Instructions for Use
Vusion® OS

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DESCRIPTION

Vusion® OS consists of implants with various widths, lengths, heights, and degrees of lordosis. The implant is provided in widths from 9mm to 11mm, lengths from 20mm to 35mm, and heights ranging from 7mm to 16mm. The implants are made from Polyetheretherketone (PEEK-OPTIMA® LT1, ASTM F2026) and contain tantalum markers (tantalum per ASTM F560), which allow radiographic confirmation of proper positioning. The implants have ridged teeth that resist rotation and migration, and holes to accommodate bone graft. The implant geometry includes a bulleted nose, fixation teeth on the superior and inferior surfaces, side windows, a graft window passing between the superior and inferior surfaces, and an insertion hole and rails for implant placement control. The implant is supplied non-sterile and sterile. Vusion OS is implanted using a standard or oblique PLIF (Posterior Lumbar Interbody Fusion) approach and is intended to be used singly or in pairs with supplemental fixation.

INDICATIONS

Vusion OS is indicated for use as an interbody fusion device at one or two contiguous levels (L2-S1) in skeletally mature 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. These patients may have had a previous non-fusion spinal surgery at the involved spinal level(s). Vusion OS is to be used with supplemental fixation and autogenous bone graft. Patients should have at least six months of non-operative treatment prior to treatment.

CONTRAINDICATIONS

Contraindications 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, ligaments 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.
10. Metal/ polymer sensitivity/ allergies to the implant materials.
11. Any other condition which would preclude the potential benefit of spinal implant surgery, such as the presence of tumors or congenital abnormalities, fracture local to the operating site, elevation of segmentation rate unexplained by other diseases, elevation of white blood count (WBC), or a marked left shift in the WBC differential count.
12. Prior fusion at the level(s) to be treated.

ADVERSE EFFECTS
Potential adverse effects include, but are not limited to:

1. Late union or non-union (pseudoarthrosis).
2. Loss of proper spinal curvature, correction, height, and/or reduction.
3. Implant migration.
4. Early or late loosening of the device.
5. Skin or muscle sensitivity.
6. Bursitis.
7. Foreign body or allergic reaction, or sensitivity to the materials used to manufacture the implant.
8. Infection.
9. Fracture of the device.
10. Decrease in bone density and/or bone fracture due to stress shielding.
11. Bone graft donor site pain or complication.
12. Loss of neurological function, appearance of radiculopathy, dural tears or leaks, and/or development of pain and/or discomfort.
13. Disc degeneration at, above, or below the level of surgery.
14. Cessation of any potential growth of the operated portion of the spine.
15. Reproductive system compromise, including sterility, impotency, and/or loss of consortium.
16. Urinary retention or loss of bladder/bowel control.
17. Loss of or increase in spinal mobility or function.
18. Epidural bleeding, hemorrhage of blood vessels, and/or hematomas.
19. Cardiovascular disorders, including venous thrombosis, pulmonary embolism, cerebrovascular accident, and/or myocardial infarction.
20. Paralysis.
21. Death.

Adverse effects may necessitate re-operation or revision.

WARNINGS AND PRECAUTIONS
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. Further, the proper selection and the compliance of the patient will greatly affect the results. Patients who smoke have been shown to have a reduced incidence of bone fusion. These patients should be advised of this fact and warned of this consequence. Obese, malnourished, and/or alcohol/drug abuse patients and those with poor muscle and bone quality and/or nerve paralysis are also poor candidates for spinal fusion or partial vertebral body replacement.

Patients with previous spinal surgery at the levels to be treated may have different clinical outcomes compared to those without a previous surgery.

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 nonunion occurs the implant may be subjected to increased loads which may result in device component fracture.

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 this system.

Never reuse a Vusion OS device under any circumstances. Even when a removed device appears undamaged, it may have small defects or internal stress patterns that may lead to early breakage.
Vusion OS has not been evaluated for safety and compatibility in the magnetic resonance (MR) environment.

Vusion OS has not been tested for heating or migration in the MR environment.

Preoperative
1. Patients who meet criteria in INDICATIONS may 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 all implants and 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.
5. Sterile packaged implants should be inspected to ensure packaging has not been damaged or previously opened.
6. Sterile packaged implants must not be used beyond the expiration date.

Intraoperative
1. Extreme caution should be used around the spinal cord and nerve roots. Damage to the nerves may 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, physical activities, smoking, consuming alcohol and any other activity that would compromise or delay the healing process.
2. The patients should be warned about bending limitations at the point of surgery.

PACKAGING AND STERILITY
Vusion OS implants are supplied in sterile or non-sterile packaging. Implants supplied in non-sterile packaging must be sterilized prior to use.

Sterile Vusion OS 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. The Vusion OS Universal Inserter Shafts should be removed from all Vusion OS Inserters 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:
Prevacuum Cycle: 4 minutes at 132° C (270° F), dry time 45 minutes

Instruments:
Prevacuum Cycle: 4 minutes at 132° C (270° F), dry time 55 minutes

It is the end users' responsibility to use only sterilizers and accessories (such as sterilization wraps, sterilization pouches, chemical indicators, biological indicators, and sterilization cassettes) that have been cleared by the Food and Drug Administration for the selected sterilization cycle specifications (time and temperature).

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 do 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, complaint'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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