NuVasive

Cohere

Technique Guide

NuVasive ACPs incorporate technology developed by Gary K. Michelson, M.D.

MICHELSON TECHNOLOGY AT WORK

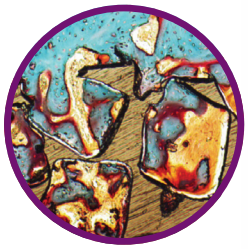
CONTENTS

ADVANCED MATERIALS SCIENCE

Traditional PEEK and titanium implants are limited by the materials from which they are created, often requiring surgeons to make compromises when selecting a spinal implant, sacrificing radiolucency for durability or favorable osteogenic properties for bone-like modulus. Adhering to the three core principles of Advanced Materials Science, surface, structure, and imaging, NuVasive has pioneered design and manufacturing methods that combine the inherent benefits of porosity with the advantageous material properties of PEEK and titanium. Intelligently designed for enhanced osseointegration,[1] biomechanical,[1] and imaging properties, the Advanced Materials Science portfolio represents the future of porous implant technologies that require no compromise.

Porous PEEK Portfolio

Porous PEEK is manufactured through a proprietary extrusion process which produces a unified porous-to-solid structure that mimics the cortical-to-cancellous transition of bone. Currently available for Cervical and Thoracolumbar applications, Cohere and Coalesce are the only porous PEEK interbody implants available in the market.

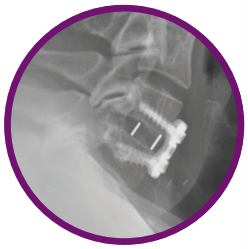


SURFACE

- Porous PEEK has been shown to enhance the activity of bone forming cells, allowing the implant to participate in the fusion process.[2,3]
- Through surface topography and porous design, Porous PEEK has been shown to exhibit more hydrophilicity and wicking ability compared to traditional interbody implants.[1]
- Porous PEEK is designed to avoid fibrous encapsulation. Preclinical data shows that bone tissue forms directly in the porous structure of Porous PEEK.[2]

STRUCTURE

- Porous PEEK has been found to resist abrasion damage and delamination under impacted insertion[2,4] and maintains high porosity under conditions that replicate anatomic loading.[4]
- With a stiffness similar to bone, Porous PEEK implants reduce stress shielding and subsidence compared with conventional solid metal implants,[1] according to preclinical data on file.



IMAGING

- Radiolucent PEEK composition enables clear radiographic visualization of the fusion site.

COHERE TECHNIQUE GUIDE

This document is intended exclusively for physicians. This document contains general information on the products and/or procedures discussed herein and should not be considered as medical advice or recommendations regarding a specific patient or their medical condition.

This surgical technique guide offers guidance but is not a substitute for the comprehensive training surgeons have received. As with any such technique guide, each surgeon should use his or her own independent medical judgment to consider the particular needs of the patient and make appropriate clinical decisions as required. A successful result is not always achieved in every surgical case.

As with all surgical procedures and permanent implants, there are risks and considerations associated with surgery and the implant, including Cohere. It may not be appropriate for all patients and all patients may not benefit.

It is the surgeon's responsibility to discuss all relevant risks with the patient prior to surgery.

All non-sterile devices must be cleaned and sterilized before use. Multi-component instrument assemblies must be disassembled prior to cleaning.

This surgical technique guide provides information supplemental to information provided in the individual system instructions for use (IFU).

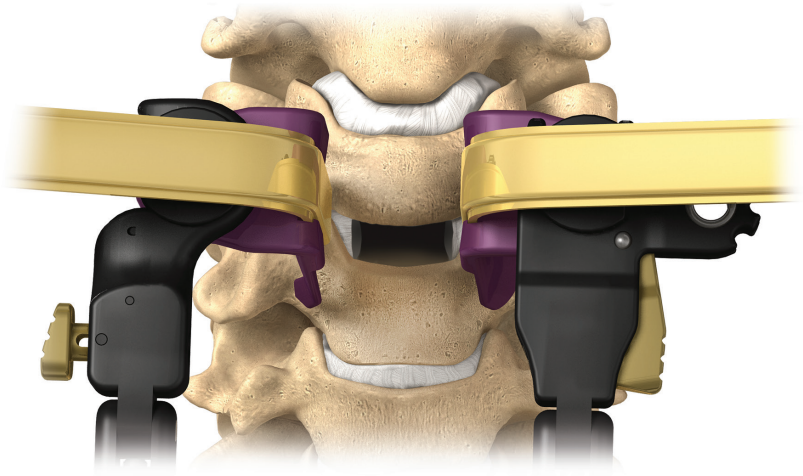
Please refer to the corresponding individual system IFU for important product information, including but not limited to, indications, contraindications, warnings, precautions and adverse effects, located at the back of this surgical technique guide, and which can also be found at nuvasive.com/eifu.

STEP 1:
PATIENT POSITIONING AND APPROACH

Place the patient's neck in a supine position, chin extended, on the operating table and apply up to 5 lbs. of traction.

Carry out the anterior approach to the appropriate level(s) in the usual manner. The technique must allow for direct anterior access to the disc and the adjacent vertebral bodies.

Apply a standard vertebral body distractor to the adjacent vertebra in the usual manner. It will also be used to distract upon completion of the decompression *(Fig. 1)*.



(Fig. 1)

STEP 2:
DISCECTOMY

Perform a complete discectomy and decompression.

After thorough removal of the disc material, remove the cartilaginous endplates with standard curettes or a drill. A rasp may be used to help distress the endplates.

If present, remove the overhanging osteophytes of the superior vertebral body as needed to improve visualization and access to the disc space.

STEP 3:
DISTRACTION, SIZING, AND PLACEMENT OF THE COHERE DEVICE

Determine the appropriate implant size by sequentially increasing the height of the trial until it fits firmly in the disc space. Confirm correct height by radiographic imaging.

Select the implant size corresponding to the appropriate decompression height *(Fig. 2)*.

Pack the Cohere implant aperture with allograft (Osteocel Pro or Osteocel Plus) or autograft.

Insert the Cohere implant into the disc space. A mallet and/or tamp may be used to gently tap the implant into place *(Fig. 3)*.

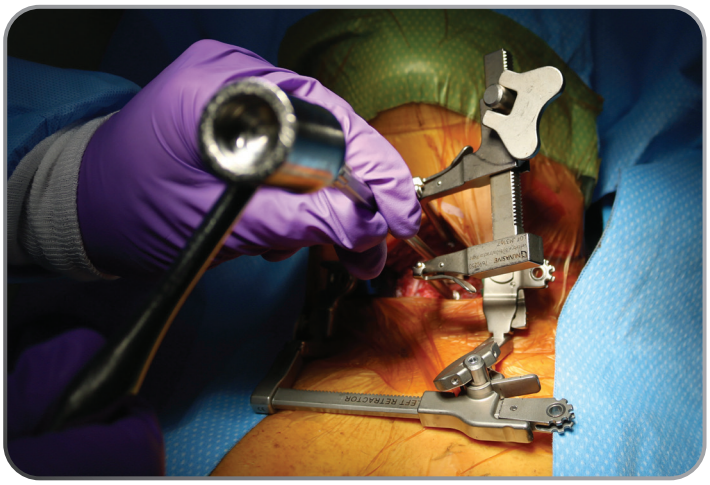
Confirm position with fluoroscopy as needed *(Fig. 4)*.

Loosen the inserter collet and remove inserter.

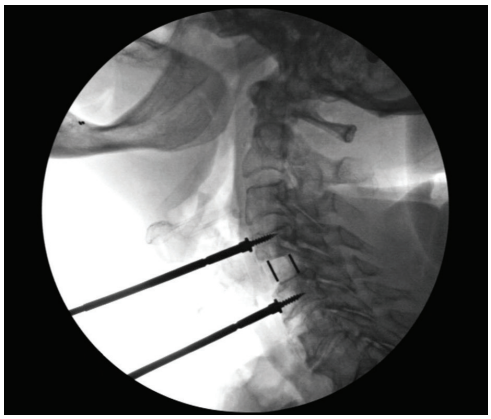
SUPPLEMENTAL INSTRUMENTATION

Complete the surgery with desired supplemental fixation, which can be an anterior cervical plate or other NuVasive cervical fixation system.

(Fig. 2)



(Fig. 3)



(Fig. 4)

CATALOG

COHERE INSTRUMENTS

DESCRIPTION	CATALOG #
Trial, 6mm (12mm x 14mm) 7° Lordosis	1100-02-0614
Trial, 7mm (12mm x 14mm) 7° Lordosis	1100-02-0714
Trial, 8mm (12mm x 14mm) 7° Lordosis	1100-02-0814
Trial, 9mm (12mm x 14mm) 7° Lordosis	1100-02-0914
Trial, 10mm (12mm x 14mm) 7° Lordosis	1100-02-1014
Trial, 6mm (14mm x 16mm) 7° Lordosis	1100-02-0616
Trial, 7mm (14mm x 16mm) 7° Lordosis	1100-02-0716
Trial, 8mm (14mm x 16mm) 7° Lordosis	1100-02-0816
Trial, 9mm (14mm x 16mm) 7° Lordosis	1100-02-0916
Trial, 10mm (14mm x 16mm) 7° Lordosis	1100-02-1016
Rasp, 14mm	1100-03-0514
Inserter Retention	1100-01-0001
Inserter Body, Cohere Interbody Fusion Device	1100-00-0001
Inserter Retention Wrench, Cohere	1100-06-000
Tamp Assembly, Cohere	1100-05-000

COHERE IMPLANTS

DESCRIPTION	CATALOG #
12X14X6mm Implant	1000-00-0614
12X14X7mm Implant	1000-00-0714
12X14X8mm Implant	1000-00-0814
12X14X9mm Implant	1000-00-0914
12X14X10mm Implant	1000-00-1014
14X16X6mm Implant	1000-00-0616
14X16X7mm Implant	1000-00-0716
14X16X8mm Implant	1000-00-0816
14X16X9mm Implant	1000-00-0916
14X16X10mm Implant	1000-00-1016

COHERE INSTRUMENT TRAY

DESCRIPTION

The Cohere Cervical Interbody Fusion Device is a spinal intervertebral fusion device manufactured from polyetheretherketone (PEEK) material.

It is provided in a variety of footprint sizes. It has two radiographic marker pins made from tantalum. The COHERE device is offered in a variety of shapes and sizes to accommodate variations in patient anatomy.

The COHERE ancillary surgical instruments are specifically designed for use with the COHERE Cervical Interbody Fusion Device. These specialized instruments are required to correctly perform the COHERE implantation procedure.

INDICATIONS FOR USE

The Cohere Cervical Interbody Fusion Device is indicated for intervertebral body fusion of the spine in skeletally mature patients. The Cohere Cervical Interbody Fusion Device is intended for use for anterior cervical interbody fusion in patients with cervical disc degeneration and/or cervical spinal instability, as confirmed by imaging studies (radiographs, CT, MRI), that results in radiculopathy, myelopathy, and/or pain at multiple contiguous levels from C2 - T1. The System is intended to be used with supplemental fixation. The System is designed for use with autogenous and/or allogeneic bone graft comprised of cancellous, cortical, and/or corticocancellous bone graft to facilitate fusion.

CONTRAINDICATIONS

- Surgical procedures other than those listed in the INDICATIONS FOR USE section of this guide.
- Patients with an active local or systemic infection
- Conditions which tend to retard healing such as blood supply limitations or previous infections.
- Skeletally immature patients where the implanted device would cross open epiphyseal plates
- Grossly distorted anatomy due to congenital abnormalities.
- Inadequate tissue coverage over surgical site.
- Insufficient quality or quantity of bone, comminuted bone surfaces or pathologic conditions such as cystic change or severe osteopenia that would impair the ability of the COHERE Cervical Interbody Fusion Device to securely fixate to the bone.
- Inadequate neuromuscular status (e.g. paralysis, inadequate muscle strength)
- Patients with conditions such as mental illness, senility or alcoholism that tend to restrict his or her ability or willingness to follow postoperative instructions during the healing process
- Patients with foreign body sensitivity, suspected or documented material allergy or intolerance. Where material sensitivity is suspected, appropriate tests should be conducted and sensitivity rules out prior to implantation.

POTENTIAL ADVERSE EVENTS AND COMPLICATIONS

Potential adverse effects resulting from use of the COHERE Cervical Interbody Fusion Device include, but are not limited to, the following:

- Loosening, cracking or fracture of the implant components.
- Loss of fixation in bone.
- Fracture of bony structures.
- Deep or superficial infection.
- Degenerative changes or instability of segments adjacent to fused vertebral levels.
- Nerve damage due to surgical trauma or presence of the device.
- Sensitivity, allergies, or other reaction to the device material.
- Tissue reactions including macrophage and foreign body reactions adjacent to implants.
- Nonunion, delayed union or pseudoarthrosis, possibly requiring further surgery.
- Malalignment of anatomical structures (i.e. loss of normal spinal contours or change in height).
- Pain, discomfort and abnormal sensations due to presence of the implant.
- Hematoma or thrombosis.

Adverse effects may necessitate re-operation, revision or removal surgery. Implant removal should be followed by adequate postoperative management.

WARNINGS, CAUTIONS AND PRECAUTIONS

The COHERE device is supplied sterile for single use only.

DO NOT ATTEMPT TO RESTERILIZE. The COHERE Cervical Interbody Fusion Device has not been evaluated for resterilization or reprocessing.

Carefully inspect product packaging and all device components for damage or defects prior to use. Do not use any device if it appears defective, damaged or otherwise compromised.

Do not modify the implant. Modified devices may not perform as intended and could result in patient injury.

The COHERE Cervical Interbody Fusion Device should be used only by those physicians who have been trained in the appropriate, specialized procedures. Knowledge of appropriate surgical techniques, instrumentation, proper selection and placement of implants and postoperative patient care and management are essential to a successful outcome.

Correct selection of COHERE Cervical Interbody Fusion Device components is extremely important. Carefully select the appropriate device size based on the needs of each individual patient.

Always handle the COHERE Cervical Interbody Fusion Device carefully. All implant surfaces must always be protected from damage during handling. Avoid contacting the implant with other tools or materials that could notch, scratch or otherwise damage the implant surface. Damage to any part of the implant's surface finish may result in loss of proper mechanical function of the device.

Never attempt to reuse. Once COHERE Cervical Interbody Fusion Device has been removed from the packaging, the device should be either used or discarded. Never attempt to reuse the implant, even though it may appear undamaged.

The surgeon must make the final decision regarding implant removal.

In the absence of a bursa or pain, removal of the implant in elderly or debilitated patients is not recommended. Extreme care must be taken when removing the device.

Use only COHERE device components and instruments when handling and implanting the COHERE device.

Over-distraction of the disc space can lead to facet over-distraction and spinous process contact.

Confirm lateral fluoroscopy shows proper sagittal alignment.

Caution: Federal law restricts the sale of COHERE devices to or on the order by a physician, per 21 CFR 801.109(b)(1).

Magnetic Resonance (MR) Safety: Refer to COHERE Cervical Interbody Fusion Device eIFUs for MR safety information.

PATIENT SELECTION INFORMATION

The surgeon is responsible for patient selection. The surgeon is responsible for understanding the appropriate indications and contraindications associated with the device and selecting the surgical procedures and techniques determined to be the best for each individual patient. Each surgeon must evaluate the appropriateness of the device and the procedure used to implant the device based on his/her own training experience.

The physician must determine if the device is appropriate for patients having any of the following physical or emotional conditions:

- Drug and/or alcohol and/or tobacco addiction and/or abuse.
- Infectious disease.
- Malignancy.
- Local bone tumors.
- Systemic or metabolic disorders or replacement
- Compromised wound healing.
- Obesity.
- Demonstrated psychological instability, inappropriate motivation or attitude.
- Unwillingness to accept the possibility of multiple surgeries for revision or replacement.
- Lack of understanding that their preoperative capacity may not be fully recovered even after successful implantation.

References

[1]Preclinical data on file; data may not be representative of clinical results.

[2]Torstrick FB, Lin ASP, Gall K, et al. Porous PEEK improves the bone-implant interface compared to plasma-sprayed titanium coating in PEEK: in vitro and in vivo analysis. Transactions of the 2017 Annual Meeting of the ORS, San Diego, CA; Poster 0835.

[3]Torstrick FB, Evans NT, Stevens HY, et al. Do surface porosity and pore size influence mechanical properties and cellular response to PEEK? *Clin Orthop Relat Res* 2016;474(11):2373-83.

[4]Evans NT, Torstrick FB, Safranski DL, et al. Local deformation behavior of surface porous polyether-ether-ketone. *J Mech Behav Biomed Mater* 2017;65:522-32.

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