

NTERYX™

3D Printed PEEK Interbody System

Surgical Technique Guide



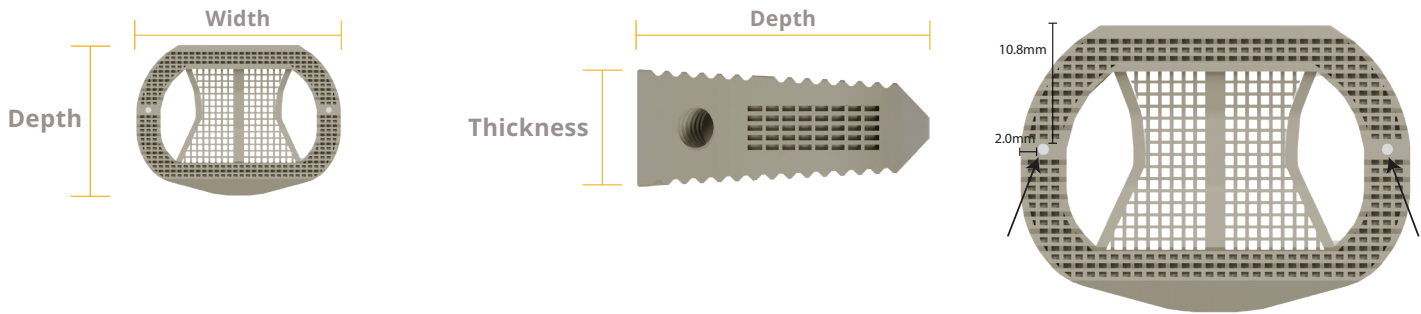
NVISION
BIOMEDICAL TECHNOLOGIES™

Product Sizes Available

Two Footprints: 25mm x 44mm and 29mm x 39mm
 Implant Heights: 10mm to 20mm in 2 mm increments;
 Lordosis: Available with 6 degrees and 12 degrees of lordosis

The NTERYX 3D Printed PEEK ALIF Interbody System devices are spinal fusion implants that are inserted into the intervertebral body space of the Lumbar spine to act as disc spacers and hold bone graft. These implants are 3D Printed with engineered porous architectures from PEEK OPTIMA™ LT1AMR5 with tantalum radiographic markers and are offered in multiple footprint, height, and lordotic angle options.

ALIF Interbody Device



Part #	Description
PAL-0610-2534	ALIF, Printed - 25x34mm, 6°, 10mm
PAL-0612-2534	ALIF, Printed - 25x34mm, 6°, 12mm
PAL-0614-2534	ALIF, Printed - 25x34mm, 6°, 14mm
PAL-0616-2534	ALIF, Printed - 25x34mm, 6°, 16mm
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PAL-1210-2534	ALIF, Printed - 25x34mm, 12°, 10mm
PAL-1212-2534	ALIF, Printed - 25x34mm, 12°, 12mm
PAL-1214-2534	ALIF, Printed - 25x34mm, 12°, 14mm
PAL-1216-2534	ALIF, Printed - 25x34mm, 12°, 16mm
PAL-1218-2534	ALIF, Printed - 25x34mm, 12°, 18mm
PAL-1220-2534	ALIF, Printed - 25x34mm, 12°, 20mm
PAL-0610-2939	ALIF, Printed - 29x39mm, 6°, 10mm
PAL-0612-2939	ALIF, Printed - 29x39mm, 6°, 12mm
PAL-0614-2939	ALIF, Printed - 29x39mm, 6°, 14mm
PAL-0616-2939	ALIF, Printed - 29x39mm, 6°, 16mm
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PAL-0620-2939	ALIF, Printed - 29x39mm, 6°, 20mm
PAL-1210-2939	ALIF, Printed - 29x39mm, 12°, 10mm
PAL-1212-2939	ALIF, Printed - 29x39mm, 12°, 12mm
PAL-1214-2939	ALIF, Printed - 29x39mm, 12°, 14mm
PAL-1216-2939	ALIF, Printed - 29x39mm, 12°, 16mm
PAL-1218-2939	ALIF, Printed - 29x39mm, 12°, 18mm
PAL-1220-2939	ALIF, Printed - 29x39mm, 12°, 20mm

Featured Instruments

T-Handle



ALIF Trial Interbody Device



Slap Hammer



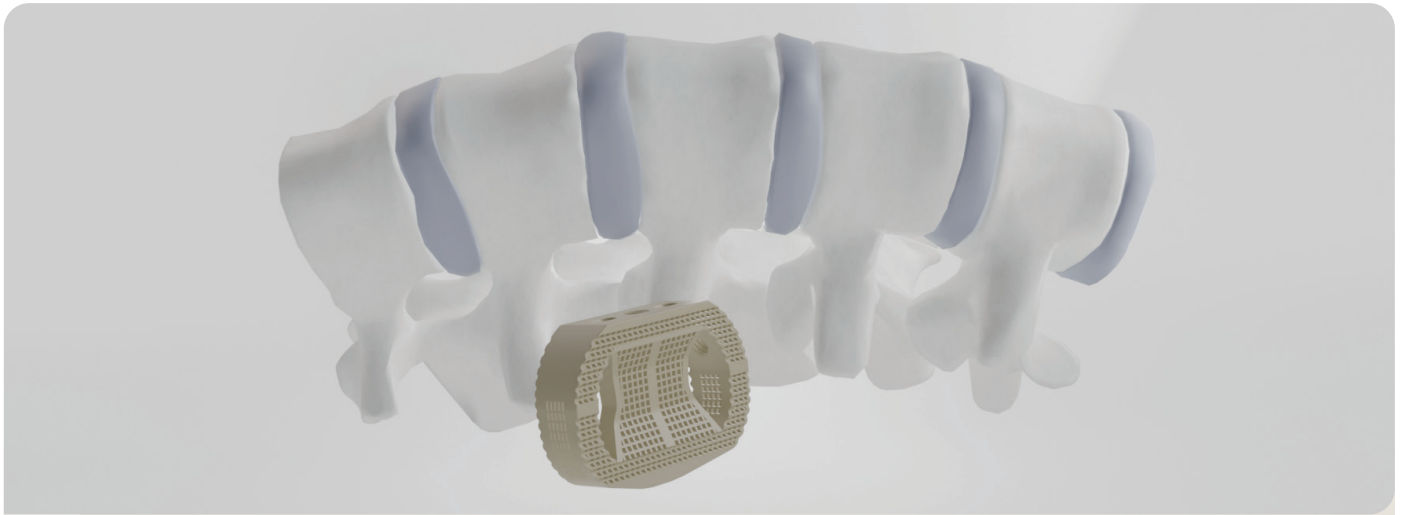
Straight Inserter, ALIF



ALIF Tamp



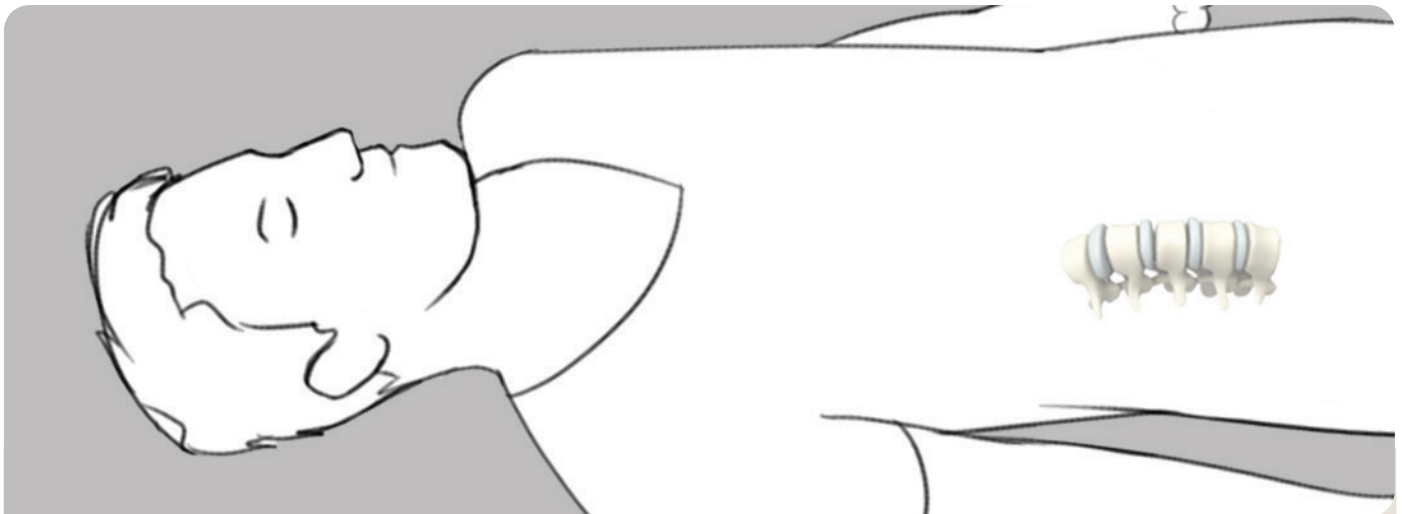
Anterior Lumbar Interbody Fusion System



1

Preoperative Planning

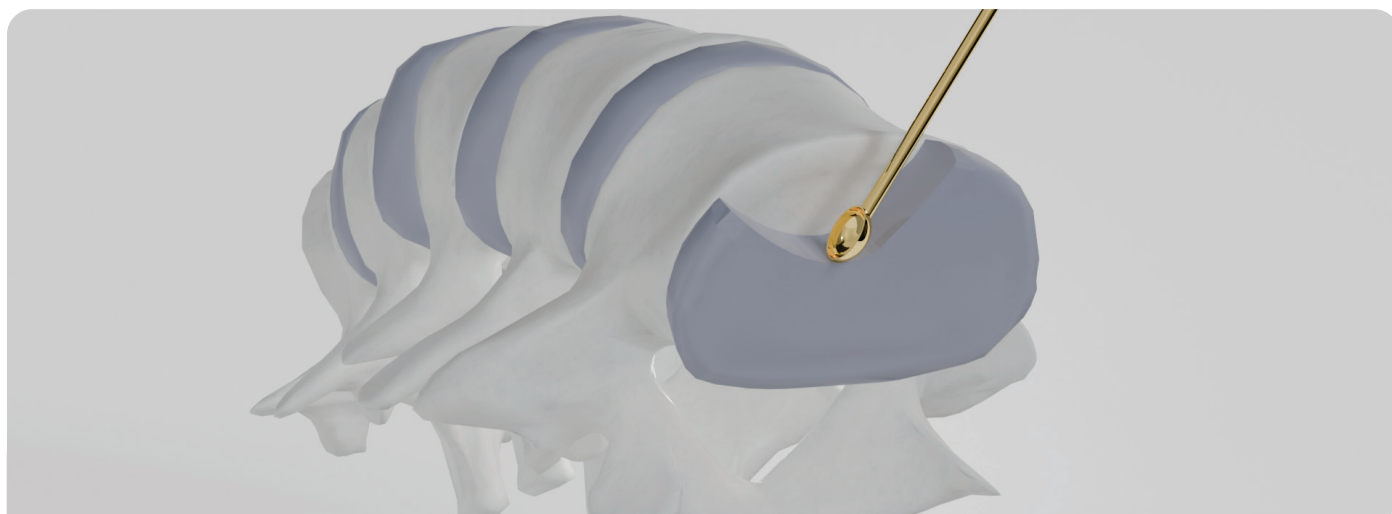
The size of implant to be used for the case should be determined prior to beginning the surgery. To maximize stability, the largest implant that can be safely inserted without neural element disruption should be chosen. All parts must be cleaned and sterilized before use.



2

Patient Positioning and Disc Access

Position the patient in a supine position for access to the lumbar spine from a standard anterior approach. A transanterior approach may alternatively be used. The intervertebral disc should be excised using standard technique.



3

Endplate Preparation

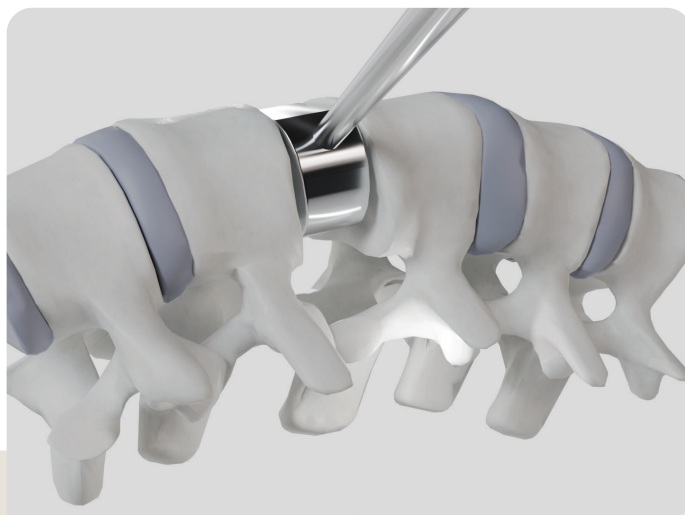
Remove the superficial cartilaginous layers of the endplates to expose bleeding bone.

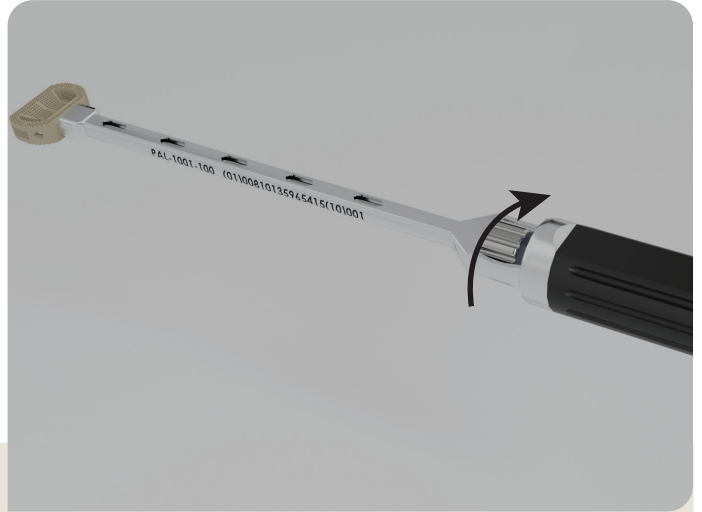
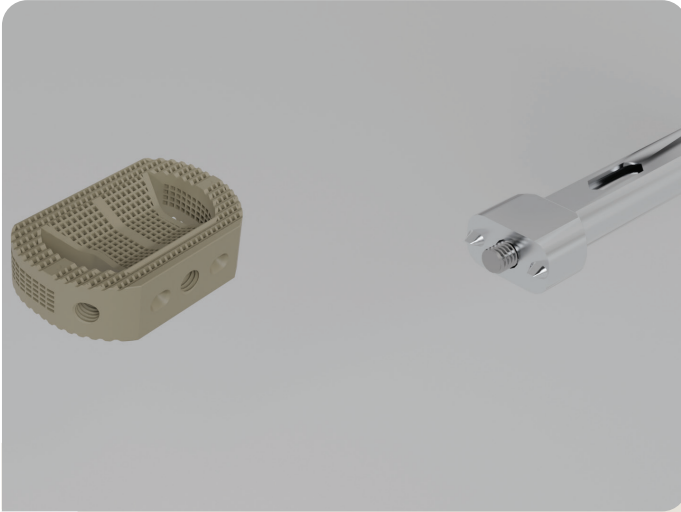


4

Selection of Implant

Once the desired level of distraction is achieved, select the trial height associated with the preoperative planning. The selection of the implant depends on the height, width, and depth of the intervertebral disc space. A tight fit is required to determine the final implant height. If necessary, controlled and light impaction with a mallet can be used to advance the trial and confirm the height. Confirmation must be completed under fluoroscopy.



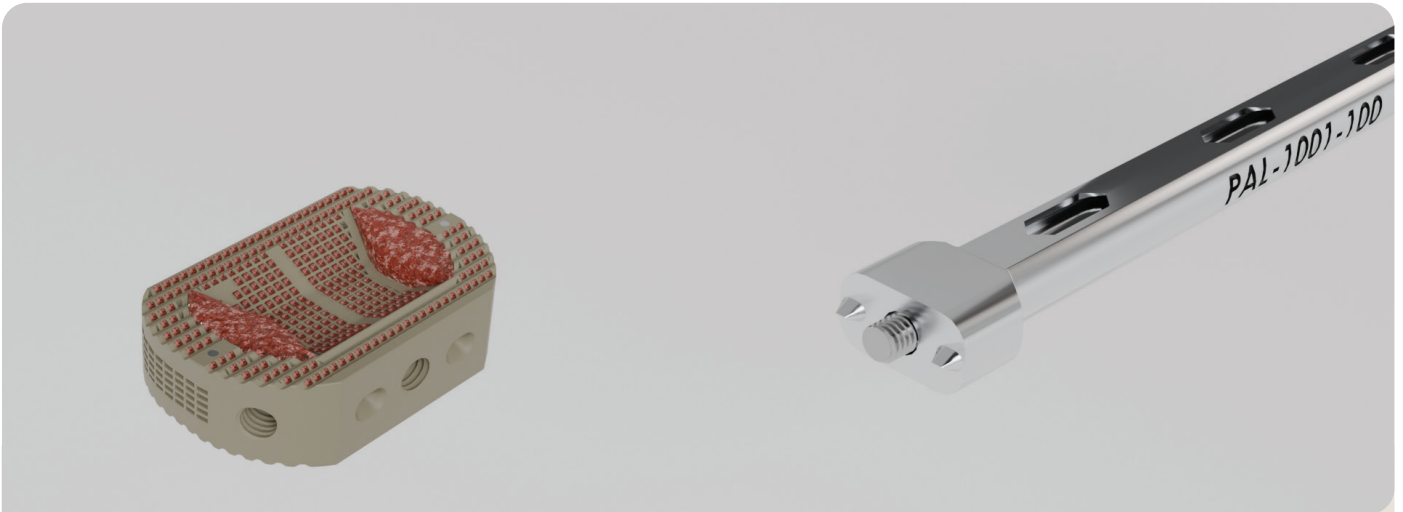


5

Connect Implant to Inserter

Select the implant that corresponds to the footprint, shape, and height determined using the trial in step 4. Engage the appropriate threaded insert of the implant that corresponds with the surgical approach with the threaded post on the inserter. Lateral holes on the implant will align with posts on the inserter for additional stability.

Pack autograft bone inside the graft area.



6

Packing the Implant

Pack autograft bone inside the graft area.

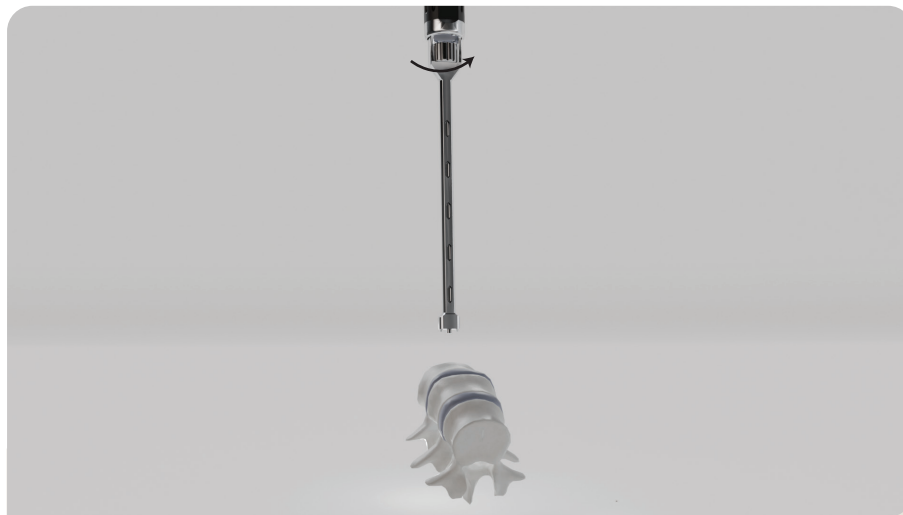


7

Insert Implant

Carefully insert the implant into the distracted segment, ensuring that the orientation is correct. If necessary, controlled and light impaction with a mallet can be used to advance the implant into the intervertebral disc space.

The slap hammer is connected to the inserter when it becomes necessary to remove the implant if advanced too far.



8

Remove Inserter

The inserter is removed by unthreading from the implant using the turn knob.

Use fluoroscopy to confirm position of implant. The implant has radiographic markers to assess the implant position. The tamp and the slap hammer instruments may be used to assist with additional positioning, if necessary.

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.

DEVICE DESCRIPTION

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 radio graphic visualization. The devices have multiple footprints to adapt to the general shape of the vertebral endplates and have a hollow center 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.

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.

Warnings and Precautions:

- 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, migration or image artifact in the MR environment. The safety of the system in the MR environment is unknown. Scanning a patient who has the device may result in injury.
- 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.
- Instruments and K-wires are to be treated as sharps.
- Do not use other manufacturers' instruments or implants in conjunction with the NTERYX 3D Printed PEEK Interbody System.

MR (Magnetic Resonance) Safety Information:

The NTERYX 3D Printed PEEK Interbody System 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 NTERYX 3D Printed PEEK Interbody System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

Potential Adverse Events:

Possible adverse effects associated with implants are infection, pain, stiffness, discomfort, or abnormal sensations and nerve or soft tissue damage due to the use of an implant or due to surgical trauma. The implant may break due to excessive activity, prolonged loading, incomplete healing, or excessive force on the implant during insertion. Metal sensitivity or histological or allergic or adverse foreign body reaction resulting from implantation of a foreign material may occur. Nerve or soft tissue damage, necrosis of the tissue or inadequate healing may result from the presence of an implant or due to surgical trauma.

Disclaimers

This publication details recommended procedures for using Nvision Biomedical Technologies' devices and instruments. It offers guidance but, as with any such technical guide, each surgeon must consider the particular needs of each patient and make appropriate adjustments when and as required. A workshop training is recommended prior to the first surgery. Please remember that the compatibility of different product systems has not been tested unless specified otherwise in the product labeling. For additional information please refer to the instructions for use (IFU) delivered with each implant. The surgeon must discuss all relevant risks, including the finite lifetime. All possible complications listed are not typical of Nvision Biomedical Technologies products but are in principle observed with any implant. Promptly inform Nvision Biomedical Technologies as soon as complications occur in connection with implants or surgical instruments used. In the event of premature failure of an implant in which a causal relationship with its geometry, surface quality, or mechanical stability is suspected, please provide Nvision Biomedical Technologies with explant(s) in a cleaned, disinfected, and sterile condition. Nvision cannot accept any other returns of used implants. The surgeon is held liable for complications associated with inadequate asepsis, inadequate preparation of osseous implant bed in the case of implants, incorrect indication or surgical technique, or with any incorrect patient information and consequent incorrect patient behavior.

Additional Information

CAUTION: Federal Law (USA) restricts this device to sale by or on the order of a physician. This brochure describes the surgical technique used by Nvision Biomedical Technologies development surgeons. As the manufacturer of this device, Nvision Biomedical Technologies does not practice medicine and does not recommend this product or any specific surgical technique for use on any individual patient. The surgeon who performs any implant procedure is responsible for determining the appropriate product(s) and utilizing the appropriate technique(s) for said implantation in each individual patient.

For further information, please contact the Customer Service Department at:

Nvision Biomedical Technologies
12449 Silicon Drive
San Antonio, TX 78249

Ordering Information

Implants

Part Number	Description
PAL-0610-2534	ALIF, Printed - 25x34mm, 6 degree, 10mm
PAL-0612-2534	ALIF, Printed - 25x34mm, 6 degree, 12mm
PAL-0614-2534	ALIF, Printed - 25x34mm, 6 degree, 14mm
PAL-0616-2534	ALIF, Printed - 25x34mm, 6 degree, 16mm
PAL-0618-2534	ALIF, Printed - 25x34mm, 6 degree, 18mm
PAL-0620-2534	ALIF, Printed - 25x34mm, 6 degree, 20mm
PAL-1210-2534	ALIF, Printed - 25x34mm, 12 degree, 10mm
PAL-1212-2534	ALIF, Printed - 25x34mm, 12 degree, 12mm
PAL-1214-2534	ALIF, Printed - 25x34mm, 12 degree, 14mm
PAL-1216-2534	ALIF, Printed - 25x34mm, 12 degree, 16mm
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PAL-1220-2939	ALIF, Printed - 29x39mm, 12 degree, 20mm

Instruments

Part Number	Description
NR-401108A	T-Handle
PL-1000T-400	Slap Hammer
AL-1000T-100	Straight Inserter, ALIF
AL-1000T-300	Parallel Distractor, ALIF
AL-1000T-302	Distractor Tip, ALIF, Small
AL-1000T-303	Rasp Distractor Tip, ALIF, Small
AL-1000T-602	ALIF Tamp, Curved
CSRW-1000T-501	Healix Medium Handle
INST-1000T-SPR	Lamina Spreaders
INST-1000T-HINT	Hintermann Pin Distractor
WD-1000T-GRFB	Trigon Graft Packing Block
WD-1000T-GRFT	Trigon Graft Packing Tamp

Trials

Part Number	Description
AL-2939T-1210	ALIF 29x39 Large Trial 12° 10mm
AL-2939T-1212	ALIF 29x39 Large Trial 12° 12mm
AL-2939T-1214	ALIF 29x39 Large Trial 12° 14mm
AL-2939T-1216	ALIF 29x39 Large Trial 12° 16mm
AL-2939T-1218	ALIF 29x39 Large Trial 12° 18mm
AL-2939T-1220	ALIF 29x39 Large Trial 12° 20mm
AL-2534T-1210	ALIF 25x34 Small Trial 12° 10mm
AL-2534T-1212	ALIF 25x34 Small Trial 12° 12mm
AL-2534T-1214	ALIF 25x34 Small Trial 12° 14mm
AL-2534T-1216	ALIF 25x34 Small Trial 12° 16mm
AL-2534T-1218	ALIF 25x34 Small Trial 12° 18mm
AL-2534T-1220	ALIF 25x34 Small Trial 12° 20mm

