Octane® Straight Intervertebral Fusion Device
Instruction for Use

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USA

General Description:
The ChoiceSpine Octane Straight Intervertebral Fusion Device 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 Octane Straight Intervertebral Fusion Device is provided sterile for single use.

Indications for Use:
The Octane Straight Intervertebral Fusion Device 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 system is designed for use 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
- pregnancy
- prior fusion surgery at the involved level(s)
- cardiovascular complications
- 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 contraindication 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 implantation of the Octane Straight Intervertebral Fusion Device 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.

A successful result may not occur in every case in which the Octane Straight Intervertebral Fusion Device is implanted. Failure 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 products, patients in malnourished or obese states, or who abuse alcohol products.

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.

MR Magnetic Resonance Environment
MR Conditional: (implants only)
Non-clinical testing has demonstrated that Octane Straight Intervertebral Fusion devices are MR conditional. A patient with these devices made of only PEEK and tantalum markers can be safely scanned in an MR system under the following conditions:

- Static magnetic field of 1.5 Tesla (1.5T) or 3.0-Tesla (3.0T).
- Maximum spatial gradient field of 19 T/m (1900 G/cm).
- Maximum MR system reported, whole-body averaged specific absorption rate (SAR) of 2.0 W/kg (normal operating mode).

Under the scan conditions defined above, the device is expected to produce a maximum temperature rise of less than or equal to 2°C after 15 minutes of continuous scanning.
In non-clinical testing, the image artifact caused by the device extends radially up to 0.5cm and 0.7cm (respectively) from the device when imaged with a gradient echo pulse sequence in a 1.5T MR system and a gradient echo pulse sequence in a 3.0T MR system.

Preoperative:
Proper selection of patients and good compliance of patients with post-surgical instructions are an integral part of the realization of a successful surgical procedure. All patients contemplating implantation of this device should be apprised of the risks associated with the procedure as well as the limitations regarding activities that the patient will face following surgery.

A successful result is not achieved in every surgical case, especially in spinal surgery where many extenuating circumstances may compromise results. Preoperative planning and operating procedures, including knowledge of surgical techniques, proper reduction, and proper selection and placement of the implant are critical considerations in achieving a successful result. Longevity of the implant depends on the weight and activity level of the patient, patient mortality, or need for component replacement secondary to patient weight and activity level.

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. An adequate inventory of sizes should be available at the time of surgery, including sizes larger and smaller than those expected to be used.

Since mechanical parts are involved, the surgeon should be familiar with the various components before using the equipment and should verify that all parts and necessary instruments are present before the surgery begins.

Intraoperative:
Based on the fatigue testing results, the physician/surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc. which may impact on the performance of the system.

Care should be used in the handling of the implant components. The implants should not be scratched or otherwise damaged. Extreme caution should be used around the spinal cord and nerve roots. Damage to the nerves will cause loss of neurological functions. Implants should be attached to the corresponding inserter such that they are fully seated on the inserter. Care should be taken not to over-tighten the implant to the inserter. It is recommended to use an imaging system to verify that the implant is properly placed and correctly aligned within the disc space. Stainless steel and titanium implants must NOT be used together in building a construct. Different manufacturers use different materials, varying tolerances and design configurations. Components of the Octane Straight Intervertebral Fusion Device must not be used with components from any other system or manufacturer.

Postoperative:
The physician's post-operative directions and warnings to the patient and the corresponding patient compliance are extremely important. It is recommended that regular, long-term postoperative follow-up be undertaken to detect early signs of component wear and to consider the course of action to be taken if such events occur.

Periodic x-rays should be taken to detect evidence of positional changes, failed fusion, and/or device fracture. In such cases, patients should be closely monitored, and the benefits of revision surgery should be considered in order to avoid further deterioration.

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.

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. 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. The patient should be advised not to smoke or consume alcohol during the autogenous bone graft healing process.

All patients should be instructed on the limitations of the device and the possibility of subsequent surgery. The patient should be instructed to limit and restrict physical activities, especially lifting and twisting motions and any type of sport participation. Patients should be advised of their inability to bend at the point of spinal fusion and taught to compensate for this permanent restriction in body motion.

If a non-union develops or the components loosen, bend, and/or break, the device(s) should be revised and/or removed immediately before serious injury occurs. Failure to immobilize a delayed or nonunion of bone will result in excessive and repeated stresses on the implant. By the mechanism of fatigue these stresses can cause eventual bending, loosening or breakage of the device(s).

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 Straight Intervertebral Fusion Device components should ever be reused under any circumstances. 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.

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

1. Early or late loosening of the components
2. Disassembly, bending or breakage of any or all of the components
3. Foreign body (allergic) reaction to the implants
4. Infection
5. Non-union (pseudarthrosis), delayed union, mal-union
6. Loss of neurological function, including paralysis (complete or incomplete), radiculopathy, dysesthesia, hyperesthesia, anesthesia, paresthesia, development or continuation of pain, numbness, neuroma, tingling sensation, dural tears, neuropathy, neurological deficits (transient, permanent, or delayed), reflex deficits, bilateral paraplegia, and/or arachnoiditis
7. Hemorrhage, hematoma, seroma, embolism, edema, stroke, excessive bleeding, phlebitis, wound necrosis, or wound dehiscence
8. Misalignment of anatomical structures or loss of spinal mobility
9. Autogenous bone graft donor complications including pain, fracture or wound healing problems
10. Atelectasis
11. Retropulsion of graft
12. Vascular damage resulting in excessive bleeding
13. Fracture, damage, degenerative changes or instability of any bone above and/or below the level of surgery
14. Bone loss due to resorption or stress shielding
15. Death

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

How Supplied:

STERILE R Octane Straight Intervertebral Fusion implants 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.

The Octane Straight Intervertebral Fusion instruments are 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 their original, sealed packaging in clean, dry conditions. The packaging should not be exposed to direct sunlight, ionizing radiation, extreme temperatures, or particulate contamination. In order to ensure sterility, implants must be used before the end of the expiration date indicated on the outer package label. Prior to use, inspect the packaging and labeling for integrity. If the device has been opened, damaged or adulterated in any way, it must not be used. In order to ensure sterility, please observe aseptic surgical procedures when removing the implant from its packaging.

Limitations and Restrictions:

Repeated sterilization 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® Straight Intervertebral Fusion device components, please call ChoiceSpine at the number below to receive instructions regarding data collection, including histopathological, mechanical, and adverse event information.

Surgical Technique Manual:

The ChoiceSpine Octane Straight Intervertebral Fusion Device Surgical Technique Manual is available by contacting ChoiceSpine Sales Support.

Caution:

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

Information:

See choicespine.com for more information.

See choicespine.com/patents/ for patent information.

Summary of Safety & Clinical Performance and Periodic Summary Update Report can be found at https://ec.europa.eu/tools/eudamed

For product complaints please contact:

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

For additional product information please contact:

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

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 an implant 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.

EC REP

EMERGO EUROPE
Westervoortsedijk 60,
6827 AT Arnhem
The Netherlands

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
	Unique Device Identification
	Medical Device