Instructions for Use
Vusion® TS

Manufacturer
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DESCRIPTION

The Vusion® implants are for use as a partial vertebral body prosthesis.

The Vusion implants are manufactured from Polyetheretherketone (PEEK-OPTIMA® LT1, ASTM F2026) and contain tantalum markers (tantalum per ASTM F560), which allow radiographic confirmation of proper positioning.. They are crescent shape and are offered in varying heights.

The implants should be used in conjunction with and stabilized by supplemental spinal fixation including, but not limited to a pedicle screw or plate fixation system.

INDICATIONS

The Vusion implants are intended for use in partial spine vertebrectomy procedures for vertebral body replacement. The indications include replacement of a collapsed, damaged, or unstable vertebral body that must be resected or excised due to tumor or trauma.

The implants are intended for use with a supplemental rod or plate fixation system.

CONTRAINDICATIONS

Contraindications may include, but are not limited to:
1. Active or suspected local or systemic infection.
2. Any pathological condition that would preclude fixation, appropriate range of motion, or adequate support or fixation of the component.
3. Certain systemic or metabolic bone conditions.
4. Skeletal immaturity.
5. Pregnancy.
6. Poor bone quality that cannot provide adequate support or fixation of the implant.
7. Any disease, ligamentous or severe muscle laxity or inadequate soft tissue coverage which may compromise the normal healing process or function of the implant.
8. Obese or overweight patients who may place undue loads on the orthosis, which can result in failure of the device.
9. Pathological conditions, neuromuscular disorders or mental conditions, whereby the risks associated with these conditions outweigh the benefits to be derived.

ADVERSE EFFECTS

All patients considered candidates for partial vertebral body replacement using a Vusion implant should be informed concerning the pathogenesis of their spinal abnormality, the rationale for partial vertebral body replacement with instrumentation and the potential adverse effects associated with the procedure. The potential adverse effects include, but are not limited to:

1. Loosening, fracture, slippage and/or migrations of the components.
2. Sensitivity or allergic reaction to the materials used to manufacture the implant.
3. Skin or muscle sensitivity.
4. Non-union or delayed union with adjacent vertebrae.

5. Infection.
6. Loss of proper spinal curvature, correction, height and/or reduction.
7. Loss of neurological function, dural tear, pain, and/or discomfort.
8. Epidural bleeding, hemorrhage of blood vessels, and/or hematomas.
9. Loss of bladder and/or bowel control.
10. Sterility, impotency, and/or consortium.
11. Bone loss and/or bone fracture due to stress shielding.
12. Bursitis.
13. Bone graft donor site pain.
14. Cardiovascular disorders including venous thrombosis, pulmonary embolism, cerebrovascular accident, and/or myocardial infarction.
15. Death.

WARNINGS AND PRECAUTIONS
Vusion TS implants should only be used by surgeons trained and experienced in partial vertebrectomy, and partial vertebral body replacement techniques.

Preoperative and operating procedures, including knowledge of surgical techniques and proper selection and placement of the implants are essential considerations in the utilization of this device.

Patient selection and compliance will greatly affect the results. Patients suffering from obesity, malnutrition, and/or poor bone quality are poor candidates for partial vertebral body replacement. Patients who smoke or abuse alcohol are poor candidates for partial vertebral body replacement.

Potential risks identified with the use of this device system, which may require additional surgery, include device component fracture, loss of fixation, non-union, fracture of adjacent vertebrae, neurological injury, and/or vascular or visceral injury.

Patients should be informed of the potential risks identified with the use of this device as well as postoperative weight bearing activity levels, which may require additional surgery. The device is designed as a load-sharing device and is to be used to obtain normal alignment until normal healing and/or fusion occurs. If delayed union or non-union occurs the implant may be subjected to increased loads which may result in device component fracture.

Preoperative
1. Patients who meet the criteria in INDICATIONS should be considered for surgery.
2. Patients with conditions such as those addressed in CONTRAINDICATIONS should not be considered for surgery.
3. The surgeon should make sure that implants and all instruments are sterilized and available prior to surgery.
4. Implants and instruments should be inspected for surface flaws and scratches and should not be used in the presence thereof.

Intraoperative
1. Extreme caution should be used around the spinal cord and nerve roots. Damage to the nerves will cause loss of neurological functions.
2. Mishandling of instruments may cause injury to patient and/or operative personnel.
3. Bone grafts should be used to ensure stability.
4. Notching and scratching of implants should be avoided.

Postoperative
1. For best possible results, patients should be counseled to avoid lifting, twisting, physical activities, smoking, consuming alcohol, and any other activity that would compromise or delay the healing process.
2. The patient should be warned about the limitation of bending at the point of surgery.

PACKAGING AND STERILITY
Vusion TS implants are supplied in sterile or non-sterile packaging. Implants supplied in non-sterile packaging **must** be sterilized prior to use. Sterile Vusion TS implants are sterilized by a minimum of 25kGy gamma irradiation at a sterility assurance level of 10^{-6}. Sterile product packaging should be inspected for flaws before

opening. In the presence of a packaging flaw, do not use. Do not re-sterilize. Do not use after expiration date.

All instruments should be thoroughly cleaned prior to sterilization. Cases should be placed in two layers of FDA cleared 1-ply polypropylene wrap, such as Kimguard KC600, using sequential wrapping techniques prior to sterilization.

For non-sterile implants, the following steam sterilization cycles must be followed in order to ensure sterility of the implants and instruments. Remove all packaging before sterilization.

Implants and Instruments:
Prevacuum Cycle: 4 minutes at 132° C (270° F)
Dry Time: 55 minutes

PRODUCT HANDLING
Implants should be used only if received with packaging intact. Damaged packaging and implants should not be used and should be returned to Ortho Development Corporation. Protect the implants from contact with objects that may damage the surface finish. Inspect each implant prior to use for visual damage.

PRODUCT COMPLAINTS
Any complaint or dissatisfaction with product quality, performance, labeling, and/or safety should be reported to Ortho Development Corporation. If any of the implants or instruments "malfunction" (i.e., do not meet any of their performance specifications or does not perform as intended), and/or are suspected to have caused or contributed to the death or serious injury of the patient, Ortho Development Corporation should be notified immediately by phone, fax or written correspondence.

When filing a complaint, please provide the product description, product number, lot number, complainant's name and address, and the nature of the complaint.

CAUTION
Federal Law (USA) restricts this device to sale, distribution and use by or on the order of a physician.

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