on instruments prior to reprocessing.
5. Solutions containing caustic soda (NaOH), aldehyde, mercury, active chlorine, chloride (such as Ringers Solution), bromine, bromide, iodine, or iodide are corrosive and should not be used.
6. Mineral oil or silicone lubricants should not be used because they coat microorganisms, prevent direct contact of the surface with steam, and are difficult to remove.
7. Do not reuse instruments labeled as Single Use. While an instrument may appear undamaged, it may have small defects or internal stress patterns that could lead to fatigue failure. In addition, the instrument has not been designed or validated for reprocessing and re-use could lead to cross-infection and/or material degradation.
8. Do not add items to sets that do not have specific places intended for them. Any addition to the set will invalidate the sterilization testing performed by Alphatec Spine.

#### **INSTRUMENT PREPARATION:**

1. Cleaning, inspection, lubrication, and sterilization must be performed by hospital personnel trained in the general procedures involving contaminant removal.
2. Instruments must be cleaned prior to lubrication and sterilization.
3. All instrument hinged, rotating, and articulating parts must be lubricated prior to sterilization with a water soluble and sterilizable lubricant intended for surgical instruments (*Hinge-Free*<sup>®</sup> for example).

#### **REPROCESSING OF REUSABLE INSTRUMENTS –**

##### **General Information for all Instruments:**

1. **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.
2. The cleaning process is the first step in effectively reprocessing reusable instruments. Adequate sterilization depends on thoroughness of cleaning.



3. 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.
4. 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"*.
5. 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, RO, DI and/or distilled water.

**CLEANING:**

1. All solutions for cleaning should be prepared per the manufacturer's instructions.
2. Instruments provided in a set, must be removed from the set for cleaning. Instrument trays, cases, and lids must be cleaned separately.
3. Ensure instruments are in the fully extended, open position throughout cleaning. Disconnect Quick Connect handles from the shafted instruments prior to cleaning.
4. Pay special attention during cleaning to complex instruments, such as those with, cannulas, hinges, retractable features, mated surfaces, and textured surface finishes.
5. Use of water with high mineral content should be avoided.

**Manual Cleaning Steps for Instruments (Required)**

<b>STEP 1</b>	Rinse instruments in ambient temperature tap water to remove excess soil
<b>STEP 2</b>	Submerge instrument in enzyme solution such as <i>Prolystica® 2X</i> Enzymatic or equivalent. Actuate the instrument while it is submerged and soak for a minimum of 10 minutes.
<b>STEP 3</b>	Actuate and scrub the instrument using a soft bristled brush and pipe cleaner 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 hard to reach areas and repeat 3 times
<b>STEP 4</b>	Rinse instruments in Deionized / Reverse Osmosis water for a minimum of 1 minute
<b>STEP 5</b>	Submerge and actuate instruments in a cleaning solution such as <i>Prolystica® 2X</i> Alkaline (pH 11.2) or equivalent and sonicate for a minimum of 10 minutes.
<b>STEP 6</b>	Thoroughly rinse instruments with Deionized / Reverse Osmosis water to remove all detergent residues.
<b>STEP 7</b>	Dry instruments with clean, lint free cloth or filtered compressed air.

**Automatic Washer Cleaning Steps**

**Important** - Manual Cleaning Steps are required before performing the Automated Washer / Disinfector Cycle Steps.

<b>STEP 1</b>	Follow steps 1 through 5 of the <i>Manual Cleaning Steps for Instruments</i> .
<b>STEP 2</b>	Thoroughly rinse instruments in ambient temperature tap water to remove detergent residuals.
<b>STEP 3</b>	Place instruments in fully extended open position into washer and process through a standard washer/disinfector instrument cycle.
<b>STEP 4</b>	PreWash, cold tap water, for a minimum of 2 minutes.
<b>STEP 5</b>	Enzyme wash (such as <i>Prolystica® 2X</i> enzymatic or equivalent), hot tap water, for a minimum of 1 minute.
<b>STEP 6</b>	Detergent wash (such as <i>Prolystica® 2X</i> Alkaline (pH11.2) or equivalent), Hot tap water (66°C/150°F minimum), for a minimum of 2 minutes.



<b>STEP 7</b>	Rinse 2x, hot tap water, for a minimum of 15 seconds.
<b>STEP 8</b>	Purified Water rinse, Hot (66°C/150°F minimum), for a minimum of 10 seconds.
<b>STEP 9</b>	Hot Air Dry, (115°C/239°F minimum), for a minimum of 10 minutes.

**INSPECTION:**

1. Inspect each instrument to ensure that all visible contamination has been removed. If contamination is noted, repeat the cleaning/disinfection process.
2. 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.
3. Check instruments with long slender features (particularly rotating instruments) for distortion.
4. Drill bits, reamers, rasps, and other cutting instruments should be inspected after processing with alkaline detergents.
5. Inspect instruments for any other damage, wear and/or corrosion.

**STERILIZATION / RESTERILIZATION:**

1. All instruments are provided non-sterile and must be cleaned and sterilized before use. Instruments should be sterilized using the appropriate cycle parameters in the tables below.
2. Trays must be double wrapped, and individual instrument must be double wrapped or sealed in sterilization pouches, so as to allow steam to penetrate and make direct contact with all surfaces.

Method	Cycle Type	Minimum Temperature	Exposure Time	Minimum Drying Time
<b>Instruments within a set</b>				
Steam	Pre-vacuum	270°F (132°C)	4 minutes	45 minutes
<b>Individual Instrument (other than Table Top Rod Cutter)</b>				
Steam	Pre-vacuum	270°F (132°C)	4 minutes	30 minutes

**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.

**MAINTENANCE OF TORQUE WRENCH:**

*CALIBRATION:* Regular calibration ensures the Torque Wrench performs according to its specifications. To ensure that the Torque Wrench operates properly and safely at all times, Alphatec recommends that the Torque Wrench be calibrated every six (6) months. Heavy use applications may necessitate much more frequent calibration. **If at any time an instrument seems to be malfunctioning, remove it from service and return it to Alphatec for recalibration or replacement immediately.** For any questions regarding calibration, please contact Alphatec Customer Service.

**COMPLAINT HANDLING/REPORTING:**

All product complaints relating to safety, efficacy or performance of the product should be reported immediately to Alphatec Spine. All complaints should be accompanied by part name,



number, and lot numbers. The person formulating the complaint should provide their name, address, and as many details as possible.

**CUSTOMER SERVICE:**

For *Surgical Technique Guides* or additional information regarding the instruments, please contact Alphatec Spine, Inc. Customer Service at (800)922-1356, (760)431-9286 or Email at [customerservice@atecspine.com](mailto:customerservice@atecspine.com).



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**R<sub>X</sub>Only** Caution: Federal law (USA) restricts these devices to sale by or on the order of a physician

**SYMBOLS:** For a listing of Symbols and Explanations, see [atecspine.com/eifu](http://atecspine.com/eifu)