HTMedical

STERILE PRODUCT and NON-STERILE SURGICAL INSTRUMENTATION

BEFORE USING PRODUCT, READ THE FOLLOWING INFORMATION THOROUGHLY.

IMPORTANT:
This booklet is designed to assist in using the NeoFuse Ti3D PLIF/TLIF/Cervical intervertebral body fusion devices. It is not a reference for surgical techniques. To obtain a surgical technique manual, contact HT Medical as directed at the end of document.

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

Single Use
As with all orthopedic implants, implants and implanted system components should **never** be reused under any circumstances. An implant once used should be discarded. Even though it may appear undamaged, it may have small defects or internal stress patterns, which may lead to failure.

NeoFuse Ti3DPLIF/TLIF/CERVICAL interbody fusion device components should **never** be mixed with components from another system unless specifically noted with the Surgical Technique Guides.

DESCRIPTION:
The PLIF/TLIF/Cervical intervertebral body fusion devices are comprised of Titanium 6Al-4V per ASTM F136, a well-known biocompatible material

The cages contain interconnected porosity and allow for radiological evaluation.

The cages include large central, vertical graft windows, and smaller interconnected graft pathways, which may be packed with bone graft material prior to implantation.

The PLIF/TLIF/Cervical devices are additively manufactured from Titanium 6Al-4V per ASTM F-136.

To achieve the best results, unless otherwise specifically described in another NeoFuse document, do not use PLIF/TLIF/Cervical components in conjunction with components from any other system or manufacturer.

HT Medical warrants that these devices are fabricated from the foregoing material specification. No other warranties, expressed or implied, are made.

INDICATIONS:
When used as a Lumbar Interbody Fusion device, NeoFuse Ti3D is indicated for use in skeletally mature patients with DDD at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). Patients should have received at least six (6) months of prior non-operative treatment prior to treatment with the device. The devices must be used with supplemental fixation and must be used with autograft / autologous bone graft to facilitate fusion for each spinal region.

When used as a Cervical Interbody Fusion device, NeoFuse Ti3D is indicated for use in skeletally mature patients with cervical degenerative disc disease (DDD) at one level or two contiguous levels from C2 to T1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. Patients should have received six (6) weeks of prior non-operative treatment prior to treatment with the device. The devices must be used with supplemental fixation and must be used with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft when used as an adjunct to fusion.

STERILIZATION:
PLIF/TLIF/Cervical implants components are clearly labeled STERILE and are provided clean and sterile. These devices are sterilized with gamma sterilization with a Verification Dose (10^{-6} SAL) 6.6 kGy (range of 5.9 to 7.3 kGy) validated by AAMI/ANSI/ISO 11134-2 – method VD_{max}^{25}.

The implants should never be cleaned or otherwise reprocessed, and should be discarded if they become soiled. Verify the expiration data and return or discard any expired devices.

The PLIF/TLIF/Cervical surgical instrumentation components are provided clean but not sterile and must be sterilized prior to use.

The NON-STERILE instruments, and fully loaded instrument trays, are recommended to be steam sterilized by the hospital using an FDA cleared wrap or container in a pre-vacuum autoclave cycle at 270^0F (132^0C) for a minimum of (4) minutes exposure time with a (30) minute drying time.

These sterilization recommendations follow the guidelines for sterilization per AAMI ST79 and ANSI/AAMI ISO 17665-1:2006.

Remove all packaging materials prior to sterilization. Use only sterile products in the operative field.

CONTRAINDICATIONS:
Contraindications may be relative or absolute. The choice of a particular device must be carefully weighed against the patient's overall evaluation. Circumstances listed below may reduce the chance of a successful outcome:

- Acute or chronic infectious diseases of any etiology and localization
- Morbid obesity
- Signs of local inflammation
- Fever or leukocytosis
- Metal/polymer sensitivity/allergies to the implant materials
- Medical or surgical conditions, which would preclude the potential, benefit of spinal implant surgery, such as the elevation of sedimentation rate unexplained by other diseases, elevation of white blood count (WBC), or a marked left shift in the WBC differential count
- Grossly distorted anatomy due to congenital abnormalities
- Rapid joint disease, bone absorption, osteopenia, and/or osteoporosis (osteoporosis is a relative contraindication since this condition may limit the degree of obtainable correction, the amount of mechanical fixation, and/or the quality of the bone graft)
- Any case not needing a bone graft and fusion or where fracture healing is not required
- Any case requiring the mixing of metals from different components
- Patients having inadequate tissue coverage over the operative site or where there is inadequate bone stock, bone quality, or anatomical definition
- Unsuitable or insufficient bone support, bone immaturity
- Any case not described in the indication
- A patient unwilling to cooperate with the postoperative instructions
- The patient's activity level, mental condition, or occupation
- Any time implant utilization would interfere with anatomical structures or expected physiological performance
- Prior fusion at the level(s) to be treated

These contraindications can be relative or absolute and must be taken into account by the physician when making his/her decision. The above list is not exhaustive.

POSSIBLE ADVERSE EVENTS:
While the expected life of spinal implant components is difficult to estimate, it is finite. These components are made of foreign materials that are placed within the body for the potential fusion of the spine and reduction of pain. However, due to the many biological, mechanical and physicochemical factors that affect these devices that cannot be evaluated in vivo; the components cannot be expected to indefinitely withstand the activity level and loads of normal healthy bone. Possible Adverse Events may include:

- Bending, disassembly or fracture of any or all implant components
- Fatigue fracture of spinal fixation devices, including screws, cages, and spacers have occurred.
- Pain, discomfort, or abnormal sensations due to the presence of the device.
- Pressure on skin from components where inadequate tissue coverage exists over the implant, with the potential extrusion through the skin.
- Dural leak requiring surgical repair. This risk is related to the surgical procedure. The intended use of the device does not require it to be close to the dura.
- Cessation of growth of the fused portion of the spine.
- Loss of proper spinal curvature, correction, height and/or reduction.
- Delayed Union or Nonunion: Internal fixation appliances are load-sharing devices, which are used to obtain alignment until normal healing occurs. In the event that healing is delayed, does not occur, or failure to immobilize occurs, the implant will be subject to excessive and repeated stresses, which can eventually cause loosening, bending or fatigue fracture.
- Loosening of spinal fixation implants can occur. Early mechanical loosening may result from inadequate initial fixation, latent infection, premature loading of the prosthesis, or trauma. Late loosening may result from trauma, infection, biological complications or mechanical problems, with the subsequent possibility of bone erosion, migration and/or pain.
- Surgical spine procedures may be associated with vascular and/or neural complications such as arterial injury or mechanical compromise, cord contusion and damage, peripheral nerve compromise and damage, including but not limited to peripheral paralysis, sensory disorders, vascular disorders, loss or disturbance of bladder and bowel functions.
- Serious complications may be associated with any surgery. These complications include, but are not limited to: genitourinary disorders; gastrointestinal disorders; vascular disorders, including thrombus; bronchopulmonary disorders, including emboli; bursitis, hemorrhage, myocardial infarction, infection, paralysis or death.
- Neurological, vascular, or soft tissue damage due directly to the unstable nature of the fracture, or to surgical trauma.
- May increase biomechanical stress on adjacent levels.
- Inappropriate or improper surgical placement of this device may cause distraction or stress shielding of the graft or fusion mass. This may contribute to failure of an adequate fusion mass to form.
- Decrease in bone density due to stress shielding.
- Intraoperative fissure, fracture, or perforation of the spine can occur due to implantation of the components.
- Postoperative fracture of bone graft, the intervertebral body, pedicle, and/or lateral mass above and/or below the level of surgery can occur due to trauma, the presence of defects, or poor bone stock.

Adverse effects may necessitate re-operation or revision.

WARNINGS AND PRECAUTIONS:
Federal law restricts this device to sale by or on the order of a licensed physician.

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

The safety and effectiveness of spinal systems have been established only for spinal conditions with significant mechanical instability or deformity requiring fusion with instrumentation. These conditions are significant mechanical instability or deformity of the thoracic and lumbar spine secondary to degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor and failed previous fusion (pseudoarthrosis). The safety and effectiveness of these devices for any other condition is unknown.

Only experienced spinal surgeons with specific training in the use of spinal systems should perform the implantation of spinal systems because this is a technically demanding procedure presenting a risk of serious injury to the patient.

Based on the fatigue testing results, 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.

This device has not been evaluated for safety and compatibility in the MR environment. This device has not been tested for heating or migration in the MR environment.

Never use a STERILE implant if the packaging is damaged.

Never use a STERILE implant that is past its expiration date.

CLEANING AND DECONTAMINATION:
All instruments must first be cleaned using the following method before sterilization and introduction into a sterile surgical field.

- Remove all gross visible soil with a damp gauze pad or wipe.
- Prepare an enzymatic cleaning solution per manufacturer's instructions. Immerse the instruments in the cleaning solution and activate the graspers so the enzymatic cleaner contacts all mated surfaces.

- Sonicate the instruments while immersed in the cleaning solution for 15 minutes.
- Transfer the instruments to fresh enzymatic cleaning solution. Thoroughly scrub all instruments with a soft bristle cleaning brush while immersed in the enzymatic cleaning solution. Be sure that thorough scrubbing also includes any lumens with an appropriate size brush.
- Thoroughly rinse all instruments with warm running water.
- A final rinse step should be performed with either reverse osmosis or distilled water and dried with a clean cloth and/or allowed to air dry.

All instruments that have been previously taken into a sterile surgical field must be first decontaminated and cleaned using this method before sterilization and reintroduction into the sterile surgical field. All modular instruments, specifically the inserters, are to be disassembled for cleaning. Additionally, immediately after use, all instruments are to be pre-processed with an initial removal of all visible soils and submerged in deionized water to prevent drying of soils before decontamination. All visible soils are to be removed so as no visual contamination is present. Manual cleaning is to be repeated until instruments are visually clean.

Note: Certain cleaning solutions such as those containing caustic soda, formalin, glutaraldehyde, bleach, and/or other alkaline cleaners may damage some devices, particularly instruments; these solutions should not be used.

All assembled trays are then to be cleaned and decontaminated with a Steris Washer Disinfector or equivalent using the following parameters:

Cycle Description	Nominal Temperature	Nominal Cycle Time
Pre-Wash	Hot or Cold (Building Supply) (Fixed)	2 Minutes
Enzyme Wash	Hot (Building Supply) (Fixed)	20 Seconds (Fixed)
Enzyme Soak	NA	1 Minute
CIP Wash	150 Deg. F	6 Minutes
Rinse 1	Hot (Building Supply) (Fixed)	15 Seconds
Rinse 2	Hot (Building Supply) (Fixed)	15 Seconds
Rinse 3	Hot (reverse osmosis or distilled water)	15 Seconds
Thermal Rinse	190 Deg. F	6 Minutes
Dryer	240 Deg. F	12 Minutes

IMPLANT SELECTION:
The choice of proper shape, size and design of the implant for each patient is crucial to the success of the surgery. The surgeon is responsible for this choice, which depends on each patient. Patient obesity may be responsible for additional stresses and strains on the device, which can speed up fatigue and/or lead to deformation or failure of the implants.

The size and shape of the bone structures determine the size, shape and type of the implants. Once implanted, the implants are subjected to stresses and strains. These repeated stresses on the implants should be taken into consideration by the surgeon at the time of the choice of the implant, during implantation as well as in the postoperative follow-up period. Indeed, the stresses and strains on the implants may cause fatigue or fracture or deformation of the implants, before the bone graft has become completely consolidated. This may result in further side effects or necessitate the early removal of the osteosynthesis device.

Improper selection, placement, positioning, and fixation of these devices may result in unusual stress conditions reducing the service life of the implant.

The surgeon is to be thoroughly familiar with the surgical procedure, instruments, and implant characteristics prior to performing surgery. Refer to the NeoFuse surgical protocols for additional procedural information. Periodic follow-up is recommended to monitor the position and state of the implants, as well as the condition of the adjoining bone.

PREOPERATIVE:
Only patients that meet the criteria described in the indications should be selected.

Patient conditions and/or pre-dispositions such as those addressed in the aforementioned contraindications should be avoided.

The surgeon must ensure that all necessary implants and instruments are on hand prior to surgery.

Care should be used in the handling and storage of the implant components. The implants should not be scratched or otherwise damaged. Implants and instruments should be protected during storage, especially from corrosive environments.

They should be carefully unpacked and inspected for damage prior to use.

The type of construct to be assembled for the case should be determined prior to beginning the surgery. An adequate inventory of implant sizes should be available at the time of surgery, including sizes larger and smaller than those that are expected for use.

The correct handling of the implant components is extremely important. Contouring or customizing of the devices is to be avoided.

Because mechanical parts are involved, the surgeon should be familiar with the various components before using the equipment and should personally assemble the devices to verify that all parts and necessary instruments are present before the surgery begins.

INTRAOPERATIVE:
At all times, extreme caution should be used around the spinal cord and nerve roots. Damage to nerves may occur resulting in loss of neurological functions.

The implant surfaces should not be scratched or notched since such actions may reduce the functional strength of the construct.

Bone grafts must be placed in the area to be fused and the graft must be in contact with viable host bone.

POSTOPERATIVE:
The physician's postoperative directions and warnings to the patient and the corresponding patient compliance are extremely important.

Detailed instructions on the use and limitations of the device should be given to the patient. If partial weight-bearing is recommended or required prior to firm bony union, the patient must be warned that bending, loosening or breakage of the components are complications which can occur as a result of excessive or early weight-bearing or excessive muscular activity. The risk of bending, loosening, or breakage of an internal fixation device during postoperative rehabilitation may be increased if the patient is active, or if the patient is debilitated, demented, or otherwise unable to use crutches or other such weight supporting devices. The patient should be warned to avoid falls or sudden jolts in spinal position.

To allow maximum chances for a successful surgical result, the patient or device should not be exposed to mechanical vibrations that may loosen the device construct. The patient should be warned of this possibility and instructed to limit and restrict physical activities, especially lifting, twisting motions and any type of sport participation.

The patient should be advised not to smoke or consume alcohol during the bone graft healing process.

The patient should be advised of their inability to bend at the point of spinal fusion and taught to compensate for this permanent physical restriction in body motion.

If a nonunion develops or if the components loosen, bend, and/or break, the device(s) should be revised and/or removed immediately before serious injury occurs. Failure to immobilize a delayed union of bone will result in excessive and repeated stresses on the implant. By the mechanism of fatigue these stresses can cause eventual bending, loosening, or breakage of the device(s).

Explanted surgical implants must never be reused.

Adequately instruct the patient in the appropriate postoperative care. The patient's ability and willingness to follow instructions is one of the most important aspects of successful healing.

Removal of the implant after healing:
Particularly in young active patients, implants may loosen, fracture, migrate, increase the risk of infection, cause pain, or stress shield bone – even after normal healing. The surgeon should consider the risks and benefits when deciding whether or not to remove an implant. Implant removal should be followed by careful postoperative management to avoid re-fractures, neural compression, or other complications. If the patient is older and has a low activity level, the surgeon may elect not to remove the implant in order to eliminate the risks of another surgery.

PACKAGING and STORAGE:
The systems are sometimes supplied as a complete set: instruments are arranged on trays and placed in specially designed storage boxes.

Routinely inspect surgical trays and reusable instruments for wear and tear. Any device with signs of corrosion, pitting, discoloration, cracking, etc. should be returned to HT Medical for inspection.

The implants are delivered in sterile packages; these must be intact at the time of receipt.

The implants are provided STERILE are individually packed in protective packaging that is labeled according to its contents.

• Always store a STERILE implant in the original protective packaging.

• Do not remove the STERILE implant from the packaging until immediately before use.

• The STERILE implant should be stored in ambient temperature in a secure location.

Both inner and outer packaging of STERILE implants, including seals, should be thoroughly inspected prior to implantation.

PRODUCT COMPLAINTS:
Any health professional having a complaint or grounds for dissatisfaction relating to the quality of the product, its identity, its durability, its reliability, its safety, its effectiveness and/or its performance, should notify HT Medical or its representative. Moreover, if a device has malfunctioned, HT Medical or its representative must be advised immediately.

If a HT Medical product has been found to have worked improperly and could have caused or contributed to the serious injury or death of a patient, the distributor or HT Medical Representative must be informed as soon as possible by telephone, email or in writing.

For all complaints, please include the device name and reference, along with the lot number of the components(s), your name and address, and an exhaustive description of the event to help HT Medical understand the causes of the complaint.

For further information or complaints, please contact:
In the USA:
HT Medical, LLC
111 W Jefferson St, Ste 100
Orlando, FL 32801

Customer Support Phone:
1.888.594.8633
General Information:
cs@htmedicalusa.com
Website: www.htmedicalusa.com