Manufactured and/or Distributed for:
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nvᶜ ANTERIOR CERVICAL 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 nvᶜ is an intervertebral body fusion device used in the cervical spine following discectomy. All devices are manufactured from PEEK Optima® LT1 per ASTM F2026 and include tantalum markers per ASTM F560 for radiographic visualization.

Device Description:

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 an anterior (ACIF) surgical approach. 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.

Indications for Use:

The nvᶜ is intended for spinal fusion procedures at one level, from C2-T1, in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine. DDD is defined as neck pain of discogenic origin with the degeneration of the disc confirmed by history and radiographic studies. One device is to be used per intervertebral space. Patients should receive six weeks of non-operative treatment prior to treatment with an intervertebral body fusion device. The nvᶜ devices must be used with supplemental fixation and are designed for use with autograft bone to facilitate fusion. The devices are to be implanted via an anterior approach.

WARNINGS:

• Implants and instruments are provided non-sterile and must be sterilized prior to use. Validated sterilization instructions are noted in this insert. nvᶜ implants should never be reused under any circumstances.
• The nvᶜ 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 surfaces from being scratched, nicked or damaged during handling and storage of the implant as these could become focal points for failure or breakage of the device.
• Due to the presence of implants, interference with CT and/or MR imaging may result. The nvᶜ system has not been evaluated for safety and compatibility in the MR environment. The nvᶜ system has 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. Components of this system should not be used in conjunction with components of any other manufacturer's spinal system.

CONTRAINDICATIONS:

Contraindications include, but are not limited to:

1. Suspected or documented material allergy or intolerance.
2. Patients with infection, inflammation, fever, leukocytosis, obesity, pregnancy, mental illness and other medical conditions which would prohibit beneficial surgical outcomes.
3. Grossly distorted anatomy caused by congenital abnormalities.
4. 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.
5. Any patient not described in the indications.
6. Any patient unwilling to follow postoperative instructions.
7. Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance.
8. Any patient having inadequate tissue coverage over the operative site or inadequate bone stock or quality.
9. Any other condition which would preclude the potential benefit of spinal implant surgery, 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.
10. Any case where the implant components selected for use would be too large or too small to achieve a successful result.
11. Prior fusion at the level(s) to be treated.

POTENTIAL ADVERSE EFFECTS:

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

1. Implant migration and/or subsidence
2. Breakage of implant
3. Foreign body (allergic) reaction to the implants
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. Inability to perform the activities of daily living
9. Fracture, micro-fracture, resorption, damage or penetration of any spinal bone
10. Loss or increase in spinal mobility or function
11. Pain, discomfort, or abnormal sensations due to the presence of the device.
12. Hemorrhage of blood vessels and/or hematomas
13. Herniated nucleus pulposus, disc disruption or degeneration at, above or below the level of surgery
14. Post-operative change in spinal curvature, loss of correction, height and/or reduction
15. 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. Implants are single-use, thus do not clean or re-sterilize an implant that has been in contact with or contaminated by blood or other infectious substances.

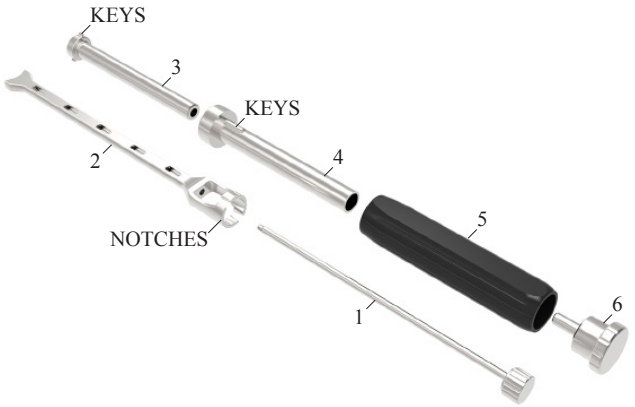
Special pre-processing handling of used instruments: The instruments, case, and caddy are reusable and must be cleaned as soon as possible after use. If cleaning must be delayed for more than 30 minutes, immerse the components in a compatible detergent solution to prevent drying and encrustation of surgical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

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



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 the 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.

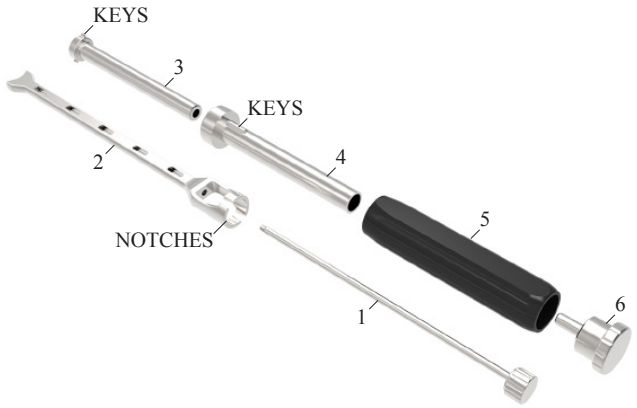
Phase	Recirculation Time (Minutes)	Temperature	Detergent Type and Concentration
Pre-Wash 1	01:00	Cold Tap Water	N/A
Enzyme Wash	01:00	Hot Tap Water	Enzol® (1 oz/gal)
Wash 1	02:00	60°C (Set point)	Prolystica™ 2X Concentrate Neutral 1/8 oz/gal
Rinse	01:00	Hot tap water	N/A
Drying	07:00	115°C	N/A

Once all components of the inserter are thoroughly dry, follow the re-assembly instructions below:

Inserter Assembly:

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

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 implants, 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 validated recommendations are in accordance with ANSI/AAMI ST79 and will provide a sterility assurance level (SAL) of 10^{-6}.

Method	Cycle	Temperature	Exposure	Dry Time
Steam	Pre-Vacuum	270°F (132°C)	4 Minutes	30 Minutes
Steam	Gravity	270°F (132°C)	15 Minutes	45 Minutes

INSPECTION, ROUTINE MAINTENANCE AND OTHER IMPORTANT INFORMATION:

• Visually inspect all instruments and check for damage, wear, and/or corrosion.
• Cutting edges of the rasps should be free of 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 rasps and trials.
• Confirm appropriate fit between the thread on the inserter and the thread on the implant.
• The case is supplied to the end user with the recommended instruments required for the nv^{c} 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 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 100 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.