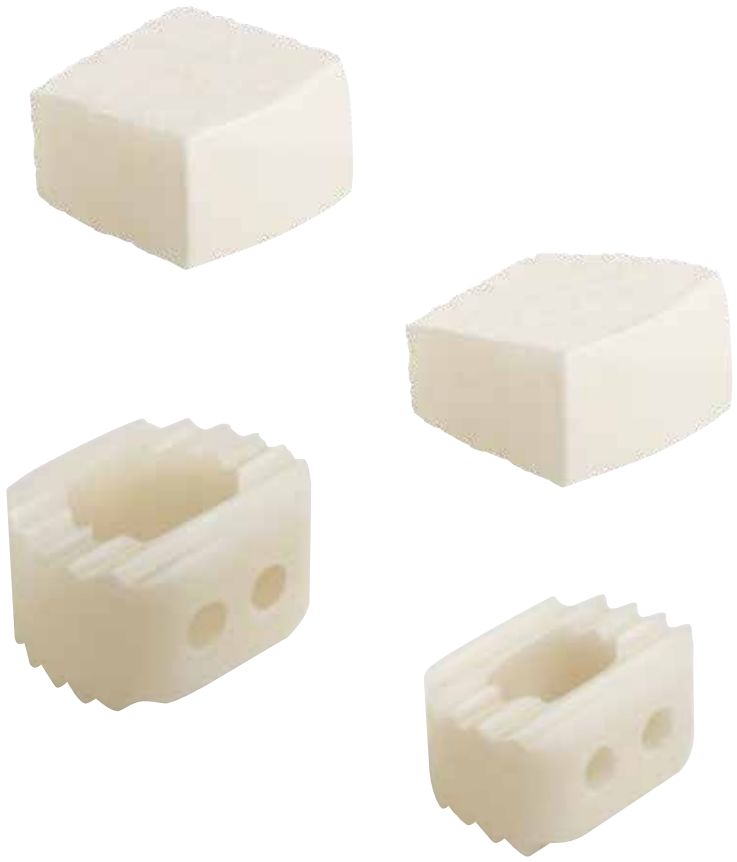
AlphaGRAFT®

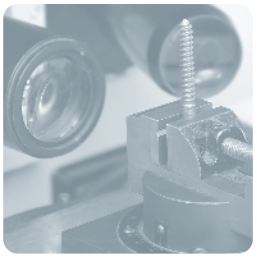
Cervical Allograft
Instrumentation System



SURGICAL TECHNIQUE GUIDE

Alphatec Spine®

Solutions for the Aging Spine®



Preface

As a next step in the evolution of spinal fixation, Alphatec Spine introduces the AlphaGRAFT Cervical Allograft Instrumentation System:

The AlphaGRAFT Cervical Allograft Instrumentation System is simple and versatile in its application, incorporating:

- Footprint specific trials for optimal implant sizing
- Universal instrumentation for disc space preparation and implant placement
- Smooth and rasping trial surfaces to match surgeon preference
- Integrated instrumentation stops to prevent accidental over insertion

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Perform Discectomy

Using commercially available pituitaries, curettes, and kerrisons, perform the discectomy at the indicated level. Remove disc material and lightly decorticate the endplates adjacent to the indicated level. Avoid removal of excessive bony endplate to minimize risk of implant subsidence.

If desired, a rasp is provided to roughen the endplates during preparation of the disc space.

Determine Implant Size

In the newly prepared disc space, insert a trial to confirm the correct disc height. The AlphaGRAFT cervical allografts are available in sizes ranging from 5-11mm in three footprint and two different lordotic angles. The trials are color coded and marked to differentiate sizes. The appropriate size is determined by selecting the trial that fits the most satisfactory fit in the prepared disc space.

If desired, rasping trials are provided to roughen the endplates during implant sizing.

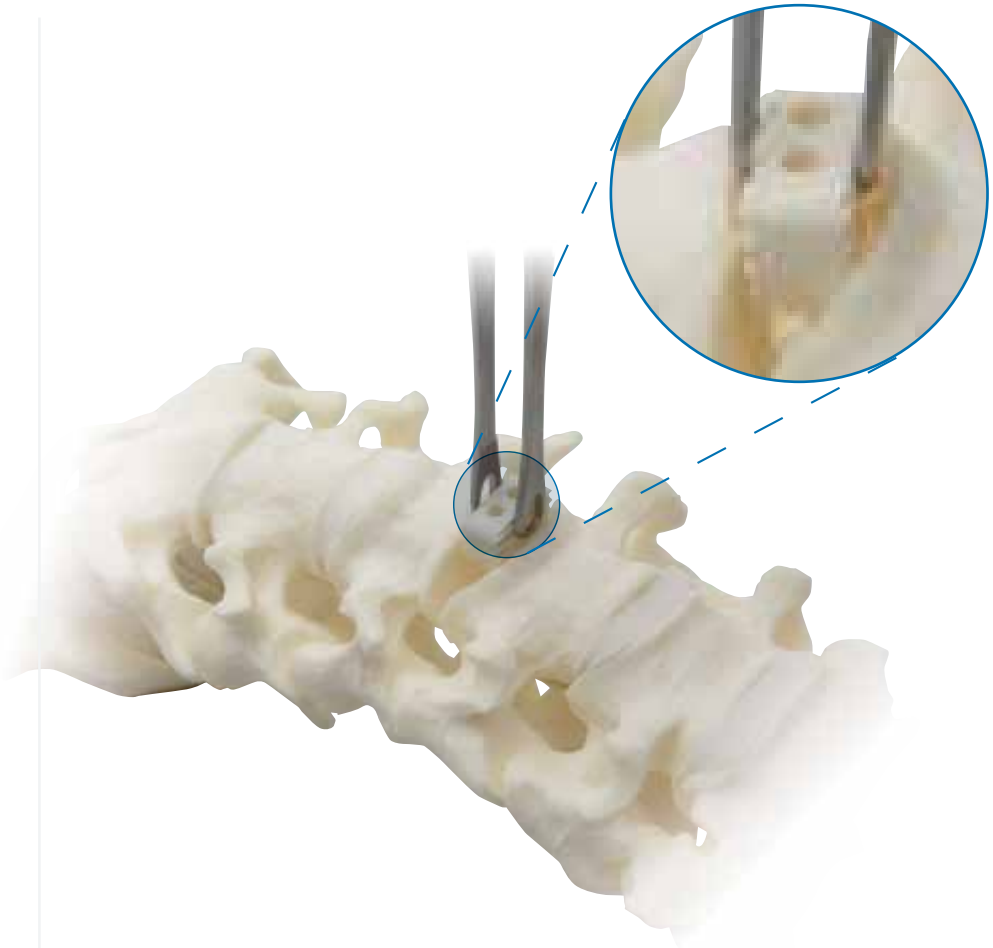
Note: The AlphaGRAFT cervical trials and tamp feature a stop located 2mm from the proximal end of the instrument tip designed to prevent over insertion into the disc space. The stops are also designed to accommodate Caspar pins when used.

Place Graft Material

Using commercially available forceps and bone tamps, pack the desired implant with bone graft prior to insertion. Take care to ensure implant is completely filled with bone graft.

Insert Implant

Select the appropriate sized implant. Load implant on the inserter and place into proper position within the prepared disc space.



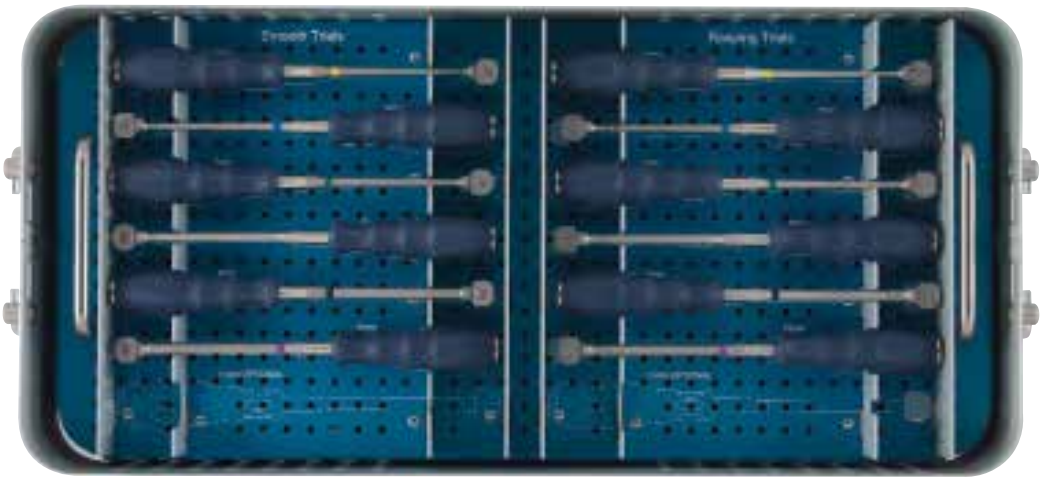
Verify Implant Position

Confirm implant position with AP and lateral fluoroscopy. Use the Implant Tamps provided to manipulate the implant into final position. The implant inserter may be used to reposition the implant as necessary. Pack additional autogenous bone grafting material anteriorly if desired. Remove distraction device if used. An anterior fixation plate (Alphatec Trestle® is recommended) can now be applied for additional fixation.

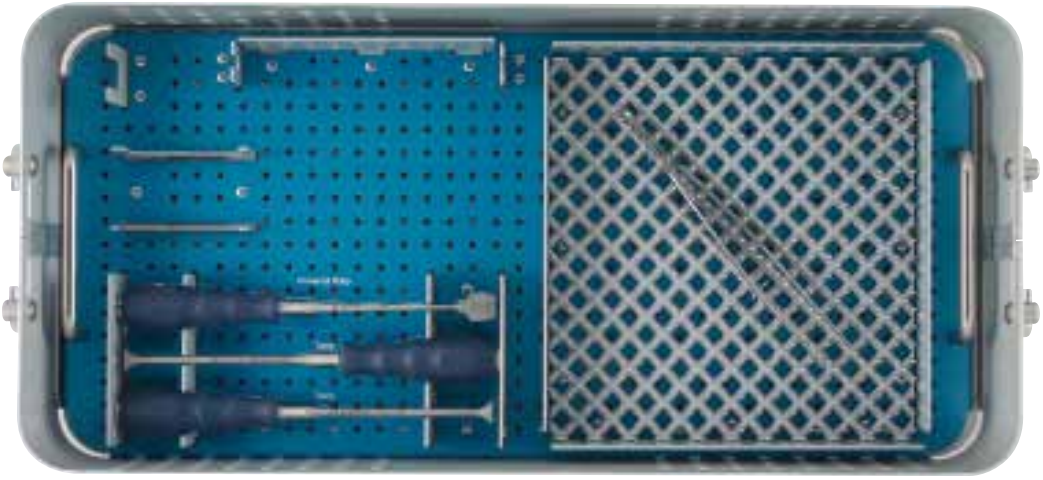
Set Detail:

Closed Case

Top Level - Smooth and Rasping Trials



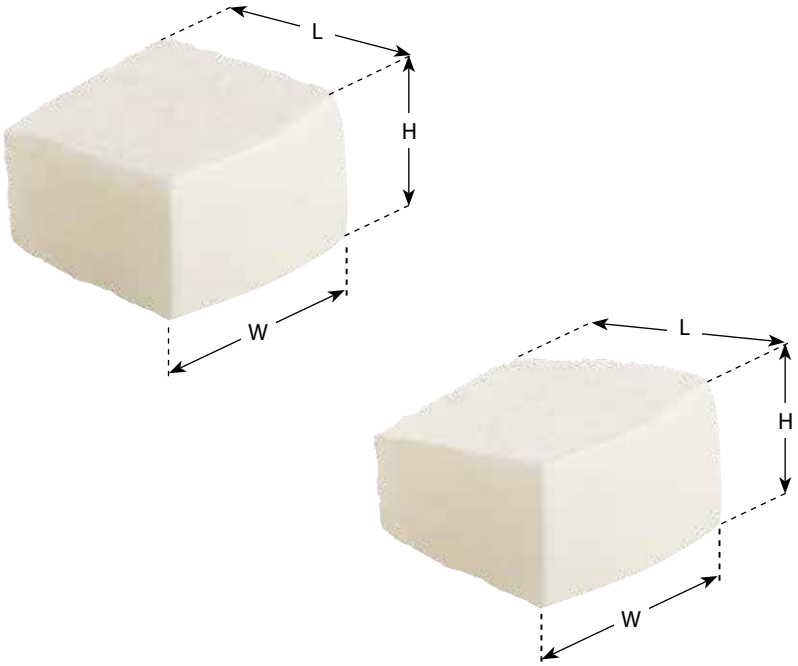
Bottom Level - Universal Instrumentation/Pin Mat



System Features

- Anterior Cortical Surface
  Designed for structural integrity
- Dense Cancellous Bone
  Allows immediate perfusion and excellent load bearing properties[1]
- Available Lordotic (7°) or Parallel
  Facilitates precise fit for individual patient requirements
- Range of Heights
  Provides for optimal distraction
- Trimmable Design
  Permits customization
- Large Footprint
  Maximizes graft-to-host bone surface area contact
- Available Frozen or Freeze Dried
  Accommodates surgeon preference

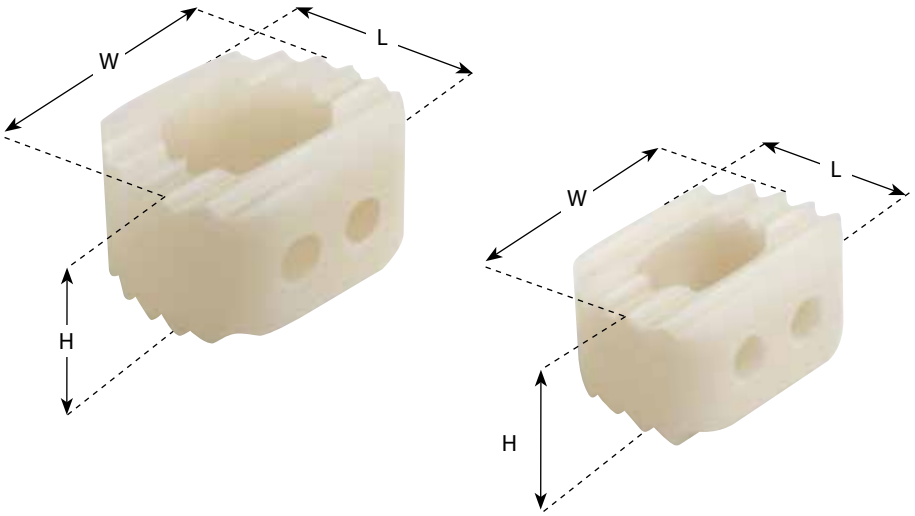
Cancellous Cervical Allografts



System Features

- Cortical Allograft
  Maximizes compressive strength[1]
- Large and Small Footprint
  Provides options for individual patient anatomy
- Available Lordotic (6°) or Parallel
  Facilitates precise fit for individual patient requirements
- Range of Heights
  Provides for optimal distraction
- Surface Serration
  Maximizes surface area for end plate integration
- Tapered Leading Edge
  Facilitates allograft introduction
- Re-hydrated
  Allows for immediate implantation

Cortical Cervical Allografts



[1]Data on file

AlphaGRAFT Lordotic Dense Cancellous (freeze dried)

Reference Number	Height*	Width	Length	Contact Area L x W (mm^2)
21-2005	5	14	14	196mm^2
21-2006	6	14	14	196mm^2
21-2007	7	14	14	196mm^2
21-2008	8	14	14	196mm^2
21-2009	9	14	14	196mm^2
21-2010	10	14	14	196mm^2
21-2011	11	14	14	196mm^2

*Indicates anterior distraction height
Set ID BNDCL - Dense Cancellous Lordotic Instruments

AlphaGRAFT Lordotic Dense Cancellous (frozen)

Reference Number	Height*	Width	Length	GraftFootprint L x W (mm^2)
21-9005	5	14	14	196mm^2
21-9006	6	14	14	196mm^2
21-9007	7	14	14	196mm^2
21-9008	8	14	14	196mm^2
21-9009	9	14	14	196mm^2
21-9010	10	14	14	196mm^2
21-9011	11	14	14	196mm^2

*Indicates anterior distraction height
Set ID BNDCL - Dense Cancellous Lordotic Instruments

AlphaGRAFT Parallel Dense Cancellous (freeze dried)

Reference Number	Height	Width	Length	Contact Area L x W (mm^2)
21-9405	5	14	14	196mm^2
21-9406	6	14	14	196mm^2
21-9407	7	14	14	196mm^2
21-9408	8	14	14	196mm^2
21-9409	9	14	14	196mm^2
21-9410	10	14	14	196mm^2
21-9411	11	14	14	196mm^2

*Indicates anterior distraction height
Set ID BNDCP - Dense Cancellous Parallel Instruments

AlphaGRAFT Parallel Dense Cancellous (frozen)

Reference Number	Height	Width	Length	GraftFootprint L x W (mm^2)
22-9405	5	14	14	196mm^2
22-9406	6	14	14	196mm^2
22-9407	7	14	14	196mm^2
22-9408	8	14	14	196mm^2
22-9409	9	14	14	196mm^2
22-9410	10	14	14	196mm^2
22-9411	11	14	14	196mm^2

*Indicates anterior distraction height
Set ID BNDCP - Dense Cancellous Parallel Instruments

AlphaGRAFT Cervical Lordotic Large

Reference Number	Height*	Width	Length	Minimum wall thickness
100305-CLL	5	15.4	13.4	3
100306-CLL	6	15.4	13.4	3
100307-CLL	7	15.4	13.4	2
100308-CLL	8	15.4	13.4	2
100309-CLL	9	15.4	13.4	2
100310-CLL	10	15.4	13.4	2
100311-CLL	11	15.4	13.4	2

*Height measured at centerline
Set ID BNCLL - Cervical Lordotic Large Instruments

AlphaGRAFT Cervical Lordotic Small

Reference Number	Height*	Width	Length	Minimum wall thickness
100305-CLS	5	13.8	10.8	3
100306-CLS	6	13.8	10.8	3
100307-CLS	7	13.8	10.8	2
100308-CLS	8	13.8	10.8	2
100309-CLS	9	13.8	10.8	2
100310-CLS	10	13.8	10.8	2

*Height measured at centerline
Set ID BNCLS - Cervical Lordotic Small Instruments

AlphaGRAFT Cervical Parallel Large

Reference Number	Height*	Width	Length	Minimum wall thickness
100305-CPL	5	15.4	13.4	3
100306-CPL	6	15.4	13.4	3
100307-CPL	7	15.4	13.4	2
100308-CPL	8	15.4	13.4	2
100309-CPL	9	15.4	13.4	2
100310-CPL	10	15.4	13.4	2
100311-CPL	11	15.4	13.4	2

*Height measured at centerline
Set ID BNCPL - Cervical Parallel Large Instruments

AlphaGRAFT Cervical Parallel Small

Reference Number	Height*	Width	Length	Minimum wall thickness
100305-CPS	5	13.8	10.8	3
100306-CPS	6	13.8	10.8	3
100307-CPS	7	13.8	10.8	2
100308-CPS	8	13.8	10.8	2
100309-CPS	9	13.8	10.8	2
100310-CPS	10	13.8	10.8	2

*Height measured at centerline
Set ID BNCPS - Cervical Parallel Small Instruments

AlphaGRAFT Cortical Cervical Allografts are manufactured by Tissue Banks International under the trademark TRANZGRAFT

INSTRUCTIONS FOR USE
Alphatec Spine Instruments

GENERAL INFORMATION:

This guide pertains to all Alphatec Spine reusable instruments and should be studied carefully. All Alphatec Spine devices may be safely and efficiently reprocessed using the manual or automated cleaning instructions outlined in this manual. The user/processor should comply with local laws and ordinances in countries where reprocessing requirements are more stringent than those detailed in this manual. New and used instruments must be thoroughly processed according to these instructions prior to use.

WARNINGS/PRECAUTIONS:

1. **It is important to read the Instructions for Use and these precautions prior to device operation**.
2. Universal Precautions should be observed by all hospital personnel that work with contaminated or potentially contaminated medical devices. Caution should be exercised when handling devices with sharp points or cutting edges.
3. Personal Protective Equipment (PPE) should be worn when handling or working with contaminated or potentially contaminated materials, devices and equipment. PPE includes gown, mask, goggles or face shield, gloves and shoe covers.
4. Do not place heavy instruments on top of delicate devices.
5. Metal brushes or scouring pads must not be used during manual cleaning procedures. These materials will damage the surface and finish of instruments. Soft-bristled, nylon brushes and pipe cleaners should be used.
6. Do not allow contaminated devices to dry prior to reprocessing. All subsequent cleaning and sterilization steps are facilitated by not allowing blood, body fluid, bone and tissue debris, saline, or disinfectants to dry on used devices.
7. Saline and cleaning/disinfection agents containing aldehyde, mercury, active chlorine, chloride, bromine, bromide, iodine or iodide are corrosive and should not be used. Instruments must not be placed or soaked in Ringers Solution.
8. Mineral oil or silicone lubricants should not be used because they: 1) coat microorganisms; 2) prevent direct contact of the surface with steam; and 3) are difficult to remove.

LIMITATIONS & RESTRICTIONS:

1. Automated cleaning using a washer/disinfector alone may not be effective for orthopedic instruments. A thorough, manual or combination manual/automated cleaning process is recommended.
2. Neutral pH enzymatic and cleaning agents are recommended and preferred for cleaning Alphatec Spine reusable devices. Alkaline agents with pH $\leq$ 12 may be used to clean stainless steel and some polymer instruments in countries where required by law or local ordinance; or where prion diseases such as Transmissible Spongiform Encephalopathy (TSE) and Creutzfeldt-Jakob Disease (CJD) are a concern. It is critical that alkaline cleaning agents be completely and thoroughly neutralized and rinsed from devices.
3. Note: Drill bits, reamers, rasps and other cutting devices should be carefully inspected after processing with alkaline detergents to ensure that cutting edges are fit for use.
4. Instruments must be removed from metal or polymer trays for manual and/or automated cleaning procedures. Instrument trays, cases and lids must be cleaned separately. Non-sterile, single-use plate and screw implants are an exception to this rule. Plates and screws may remain in the tray or caddy for reprocessing.
5. Repeated processing, according to the instructions in this manual has minimal affect on Alphatec Spine reusable manual instruments unless otherwise noted. End of life for stainless steel or other metal surgical instruments is normally determined by wear and damage due to the intended surgical use and not to reprocessing.
6. Use of hard water should be avoided. Softened tap water may be used for initial rinsing. Purified water should be used for final rinsing to eliminate mineral deposits on instruments. One or more of the following processes may be used to purify water: ultra-filter (UF), reverse-osmosis (RO), deionized (DI), or equivalent.
7. Ethylene oxide (EO), gas plasma and dry heat sterilization methods are not recommended for sterilization of Alphatec Spine reusable instruments.
8. Steam (moist heat) is the recommended sterilization method for Alphatec Spine instruments.

Safety Precaution:

The total weight of a wrapped instrument tray or case should not exceed 11.4kg/25lbs for the safety of the personnel handling instrument sets. When placed in a sterilization container with gasketed lid, the total package should not exceed 16kg/35lbs.

1. Trays and cases with lids may be wrapped in standard medical grade, steam sterilization wrap using the AAMI double wrap method or equivalent.
2. Trays and cases with lids may also be placed in an approved sterilization container with gasketed lid for sterilization. Follow the sterilization container manufacturer's instructions for inserting and replacing sterilization filters in sterilization containers.

Note: Areas designated for specific devices shall contain only devices specifically intended for these areas. Note: These validated reprocessing instructions are not applicable to Alphatec Spine trays that include devices that are not manufactured and/or distributed by Alphatec Spine. Instrument trays and cases without defined, preconfigured layouts or containing undefined universal spaces or compartments should only be used under the following conditions:

1. The total weight of a wrapped instrument tray or case should not exceed 11.4kg/25lbs. When placed in a sterilization container with gasketed lid the total sterilization package should not exceed 16kg/35lbs.
2. Any device capable of disassembly must be disassembled prior to placement in the case.
3. All devices must be arranged to ensure steam penetration to all instrument surfaces. Instruments should not be stacked or placed in close contact.
4. The user must ensure that the instrument case is not tipped or the contents shifted once the devices are arranged in the case. Silicon mats may be used to keep devices in place.
5. Only devices manufactured and/or distributed by Alphatec Spine should be included in Alphatec Spine instrument trays. Alphatec Spine validated reprocessing instructions are **not applicable** to Alphatec Spine trays that include devices that are not manufactured and/or distributed by Alphatec Spine.

STORAGE:
Sterile, packaged instruments should be stored in a designated, limited access area that is well ventilated and provides protection from dust, moisture, insects, vermin, and temperature/ humidity extremes.

IMPORTANT NOTICE:
The instructions provided in this Quick Reference Guide have been validated by Alphatec Spine as being capable of preparing orthopedic devices for use. It is the responsibility of the Hospital to ensure that reprocessing is performed using the appropriate equipment and materials, and that personnel in the reprocessing facility have been adequately trained in order to achieve the desired result. Equipment and processes should be validated and routinely monitored. Any deviation by the processor from these instructions should be properly evaluated for effectiveness to avoid potential adverse consequences.

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