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NuVasive Modulus Interbody System
Intervertebral Body Fusion Device
INSTRUCTIONS FOR USE

CE 0086 Rx ONLY 9402506-EN A

GRAPHICAL SYMBOLS	
www.nuvasive.com	Consult Instructions Before Use. Available on the NuVasive website at www.nuvasive.com
	Single Use Only
REF	Catalog Number
LOT	Lot Number
QTY	Quantity
MATL Ti6Al-4V ELI	Material: Titanium Alloy
STERILE R	Sterilization by Irradiation
	Use By

ENGLISH

Description
The *NuVasive Modulus Interbody System implants* are manufactured from Ti-6Al-4V ELI conforming to ASTM F3001. The implants are available in a variety of different shapes and sizes to suit the individual pathology and anatomical conditions of the patient.

Indications for Use
The *NuVasive Modulus Interbody System* is indicated for intervertebral body fusion of the spine in skeletally mature patients. The System is designed for use with autogenous and/or allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft to facilitate fusion and supplemental internal spinal fixation systems cleared by the FDA for use in the thoracolumbar spine. The devices are to be used in patients who have had at least six months of non-operative treatment.
The *NuVasive Modulus Interbody System* is intended for use in interbody fusions in the thoracolumbar spine from T1 to T12 and at the thoracolumbar junction (T12-L1), and for use in the lumbar spine from L1 to S1, for the treatment of symptomatic disc degeneration (DDD) or degenerative spondylolisthesis at one or two adjacent levels, including thoracic disc herniation (with myelopathy and/or radiculopathy with or without axial pain). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The *NuVasive Modulus Interbody System* is also indicated for use in the treatment of multilevel degenerative scoliosis in the thoracolumbar spine.

Contraindications
Contraindications include, but are not limited to:
1. Infection, local to the operative site.
2. Signs of local inflammation.
3. Patients with known sensitivity to the materials implanted.
4. Patients who are unwilling to restrict activities or follow medical advice.
5. Patients with inadequate bone stock or quality.
6. Patients with physical or medical conditions that would prohibit beneficial surgical outcome.
7. Prior fusion at the level(s) to be treated.

Potential Adverse Events and Complications
As with any major surgical procedures, there are risks involved in spinal/orthopedic surgery. Infrequent operative and postoperative complications that may result in the need for additional surgeries include: early or late infection; damage to blood vessels, spinal cord or peripheral nerves, pulmonary emboli; loss of sensory and/or motor function; pleural effusions, hemothorax, chylothorax, pneumothorax, subcutaneous emphysema, need for chest tube insertion, intercostal neuralgia, rib fracture, diaphragm injury; atelectasis; impotence; permanent pain and/or deformity. Rarely, some complications may be fatal.
The treatment of multilevel degenerative scoliosis may be associated with a lower interbody fusion rate compared to one- and two-level interbody fusions.
Potential risks identified with the use of this system, which may require additional surgery, include:
- Bending, fracture or loosening of implant component(s)
- Loss of fixation
- Nonunion or delayed union
- Fracture of the vertebra
- Neurological, vascular or visceral injury
- Metal sensitivity or allergic reaction to a foreign body
- Infection
- Decrease in bone density due to stress shielding
- Pain, discomfort or abnormal sensations due to the presence of the device
- Nerve damage due to surgical trauma
- Bursitis
- Dural leak
- Paralysis
- Death

Warnings, Cautions and Precautions
The subject device is intended for use only as indicated.
The implantation of spinal systems should be performed only by experienced spinal surgeons with specific training in the use of this spinal system because this is a technically demanding procedure presenting a risk of serious injury to the patient.
Correct selection of the implant is extremely important. The potential for success is increased by the selection of the proper size of the implant. While proper selection can minimize risks, the size and shape of human bones present limitations on the size and strength of implants. Metallic and internal fixation devices cannot withstand the activity levels and/or loads equal to those placed on normal, healthy bone. These devices are not designed to withstand the unsupported stress of full weight or load bearing alone.
Caution must be taken due to potential patient sensitivity to materials. Do not implant in patients with known or suspected sensitivity to the aforementioned materials.
These devices can break when subjected to the increased load associated with delayed union or nonunion. Internal fixation appliances are load-sharing devices that hold bony structures in alignment until healing occurs. If healing is delayed, or does not occur, the implant may eventually loosen, bend, or break. Loads on the device produced by load bearing and by the patient's activity level will dictate the longevity of the implant.
Corrosion of the implant can occur. Implanting metals and alloys in the human body subjects them to a constantly changing environment of salts, acids, and alkalis, which can cause corrosion. Placing dissimilar metals in contact with each other can accelerate the corrosion process, which in turn, can enhance fatigue fractures of implants. Consequently, every effort should be made to use compatible metals and alloys in conjunction with each other.
Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without a previous surgery.
Based on fatigue testing results, when using the *Modulus Interbody System*, 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.
Care should be taken to insure that all components are ideally fixated prior to closure.
Patient Education: Preoperative instructions to the patient are essential. The patient should be made aware of the limitations of the implant and potential risks of the surgery. 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.
Single Use: Reuse of a single use device that has come in contact with blood, bone, tissue or other body fluids may lead to patient or user injury. Possible risks associated with reuse of a single use device include, but are not limited to, mechanical failure, material degradation, potential leachables, and transmission of infectious agents. Resterilization may result in damage or decreased performance.
Magnetic Resonance (MR) Safety: The *Modulus Interbody System* has not been evaluated for safety and compatibility in the MR environment. The *Modulus Interbody System* has not been tested for heating or migration in the MR environment.
Compatibility: Do not use the *Modulus Interbody System* with components of other systems. Unless stated otherwise, NuVasive devices are not to be combined with the components of another system.
Notching, striking, and/or scratching of implants with any instrument should be avoided to reduce the risk of breakage.

Preoperative Warnings
1. Only patients that meet the criteria described in the indications should be selected.
2. Patient condition and/or predispositions such as those addressed in the aforementioned contraindications should be avoided.
3. Care should be used in the handling and storage of the *Modulus implants*. Assure highly aseptic surgical conditions, and use aseptic technique when removing the *Modulus implant* from its packaging. Inspect the implant and packaging for signs of damage, including scratched or damaged devices or damage to the sterile barrier. Do not use the *Modulus implants* if there is any evidence of damage.
4. Inspect all components for damage before use.
5. Care should be used during surgical procedures to prevent damage to the device(s) and injury to the patient.

Postoperative Warnings
During the postoperative phase it is of particular importance that the physician keeps the patient well informed of all procedures and treatments.
Damage to the weight-bearing structures can give rise to loosening of the components, dislocation and migration, as well as other complications. To ensure the earliest possible detection of such catalysts of device dysfunction, the devices must be checked periodically postoperatively, using appropriate radiographic techniques.

Method of Use
Please refer to the Surgical Technique for this device.

Packaging
Packages for each of the components should be intact upon receipt. All implant and instrument sets should be carefully examined for completeness, and for lack of damage, prior to use. Damaged packages or products should not be used, and should be returned to NuVasive.

Handling of the Implant
- Before removing the implants from the package, make sure that the protective packaging is unopened and undamaged. If the packaging is damaged, the implants have to be considered as NON-STERILE and may not be used.
- Upon removal from the package, compare the descriptions on the label with the package contents (product number and size)
- Note the STERILE expiry date. Implants with elapsed STERILE expiry dates have to be considered as non-sterile.
- Take particular care that aseptic integrity is assured during removal of the implant from the inner packaging.
- Open the packages carefully, beginning from the triangular corner. Take suitable measures to ensure that the implant does not come into contact with objects that could damage its surfaces. Use only the recommended instruments for implantation of the *Modulus implants*. Damaged implants must not be used.

Cleaning and Decontamination

All instruments must first be thoroughly cleaned using the validated methods prescribed in the NuVasive Cleaning and Sterilization Instructions (doc #9400896) before sterilization and introduction into a sterile surgical field. Contaminated instruments should be wiped clean of visible soil at the point of use, prior to transfer to a central processing unit for cleaning and sterilization. The validated cleaning methods include both manual and automated cleaning. Visually inspect the instruments following performance of the cleaning instructions to ensure there is no visual contamination of the instruments prior to proceeding with sterilization. If possible contamination is present at visual inspection, repeat the cleaning steps. Contaminated instruments should not be used, and should be returned to NuVasive. Contact your NuVasive representative for any additional information related to cleaning of NuVasive surgical instruments.

Instruments with a "D" prefix part number (e.g. DXXXXXXX) may be disassembled. Please refer to the additional disassembly instructions for these instruments.

Sterilization

All instruments are provided non-sterile and must be sterilized prior to use. All non-sterile instruments of the *Modulus Interbody System* are sterilizable by steam autoclave using standard hospital practices. In a properly functioning and calibrated steam sterilizer, effective sterilization may be achieved using the parameters prescribed in the NuVasive Cleaning and Sterilization Instructions (doc #9400896).

How Supplied

The *Modulus implants* are supplied pre-packaged and sterile. The integrity of the packaging should be checked to ensure that the sterility of the contents is not compromised. Remove the device from the packaging using aseptic technique, only after the correct size has been determined.

Information

To obtain a Surgical Technique Manual or should any information regarding the products or their uses be required, please contact your local representative or NuVasive directly at 800-475-9131. You may also email: customerservice@nuvasive.com.