

NTERYX™

3D Printed PEEK Interbody System

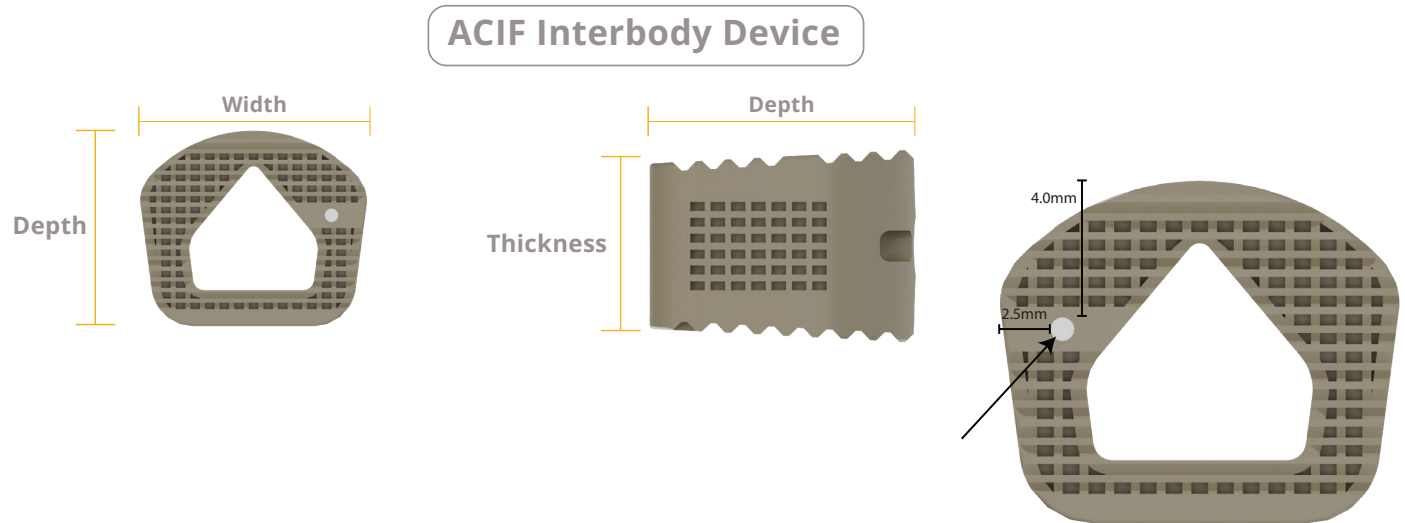
Surgical Technique Guide



Product Sizes Available

Two Footprints: 12mm x 14mm and 14mm x 16mm
 Implant Heights: 6mm to 10mm in 1 mm increments;
 Lordosis: all implants have 6 degrees of lordosis

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



Part #	Description
PAC-0606-1214	Cervical, Printed - 12x14mm, 6°, 6mm
PAC-0607-1214	Cervical, Printed - 12x14mm, 6°, 7mm
PAC-0608-1214	Cervical, Printed - 12x14mm, 6°, 8mm
PAC-0609-1214	Cervical, Printed - 12x14mm, 6°, 9mm
PAC-0610-1214	Cervical, Printed - 12x14mm, 6°, 10mm
PAC-0606-1416	Cervical, Printed - 14x16mm, 6°, 6mm
PAC-0607-1416	Cervical, Printed - 14x16mm, 6°, 7mm
PAC-0608-1416	Cervical, Printed - 14x16mm, 6°, 8mm
PAC-0609-1416	Cervical, Printed - 14x16mm, 6°, 9mm
PAC-0610-1416	Cervical, Printed - 14x16mm, 6°, 10mm

Featured Instruments

T-Handle



ACIF Inserter



ACIF Tamp



ACIF Trial Interbody Device



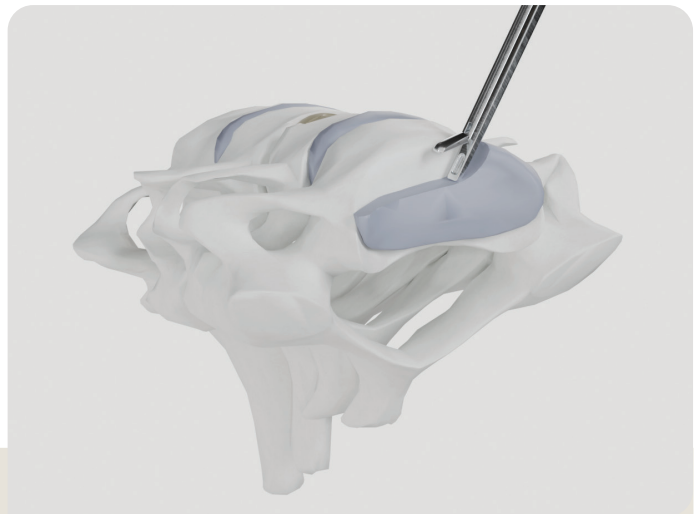
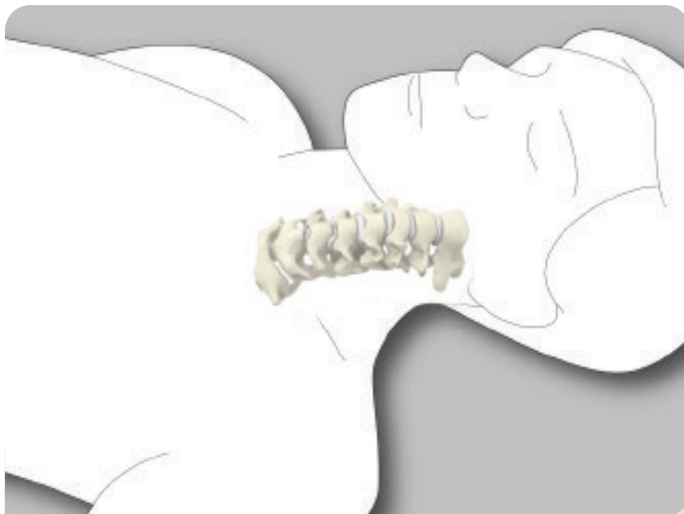
Anterior Cervical Interbody Fusion System



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 cervical spine from a standard anterior approach. The intervertebral disc should be excised using standard technique.



3

Endplate Preparation

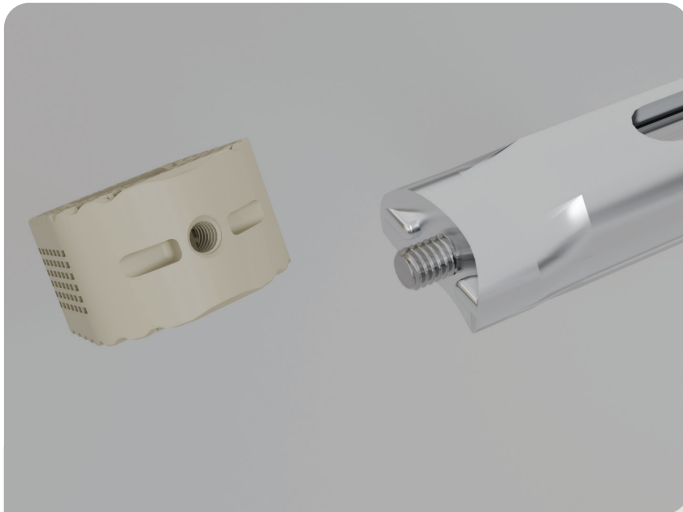
Remove the superficial cartilaginous layers of the endplates to expose bleeding bone.



4

Selection of Implant

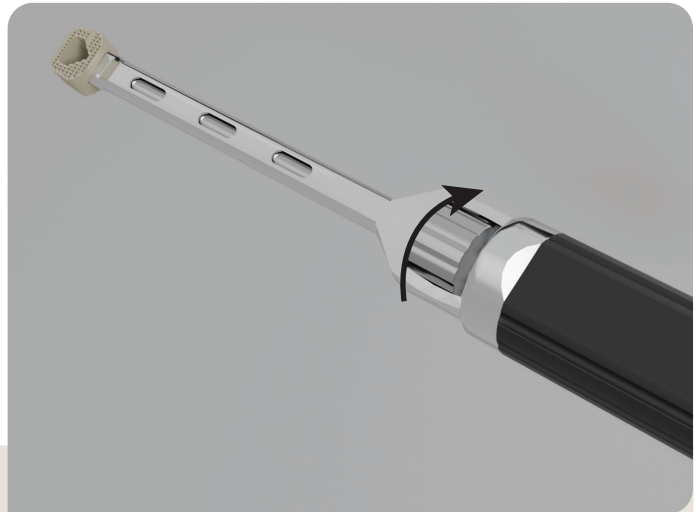
The selection of the implant depends on the height, width, and depth of the intervertebral disc space. Select the trial height associated with the preoperative planning. If necessary, controlled and light tapping with a mallet can be used to advance the trial and confirm the height. Final implant height confirmation must be completed under fluoroscopy.

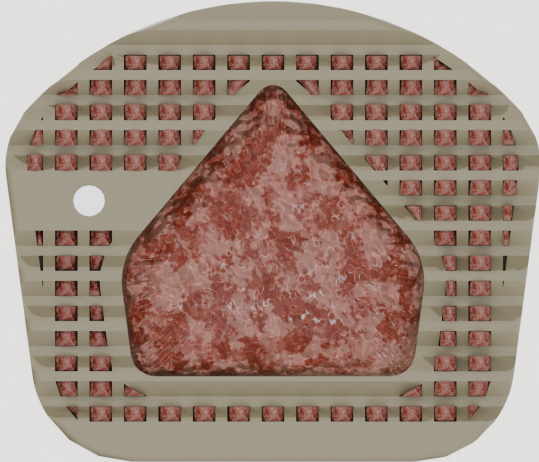


5

Engage Implant

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

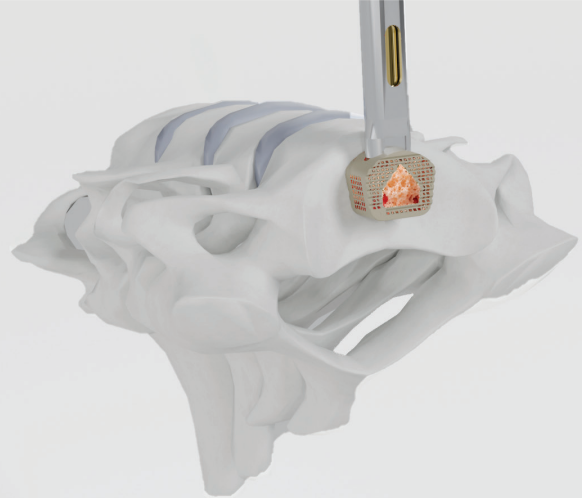




5A

Packing the Implant

Pack autograft bone inside the graft area.



6

Insert Implant

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



7

Removing the Inserter

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

The tamp instrument 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

Implants 0°

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PAC-0606-1214	Cervical, Printed - 12x14mm, 6 degree, 6mm
PAC-0607-1214	Cervical, Printed - 12x14mm, 6 degree, 7mm
PAC-0608-1214	Cervical, Printed - 12x14mm, 6 degree, 8mm
PAC-0609-1214	Cervical, Printed - 12x14mm, 6 degree, 9mm
PAC-0610-1214	Cervical, Printed - 12x14mm, 6 degree, 10mm
PAC-0606-1416	Cervical, Printed - 14x16mm, 6 degree, 6mm
PAC-0607-1416	Cervical, Printed - 14x16mm, 6 degree, 7mm
PAC-0608-1416	Cervical, Printed - 14x16mm, 6 degree, 8mm
PAC-0609-1416	Cervical, Printed - 14x16mm, 6 degree, 9mm
PAC-0610-1416	Cervical, Printed - 14x16mm, 6 degree, 10mm

Trials

Part Number	Description
AC-1416T-309	ACIF 14x16 Trial 6mm 6°
AC-1416T-310	ACIF 14x16 Trial 7mm 6°
AC-1416T-311	ACIF 14x16 Trial 8mm 6°
AC-1416T-312	ACIF 14x16 Trial 9mm 6°
AC-1416T-313	ACIF 14x16 Trial 10mm 6°
AC-1214T-309	ACIF 12x14 Trial 6mm 6°
AC-1214T-310	ACIF 12x14 Trial 7mm 6°
AC-1214T-311	ACIF 12x14 Trial 8mm 6°
AC-1214T-312	ACIF 12x14 Trial 9mm 6°
AC-1214T-313	ACIF 12x14 Trial 10mm 6°

Instruments

Part Number	Description
AC-1000T-500	ACIF Handle
AC-1000T-100	ACIF Insertor
AC-1000T-200	ACIF Tamp

