Spineology®

OptiMesh Align™ Expandable Interbody Fusion System

DESCRIPTION

The OptiMesh Align Expandable Interbody Fusion System mesh implant is a porous container knitted from polyester yarn made of polyethylene terephthalate (PET) thread. Each mesh is supplied on a disposable holder for ease of handling and placement. The OptiMesh Align device is packaged into double Tyvek/Mylar film pouches, placed in a carton, and then terminally sterilized by gamma radiation. The PET material is radiolucent and is not bioresorbable.

The OptiMesh Align device is designed to contain and allow compaction of bone graft material. The compaction process during filling deploys the mesh and provides containment to allow formation of a solid graft pack capable of supporting axial load with posterior supplemental fixation. The bone graft material used to fill the mesh implant includes AFT Allograft Filler Tube, which provides pre-filled graft material within a disposable delivery tube.

The OptiMesh Align Expandable Interbody device is designed as a single- or dual chamber device with a load bearing anterior geometry and a load sharing posterior geometry designed for use with posterior supplemental fixation. The device is offered in three sizes. The table below lists the available OptiMesh Align Interbody device sizes.

Catalog Number	Size
400-2610	Small
400-2620	Large
400-2625	Extra-Large

The OptiMesh Align Expandable Interbody Fusion System is intended for use to contain bone graft as an adjunct to fusion in instrumented lumbar fusion procedures for the treatment of degenerative disc disease (DDD).

AFT is a bone void filler available from the Musculoskeletal Transplant Foundation (MTF), Edison, NJ. AFT contains corticocancellous bone chips, demineralized bone matrix (DBM) and sodium hyaluronate. Please refer to the AFT package insert for more information.

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INDICATIONS FOR USE

The OptiMesh Align Expandable Interbody Fusion System is indicated for use as an adjunct to fusion in an intervertebral body fusion at one level in the lumbar spine from L2 to S1 in skeletally mature patients with degenerative disc disease (DDD) with up to Grade I spondylolisthesis at the involved level. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history, physical examination, and radiographic studies. Eligible patients shall have undergone six (6) months of conservative (non-operative) care. The OptiMesh Align Interbody device, along with a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion, is intended for use with supplemental posterior fixation systems intended for use in the lumbar spine.

CONTRAINDICATIONS

Contraindications include, but are not limited to:

- Infection
- Fever or leukocytosis
- Rapid joint disease, bone absorption, osteopenia, and/or osteoporosis
- Prior fusion surgery at the involved level
- Vascular deficiency at the surgical site
- Any patient unwilling or unable to cooperate with the postoperative instructions
- Any medical condition that would preclude the patient from having surgery or would impede the benefit of implant surgery
- Patients requiring post-operative radiation treatment
- Known or suspected sensitivity to implant materials
- Morbid obesity
- Mental illness
- Pregnancy

PRECAUTIONS

- The implantation of this device should be performed only by experienced spinal surgeons with specific training in the use of this system and thorough understanding of the surgical use of the device. Lumbar interbody fusion is a technically demanding procedure presenting a risk of serious injury to the patient.
- The success of any spinal fusion is dependent upon many factors that include, but are not limited to, the health and metabolism of the patient. Medical conditions or disease states that alter a patient's normal metabolism may interfere with bone healing.
- Patient selection and compliance will greatly affect the results. Patients suffering from obesity, malnutrition, and/or poor bone quality are poor candidates for spinal fusion. Patients who smoke or abuse alcohol are poor candidates for spinal fusion. Younger patients (less than 59 years of age) with lower preoperative mental health status may not achieve the desired clinical outcomes.
- 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.
- This procedure should only be performed with imaging equipment that can be properly aligned with the target level to provide clear bi-planar radiographic information on instrument positioning.
- It is important to choose the correct implant size. Surgeons should be fully trained and familiar with use of the instruments and proper placement of the implant.
- The surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc., which may impact the performance of the system.
- The OptiMesh implant is a porous fabric mesh. It can be damaged or torn through improper handling or use, and it is not intended to be trimmed or cut in any circumstances. A torn mesh can lead to loss of graft containment.
- The implant is provided sterile. Product packaging should be inspected for continuity and the components should be handled appropriately to ensure sterility. Do not use if packaging has been damaged or shelf life exceeded.
- Patients who are taking medications that may interfere with bone or soft tissue healing (e.g. long-term steroid use) may not be suitable candidates as these medications may interfere with bone growth and graft incorporation.
- As with any permanent implant, a perioperative antibiotic protocol is recommended.
- An implant should never be reused.
- Resterilization of the mesh is not recommended under any circumstances.
- Patients receiving an OptiMesh implant should have had at least six months of non-operative treatment.
- A successful result is not always achieved in every surgical case due to many extenuating circumstances. This device is intended for temporary stabilization of the spine in order to obtain a solid fusion mass using a bone graft. The durability and success of the implant will be compromised in cases where a non- union develops, or when used without a bone graft.
- Potential risks identified with the use of this device system, which may require additional surgery, are identified below.
- This system should not be used with components of any other system or Manufacturer.
- AFT: Trace amounts of Gentamicin, Primaxin and Amphotericin B antibiotics may be present. Trace amounts of Polysorbate-80, Ethanol, Methanol, Isopropanol, Polyoxyethylene (10) Phenol Ether and Hydrogen peroxide may be present. *Caution* should be

exercised if the patient is allergic to any of these substances.

POTENTIAL ADVERSE EFFECTS

All patients considered candidates for fusion using an OptiMesh implant should be informed concerning the pathogenesis of their spinal abnormality, the rationale for fusion with instrumentation, and the potential adverse effects associated with the procedure. Possible adverse effects or risks include, but are not limited to, the following, which may require additional surgery:

- Device failure: mesh tearing, loss of graft containment
- Bone graft shifting
- Device migration
- Allergic or foreign body reaction to implant materials
- Non-union or delayed union
- Adjacent level deterioration
- Incomplete relief of symptoms
- Loss of proper spinal curvature, correction, height, and/or reduction
- Loss of neurological function, nerve root damage, dural tear, pain and/or discomfort
- Risks specific to Posterior Fixation Systems
- Pain due to hardware irritation (due to supplemental fixation)
- Epidural bleeding, hemorrhage of blood vessels, and/or hematomas
- Side effects from anesthesia
- Infection of soft tissue and/or bone (osteomyelitis)
- Seroma
- The use of allograft bone tissue may pose a risk of disease or infection
- Loss of bladder and/or bowel control
- Sterility, impotency, and/or loss of consortium
- Bone loss and/or bone fracture due to stress shielding
- Vertebral endplate injury
- Bursitis
- Bone graft donor site pain or other complications
- Cardiovascular disorders including venous thrombosis, pulmonary embolism, cerebrovascular accident, and/or myocardial infarction
- Soft tissue injury
- Skin or muscle sensitivity
- Edema
- Death

CLINICAL SUMMARY

Spineology conducted a 24-month, prospective, single arm, multi-center study with 102 subjects. Subjects were skeletally mature adults with low back pain and pain-related disability, who presented with symptomatic single level degenerative disc disease between L2 and S1. The clinical study was designed to meet a pre-determined performance goal at 24 months post-implantation. The performance goal was based on four (4) individual parameters: pain (evaluated by Visual Analog Scale - VAS), function (evaluated by Oswestry Disability Index – ODI), fusion (evaluated by imaging), and safety (evaluated by adverse events).

Eighty-two (82) of the ninety-six (96) subjects (85.4%) had at least a 20 mm improvement in VAS pain score. Seventy-eight (78) of the ninety-six (96) subjects (81.3%) had at least a 15-point improvement in ODI score. Ninety-five (95) of the ninety-six (96) subjects (99.0%) achieved a fusion. Ninety-one (91) of the ninety-eight (98) subjects (92.9%) were free from device-related serious adverse events and secondary surgical interventions at the index level. The most common study-related adverse events were pain (15.7%- 16/102), symptomatic adjacent level DDD (5.9% -6/102), and lumbar muscle spasm/strain (4.9%- 5/102). Most subjects were reported to have improved or maintained their neurological status, with 5.3% (5/95), 2.1% (2/96) and 1.0% (1/96) of subjects reported to have worsened in their reflex, sensory and strength neurological assessments, respectively. Each of the four individual parameters of the pre-determined performance goal were met to support safety and effectiveness.

MRI WARNING

The OptiMesh device has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of the OptiMesh device is unknown. Scanning a patient who has this device may result in patient injury.

IMPLANT HANDLING

Exercise care in handling implants. Protect the implants from contact with objects that may damage the mesh. Inspect each implant prior to use and do not use if any damage is suspected.

STERILE PRODUCT PACKAGING

Implants and instruments provided sterile should be inspected for package continuity. Packages for each of the sterile products should be intact upon receipt. Do not use sterile product if the packaging has been damaged or the shelf life has been exceeded. Devices must be handled properly to maintain sterility. Damaged packages or products should not be used and should be returned to Spineology.

- **Note that products provided sterile are for single use only.**
- **Do not re-sterilize products provided sterile.**

STORAGE

Store the OptiMesh implants and AFT at room temperature conditions. Protect from excessive heat. No refrigeration or freezing is required. Please refer to the AFT package insert for more information.

DISPOSAL

Dispose of excess or unused bone tissue, and all packaging that has been in contact with the tissue, in accordance with recognized procedures for discarding regulated medical waste materials.

DEVICE REMOVAL / REVISION

Please refer to the OptiMesh Align Expandable Interbody Surgical Technique Guide document L- 00004 for instructions. Please contact your Spineology representative if you need a replacement document.

INSTRUMENT HANDLING

Surgical instruments must be handled with care. Improper handling may result in damage and may impair proper functioning of the device. Instruments which exhibit signs of damage or deterioration, including discoloration or corrosion, must be replaced. Ensure that all components of the system are available for use prior to surgery. Instruments must be sterilized before use and are to be cleaned, decontaminated, and re-sterilized immediately after use.

INSTRUMENT CLEANING, DECONTAMINATION, AND STERILIZATION

All instruments provided non-sterile must be cleaned, decontaminated, and sterilized by the hospital before use. Please refer to the OptiMesh Align Expandable Interbody Reprocessing Instructions for Spineology Surgical Instruments document L-00007 for instructions. Please contact your Spineology representative if you need a replacement document.

FURTHER INFORMATION OR PRODUCT COMPLAINTS:

Contact Spineology at:

Spineology Inc.
7800 Third Street N., Suite 600
Saint Paul, MN 55128-5455
Phone: 1.651.256.8500
Fax: 1.651.256.8505

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