GRAFT DELIVERY SYSTEM
INSTRUCTIONS FOR USE

GENERAL INFORMATION:
The Graft Delivery System shall focus on the delivery of bone graft into the disc space. The device shall provide a means to deliver the bone graft into the disc space. The device will be of an appropriate length, size, and design to facilitate use in skeletally mature patients and in conjunction with the current thoracolumbar approaches performed.

INTENDED USE:
The Graft Delivery System is a reusable device intended to deliver bone graft or manipulate tissue to support implantation of orthopedic devices in skeletally mature patients.

WARNINGS/CAUTIONS/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.

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.
- 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, RO, DI and/or distilled water.

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:

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

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

Automatic Washer Cleaning Steps for Instruments

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

Step 1	Follow steps 1 through 5 of the Manual Cleaning Steps for Instruments.
Step 2	Thoroughly rinse instruments in ambient temperature tap water to remove detergent residuals.
Step 3	Place instruments in fully extended open position into washer and process through a standard washer/disinfector instrument cycle
Step 4	Prewash, cold tap water, for a minimum of 2 minutes.

Step 5	Enzyme wash (such as Prolystica® 2X enzymatic or equivalent), hot tap water, for a minimum of 1 minute.
Step 6	Detergent wash (such as Prolystica® 2X Alkaline (pH11.2) or equivalent), Hot tap water (66°C/150°F minimum), for a minimum of 2 minutes.
Step 7	Rinse 2x, hot tap water, for a minimum of 15 seconds.
Step 8	Purified Water rinse, Hot (66°C/150°F minimum), for a minimum of 10 seconds
Step 9	Hot Air Dry, (115°C/239°F minimum), for a minimum of 10 minutes.

INSPECTION:

- Inspect each instrument 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 with alkaline detergents.
- Inspect instruments for any other damage, wear and/or corrosion.

STERILIZATION AND RESTERILIZATION:

- 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.
- Trays must be double wrapped, and individual instruments must be double wrapped or sealed in sterilization pouches, so as to allow steam to penetrate and make direct contact with all surfaces.

Sterilization Parameters

Set Type	Method	Cycle Type	Temperature	Exposure Time	Minimum Drying Time	Minimum Cool Down Time
Instruments within a set	Steam	Pre-vacuum	270°F (132°C)	4 minutes	45 minutes	75 minutes
Individual Instrument	Steam	Pre-vacuum	270°F (132°C)	4 minutes	30 minutes	60 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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