COHERE TLIF-A

# Technique guide

NuVasive

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 the use of Cohere TLIF-A. 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) regarding the products referenced herein.

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**.

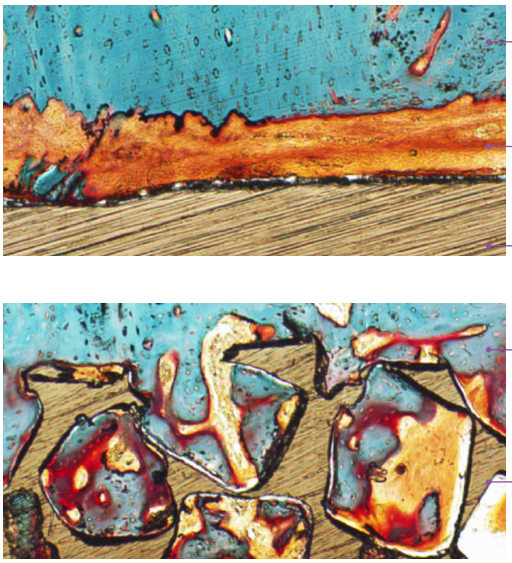
# Contents

# Cohere TLIF-A system overview

## Surface

### Porous surface designed to participate in fusion

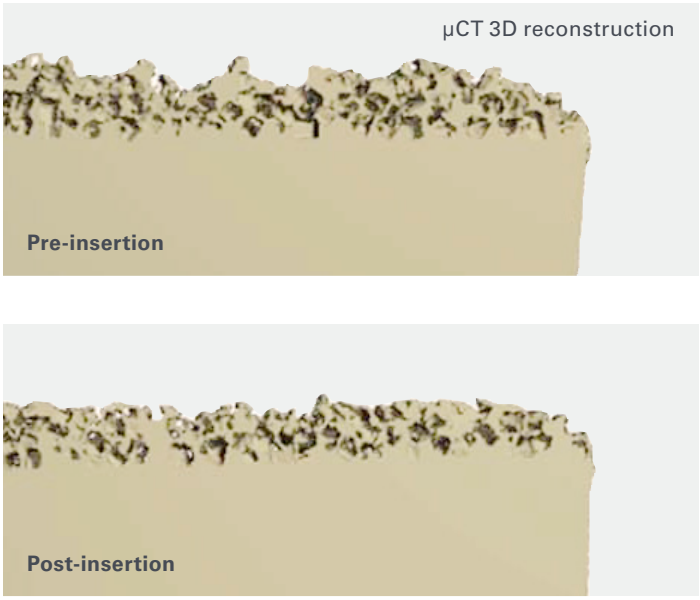
- Porosity elicits a significantly stronger osteogenic response at the cellular level compared to roughened or nano-roughened surfaces[1-4] on their own.
- Porous endplate design promotes new bone on-growth and in-growth,[5] leading to greater integration strength than smooth PEEK.[6,7]
- The increased surface area and wicking capability of the porous surface has been found to improve blood to implant contact compared with traditional interbody implants.[5]




## Structure

### Durable structure mimics the architecture and stiffness of bone

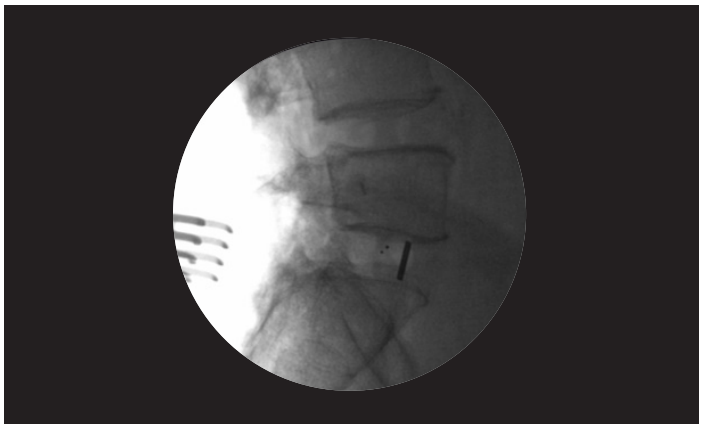
- Cohere TLIF-A is manufactured through a proprietary extrusion process, which results in a unified porous-to-solid structure.
- Cohere maintains high porosity under conditions that replicate anatomic loading and has been shown to resist abrasion damage and delamination under impacted insertion.[8,9]
- With a stiffness similar to bone, Cohere implants have demonstrated reduced stress shielding and risk of subsidence, compared with solid titanium implants.[10]




## Imaging

### Created with imaging in mind

Cohere leverages the radiolucent properties of PEEK to enable radiographic visualization on a variety of imaging modalities.



# Technique guide

## Equipment requirements

**COHERETLIFACOREIMP**

- Cohere TLIF-A implant set contains all core implant sizes.

**COHERETLIFACOREINS**

- Cohere TLIF-A instrument sets contain trials, inserters, removal tool, T-handles and tamps.

**MT2ACCESS (optional)**

- MAS TLIF 2 access set contains the MAS TLIF 2 blades, retractor body and instrumentation.

**EXGENINS and EXDISCPREPSTRT or EXDISCPREPBAY**

- Excavation sets contain paddle sizers, shavers, curettes and Kerrisons.

**Fixation options**

- Reline

**Biologic options**

- Osteocel Plus
- Osteocel Pro
- Graft Delivery System (GDS)

For a complete list of intended uses, indications, device description, contraindications, warnings and precautions, please refer to the Cohere thoracolumbar interbody system IFU found at **nuvasive.com/eIFU**

## Highlighted instrumentation

### Sizing and trialing

Modulus trial inserter

Cohere pivoting trial

### Implant insertion

Cohere TLIF-A inserter, inline

Cohere TLIF-A inserter, offset

Cohere TLIF-A removal tool


Modulus TLIF-A tamp, fork

Coroent anterior TLIF tamp

# Patient positioning and OR setup

Place the patient on the operating table in a prone position. Prepare and drape in a conventional manner. Fluoroscope should have easy access to the surgical field for both A/P and lateral views. Fluoroscopic monitors and NVM5 unit should be placed in clear view *(Fig. 1)*.

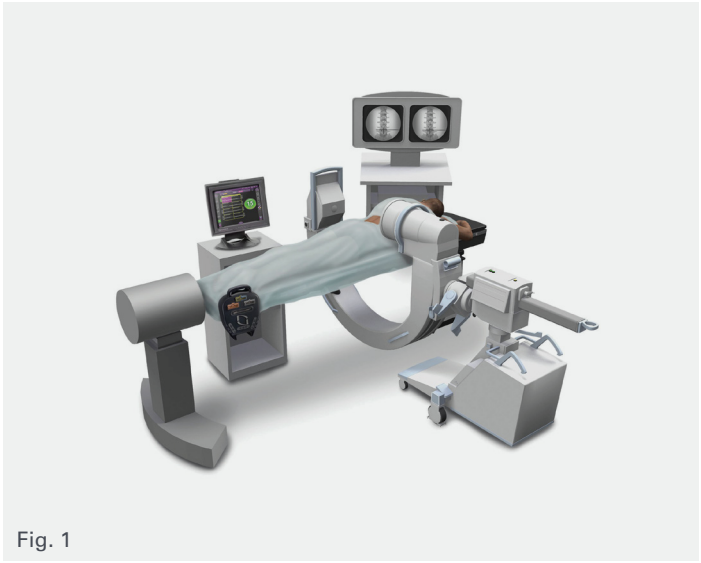


Fig. 1

## Patient preparation for lumbar neuromonitoring with NVM5

For TLIF procedures utilizing electromyography (EMG) neuromonitoring, place the EMG electrodes on the patient prior to positioning and orient the NVM5 screen toward the operative surgeon. Refer to the NVM5 electrode patient prep guides for more information.

Once electrodes are properly placed, execute a twitch test to detect the presence of neuromuscular blocking agents, which can impact the accuracy of EMG monitoring.


**Step 1**

# Anatomical landmark identification and initial incisions

Localize the disc space using fluoroscopy in the A/P and lateral views. Target the pedicles above and below the affected level and mark the location of each pedicle. Make a skin incision between the pedicle markings, sized appropriately for the retractor being used.

**Step 2**

# Exposure

Using finger dissection, a Cobb or curette, release tissue from the facet joint, as necessary, at the affected level.

**Step 3**

# Decompression and discectomy

After achieving access to the target anatomy and completing a decompression, perform the necessary thorough annulotomy and discectomy *(Fig. 2)*.

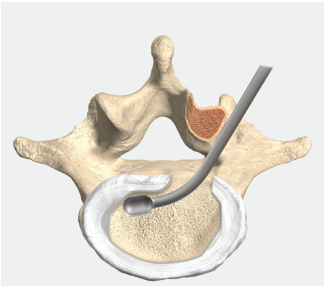


Fig. 2

## NVM5: Free-run EMG

Use free run EMG to continuously monitor for mechanical disturbances to neural structures when using the Cohere TLIF-A implant and inserter.

## Step 4

# Sizing

Once the discectomy at the desired level has been completed, determine the desired height and width, using the provided pivoting trials.

Select the trial shaft and insert it into the distal end of the trial inserter confirming the trial shaft is in the appropriate orientation by referencing the laser mark on the distal end of the trial inserter. Rotate the thumbwheel on the trial inserter clockwise to bring the trial to the locked position for initial insertion *(Fig. 3)*.

***Note:*** *Confirm that the thumbwheel is fully rotated until a hard stop is felt prior to impacting the trial. A red indicator should appear in the proximal window of the trial inserter to indicate the trial body is in the locked position. The red indicator should disappear when the trial body is able to pivot.* ***Only impact on the trial inserter when the trial tip is locked in the inline position and the red indicator is visible. When removing the trial from the disc space, confirm that the red indicator is not visible.***

Impact the assembled trial inserter into the disc space at an oblique angle *(Fig. 4)*. Once the distal tip of the trial is at the contralateral anterior annulus, rotate the thumbwheel counter clockwise, until the red indicator is no longer visible, to bring the assembled trial inserter to the pivot position. The trial should remain connected to the trial inserter but will now be free to pivot up to 90° from the distal portion of the inserter *(Fig. 5)*. Position hand and trial inserter handle medially to assist with pivoting the trial body and impact until trial body is positioned to the anterior one-third of the disc space.

Sequentially increase the trial size until the desired disc height is established. Use A/P and lateral fluoro to confirm the proper placement and trajectory.

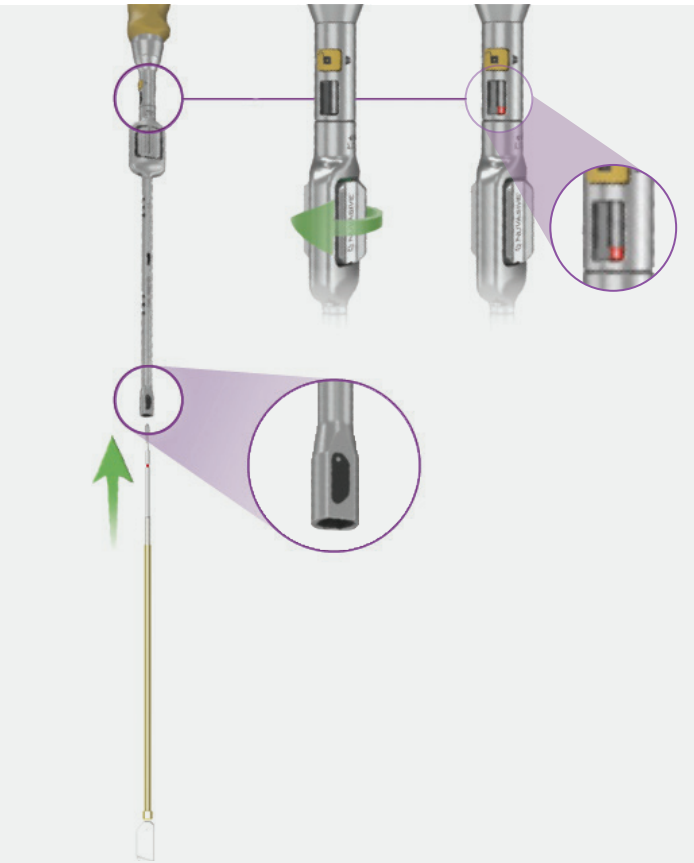


Fig. 3

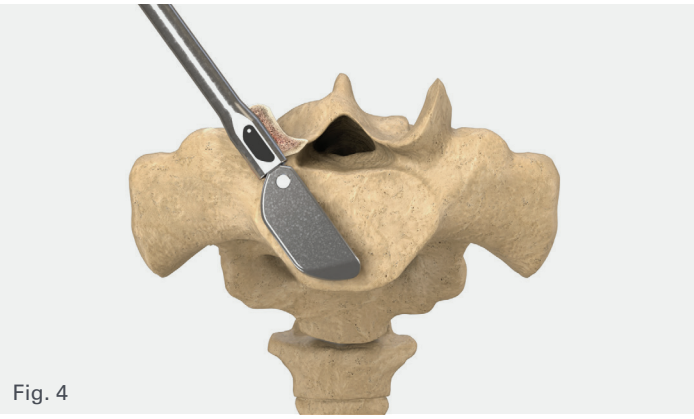


Fig. 4

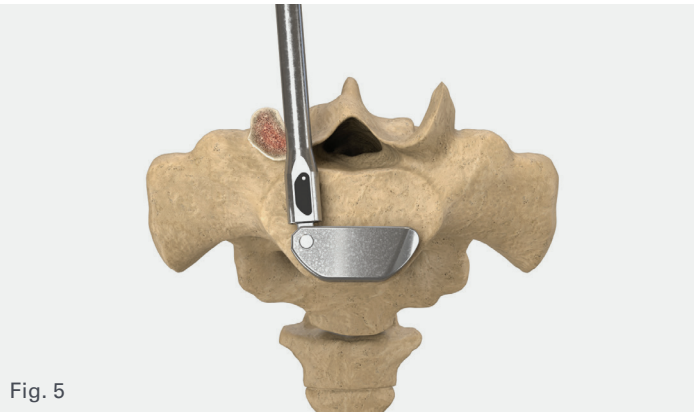


Fig. 5

# Sizing (cont.)

***Note:*** *Trial body width, length and lordosis match the true width, length, and lordosis of the implant. Trial height matches the labeled implant height, and correlated to true implant height for optimal tactile feel. The "M" laser marking on the trial should face medial and the "L" laser marking should face lateral.*

***Note:*** *To disassemble the trial shaft from the trial inserter, depress the gold button on the trial inserter and rotate the thumbwheel counter clockwise. The trial shaft should begin to release from the trial inserter. Continue rotating the thumbwheel until the trial shaft is fully released (Fig. 6).*

***Tip:*** *Confirm the trial is articulated 90° when a small radiolucent gap is visible between the distal end of the trial inserter and articulated trial body (Fig. 7).*

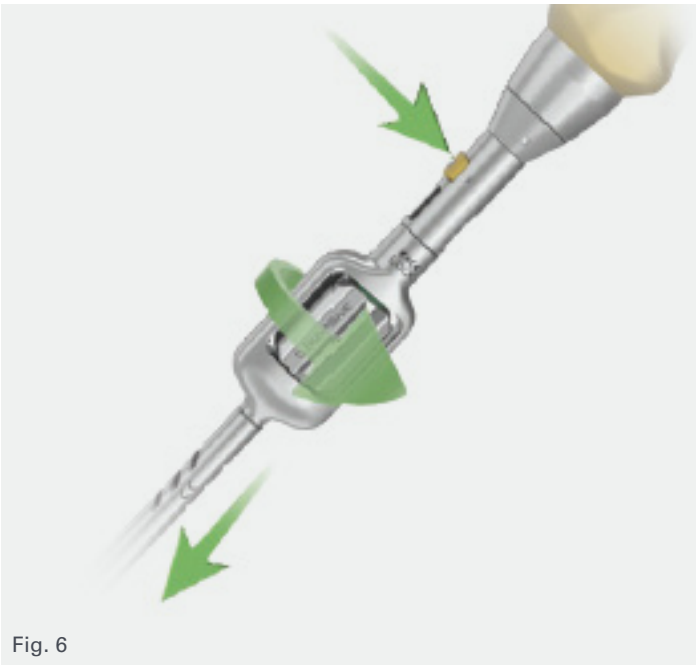


Fig. 6

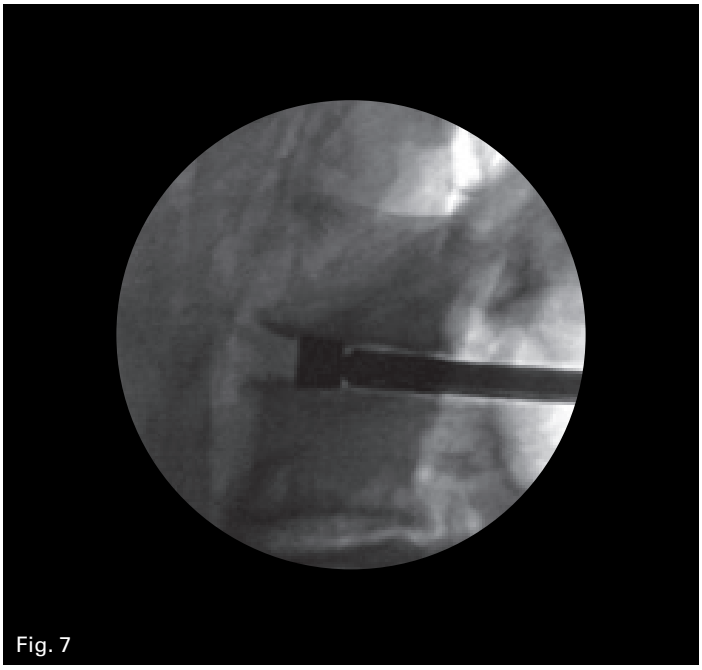


Fig. 7

## Step 5

# Inserter selection and implant attachment

Select either the inline *(Fig. 8)* or offset inserter *(Fig. 9)*.

Confirm that the inserter is in the unlocked position by depressing the paddle marked with the green pivot symbol. This should release the proximal lever to the pivot position. Next, depress the red button etched with the unlock symbol to prepare the inserter for attachment *(Fig. 10)*.

Align the interbody so it is oriented to the laser etched marking on the distal end of the inserter. Attach the distal aspect of the inserter to the inserter feature of the interbody *(Fig. 11)*.

Depress the proximal lever on the inserter so it sits flush with the inserter *(Fig. 12)*.

***Tip:*** *Confirm that the lever is fully seated under the collar to confirm the lock position.*

When in the lock position, the implant is rigid and in line with the inserter and unable to articulate *(Fig. 13)*.

***Tip:*** *Both the inline and offset inserters allow up to 90° of articulation.*

***Tip:*** *Confirm that the interbody is oriented to the laser etched marking on the distal end of the inserter (Fig. 14).*

Fig. 8

Fig. 9

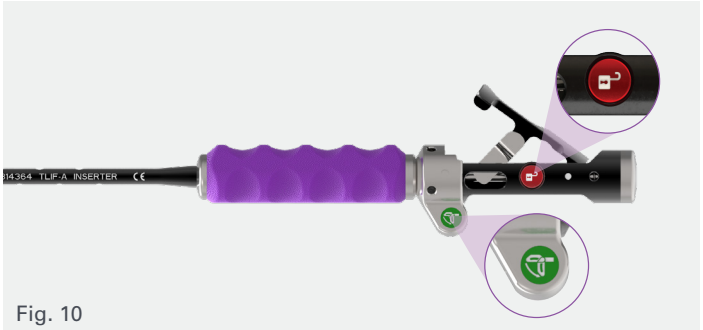


Fig. 10

Fig. 11

Fig. 12

Fig. 13


Fig. 14

## Step 6

# Implant insertion

With the inserter in the locked position, insert the implant into the disc space at a 30° oblique trajectory to achieve proper placement and crossing of midline *(Fig. 15)*.

Once the distal tip of the implant is at the contralateral anterior annulus, proper depth has been achieved. Depress the paddle marked with the green pivot symbol to place the inserter into pivot mode. The interbody should remain connected to the inserter but will now be free to pivot up to 90° from the distal potion of the inserter. Position hand and inserter handle medially to assist with pivoting the implant *(Fig. 16)*. Continue to impact until the implant reaches the anterior one-third of the disc space.

Fig. 15

**Warning**

Do not position inserter past 90° with respect to the implant. Hyper angulation during impaction may result in implant disengagement.

Fig. 16

To release the implant from the inserter, depress the red button etched with the unlock symbol. The inserter can now be disengaged from the implant *(Fig. 17)*.

***Note:*** *The "M" laser marking on the inserter should face medial and the "L" laser marking should face lateral.*

***Reminder:*** *The offset inserter's torsion lock rotates the opposite direction of the inline inserter. The surgeon should "pull" the torsion lock laterally instead of "push" (Fig. 18).*

Fig. 18

Fig. 17

## Step 7

# Implant manipulation

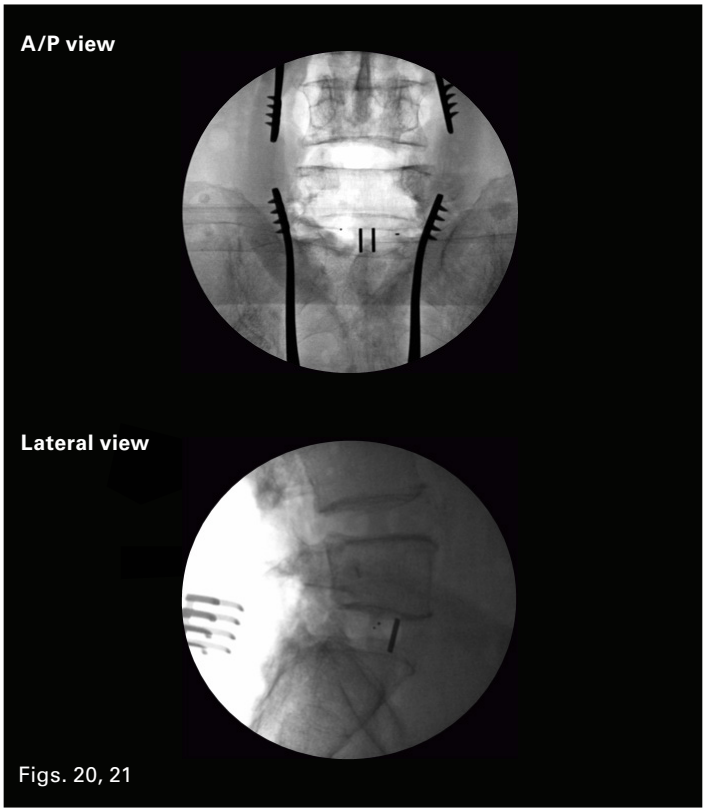
If further manipulation is appropriate, utilize either the straight or forked tamp. Place either tamp into the inserter feature of the implant and mallet until the implant is in the ideal position in the anterior one-third of the disc space *(Fig. 19)*.


Fig. 19

## Step 8

# Final placement

Final position of the implant can be confirmed under fluoroscopy *(Figs. 20, 21)*. The implant should rest in the anterior third of the disc space.




Figs. 20, 21

## Step 9

# Fixation

Place desired fixation option, such as Reline *(Fig. 22)*. See the supplemental fixation system IFU and surgical technique guide for instructions.

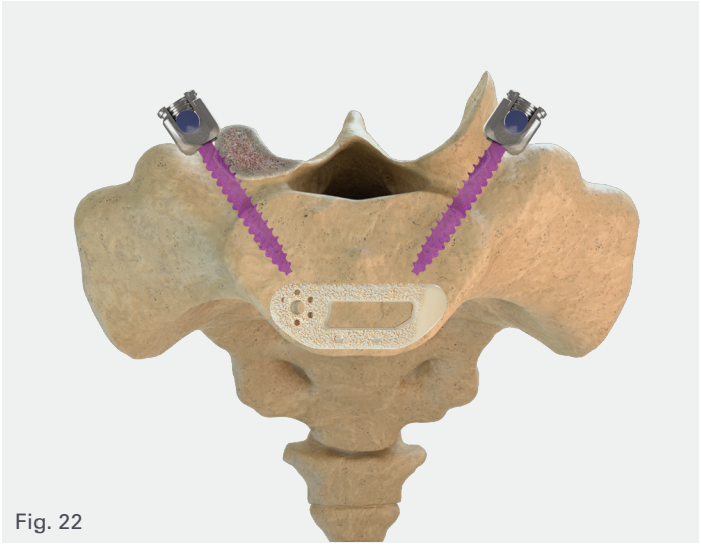


Fig. 22

## Step 10

# Implant removal

Exposure is performed in the same fashion as the primary surgery. Prior to implant removal, the spinal fixation system must first be removed following instructions provided in the system surgical technique.

If the implant must be removed, first confirm the removal tool is in the unlocked position by depressing the red button etched with the unlock symbol to prepare the removal tool for attachment *(Fig. 23)*.

Attach the distal aspect of the removal tool to the inserter engagement feature of the implant. Depress the proximal lever on the removal tool until a hard stop is felt. Attach the Hudson adaptor and slap-hammer, and remove the implant. *(Fig. 24)*.

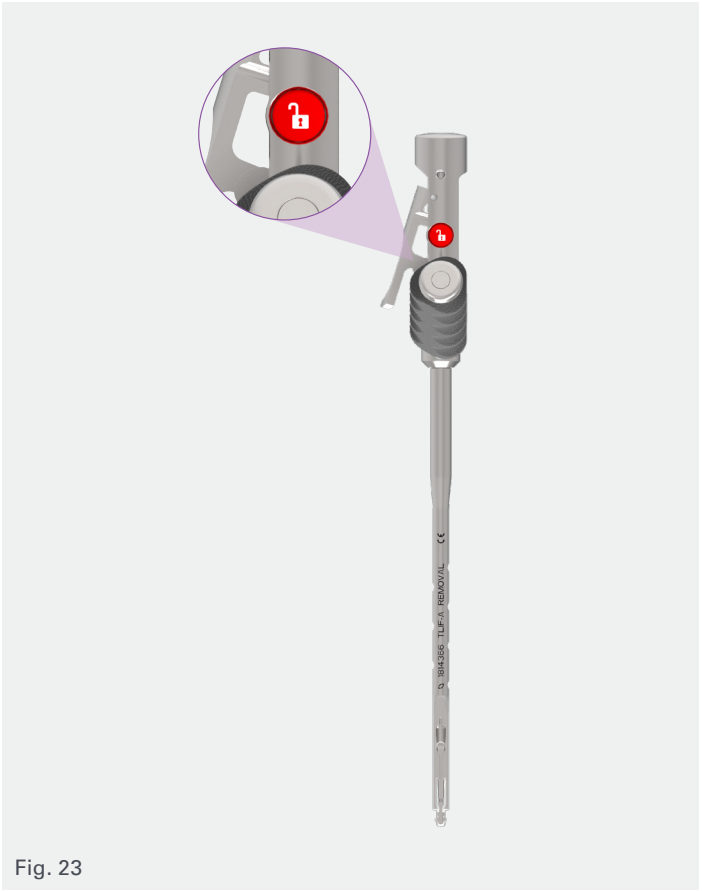



Fig. 23

Fig. 24

# Cohere TLIF-A system

## Cohere TLIF-A instruments

### Cohere TLIF-A inserter, inline


### Cohere TLIF-A inserter, offset

### Cohere TLIF-A removal tool

### Cohere TLIF-A trial inserter

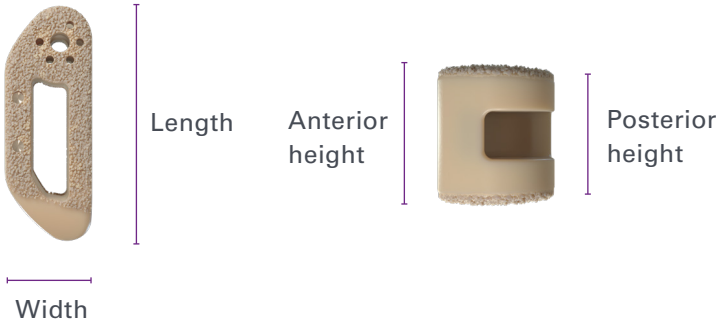
### Cohere TLIF-A trial

# Cohere TLIF-A instruments (cont.)

## Modulus TLIF-A tamp, fork


## Coroent anterior TLIF-A tamp

# Sizing guide




***Important:*** *Labeled implant footprint height references anterior height. Refer to the packaging and table below to identify the posterior height of the implant.*

## COHERETLIFACOREIMP

| Catalog no. | AHxWxL | Anterior height (mm) | Posterior height (mm) |
|---|---|---|---|
| 4109308P2 | 10x9x30 mm, 8° | 10 | 8.5 |
| 4119308P2 | 11x9x30 mm, 8° | 11 | 9.5 |
| 4129308P2 | 12x9x30 mm, 8° | 12 | 10.5 |
| 4139308P2 | 13x9x30 mm, 8° | 13 | 11.5 |
| 4119305P2 | 11x9x30 mm, 15° | 11 | 8.5 |
| 4129305P2 | 12x9x30 mm, 15° | 12 | 9.5 |
| 4139305P2 | 13x9x30 mm, 15° | 13 | 10.5 |
| 4111308P2 | 11x11x30 mm, 8° | 11 | 9.5 |
| 4121308P2 | 12x11x30 mm, 8° | 12 | 10.5 |
| 4131308P2 | 13x11x30 mm, 8° | 13 | 11.5 |
| 4141308P2 | 14x11x30 mm, 8° | 14 | 12.5 |
| 4121305P2 | 12x11x30 mm, 15° | 12 | 9 |
| 4131305P2 | 13x11x30 mm, 15° | 13 | 10 |
| 4141305P2 | 14x11x30 mm, 15° | 14 | 11 |
| 4151305P2 | 15x11x30 mm, 15° | 15 | 12 |

# Instructions for use

## DESCRIPTION

The NuVasive Cohere Thoracolumbar Interbody System consists of an interbody, internal fixation plate and bone screws manufactured from PEEK Scoria (Polyether-ether-ketone), Titanium Alloy (Ti-6Al-4V ELI) conforming to ASTM F136/ ISO 5832-3, Ti-6Al-4V conforming to ASTM F1472, or Tantalum (Ta) conforming to ASTM F560/ ISO 13782. The fixation plate also includes components manufactured from Nickel-Cobalt-Chromium-Molybdenum Alloy (Carpenter MP35N alloy) conforming to ASTM F562. The implants are available in a variety different shapes and sizes to suit the individual pathology and accommodate anatomical conditions of the patient.

## INDICATIONS FOR USE

The NuVasive Cohere Thoracolumbar Interbody System is indicated for intervertebral body fusion of the spine in skeletally mature patients. The System is designed for use with autogenous and/or allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft to facilitate fusion. When used with or without the Cohere XLIF internal fixation, the system is indicated for use with supplemental spinal fixation systems cleared by the FDA for use in the thoracolumbar spine. The devices are to be used in patients who have had at least six months of non-operative treatment.

The NuVasive Cohere Thoracolumbar Interbody System is intended for use in interbody fusions in the thoracic spine, from T1 to T12, and at the thoracolumbar junction (T12-L1), and in the lumbar spine, from L1 to S1, for the treatment of symptomatic disc disease (DDD), degenerative spondylolisthesis, and/or spinal stenosis at one or two adjacent levels, including thoracic disc herniation (with myelopathy and/or radiculopathy with or without axial pain). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The NuVasive Cohere Thoracolumbar Interbody System can be used as an adjunct to fusion in patients diagnosed with multilevel degenerative scoliosis and sagittal deformity.

## CONTRAINDICATIONS

*Contraindications include but are not limited to:*

1. Infection, local to the operative site.
2. Signs of local inflammation.
3. Patients with known sensitivity to the materials implanted.
4. Patients who are unwilling to restrict activities or follow medical advice.
5. Patients with inadequate bone stock or quality.
6. Patients with physical or medical conditions that would prohibit beneficial surgical outcome.
7. Prior fusion at the level(s) to be treated.

## POTENTIAL ADVERSE EVENTS AND COMPLICATIONS

As with any major surgical procedures, there are risks involved in spinal/orthopedic surgery. Infrequent operative and postoperative complications that may result in the need for additional surgeries include: early or late infection; damage to blood vessels, spinal cord or peripheral nerves; pulmonary emboli; loss of sensory and/or motor function; pleural effusions, hemothorax, chylothorax, pneumothorax, subcutaneous emphysema, need for chest tube insertion, intercostal neuralgia, rib fracture, diaphragm injury; atelectasis; impotence; permanent pain and/or deformity. Rarely, some complications may be fatal. The treatment of multilevel degenerative scoliosis may be associated with a lower interbody fusion rate compared to one- and two-level interbody fusions.

*Potential risks identified with the use of this system, which may require additional surgery, include:*

- Bending, fracture or loosening of implant component(s)
- Loss of fixation
- Nonunion or delayed union
- Fracture of the vertebra
- Proximal junctional kyphosis (PJK)
- Neurological, vascular or visceral injury
- Metal sensitivity or allergic reaction to a foreign body
- Tissue reactions including macrophage and foreign body reactions adjacent to implants
- Infection
- Decrease in bone density due to stress shielding
- Degenerative changes or instability of segments adjacent to fused vertebral levels
- Malalignment of anatomical structions (i.e. loss of normal spinal contours or change in height)
- Pain, discomfort or abnormal sensations due to the presence of the device
- Nerve damage due to surgical trauma
- Bursitis
- Dural leak
- Paralysis
- Death

**WARNINGS, CAUTIONS AND PRECAUTIONS**

The subject device is intended for use only as indicated.

The implantation of spinal systems should be performed only by experienced spinal surgeons with specific training in the use of this spinal system because this is a technically demanding procedure presenting a risk of serious injury to the patient.

Correct selection of the implant is extremely important. The potential for success is increased by the selection of the proper size of the implant. While proper selection can minimize risks, the size and shape of human bones present limitations on the size and strength of implants. Metallic internal fixation devices cannot withstand the activity levels and/or loads equal to those placed on normal, healthy bone. These devices are not designed to withstand the unsupported stress of full weight or load bearing alone. Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without a previous surgery.

Caution must be taken due to potential patient sensitivity to materials. Do not implant in patients with known or suspected sensitivity to the aforementioned materials.

Exercise caution when choosing implant sizes, as larger implants may not be suitable for the thoracic spine. These devices can break when subjected to the increased load associated with delayed union or nonunion. Internal fixation appliances are load-sharing devices that hold bony structures in alignment until healing occurs. If healing is delayed, or does not occur, the implant may eventually loosen, bend, or break. Loads on the device produced by load bearing and by the patient's activity level will dictate the longevity of the implant.

Corrosion of the implant can occur. Implanting metals and alloys in the human body subjects them to a constantly changing environment of salts, acids, and alkalis, which can cause corrosion. Placing dissimilar metals in contact with each other can accelerate the corrosion process, which in turn, can enhance fatigue fractures of implants. Consequently, every effort should be made to use compatible metals and alloys in conjunction with each other.

Based on fatigue testing results, when using the Cohere Thoracolumbar Interbody System, the physician/surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc., which may impact on the performance of this system.

All components should be final tightened per the specifications in the Surgical Technique. Implants should not be tightened past the locking point, as damage to the implant may occur.

Notching, striking, and/or scratching of implants with any instrument should be avoided to reduce the risk of breakage.

For Cohere TLIF-A implants, do not position inserter past 90° with respect to the implant. Hyper angulation during impaction may result in implant disengagement.

The Cohere XLIF 40 mm length implants are not indicated for use with the XLIF AMS Plate. The XLIF AMS Plate may be used in conjunction with any of the 45 mm – 60 mm length Cohere XL, XLW, or XLXW implants.

Care should be taken to ensure that all components are ideally fixated prior to closure.

This device contains nickel. Do not implant in patients with known or suspected nickel sensitivity

**Patient education**: Preoperative instructions to the patient are essential. The patient should be made aware of the limitations of the implant and potential risks of the surgery. The patient should be instructed to limit postoperative activity, as this will reduce the risk of bent, broken or loose implant components. The patient must be made aware that implant components may bend, break or loosen even though restrictions in activity are followed.

**Single use/do not re-use**: Reuse of a single use device that has come in contact with blood, bone, tissue or other body fluids may lead to patient or user injury. Possible risks associated with reuse of a single use device include, but are not limited to, mechanical failure, material degradation, potential leachables, and transmission of infectious agents.

**Compatibility**: Do not use Cohere Thoracolumbar Interbody System with components of other systems. Unless stated otherwise, NuVasive devices are not to be combined with the components of another system. All implants should be used only with the appropriately designated instrument (Reference Surgical Technique). Instruments and implants are not interchangeable between systems.

**MRI Safety Information for Cohere XLIF internal fixation (XLIF AMS Plate and Bone Screws):** The Cohere XLIF AMS Plate and bone screws have not been evaluated for safety and compatibility in the MR environment. They have not been tested for heating, migration, or image artifact in the MR environment. The safety of the Cohere XLIF AMS Plate and bone screws in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

**MRI Safety Information for Cohere Thoracolumbar Interbodies:** In accordance with ASTM F2503 Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment, NuVasive, Inc.'s Cohere Thoracolumbar Interbody System product line should be labeled MR Conditional, following analysis comparing Cohere Thoracolumbar interbody devices to non-clinically tested MR Conditional devices.

Non-clinical analysis has demonstrated that the Cohere devices are MR Conditional. A patient with this device can be safely scanned in an MR system with the following conditions:

1. Static magnetic field of 1.5-Tesla (1.5T) or 3.0-Tesla (3.0T).
2. Maximum spatial gradient field of 19 T/m (1900 G/cm).
3. Maximum MR system reported, whole-body averaged specific absorption rate (SAR) of 2.0 W/kg (normal operating mode)

Under the scan conditions defined above, the device is expected to produce a maximum temperature rise of less than or equal to 3°C after 15 minutes of continuous scanning.

In non-clinical analysis, the image artifact caused by the device extends radially up to 0.7cm and 0.8cm, respectively, from the device when imaged with a gradient echo pulse sequence in a 1.5T MR system and a gradient echo pulse sequence in a 3.0T MR system.

**Compatibility:** Do not use Cohere Thoracolumbar Interbody System with components of other systems. Unless stated otherwise, NuVasive devices are not to be combined with the components of another system. All implants should be used only with the appropriately designated instrument (Reference Surgical Technique).

Instruments and implants are not interchangeable between systems.

**PREOPERATIVE WARNINGS**

1. Only patients that meet the criteria described in the indications should be selected.
2. Patient condition and/or predispositions such as those addressed in the aforementioned contraindications should be avoided.
3. Care should be used in the handling and storage of the Cohere implants. The implants should not be scratched or damaged. Implants and instruments should be protected during storage and from corrosive environments.

   **For Sterile Implants:** Assure highly aseptic surgical conditions, and use aseptic technique when removing the Cohere implant from its packaging. Inspect the implant and packaging for signs of damage, including scratched or damaged devices or damage to the sterile barrier. Do not use the Cohere implants if there is any evidence of damage.
4. Refer to Cleaning and Sterilization Instructions below for all non-sterile parts.
5. Care should be used during surgical procedures to prevent damage to the device(s) and injury to the patient.

**POST-OPERATIVE WARNINGS**

During the postoperative phase it is of particular importance that the physician keeps the patient well informed of all procedures and treatments.

Damage to the weight-bearing structures can give rise to loosening of the components, dislocation and migration as well as to other complications. To ensure the earliest possible detection of such catalysts of device dysfunction, the devices must be checked periodically postoperatively, using appropriate radiographic techniques.

**METHODS OF USE**

Please refer to the Surgical Technique for this device.

**PACKAGING**

Packages for each of the components should be intact upon receipt. Devices should be carefully examined for completeness, and for lack of damage, prior to use. Damaged packages or products should not be used, and should be returned to NuVasive.

Instruments provided non-sterile can be single-use or reusable. Discard single-use instruments after use. Reusable instruments should be reprocessed using instructions provided below.

All implants and instruments provided sterile are intended for single use only. Do not use if package is opened or damaged. This product should NOT be re-sterilized. Discard single-use instruments after use.

**HANDLING OF THE STERILE IMPLANT**

- Before removing the implants from the package, make sure that the protective packaging is unopened and undamaged. If the packaging is damaged, the implants have to be considered as NON-STERILE and may not be used.
- Upon removal from the package, compare the descriptions on the label with the package contents (product number and size)
- Note the STERILE expiry date. Implants with elapsed STERILE expiry dates have to be considered as non-sterile and may not be used.
- Take particular care that aseptic integrity is assured during removal of the implant from the inner packaging.
- Open the packages carefully. Take suitable measures to ensure that the implant does not come into contact with objects that could damage its surfaces. Use only the recommended instruments for implantation of the implants. Damaged implants must not be used.

**CLEANING AND DECONTAMINATON**

All non-sterile instruments must first be thoroughly cleaned using the validated methods prescribed in the NuVasive Cleaning and Sterilization Instructions (doc #9400896) before sterilization and introduction into a sterile surgical field. Contaminated instruments should be wiped clean of visible soil at the point of use, prior to transfer to a central processing unit for cleaning and sterilization. The validated cleaning methods include both manual and automated cleaning. Visually inspect the instruments following performance of the cleaning instructions to ensure there is no visual contamination of the instruments prior to proceeding with sterilization. If possible contamination is present at visual inspection, repeat the cleaning steps. Contaminated instruments should not be used, and should be returned to NuVasive. Contact your local representative or NuVasive directly for any additional information related to cleaning of NuVasive surgical instruments.

Instruments with a “D” prefix part number (e.g. DXXXXXXX) may be disassembled. Please refer to the additional disassembly instructions for these instruments.

**STERILIZATION**

All non-sterile instruments and implants are sterilizable by steam autoclave using standard hospital practices, in addition to NuVasive’s validated parameters. In a properly functioning and calibrated steam sterilizer, effective sterilization may be achieved using the parameters prescribed in the NuVasive Cleaning and Sterilization Instructions (doc #9400896).

**INFORMATION**

To obtain a Surgical Technique Manual or should any information regarding the products or their uses be required, please contact your local representative or NuVasive directly at +1-800-475-9131. You may also email: info@nuvasive.com.

This Instructions for Use document is intended for the US market only. For OUS Instructions for Use, please refer to document #9402774 for Sterile implants.

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