Manufactured and/or Distributed for:
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nv^a, nv^p, and nv^t LUMBAR INTERBODY FUSION SYSTEM

Instructions For Use

Devices Single Use Only
Instruments Reusable
NON STERILE

CAUTION: FEDERAL (USA) LAW RESTRICTS THIS DEVICE TO SALE
BY OR ON THE ORDER OF A PHYSICIAN

IMPORTANT INFORMATION FOR PHYSICIANS, SURGEONS, AND/OR STAFF

The nv^a, nv^p, and nv^t are an intervertebral body fusion device used in the lumbar spine following discectomy. All devices are manufactured from PEEK Optima® LT1 per ASTM F2026 and include tantalum markers per ASTM F560 for radiographic visualization.

The devices have multiple footprints to adapt to the general shape of the vertebral endplates and have a hollow centre to accommodate bone graft. The devices are implanted via a variety of approaches including anterior, posterior, or transforaminal. Each footprint is available in multiple heights to accommodate patient variability and there are anti-migration features on the superior and inferior surfaces designed to improve fixation, stability, and prevent back out and migration.

Indications for Use:

The nv^a, nv^p, and nv^t are intended for intervertebral body fusion in the lumbar spine in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1 of the lumbosacral spine. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. These patients should have had six months of non-operative treatment prior to treatment with an intervertebral cage. DDD patients may also have Grade 1 spondylolisthesis or retrolisthesis at involved levels. The device systems must be used with supplemental fixation and autograft to facilitate fusion and are implanted via an anterior, posterior, or transforaminal approach.

WARNINGS:

• Implant devices and instruments are provided non-sterile and must be sterilized prior to use. Recommended sterilization instructions are noted in this insert. The nv^a, nv^p, and nv^t devices should never be reused under any circumstances.
• The nv^a, nv^p, and nv^t implant devices must be implanted by an experienced spinal surgeon with specific training in the use of spinal system(s) because these are technically demanding procedures presenting risks of serious injury to the patient. Preoperative planning, including knowledge of the surgical technique, proper selection of device size, proper placement of the device is critical for the achievement of successful results. Conditions such as levels of implantation, patient weight, patient activity level and other patient conditions may impact the performance of the system and should be taken into consideration during patient selection.
• Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without a previous surgery.
• Care must be taken to protect implant device surfaces from being scratched, nicked or damaged during handling and storage of the implant devices as these could become focal points for failure or breakage of the implant device.
• Due to the presence of implants, interference with CT and/or MR imaging may result. The nv^a, nv^p, and nv^t devices have not been evaluated for safety and compatibility in the MR environment. The nv^a, nv^p, and nv^t devices have not been tested for heating or migration in the MR environment.
• Some degree of corrosion occurs on all metal and alloy devices. Contact of dissimilar metals, however, may accelerate the corrosion process. Do not use dissimilar components together. Components of this system should not be used in conjunction with components of any other system or manufacturer.
• 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.

CONTRAINDICATIONS:

Contraindications include, but are not limited to:

1. Use in the cervical spine
2. Suspected or documented material allergy or intolerance.
3. Patients with infection, inflammation, fever, leukocytosis, obesity, pregnancy, mental illness and other medical conditions which would prohibit beneficial surgical outcomes (such as the presence of tumors, fracture local to the operating site, elevation of sedimentation rate unexplained by other diseases, elevation of white blood count (WBC), or a marked shift in the WBC differential count.)
4. Grossly distorted anatomy caused by congenital abnormalities.
5. Rapid joint disease, bone absorption, osteopenia. Osteoporosis is a relative contraindication since this condition may limit the degree of obtainable correction, stabilization, and/or the amount of mechanical fixation.
6. Any patient not described in the indications.
7. Any patient unwilling to follow postoperative instructions.
8. Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance.
9. Any patient having inadequate tissue coverage over the operative site or inadequate bone stock or quality.
10. Any case where the implant components selected for use would be too large or too small to achieve a successful result.
11. Any case where the implant would interfere with anatomical structures or expected physiological performances.
12. Prior fusion at the level(s) to be treated.
13. Reuse or multiple use.

POTENTIAL ADVERSE EFFECTS:

Possible adverse effects or complications include, but are not limited to:

1. Implant device migration and/or subsidence
2. Breakage of implant device
3. Foreign body (allergic) reaction to the implant devices
4. Post-operative change in spinal curvature, loss of correction, height, and/or reduction
5. Infection
6. Loss of neurological function including paralysis (partial or complete), radiculopathy, and/or the development or continuation of pain, numbness, spasms, or sensory loss
7. Non-union (pseudoarthrosis), delayed union, mal-union
8. Physiological reaction to implant devices due to foreign body intolerance including inflammation, local tissue reaction, and possible tumor formation.
9. Inability to perform the activities of daily living
10. Fracture, micro-fracture, resorption, damage or penetration of any spinal bone
11. Loss or increase in spinal mobility or function
12. Cessation of growth of the fused portion of the spine
13. Pain, discomfort, or abnormal sensations due to the presence of the device.
14. Hemorrhage of blood vessels and/or hematomas
15. Herniated nucleus pulposus, disc disruption or degeneration at, above or below the level of surgery
16. Post-operative change in spinal curvature, loss of correction, height and/or reduction
17. Scar tissue formation possibly causing neurological and/or vascular compromise
18. Death.

CLEANING, DECONTAMINATION AND STERILIZATION:

Unused Components: The instruments, case and caddy must be cleaned prior to sterilization. If there are any visual signs of contaminants, soil or debris, the cleaning steps below must be taken prior to sterilization. Implant devices are single-use, thus do not clean or re-sterilize an implant device that has been in contact with or contaminated by blood or other infectious substances.

Special pre-processing handling of used instruments: The instruments, case, and caddy are reusable and must be cleaned as soon as possible after use. If cleaning must be delayed for more than 30 minutes, immerse the components in a compatible detergent solution to prevent drying and encrustation of surgical soil.

The implantable devices, instruments, case, and caddy are supplied non-sterile and must be cleaned and sterilized prior to use. In the event that an unused implant device or instrument has visual signs of contaminants, soil or debris, the implant device or instrument should not be used until cleaned and sterilized in accordance with the recommended parameters below. The implant devices are single-use only, therefore do not clean or re-sterilize a device that has been in contact with or contaminated by blood or other infectious substances. These implant devices must be disposed of in accordance with facility protocol.

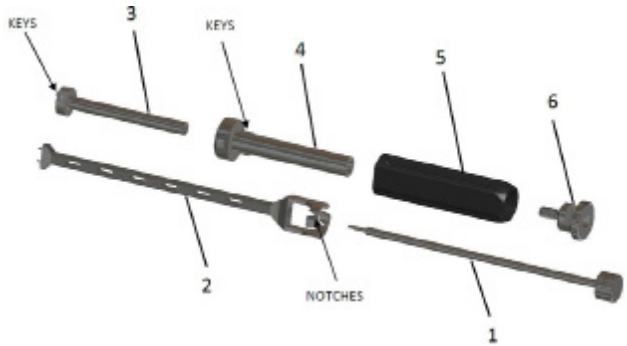
The inserter instrument must be disassembled for proper cleaning.

Inserter Disassembly:

A. Unscrew strike plate (6) from handle (5)
B. Slide handle (5) off of inserter tube (4)
C. Pull inserter tube (4) off of inserter core (3)
D. Push inserter core (3) towards knob on threaded rod (1)
E. Rotate core (3) counterclockwise until keys align with openings in the base of the outer shaft (2)
F. Remove core (3) from outer shaft (2)
G. Slide threaded rod (1) out of outer shaft (2)

Legend for (2); Diagram shows ALIF Straight Inserter Shaft

ALIF Straight Inserter Shaft	
ALIF Trans-Anterior Inserter Shaft	
PLIF Straight Inserter Shaft	
TLIF Curved Inserter Shaft	



Manual Cleaning Instructions:

1.) Prepare Enzol® or other neutral cleaning detergent according to the manufacturer's recommendation at 1 oz/gal using warm tap water (27-49°C).
2.) Fully immerse devices, instruments, case, and caddy in the detergent and allow soaking for 2-3 minutes.
3.) Thoroughly scrub items with an appropriate sized soft bristled brush, paying additional attention to threads, lumens or other internal channels, where applicable.
4.) Rinse the items with lukewarm tap water (27-49°C) for approximately 2-3 minutes, followed by a final rinse using deionized water for a minimum of 1 minute.
5.) Allow the items to dry for a minimum of 20 minutes or until no condensation or moisture is visible.
6.) Dry the exterior with a clean, lint free cloth to remove condensation, if necessary.

Automated Cleaning Instructions

1.) Prepare Enzol® or other neutral cleaning detergent per manufacturer's recommendations at 1 oz/gal using warm tap water (27-49°C).
2.) Fully immerse devices, instruments, case, and caddy in the detergent and allow soaking for 2 - 3 minutes.
3.) Use a soft bristled brush to remove soil. Pay close attention to crevices and hard to reach areas.
4.) Remove devices, instruments, case, and caddy from the detergent and rinse with tap water for 1 minute.
5.) Prepare Enzol® per manufacturer's recommendations at 1 oz/gal using warm tap water (27-49°C) in an ultrasonic cleaner.
6.) Place devices, instruments, case, and caddy in ultrasonic cleaner and sonicate for 10 minutes.
7.) Transfer devices, instruments, case, and caddy into an automated washer for processing.
8.) Select the cycle and ensure the following set of cycle parameters are properly programmed.
    a. Motor speed: High
9.) Remove devices, instruments, case, and caddy from the washer.
Once all components of the inserter are thoroughly dry, follow the assembly instructions below:

Phase	Recirculation Time (Minutes)	Temperature	Detergent Type and Concentration
Pre-wash 1	01:00	Cold tap water	N/A
Enzyme Wash	01:00	Hot tap water	Enzol® (1 oz/gal)
Wash 1	02:00	60°C (Set point)	Prolystica™ 2X Concentrate Neutral 1/8 oz/gal
Rinse 1	01:00	Hot tap water	N/A
Drying	07:00	115°C	N/A

Inserter Assembly:

1. Slide threaded rod (1) into outer shaft (2)
2. Slide inserter core (3) into outer shaft (2), twist clockwise and pull slightly until keys sit in notches.
3. Slide inserter tube (4) onto core (3)
4. Slide tube (4) into handle (5), align keys on outside of tube into slots in handle
5. Thread strike plate (6) into handle (5)

Legend for (2); Diagram shows ALIF Straight Inserter Shaft

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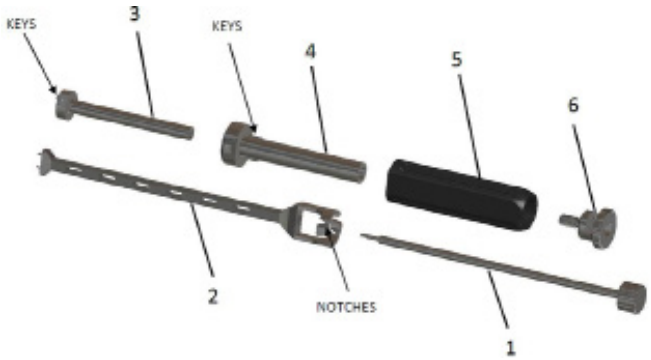

After cleaning/decontamination, each item must be visually inspected ensure there are no visual contaminants or debris on the instrument. If contaminants or debris are visible, repeat the cleaning steps listed above. If contaminants are still not removed, dispose of the items in accordance with facility protocol.

STERILIZATION:

The implant devices, instruments, case and caddy are supplied non-sterile and must be sterilized prior to use. The recommended sterilization method and parameters are listed in the table below and the sterilization must be conducted with a FDA cleared wrap. These recommendations are in accordance with ANSI/AAMI ST79.

Method	Cycle	Temperature	Exposure Time	Dry Time
Steam	Pre-Vacuum	270°F (132°C)	4 Minutes	40 Minutes

INSPECTION, ROUTINE MAINTENANCE AND OTHER IMPORTANT INFORMATION:

• Visually inspect all instruments and check for damage, wear, and/or corrosion.
• Cutting edges of the rasp distractor tips and paddle shavers should be free nicks and have a continuous sharp edge.
• Moveable parts of the inserter should have smooth movement without excessive play
• Ensure a tight fit between the handles and the shavers and trials.
• Confirm appropriate fit between the thread on the inserter and the thread on the implant device.
• The case is supplied to the end user with the recommended instruments required for the nv^a, nv^p, or nv^t devices system.
• A complete case with devices and instruments should not exceed 25 lbs and cases should not be stacked at any time.
• Inspection of the case should be performed after each use. If there are any excessive dents, scrapes, corrosion or discoloration, the case must be replaced
• All handling, inspection, and maintenance must be performed by trained personnel only.

If any of the items do not meet acceptable inspection criteria, they must be sent to Nvision Biomedical Technologies for replacement.

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PRODUCT COMPLAINTS:

Any healthcare professional who has a complaint or who has experienced any dissatisfaction in the product quality, durability, reliability, safety, effectiveness, and/or performance should notify Nvision Biomedical Technologies, LLC at 1350 N. Loop 1604 E, Suite 103 San Antonio, TX 78232, (210) 545-3713.

FURTHER INFORMATION:

Recommended surgical technique is available at no charge upon request. If further information is needed or required, please contact Nvision Biomedical Technologies, LLC at 1350 N. Loop 1604 E, Suite 103 San Antonio, TX 78232, (210) 545-3713.