# Octane® A/T/P Spinal Implant System
# Instructions for Use


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**General Description:**
The ChoiceSpine Octane-A/T/P Spinal Implant is an implant constructed of medical grade Polyetheretherketone, (PEEK-OPTIMA® LT1) as described by ASTM F2026. The implant incorporates ridges on the superior and inferior surfaces to resist expulsion. The device is open in the transverse plane to allow insertion of bone graft prior to placement, and fenestrated along the sides. The radiolucent PEEK-OPTIMA® material allows visualization of the defect site on radiography to assess bone growth and incorporates tantalum markers conforming to ASTM F560 to permit verification of position. The ChoiceSpine Octane Spinal Implant is provided sterile in three (3) styles:

- The Octane-T Spinal Implant, available heights of 7mm to 17mm, in 2mm increments;
- The Octane-P Spinal Implant, available in heights of 7mm to 17mm, in 2mm increments; and
- The Octane-A Spinal Implant, available in heights of 9mm to 19mm, in 2mm increments, and with a convex superior and inferior surface, angled at either 6° or 12° and in Small, Medium, or Large transverse profile.

**Indications for Use:**

**When used as a vertebral body replacement:**
The ChoiceSpine Octane-A/T/P Spinal Implant is indicated for use in the thoracolumbar spine (T1 to L5) for partial or total replacement of a collapsed, damaged, or unstable vertebral body due to tumor or trauma (i.e., fracture), to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. The Octane device is designed to restore the biomechanical integrity of the anterior, middle, and posterior spinal column, even in the absence of fusion for a prolonged period. The device may be used with autogenous bone and/or allogenic bone graft composed of cancellous and/or corticocancellous bone graft, and supplemental fixation to facilitate fusion.

**When used as an intervertebral body fusion device:**
The Octane-A/T/P Spinal Implant is intended for spinal fusion procedures at one or two contiguous levels in the lumbar spine from L2 to S1 in patients with Degenerative Disc Disease (DDD,) with up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). DDD is defined as back pain of discogenic origin, with degeneration of the disc confirmed by history and radiographic studies. Patients should be skeletally mature and have had at least 6 months of non-operative treatment. The device may be used with autogenous bone and/or allogenic bone graft composed of cancellous and/or corticocancellous bone graft, and with supplemental fixation systems cleared for use in the lumbosacral spine.

**Contraindications:**
Contraindications include, but are not limited to systemic, spinal, or localized infection; morbid obesity; signs of local inflammation; fever or leukocytosis; sensitivity/allergies to implant materials; any medical or surgical condition which would preclude the potential benefit of spinal implant surgery, such as the elevation of sedimentation rate unexplained by other diseases, elevation of white blood count (WBC), or a marked left shift in the WBC differential count; grossly distorted anatomy due to congenital abnormalities; rapid joint disease, bone absorption, osteopenia, and/or osteoporosis (osteoporosis is a relative contra-indication since this condition may limit the degree of obtainable correction, the amount of mechanical fixation, and/or the quality of the bone graft); any patient having inadequate tissue coverage over the operative site or where there is inadequate bone stock, bone quality, or anatomical definition; any case not described in the indications; any patient unwilling to cooperate with the postoperative instructions; any time implant utilization would interfere with anatomical structures or expected physiological performance.

**Warnings and Precautions:**
The ChoiceSpine Octane-A/T/P Spinal Implant should only be implanted by surgeons who are fully experienced in the use of such implants and the required specialized spinal surgery techniques. Further, the proper selection and compliance of the patient will greatly affect the results. The surgeon should consider the patient conditions (e.g., smoker, malnutrition, obesity, alcohol and drug abuse, poor muscle and bone quality), which may impact system performance.

The ChoiceSpine Octane-A/T/P Spinal Implant is not intended to be the sole means of spinal support. This device is intended to be used with supplemental spinal fixation systems that have been cleared for use in the cervical spine. Autogenous and or/allogenic bone grafting must be part of the spinal fusion procedure in which the ChoiceSpine Octane-A/T/P Spinal Implant is utilized. Use of this product without an autogenous /allogenic bone graft or in cases that develop into a nonunion will not be successful. The spinal implant cannot stand body loads without the support of bone. In this event, bending, loosening, disassembly and/or breakage of the device will eventually occur.

**Preoperative:**
- Patient should be in the previously described diagnostic categories delineated under INDICATIONS FOR USE.
- Patient should not be in any contraindicated group listed under CONTRAINDICATIONS.
- Handling procedures conforming to accepted standards are mandatory.
- The recommended techniques for implanting this device should be reviewed by the surgeon prior to use.
- The surgeon should inspect the available components of the Octane Spinal Implant System prior to surgery to assure that all necessary devices are present

**Intraoperative:**
- The surgeon is expected to follow the instructions made available in training manuals and literature relative to use of the ChoiceSpine Octane Spinal Implant System.
- The surgeon is expected to follow and exercise extreme care in the placement of implants, particularly in regard to neural elements.
- Radiographs should be made if there is any question as to the location of the intended or actual placement of the implants.

**Postoperative:**
- The patient is expected to follow the detailed instructions of the operating surgeon.
- Detailed instructions on the use and limitations of the device should be given to the patient. If partial weight-bearing is recommended or required prior to form bony union, the patient must be warned that loosening or breakage of the implant is a complication which can occur as a result of excessive or early weight-bearing or excessive muscular activity. The risk of loosening of an implant during postoperative rehabilitation may be increased if the patient is active, or if the patient is debilitated, demented, or otherwise unable to use crutches or other such weight supporting devices. The patient should be warned to avoid falls or sudden jolts in spinal position.
- To allow maximum chances for a successful surgical result, the patient/device should not be exposed to mechanical vibrations that may loosen the implant. The patient should be warned of this possibility and instructed to limit and restrict physical activities, especially lifting, twisting motions, and any type of sports participation. The patient should be advised not to smoke or consume any alcohol during the bone graft healing process.
- If a nonunion develops or if the implant loosens and/or break, the device(s) should be revised and/or removed immediately before serious injury occurs. Failure to immobilize a delayed union or nonunion will result in excessive and repeated movement causing stress on the implant. Continual loading and unloading of the implant may cause eventual loosening, or breakage of the device(s). It is important that immobilization of the surgical site be maintained until bony union consolidated and been confirmed by radiographic examination. The patient must be adequately warned of these hazards and closely supervised to ensure cooperation until bony union is confirmed.
- Any retrieved devices should be treated in such a manner that reuse in another surgical procedure is not possible. As with all orthopedic implants, none of the Octane VBI devices should ever be reused, under any circumstances.

**Potential Complications and Adverse Effects:**
- Possible complications and adverse effects include, but are not limited to loosening or fracture of the implants or instruments;
- nonunion or pseudoarthrosis, possibly requiring further surgery;
- infection;
- nerve or vascular damage due to surgical trauma, including loss of neurological function, dural tears, radiculopathy, paralysis, and cerebral spinal fluid leakage;
- sensitivity to a foreign body;

- pain or discomfort;
- bone loss due to resorption or stress shielding, or bone fracture at, above or below the level of surgery (fracture of the vertebra);
- hemorrhage of blood vessels and/or hematomas;
- misalignment of anatomical structures, including loss of proper spine curvature; correction, reduction and/or height;
- bone graft donor site pain;
- inability to resume activities of daily living;
- re-operation;
- death.

Additional surgery may be necessary to correct some of these potential adverse effects.

**Warnings:**
The surgeon should be aware of the following:
- The correct selection of the implant is extremely important. The potential for success is increased by the selection of the proper size of the implant. The size and shape of the human spine presents limiting restrictions of the size and strength of implants used. No implant can be expected to withstand the unsupported stresses of full weight bearing indefinitely.
- The device is not intended or expected to be the only mechanism of support of the spine. Regardless of the etiology of the spine pathology for which the implantation of this device was chosen, it is the expectation and requirement that adequate anterior column support exists, either by virtue of existing anatomy or by means of a spinal fusion or arthrodesis. Without solid biological anterior column support, the device cannot be expected to support the spine indefinitely and will fail in any of several modes. These modes may include bone-implant interface failure, implant failure, or bone failure.
- The surgeon must ensure that all necessary implants and instruments are on hand prior to surgery. The device must be handled and stored carefully, protected from damage, which includes corrosive environments. They should be carefully unpacked and inspected prior to use.
- All instruments must be cleaned and sterilized prior to use.
- As with all orthopedic implants, the Octane Spinal Implants should never be reused, under any circumstances.
- Proper implant selection and patient compliance to postoperative precautions will greatly affect surgical outcomes. Patients who smoke have been shown to have increased incidence of nonunion. Therefore, these patients should be advised of the fact and warned of the potential consequences.
- Postoperative care is important. The patient should be instructed in the limitations of his/her implant and should be cautioned regarding weight bearing and body stress on the appliance prior to secure bone healing.
- Implants must not be reused. Any implant, once used, should be discarded; even though it may appear undamaged, it may have small defects and internal stress patterns which may lead to early breakage.
- The ChoiceSpine Octane-A/T/P Spinal Implants have not been tested for safety and compatibility in the MR environment. The ChoiceSpine Octane-A/T/P Spinal Implant have not been tested for heating, migration, or image artifact in the MR environment. The safety of the ChoiceSpine Octane A/T/P Spinal Implant System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

**Precaution:**
The implantation of the ChoiceSpine Octane Spinal Implant is a technically demanding procedure presenting a risk of serious injury to the patient, and should only be performed by experienced spinal surgeons with specific training in the use of this system

**How Supplied:**
STERILE R The ChoiceSpine Octane-A/T/P Spinal Implant devices are supplied "Sterile" (gamma radiation) with SAL of $10^{-6}$ and intended for single use only. The sterility can only be assured if the packaging is intact. Do not use this device if the sterile packaging has been opened or damaged. Contact your local sales representative or distributor for replacement. Remove all packaging material prior to use. Only sterile implants should be used in surgery.

NON STERILE Instruments provided clean but non-sterile and must be sterilized prior to use. Instruments can be reprocessed using the recommended cleaning instructions.

**Cleaning and Decontamination:**
All instruments are supplied to the health care facility clean but non-sterile. Additionally, all instruments that have been previously taken into a sterile surgical field must first be decontaminated and cleaned using established hospital methods before sterilization and reintroduction into a sterile surgical field. Implants that have been implanted and then removed must be discarded. Cleaning and disinfecting of instruments can be accomplished by using alkali aldehyde-free solvents at high temperatures. Cleaning and decontamination can include the use of neutral cleaners followed by a deionized water rinse.

**Note:** Certain cleaning solutions such as those containing formalin, glutaraldehyde, bleach and/or alkaline cleaners may damage some devices, particularly instruments; these solutions should not be used.

All products should be treated with care. Improper use and handling may lead to damage and possible improper functioning of the device.

These devices are packaged in a convenience caddy/case. All devices must be removed from the case, inspected and cleaned via one of the appropriate methods below. Where applicable, instruments should be disassembled prior to cleaning and reassembled prior to sterilization. All devices must be placed back into the caddy and case prior to steam sterilization.

**Recommended Cleaning:**
The terms "Steris 444", "Enzol®" and "Prolystica®" are tradenames of ultrasonic equipment and detergents utilized on the recommended cleaning instructions. Any ultrasonic washer or equivalent ultrasonic detergent can be utilized when used in accordance to the manufacturer's instructions and labeling.

**Automated Cleaning:**
1. Rinse instrument(s) under cool running tap water (< 35 °C) to remove gross soil. Use a sterile syringe to flush water through and around cracks, crevices, and hard to reach areas.
2. Use a soft bristle brush as needed to remove soil, paying close attention to threads, crevices, and hard to reach areas.
3. Transfer instrument(s) into a STERIS 444 washer with the following parameters. Incline the instrument(s) to assist in drainage. Motor speed: High

| Phase | Time (min) | Temperature | Detergent |
|---|---|---|---|
| Pre-Wash 1 | 1:00 | Cold Tap Water | N/A |
| Enzyme Wash | 1:00 | Hot Tap Water | Enzol® at 1 oz per 1 gal water |
| Wash 1 | 2:00 | 60°C | Prolystica® 2x Conc. Neutral at 1/8 oz per 1 gal water |
| Rinse 1 | 1:00 | Hot Tap Water | N/A |
| Drying | 7:00 | 115°C | N/A |

4. Remove instrument(s) from washer & visually inspect for soil. Repeat if necessary

**Mechanical Cleaning (Ultrasonic):**
1. Rinse instrument(s) under cool running tap water (< 35 °C) to remove gross soil. Use a sterile syringe to flush water through & around cracks, crevices, & hard to reach areas.
2. Prepare Enzol® solution of one (1) ounce per one (1) gallon of warm tap water (< 55 °C).
3. Fully immerse instrument(s) in the detergent for at least one (1) minute.
4. Use a soft bristle brush as needed to remove soil, paying close attention to threads, crevices, & hard to reach areas.
5. Use a sterile syringe to flush detergent through & around cracks, crevices, & hard to reach areas.
6. Remove instrument(s) from detergent & rinse with cool tap water (< 35°C) for at least one (1) minute.
7. Prepare the ultrasonic cleaner with an Enzol® solution of one (1) ounce per one (1) gallon of warm tap water (< 55°C).
8. Load instrument(s) into the cleaner & sonicate for ten (10) minutes.
9. Remove instrument(s) from cleaner & thoroughly rinse using reverse osmosis/deionized (RO/DI) water for at least one (1) minute.
10. Dry instrument(s) using a clean, soft towel & filtered, pressurized air (20 psi).
11. Visually inspect for soil. Repeat if necessary

**Manual Cleaning:**
1. Rinse instrument(s) under cool running tap water (< 35 °C) to remove gross soil. Use a sterile syringe to flush water through & around cracks, crevices, & hard to reach areas.
2. Prepare Enzol® solution of one (1) ounce per one (1) gallon of warm tap water (< 55 °C).
3. Fully immerse instrument(s) in the detergent for at least one (1) minute.
4. Use a soft bristle brush as needed to remove soil, paying close attention to threads, crevices, & hard to reach areas.
5. Use a sterile syringe to flush detergent through & around cracks, crevices, & hard

to reach areas.

6. Remove instrument(s) from detergent & thoroughly rinse with reverse osmosis/deionized (RO/DI) water for at least one (1) minute. Use a sterile syringe to aid in rinsing.
7. Dry instrument(s) using a clean, soft cloth & filtered, pressurized air (20 psi).
8. Visually inspect for soil. Repeat if necessary

**Care and Handling:**

- All products should be treated with care. Improper use and handling may lead to damage and possible improper functioning of the device.
- Refer to ASTM standard F1744-96, "Standard Guide for Care and Handling of Stainless-Steel Surgical Instruments" for additional information.
- Before use, instruments should be visually inspected, and function should be tested to ensure instruments are functioning properly. If instruments are discolored, have loose screws/pins, are out of alignment, cracked, show excessive wear, or have other irregularities. DO NOT use.
- Lubricate instruments to protect instruments during sterilization and storage. This should be done with a water soluble, preserved lubricant after each cleaning. The lubricant should contain a chemical preservative to prevent bacterial growth and be made with distilled water. Excess lubricant should be wiped off prior to storage and sterilization.

**Sterilization:**

ChoiceSpine instruments are provided non-sterile and must be sterilized prior to use. All packaging materials must be removed prior to sterilization. Instruments are recommended to be steam sterilized by the hospital using the following process parameters:

**Steam Sterilizer Type: Pre-vacuum**
**Temperature: 132°C**
**Duration: 4 minutes**
**Drying Time: 40 minutes**

All devices are to be wrapped in two-layers of 1-ply polypropylene wrap (Kimguard KC600 or equivalent) using various wrapping techniques per ANSI/AAMI ST79.

This steam sterilization cycle is not considered by the FDA to be a standard sterilization cycle. It is the end user's responsibility to use only sterilizers and accessories (such as sterilization wraps or pouches, chemical or biological indicators, and sterilization cassettes) that have been cleared by the FDA for the sterilization cycle specifications (time and temperature). Alternative sterilization methods or cycles may be used but should be validated according to hospital practices and procedures. The use of an FDA cleared wrap is recommended to ensure devices remain sterile prior to implantation.

**Patient Education:**

It is essential to provide preoperative instructions to the patient. S/he should be made aware of the potential risks of the surgery and the implant limitations. The patient should be instructed to limit postoperative activity, as this will reduce the risk of bent, broken or loose implant components. The patient must be made aware that implant components may bend, break, or loosen even though restrictions in activity are followed.

**Storage and Handling:**

Implants should be stored in the implant sterilization case in clean, dry, well-ventilated conditions away from floors, ceilings, and outside walls. Store and transport sterile implants in such a way as to maintain sterility and functional integrity. Do not use implants if the sterilization wrap is compromised. Implants should remain covered until needed to avoid contamination. Only those to be implanted should be handled.

**Limitations and Restrictions:**

Repeated sterilization of instruments according to these instructions has a minimal effect on ChoiceSpine devices. Sterilization equipment varies in performance characteristics and must be validated accordingly. The sterilizing facility is responsible for the routine validation and monitoring of all equipment, materials and personnel used in their facility to ensure the desired results are achieved.

These instructions have been validated as being capable of sterilizing these ChoiceSpine instruments. Any deviations from these procedures must be evaluated for efficacy by the sterilizing facility.

**Device Retrieval Efforts:**

Should it become necessary to remove any or all of the Octane®-A/T/P Spinal Implant components, please call ChoiceSpine at the number below to receive instructions regarding data collection, including histo-pathological, mechanical, and adverse event information.

**Caution:**

Federal Law (USA) restricts this device to sale by or on the order of a physician.

**Product Complaints:**

Any dissatisfaction with the product quality, labeling, or performance should be reported to ChoiceSpine immediately by the customer or health care provider. Furthermore, ChoiceSpine should be notified immediately of any device malfunction by telephone, fax, or written correspondence. When filing a complaint, the name, part number, and lot number of the part should be provided along with the name and address of the person filing the complaint.

Some components may not be currently available. Please contact your ChoiceSpine representative for additional information. The products discussed herein may be available under different trademarks in different countries. All copyrights and pending and registered trademarks are property of ChoiceSpine. For more information on a specific product or trademark, please contact your local ChoiceSpine representative.

**Information:**

See choicespine.com for more information.

See choicespine.com/patents/ for patent information.

**For product complaints please contact:**

ChoiceSpine, LLC
Quality/Regulatory Department
400 Erin Drive
Knoxville, TN 37919
Phone: 865-246-3333; Fax: 865-588-4045

**For additional product information please contact:**

ChoiceSpine, LLC
Sales Support
400 Erin Drive
Knoxville, TN 37919
Phone: 865-246-3333 or fax: 865-588-4045
salessupport@choicespine.com

**Symbol Legend:**

| Symbol | Definition |
|---|---|
|  | Do not reuse |
|  | Caution, consult instructions for use for warnings and precautions |
|  | Consult instructions for use |
|  | Do not use if package is damaged |
|  | Lot number |
|  | Reference number |
|  | Serial Number |
|  | Sterilized by irradiation |
|  | Use by |
|  | Manufacturer |
|  | Date of Manufacture |
|  | Federal law (USA) restricts this device to sale by or on the order of a physician |
|  | Non-Sterile |
|  | European Medical Devices |
|  | Authorized representative in the European Community |
|  | MR Conditional |
|  | Sterilized by Ethylene Oxide |