Spineology

Duo™ Ti
Expandable Interbody Fusion System

DESCRIPTION

The Duo™ Ti Expandable Interbody Fusion Device is an intervertebral implant designed to provide mechanical support of the intradiscal space as an adjunct to fusion. The device is made of OsteoSync™ titanium, titanium alloy, and polyethylene terephthalate (PET). It is available in varying lengths, heights, and lordotic angles and is provided sterile. It is designed with a porous central cavity for graft containment. The device features a rounded nose to aid implant insertion and includes ridged teeth to resist migration.

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INDICATIONS

The Duo Expandable Interbody Fusion Device is indicated for intervertebral body fusion at one level or two contiguous levels in the lumbar spine from L2 to L5 in patients with degenerative disc disease (DDD) with up to Grade I spondylolisthesis at the involved level(s). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. The Duo device is designed for use with autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft as an adjunct to fusion and is intended for use with supplemental fixation systems cleared by the FDA for use in the lumbar spine.

CONTRAINDICATIONS

Contraindications include, but are not limited to:

- Infection
- Morbid obesity
- Mental illness
- Fever or leukocytosis
- Pregnancy
- Rapid joint disease, bone absorption, osteopenia, and/or osteoporosis
- Prior fusion surgery at the involved level(s)
- Cardiovascular complications
- Any patient unwilling to cooperate with the postoperative instructions
- Known or suspected sensitivity to implant materials
- Any medical condition that would preclude the patient from having surgery or would impede the benefit of implant surgery

PRECAUTIONS

- The implantation of this device should be performed only by experienced spinal surgeons with specific training in the use of systems of this type because this 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.
- 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.
- 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 physician/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 mesh component of Duo Ti is not intended to be trimmed or cut in any circumstances. Handle with care to prevent tearing or damage.
- 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.
- Patients receiving a Duo Ti 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.

POTENTIAL ADVERSE EFFECTS

All patients considered candidates for fusion using Duo Ti implants 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:

- Bending, loosening, fracture, slippage, and/or migration of the component
- Foreign body reaction to the implant
- Skin or muscle sensitivity
- Non-union or delayed union
- Infection of soft tissue and/or bone (osteomyelitis); fever
- Incomplete relief of symptoms
- Loss of proper spinal curvature, correction, height, and/or reduction
- Loss of neurological function, dural tear, pain and/or discomfort
- Epidural bleeding, hemorrhage of blood vessels, and/or hematomas
- 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
- Edema
- Death

MRI WARNING

The Duo Ti 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 Duo Ti device in the MR environment 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 surface. 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. If a loaner or consignment system is used, all sets should be carefully checked for completeness and all components including instruments should be carefully checked to ensure that there is no damage prior to use. 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 implants and instruments provided sterile at room temperature conditions.

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 Duo Ti Expandable Interbody Fusion System Surgical Technique Guide document L584 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 Duo Ti Expandable Interbody Fusion System Reprocessing Instructions for Spineology Surgical Instruments document L585 for instructions. Please contact your Spineology representative if you need a replacement document.

FURTHER INFORMATION OR PRODUCT COMPLAINTS

Contact Spineology at:

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