The Octane-M Spinal Implant is an intervertebral body fusion device (IBF) cleared for use in the lumbosacral spine. Degenerative Disc Disease (DDD) with or to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s) 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 should be used in achieving a successful result. Proper selection of patients and good compliance of patients with post-operative instructions are critical considerations in achieving a successful result.

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 fusion is often an arduous process of the planning and operating procedures, including knowledge of surgical techniques and proper selection and use 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 device 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 result. All patients contemplating implantation of this device should be apprised of the risks associated with the procedure as well as the limitations and restrictions. Scanning a patient who has this device may result in patient injury.

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Drying Time: 40 minutes

All devices are to be wrapped in two-layer of 1-ply polypropylene wrap (Kimguard IQ600 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 pre-operative 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 instrument 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-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 (USA) restricts this device to sale by or on the order of a physician.

Information:
See www.choicespine.com/patents.html for details.

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
Customer Service Department
400 Erin Drive
Knoxville, TN 37919
Phone: 865-246-3333 or fax: 865-588-4045
customerservice@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.

Symbol Legend:

Symbol | Definition
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☑️ | Do not reuse
⚠️ | Caution, consult instructions for use for warnings and precautions
☐️ | Consult instructions for use
☒️ | Do not use if package is damaged
_lot | Lot number
_ref | Reference number
_sn | Serial Number
_qpc | Sterilized by irradiation
_used | Use by
_mfr | Manufacturer
_dmm | Date of Manufacture
_fda | Federal law (USA) restricts this device to sale by or on the order of a physician
_non | Non-Sterile
_eud | European Medical Devices
_afr | Authorized representative in the European Community