ChoiceSpine™
Propelling Spinal Surgery

Octane® M

DESCRIPTION
The ChoiceSpine™ Octane® M Spinal Implant is an intervertebral body fusion device constructed of medical grade Polyetheretherketone (PEEK) as described by ASTM F2026. The implant incorporates ridges on the superior and inferior surfaces to resist expulsion. The device is provided in various configurations and heights and contains a hollow core to receive autogenous bone graft. The device incorporates tantalum markers conforming to ASTM F560 to permit verification of position.

INDICATIONS FOR USE
The Octane M Spinal Implant is an intervertebral body fusion device 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 six (6) months of non-operative treatment. The device is intended for use with autogenous bone graft, and with supplemental internal fixation systems (i.e. posterior pedicle screw and rod systems, anterior plate systems, and anterior screw and rod systems) cleared for use in the lumbosacral spine.

CONTRAINDICATIONS
Contraindications include, but are not limited to:
- systemic, spinal, or localized infection;
- morbid obesity;
- active pregnancy;
- signs of local inflammation;
- fever or leukocytosis;
- 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 M 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. In addition, based on the fatigue test results, the surgeon should consider the levels of implantation, patient weight, patient activity level, and other patient conditions (e.g., smoking, occupation), which may impact on the performance of the implants.

Due to the presence of implants, imaging artifacts may appear on roentgenographic, CT, and/or MR imaging.

The Octane M Spinal Implant has not been tested for safety and compatibility in the MR environment. The Octane M Spinal Implant has not been tested for heating or migration in the MR environment.

Preoperative:
A successful result is not achieved in every surgical case, especially in spinal surgery where many extenuating circumstances may compromise results. Failure rates in spinal fusion procedures are published, and spinal fusion failure is an accepted risk of the procedure. Preoperative planning and operating procedures, including knowledge of surgical techniques and proper selection and placement of the implant are critical considerations in achieving a successful result.

The surgeon must ensure that all necessary implants and instruments are on hand prior to surgery. The devices must be handled and stored carefully and protected from damage.

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. Only patients that meet the criteria described in the indications should be selected. Patient conditions and/or predispositions such as those mentioned in the contraindications should be avoided.

Intraoperative:
The surgeon should follow established practices and specific instructions for implantation of the devices.

Bone grafts must be placed in the area to be fused. 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 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.

Care must be taken during positioning the device in the intervertebral space so as not to apply excessive forces that could cause cracking of the device.

When implanting a multi-piece Octane M Spinal Implant:
Both endplate components must be inserted into the intervertebral space while simultaneously attached to the inserter rails; inserting a single endplate will not permit proper assembly of the device. Attention should be paid that the endplate components are locked to the inserter rails prior to insertion into the intervertebral space; failure to lock the endplate components to the inserter rails may result in dislodging from the inserter rails.

During device assembly, the alignment of the spacer within the inserter rails should be visually confirmed. Misalignment may compromise the ability of the implant to properly assemble.

Dural surface and traversing and exiting nerve roots must be protected at all times with appropriate technique and/or nerve root retractors based on the experience of the spinal surgeon.

After the spacer will no longer advance, completion of device assembly should be confirmed using fluoroscopy.

The device must be filled with autogenous bone graft after in-situ assembly through the opening in the rear; pre-filling of the spacer component may compromise the ability for the implant to assemble. When filling the assembled device an appropriately sized bone funnel or forceps may be used. The autogenous bone graft must be sufficiently morselized to facilitate filling the device; a tamp should be used to pack the device to ensure adequate fill.

When implanting a single-piece Octane M Spinal Implant:
The device must be pre-filled with autogenous bone graft. This should be performed after assembly to the inserter and prior to insertion into the disc space.

Different manufacturers use different materials, varying tolerances and design configurations. The Octane M Spinal Implant must not be used with components from any other system or manufacturer since dimensional compatibility cannot be assured.

Postoperative:
The physician's post-operative directions and warnings to the patient and the corresponding patient compliance are extremely important.

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

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. The device is not intended or expected to be the only mechanism of support of the spine. No implant can be expected to withstand the unsupported stresses of full weight bearing indefinitely. 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 decision to remove the implants should take into consideration the risk to the patient of additional surgeries, as well as the difficulty of removal.

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.

COMPLICATIONS AND ADVERSE REACTIONS
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

HOW SUPPLIED
Implants are supplied sterile (gamma radiation) to a sterility assurance level (SAL) of 10^{-6} and are intended for single use only. Never resterilize an implant. Resterilization may adversely affect implant materials and result in premature failure.

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.

DEVICE RETRIEVAL EFFORTS
Should it become necessary to remove any or all of the Octane M components, please call ChoiceSpine at the number below to receive instructions regarding data collection, including histopathological, mechanical, and adverse event information.

CAUTION
Federal law restricts this device to sale by or on the order of a physician.

INFORMATION
For further product information, please contact Customer Service, ChoiceSpine, LP, 400 Erin Drive, Knoxville, TN 37919 USA, (865) 243-3383, or FAX (865) 588-4045. For product complaints, please contact Quality/Regulatory Department, Choice Spine, LP 400 Erin Drive, Knoxville, TN 37919 USA, (865) 246-3333 or FAX (865) 588-4045.

Patent: covered by one or more patents. See www.choicespine.com/about-us/patents/ for details.

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Some components may not be currently available. Please contact your ChoiceSpine representative for additional information.