Ascend™ NanoTec™ VBR System
INSTRUCTIONS FOR USE

GENERAL INFORMATION:
The Ascend NanoTec VBR System is a cervical and thoracolumbar vertebral body replacement system designed to be inserted in the anterior, anterolateral, lateral, and posterior approaches. The implants consist of static and expandable VBR cores, and integrated or modular endplates offered in a range of diameters and heights, endplates, footprints, and lordotic angles, to accommodate individual patient anatomy. The cores are made of titanium alloy per ASTM F136 and cobalt chrome alloy per ASTM F1537, while the endplates are made of titanium alloy per ASTM F136 or hybrid titanium consisting of commercially pure titanium (CP-Ti) Grade 2 per ASTM F67 and titanium alloy per ASTM F136 with a nano-scale hydroxyapatite surface treatment.

Use Ascend NanoTec VBR devices with supplemental fixation systems from Alphatec Spine such as: Trestle Luxe® Cervical Plate System, Insignia™ Anterior Cervical Plate System, Invictus® OCT Spinal Fixation System, Zodiac® Polyaxial Spinal Fixation System, Arsenal® Spinal Fixation System, Illico® MIS Posterior Fixation System, Invictus® Spinal Fixation System, or ATEC Trauma Plate.

INDICATIONS FOR USE:
The Ascend VBR System with advanced NanoTec surface treatment is intended for use in skeletally mature patients in the cervical spine (C2-T1) and in the thoracolumbar spine (T1-L5) to replace a collapsed, damaged, or unstable vertebral body due to tumor, osteomyelitis, trauma (i.e., fracture), or for reconstruction following corpectomy performed to achieve decompression of the spinal cord and neural tissues in degenerative disorders.

The Ascend NanoTec VBR System is also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical, thoracic, and lumbar spine in whom life expectancy is of insufficient duration to permit achievement of fusion, with bone graft used at the surgeon's discretion.

The Ascend NanoTec VBR System is intended to be used with supplemental spinal fixation systems cleared for use in the cervical, thoracic, and/or lumbar spine. The use of bone grafting material with the Ascend NanoTec VBR System is optional.

CONTRAINDICATIONS:
The Ascend NanoTec VBR system is contraindicated for:

1. Patients with bone resorption related disease (e.g., osteopenia), bone and/or joint disease, or deficient soft tissue at the wound site.
2. Patients with infection (excluding osteomyelitis), inflammation, fever, elevated white blood count, obesity, pregnancy, mental illness, and other medical conditions which would prohibit beneficial surgical outcome.
3. Patients with allergy or intolerance to titanium or cobalt chrome.
4. Patients resistant to following postoperative restrictions on movement especially in athletic and occupational activities.
5. Reuse or multiple uses of the implant.

WARNINGS/CAUTIONS/PRECAUTIONS:

1. The VBR cores and cores with integrated endplates are provided non-sterile and must be sterilized prior to use. Refer to the CLEANING and STERILIZATION sections.
2. The modular endplates are provided sterile.
    - Visually inspect the packaging for signs of damage and breaches of packaging integrity prior to use. Do not use devices if package is opened, damaged, or past the expiry date.
    - Do not re-sterilize sterile packaged devices.
    - Do not use scratched or damaged devices.
3. Components of this system should not be used with components from other systems or manufacturers.
4. All instruments are provided non-sterile and must be cleaned and sterilized prior to surgery. See CLEANING and STERILIZATION sections in this IFU.
5. Implants are single use devices. Do not reuse. While an implant may appear undamaged, it may have small defects or internal stress patterns that could lead to fatigue failure. In addition, the removed implant has not been designed or validated for the decontamination of microorganisms. Reuse of this product could lead to cross-infection and/or material degradation as a result of the decontamination process.
6. These implants are used only to provide internal fixation, in conjunction with supplemental fixation. A successful result may not be achieved in every instance.
7. Potential risks identified with the use of these devices, which may require additional surgery, include device component failure, loss of fixation, pseudarthrosis (i.e., non-union), fracture of the vertebra, neurological injury, and/or vascular or visceral injury.
8. Risk factors that may affect successful surgical outcomes include: alcohol abuse, obesity, patients with poor bone, muscle and/or nerve quality. Patients who use tobacco or nicotine products should be advised of the consequences that an increased incidence of non-union has been reported with patients who use tobacco or nicotine products.
9. An Ascend NanoTec VBR implant must not be re-expanded and reused if it has been filled with graft, as mechanical failure may occur.
10. If implant pre-packing with bone graft is desired, the Inserter with Expansion Driver must be attached to the implant prior to pre-packing to allow for proper expansion of the implant.
11. Implantation should be performed only by experienced spinal surgeons with specific training in the use of this device because this is a technically demanding procedure presenting a risk of serious injury to the patient.
12. Placement and positional adjustment of implants must only be performed with system-specific instruments. They must not be used with other instrumentation unless specifically recommended by Alphatec Spine Inc., because the combination with other instrumentation may be incompatible.
13. The physician/surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc., which may affect the performance of this system.
14. Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without previous surgery.
15. Additional care should be taken to ensure a thorough vertebrectomy is completed in order to correctly size, place, and expand the device. An incomplete vertebrectomy may result in difficulty to fully deploy and place the device in its intended position.
16. Incorrect preparation of the endplates may increase the risk factor for subsidence or vertebral body fracture, careful attention should be given to endplate preparation prior to insertion of the device.
17. Avoid over-distraction which can lead to neural injury.

18. When used in the cervical spine at one or two levels, the Ascend NanoTec VBR System is intended to be used with supplemental fixation cleared by the FDA for use in the cervical spine. When used at more than two levels, supplemental fixation should include posterior fixation that is cleared by the FDA.
19. Do not use excessive torque when disengaging the active lock mechanism as excessive torque may damage the mechanism.
20. Once the VBR implant is collapsed, do not continue collapsing as over-collapsing may damage the implant.

MRI SAFETY INFORMATION:

The Ascend NanoTec VBR 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 Ascend NanoTec VBR System in the MR environment is unknown. Performing an MR exam on a person who has this medical device may result in injury or device malfunction.

POSSIBLE ADVERSE EFFECTS:

Possible adverse effects include:

1. Initial or delayed loosening, bending, dislocation, and/or breakage of device components.
2. Physiological reaction to implant devices due to foreign body intolerance including inflammation, local tissue reaction, seroma, and possible tumor formation.
3. Loss of desired spinal curvature, spinal correction and/or a gain or loss in height.
4. Infection and/or hemorrhaging.
5. Non-union and/or pseudarthrosis.
6. Neurological disorder, pain and/or abnormal sensations caused by improper placement of the device, and/or instruments.
7. Subsidence of the device into the vertebral body.
8. Revision surgery.
9. Death.

PREOPERATIVE MANAGEMENT:

1. Only patients meeting the criteria listed in the indications for the use section should be selected.
2. Surgeons should have a complete understanding of the surgical technique, system indications, contraindications, warnings and precautions, safety information, as well as functions and limitations of the implants and instruments.
3. Careful preoperative planning should include implantation strategy and a verification of required inventory for the case.
4. The condition of all implants and instruments should be checked prior to use. Damaged and/or worn implants and instruments should not be used.

INTRAOPERATIVE MANAGEMENT:

1. The surgical technique manual should be followed carefully.
2. To prevent possible nerve damage and associated disorders, extreme caution should be taken to avoid the spinal cord and nerve roots at all times. Fluoroscopy should be employed where view of device is obstructed.
3. Due to potential risk of neural injury in the cervical spine, use of fluoroscopy and/or neuromonitoring during cervical procedures is recommended.
4. It is essential when utilizing the lateral or banana endplate offering to clear all disc material prior to VBR insertion as the lateral and banana endplate geometries are designed to span the apophyseal ring.
5. To reduce the risk of cross-threading, confirm the endplate is properly seated on the core

prior to attachment.

6. Ensure the attachment handle remains attached to the inserter if malleting is required. Do not mallet directly on the inserter without the attachment handle.

POSTOPERATIVE MANAGEMENT:

Postoperative management by the surgeon is essential. This includes instructing, warning, and monitoring the compliance of the patient.

1. Patient should be informed regarding the purpose and limitations of the implanted devices.
2. The surgeon should instruct the patient regarding the amount and time frame after surgery of any weight bearing activity. The increased risk of bending, dislocation, and/or breakage of the implanted devices, as well as an undesired surgical result are consequences of any type of early or excessive weight bearing, vibratory motion, falls, jolts or other movements preventing proper healing.
3. Implanted devices should be revised or removed if bent, dislocated, or broken.
4. Immobilization should be considered in order to prevent bending, dislocation, or breakage of the implanted device in case of delayed, malunion, or nonunion of bone.
5. Postoperative patients should be instructed not to use tobacco or nicotine products, consume alcohol, or use non-steroidal anti-inflammatory drugs and aspirin, as determined by the surgeon. Complete postoperative management to maintain the desired result should also follow implant surgery.

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.

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 functioning.

Visually inspect the instrument after each cleaning step to ensure the instrument is clean. If not clean, repeat the step until clean.

Manual Cleaning (Required)

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

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.
- 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 VBR cores and 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
Implants/Instrument Mixed Set	Pre-vacuum	132°C (270°F)	4 Minutes	30 Minutes	60 Minutes
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.”

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 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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