General Description: The Octane Straight PC Intervertebral Fusion Device is an implant constructed of medical grade polyetheretherketone (PEEK-OMP™) 1500 with an outer surface designed to allow good fixation of the bone graft 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 becomes a solid unit upon PEEK-OMP™ polymer bond formation. Visualization of the defect site on radiography to assess bone growth and incorporation of the device in the bone bed can be used with the verification of position. The device is plasma coated with commercial pure titanium (Ti-6Al-4V) per ASTM F1536. The Octane Straight PC Intervertebral Fusion Device is provided sterile for single use.

Indications for Use: The Octane Straight PC Intervertebral Fusion Device is intended for spinal implants within the anterior column from T2 to L1 in patients with Degenerative Disc Disease (DDD), with up to Grade 1 spondylolisthesis or retroplasty 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 at least 6 months of non-operative treatment. The device system is designed for use with autogenous bone and/or allogenic bone graft composed of cancellous bone, cortical bone, or bone graft, and with supplemental fixation systems cleared for use in the lumbar spinal region.

Contraindications: Contraindications include, but are not limited to: systemic, spinal, or localised infection mortally debilitated signs of local or systemic infection fever or leukocytosis open wound, infection at the surgical site prior surgery at the involved level(s) cardiovascular complications hematomas or seromas complications of any kind any medical or surgical condition which would preclude the potential benefit of the device improper anatomical orientation or misalignment of the device may result in the failure to achieve fusion or may limit the degree of acceptable correction, the amount of mechanical fixation, and/or the quality of the bone graft any pre-existing condition of the operative site or where there is inadequate bone stock, bone quality, or bone anatomy, defined as follows:

- any case not described in the indications
- any condition that would contraindicate the postoperative instructions any time implant utilization would interfere with anatomical structures or expected physiological performance

Warnings and Precautions: The Octane Straight PC Intervertebral Fusion Device should be performed only by experienced spinal surgeons with specific training in the use of the device. Each use of this device demands an ongoing procedure preventing a risk of serious injury to the patient.

A successful result may not occur in every case in which the Octane Straight PC Intervertebral Fusion Device is utilized. The safety rates in spinal fusion procedures are published, and spinal fusion failure is an accepted risk of the procedure. This is particularly true for patients who choose to smoke tobacco, patients in multiple or obese states, or who abuse alcohol products.

The device is not intended or expected to be the only mechanism of support for 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 anatomic structures or expected physiological performance (osteoporosis is a relative contraindication since this condition may increase the risk of failure).

Potential Complications and Adverse Effects: Potential complications and adverse effects include, but are not limited to:

1. Infection
2. Disassembly, bending or breakage of any or all of the components
3. Foreign body (allergic) reaction to the implants
4. Non-un-union (pseudarthrosis), delayed union, mal-union
5. Compartment syndrome or crush syndrome (complete or incomplete), radiculopathy, dysraphy, hypereosinophilia, anaphylaxis, pancreatitis, development or continuation of pain, numbness, neuritis, tiling deformity, dural leak, neurological, neurophysiological defects (transient, permanent, and or delayed), reflex defects, bilateral paraplegia, unilateral paraplegia, quadriparesis, and/or quadriplegia
6. Herniography, hematoma, seroma, embolism, edema, stroke, excessive bleeding, phlebitis, wound necrosis, or wound dehiscence
7. Necrosis
8. Acute biological or autograft bone donor complications including pain, fracture, or osteomyelitis from the procedure
9. Asepsis
10. Abdomenis:
11. Retroposition of graft
12. Excessive bleeding resulting in excessive bleeding
13. Fracture, damage, degeneration or instability of any bone graft or bone implant
14. Bone loss due to resorption or stress shielding

Additional surgery may be necessary to correct any time of these potential adverse events.

How Supplied: The Octane Straight PC Intervertebral Fusion Devices are provided in a variety of sizes and are intended for single use. The device can be used to correct deformity or to stabilize a vertebral fracture. The device may be used with deionized water.

All the Octane Straight Intervertebral Fusion Devices are non-sterile and must be sterilized prior to use. Instruments should be reprocessed using the recommended cleaning instructions.

Cleaning and Decontamination: The Octane Straight Intervertebral Fusion Devices are non-sterile and are used sterile within 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/clinic protocols before sterilization and reinsertion into a sterile surgical field. Implants that have been implanted and then removed must be thoroughly cleaned and decontaminated using all biocidal-aldehyde-free solvents at high temperatures. Cleaning and decontamination can include the use of neutral cleaners followed by a decontamination step.

Note: Certain cleaning solutions such as those containing formaldehyde, glutaraldehyde, or peracetic acid and/or 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 failure 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 cleaning methods provided. Failure to clean and/or reprocess the device as recommended can result in a failure of the device. The FDA has recommended using these methods when used in accordance with the manufacturer’s instructions in order to promote sterility.

Automated Cleaning: 1. Rinse instrument(s) under cool running tap water (≤ 35 °C) to remove gross soil. Use a soft brush to scrub lightly to remove soils, gross debris, and hard to reach areas. 2. Decontamination. Use a solution of one (1) ounce per one (1) gallon of warm tap water (< 55 °C). Non-automated or non-disposable containers should be used for container sterilization methods below. Where applicable, instruments should be disassembled prior to cleaning and reprocessing. Do not use an ultrasonic cleaner with an Enzol® solution of one ounce (1) per one (1) gallon of water (< 55 °C). 4. Dry instrument(s) using a clean, soft & pressurized air, pressurized air (20 psi) or a Sterilizer clean, soft & filtered, filtered air (20 psi). 5. Visually inspect instrument for reprocess.

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, hard to reach areas. 2. Decontamination. Use a solution of one (1) ounce per one (1) gallon of warm tap water (< 55 °C). Non-automated or non-disposable containers should be used for container sterilization methods below. Where applicable, instruments should be disassembled prior to cleaning and reprocessing. Do not use an ultrasonic cleaner with an Enzol® solution of one ounce (1) per one (1) gallon of water (< 55 °C). 4. Dry instrument(s) using a clean, soft & filtered, filtered air (20 psi).


Care and Handling: 1. All products should be treated with care. Improper use and handling may lead to failure of the device. 2. Refer to ASTM standard F1444-96, "Standard Guide for Care and Handling of Stainless Steel Surgical Instruments" for additional information. 3. Before use, instrument should be visually inspected, and function should be tested to ensure instruments are functioning properly. If instruments are discarded, have loose screws/pins, are out of alignment, or have lost screws/pins, they cannot be utilized. 4. Lubricate instruments to protect instruments during sterilization and storage. This should be done with a water soluble, preserved lubricant that is not inhibiting the passage of steam or any other sterilization method. 5. Lubricate instruments to prevent bacterial growth and be made with distilled water. Excess lubricant should be wiped off prior to storage and sterilization.

Sterilization: Chondiochrome 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 procedures:

Steam Sterilizer Type: Pre-vacuum Temperature: 121°C (250°F) Drying Time: 40 minutes

All devices are to be wrapped in two-layer of 1-ply polypropylene wrap or similar material (2 Mil 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 approved by the manufacturer (such as, biological indicators, and sterilization cassettes) that have been cleared by the FDA for the sterilization cycle specifications (time and temperature). Failure to use sterilizers and methods cycles may or may be used should be validated according to the sterilizer manufacturer’s instructions. This wrap is recommended to ensure devices remain sterile prior to implantation.