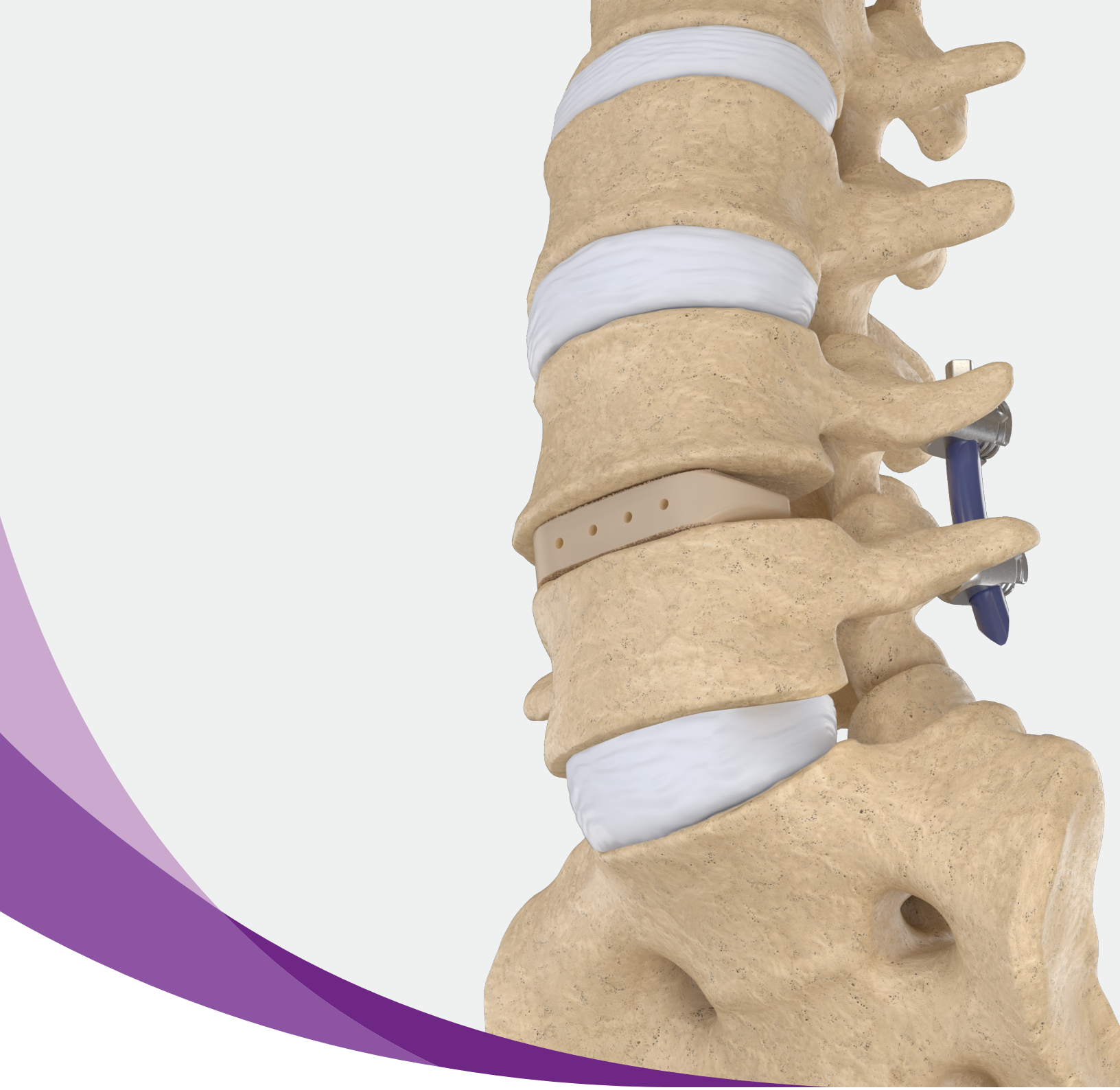

COHERE XLIF

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 use of the Cohere XLIF device. 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**

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Cohere XLIF technique guide

Cohere XLIF is a unique lateral interbody implant within the porous PEEK branch of the NuVasive Advanced Materials Science (AMS) portfolio. The implant design is rooted in the foundational principles of AMS—**surface, structure and imaging**—and strives to advance the osseointegration and biomechanical properties of traditional implant materials.

Note: *The Cohere XLIF implant was designed for use in the NuVasive eXtreme Lateral Interbody Fusion (XLIF) procedure. Please reference the XLIF surgical technique (document #9500138) for details on the XLIF technique.*

Step 1

After endplate preparation

After access to the disc space and careful preparation of the endplates using the standard XLIF technique, trialing can begin to determine an appropriate implant size.

Step 2

Implant sizing

A Coroent XL or XLW trial is threaded onto the inserter, and the thumb-wheel lock is tightened to secure the trial *(Fig. 1)*.

Under A/P fluoroscopy, the trial is gently impacted into the disc space until centered to determine the desired implant size *(Fig. 2)*.

Proper A/P position is verified using lateral fluoroscopy *(Fig. 3)*.

If satisfied with placement and fit of the trial, the surgeon can remove the trial from the disc space. The slap hammer can be used, if appropriate, to facilitate trial removal.

Fig. 1

Fig. 2

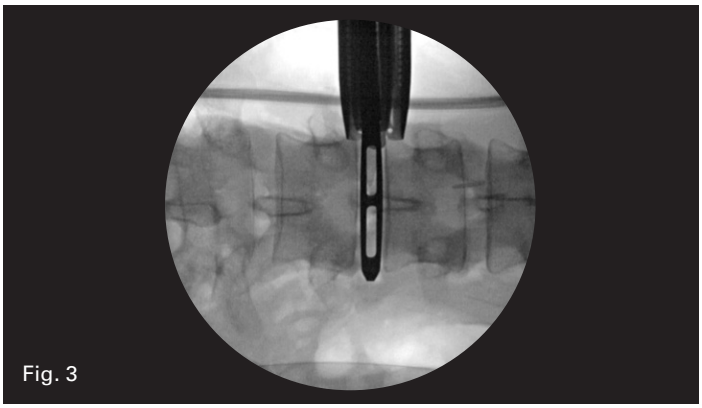

Fig. 3

Step 3

Implant choice and graft loading

After choosing the appropriate size implant for the specific patient anatomy and pathology, fill the implant aperture with graft material. A loading block may be used to confirm the graft window is completely filled.

The implant may then be loaded onto the Coroent XLW inserter *(Fig. 4)*, which is compatible with all Cohere XL and XLW implants. This inserter can be found in the Coroent XL set, as well as the Coroent XLW instruments modular set.

Fig. 4

Step 4

Implant placement

XLIF slides may be used to protect the endplates and contain graft material during implant insertion. Fluoroscopy should be used to verify XLIF slides are positioned properly. The inserter is placed with the attached implant between the XLIF slides. The implant is advanced across the disc space under A/P fluoroscopy.

During insertion of the implant, placement is also monitored with NVM5 free run electromyography.

Placement of the implant is dictated by patient anatomy and the spinal pathology that is being treated. Generally, the implant spans the ring apophysis, is centered across the disc space from a medial/lateral perspective, and is near the center of the disc space from an A/P perspective *(Figs. 5, 6)*.

All Cohere XL and XLW implants have titanium markers that can be used to confirm correct implant alignment *(Fig. 7)*.

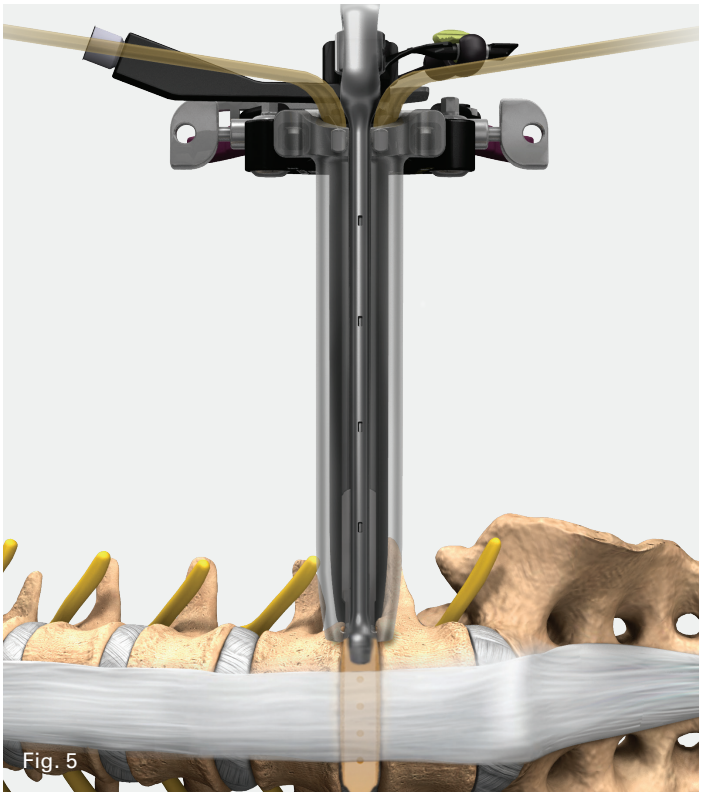

Fig. 5

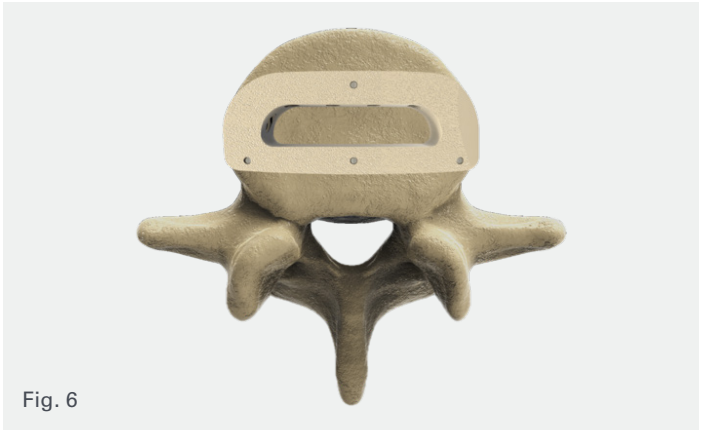

Fig. 6

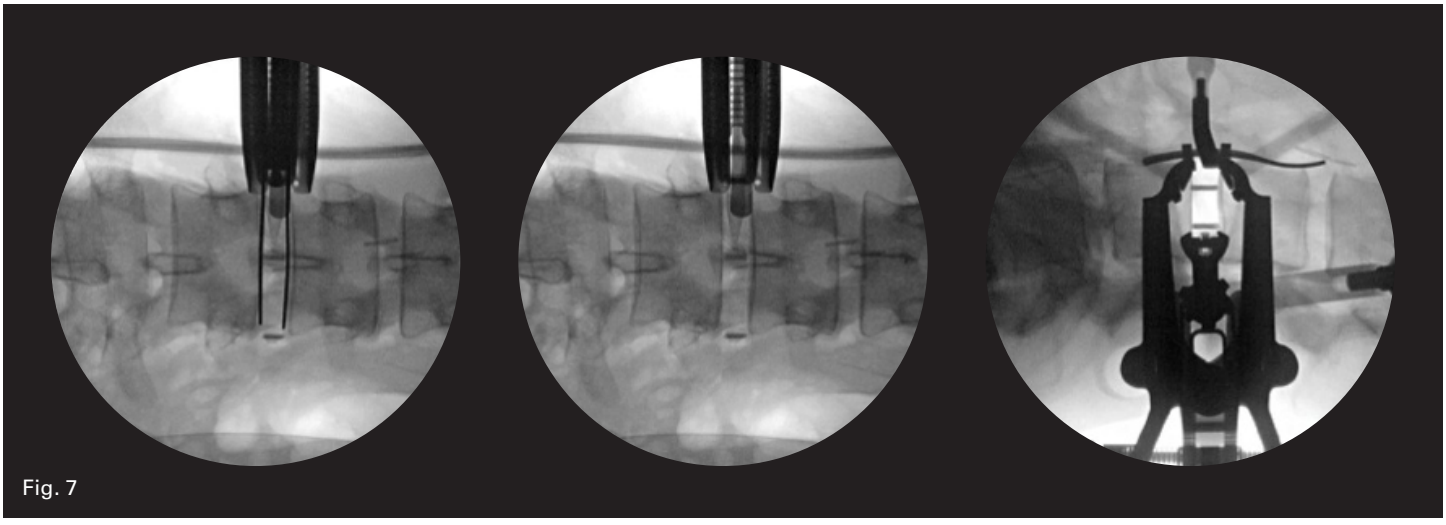

Fig. 7

Step 5

Closure

Once the procedure is completed, the inserter and Maxcess 4 retractor are removed while using direct visualization to assess for bleeding in the disc space or surgical corridor. The locking intradiscal shim should be removed from the C-blade prior to removing the Maxcess 4 retractor. The skin is closed using standard surgical techniques *(Fig. 8).*

Supplemental instrumentation should be applied at the surgeon's discretion.

Step 6

Implant removal

If it becomes necessary to revise the implanted Cohere device, access to the implantation site can be achieved in a similar fashion to the original access. Once the implanted device is exposed, it can be removed by reattaching the inserter. If the device is difficult to remove, additional engagement or dislodging may be achieved with the XLIF revision instruments.

All supplemental instrumentation should be revised in accordance with its respective product technique guide.

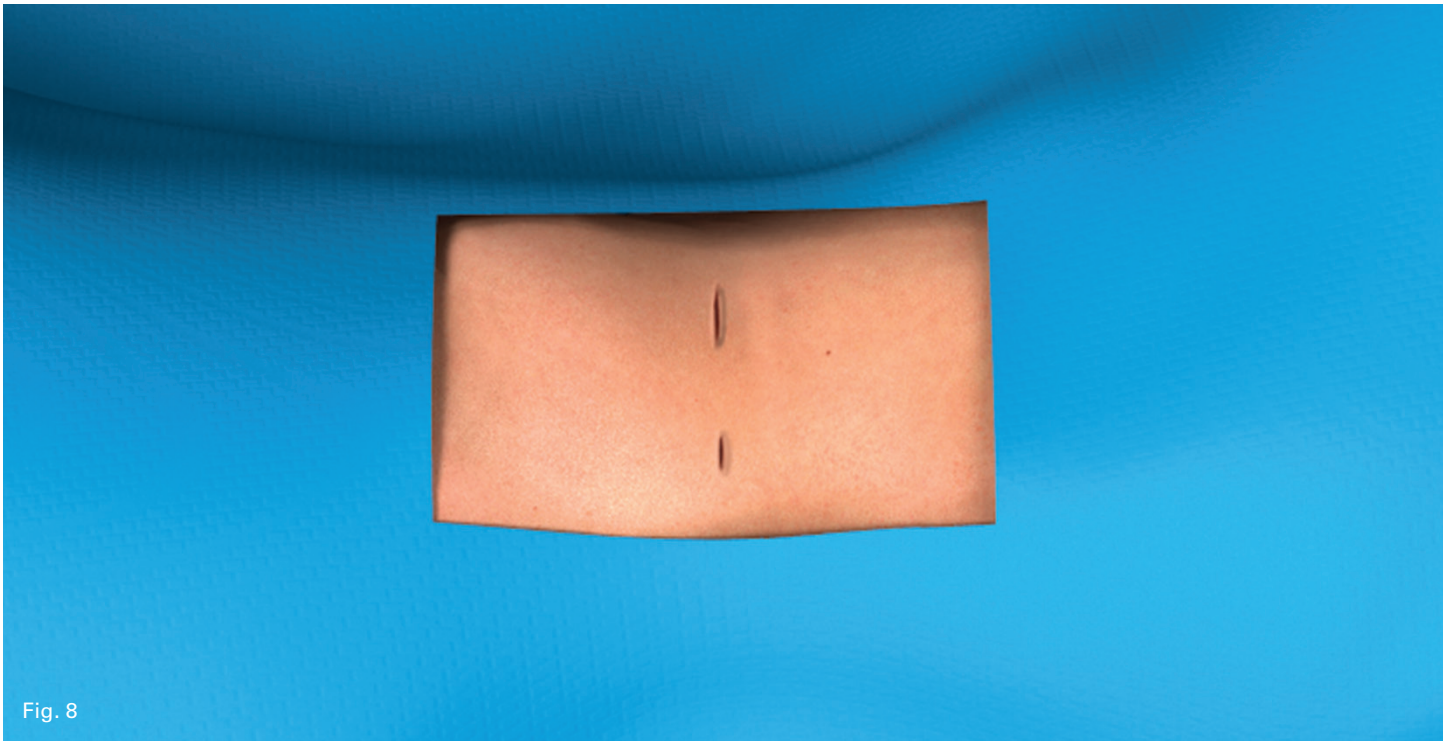

Fig. 8

Catalog

Cohere XL 10°

Description	Catalog no.
Cohere XLIF, 8x18x45 mm, 10°	8180845P2
Cohere XLIF, 8x18x50 mm, 10°	8180850P2
Cohere XLIF, 8x18x55 mm, 10°	8180855P2
Cohere XLIF, 8x18x60 mm, 10°	8180860P2
Cohere XLIF, 10x18x45 mm, 10°	8181045P2
Cohere XLIF, 10x18x50 mm, 10°	8181050P2
Cohere XLIF, 10x18x55 mm, 10°	8181055P2
Cohere XLIF, 10x18x60 mm, 10°	8181060P2
Cohere XLIF, 12x18x45 mm, 10°	8181245P2
Cohere XLIF, 12x18x50 mm, 10°	8181250P2
Cohere XLIF, 12x18x55 mm, 10°	8181255P2
Cohere XLIF, 12x18x60 mm, 10°	8181260P2

Cohere XLW 10°

Description	Catalog no.
Cohere XLIF, 8x22x45 mm, 10°	8220845P2
Cohere XLIF, 8x22x50 mm, 10°	8220850P2
Cohere XLIF, 8x22x55 mm, 10°	8220855P2
Cohere XLIF, 8x22x60 mm, 10°	8220860P2
Cohere XLIF, 10x22x45 mm, 10°	8221045P2
Cohere XLIF, 10x22x50 mm, 10°	8221050P2
Cohere XLIF, 10x22x55 mm, 10°	8221055P2
Cohere XLIF, 10x22x60 mm, 10°	8221060P2
Cohere XLIF, 12x22x45 mm, 10°	8221245P2
Cohere XLIF, 12x22x50 mm, 10°	8221250P2
Cohere XLIF, 12x22x55 mm, 10°	8221255P2
Cohere XLIF, 12x22x60 mm, 10°	8221260P2

Cohere XLW 15°

Description	Catalog no.
Cohere XLIF, 8x22x45 mm, 15°	8150845P2
Cohere XLIF, 8x22x50 mm, 15°	8150850P2
Cohere XLIF, 8x22x55 mm, 15°	8150855P2
Cohere XLIF, 8x22x60 mm, 15°	8150860P2
Cohere XLIF, 10x22x45 mm, 15°	8151045P2
Cohere XLIF, 10x22x50 mm, 15°	8151050P2
Cohere XLIF, 10x22x55 mm, 15°	8151055P2
Cohere XLIF, 10x22x60 mm, 15°	8151060P2
Cohere XLIF, 12x22x45 mm, 15°	8151245P2
Cohere XLIF, 12x22x50 mm, 15°	8151250P2
Cohere XLIF, 12x22x55 mm, 15°	8151255P2
Cohere XLIF, 12x22x60 mm, 15°	8151260P2

Instructions for use

DESCRIPTION

The NuVasive Cohere Thoracolumbar Interbody System is manufactured from PEEK Scoria (Polyether-ether-ketone), and Ti-6Al-4V conforming to ASTM F1472/ ISO 5832-3 or Ti-6Al-4V ELI conforming to ASTM F136, or Tantalum (Ta) conforming to ASTM F560/ ISO 13782. The implants are available in a variety of sizes to accommodate anatomical conditions.

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) or degenerative spondylolisthesis 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.

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
- Neurological, vascular or visceral injury
- Metal sensitivity or allergic reaction to a foreign body
- Infection
- Decrease in bone density due to stress shielding
- 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.

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

Warning: 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.

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.

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 F2503-13 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.

PRE-OPERATIVE 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.

METHOD 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 DECONTAMINATION

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 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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