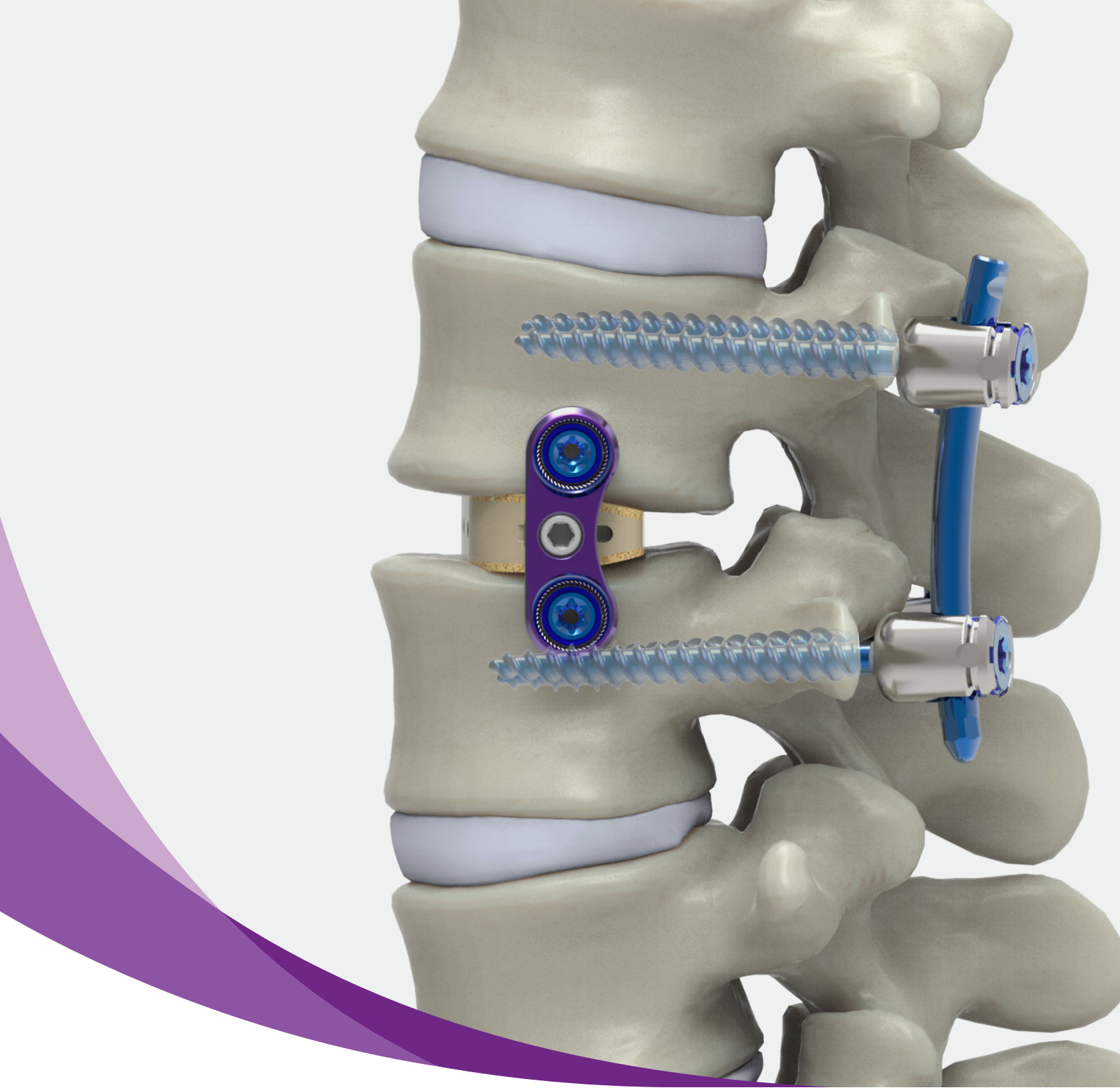

COHERE XLIF AMS Plate

Surgical 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 Advanced Materials Science (AMS) Plate. 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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- Maxcess 4 articulating arm tray
- Maxcess fixation shim kit
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- NVM5 electromyography (EMG) module
- NVM5 XLIF dilator kit
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- Iliac crest *(Fig. 2)*
- Neural anatomy *(Fig. 1)*
- Vascular anatomy (e.g., aorta, vena cava and left common iliac vein) *(Fig. 1)*
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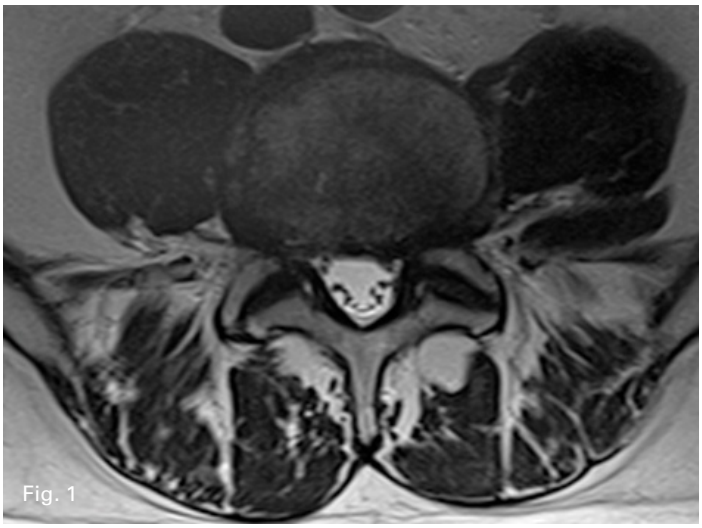

Fig. 1

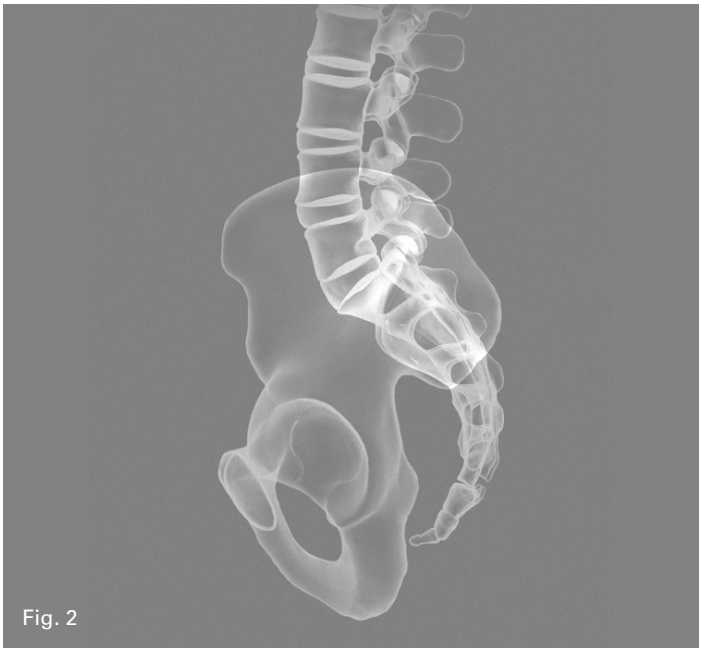

Fig. 2

Disc removal and endplate preparation

Complete disc removal and endplate preparation via conventional XLIF technique (document #9500138).

Osteophyte removal *(optional)*

The lateral surface of vertebral bodies is prepared as appropriate, removing lateral osteophytes with the osteophyte removal tool, pituitary or Kerrison rongeur. Care should be taken to remove only the appropriate amount of the osteophyte.

Plate selection: Single and dual sided options

Cohere XLIF AMS Plate is available in both single sided and dual sided variations *(Figs. 3, 4)*. Select the appropriate plate that accommodates the desired surgical goal and patient anatomy and follow the corresponding technique below.

Note: *When used with or without the Cohere XLIF AMS Plate (single- or dual-sided), the Cohere XLIF system is intended for use with supplemental spinal fixation.*

Step 1

Plate sizing

Select the Cohere XLIF AMS Plate that corresponds with the desired Cohere XLIF interbody. For example, a size 10 mm Cohere XLIF AMS Plate should be used with a size 10 mm Cohere XLIF interbody.

Step 2

Plate attachment to inserter

Use the Modulus XLIF Plate inserter thumbwheel to attach to the plate to the distal end of the inserter. The distal inserter flanges will engage and secure the plate to the inserter. Confirm the inserter flanges are fully seated into the lateral pockets of the plate *(Fig. 5)*.

Warning

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

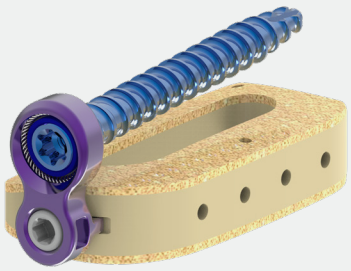

Fig. 3

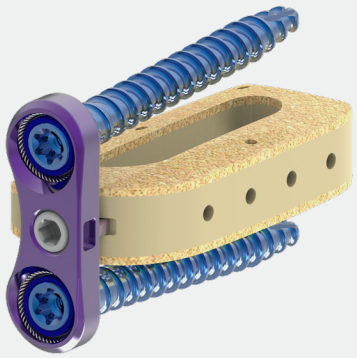

Fig. 4

Fig. 5

Step 3

Plate delivery

Cohere XLIF AMS Plate can be attached to the interbody either before or after interbody insertion. The same technique for plate attachment is used for both the single and dual sided plates.

It is recommended to orient the single sided plate for attachment to the upper vertebral body. The dual sided plate should be oriented with the curve facing posteriorly, to allow for anterior placement of the cage (if desired).

Option A: Plate attachment to interbody (before insertion)

Attach the plate inserter torque handle to the distal end of the Modulus XLIF Plate inserter. Next, align the plate screw with the inserter feature on the Cohere XLIF interbody and rotate the handle clockwise to drive the plate screw into the interbody. The handle will torque off at 22 in-lbs.

Remove the torque handle and replace it with the Modulus XLIF inserter T-handle. Impact and insert the plate and interbody construct into the disc space, only opening up the retractor as much as necessary *(Fig. 6)*.

Option B: Plate attachment to interbody (after insertion)

Insert the Cohere XLIF interbody into the disc space (document #9500138). Remove the inserter from the Cohere XLIF interbody. Attach the plate inserter torque handle to the distal end of the Modulus XLIF Plate inserter.

Align the plate screw with the Cohere XLIF interbody's threaded inserter feature *(Fig. 7)* and rotate the torque handle to drive the plate screw into the Cohere XLIF interbody. The handle will torque off at 22 in-lbs.

Once the plate and interbody are in their desired position, the plate inserter may be removed. To disengage the plate inserter, turn the thumbwheel counterclockwise until the distal flanges release from the plate pockets.

Note: *If the bed was "broken" during plate and interbody placement, it is recommended to "unbreak" the bed before pilot hole preparation and bone screw delivery confirm the load is maintained on the implant.*

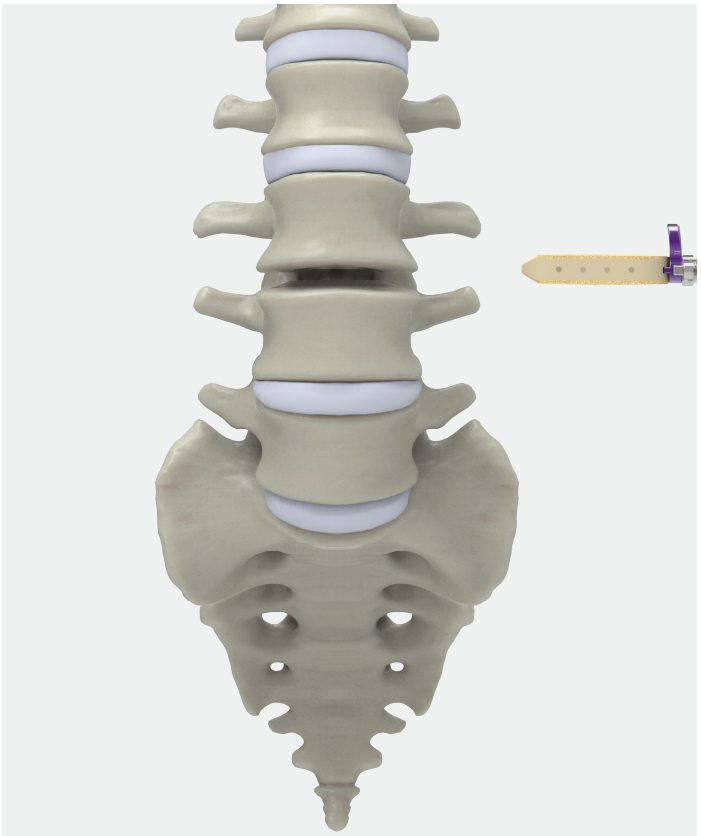

Fig. 6

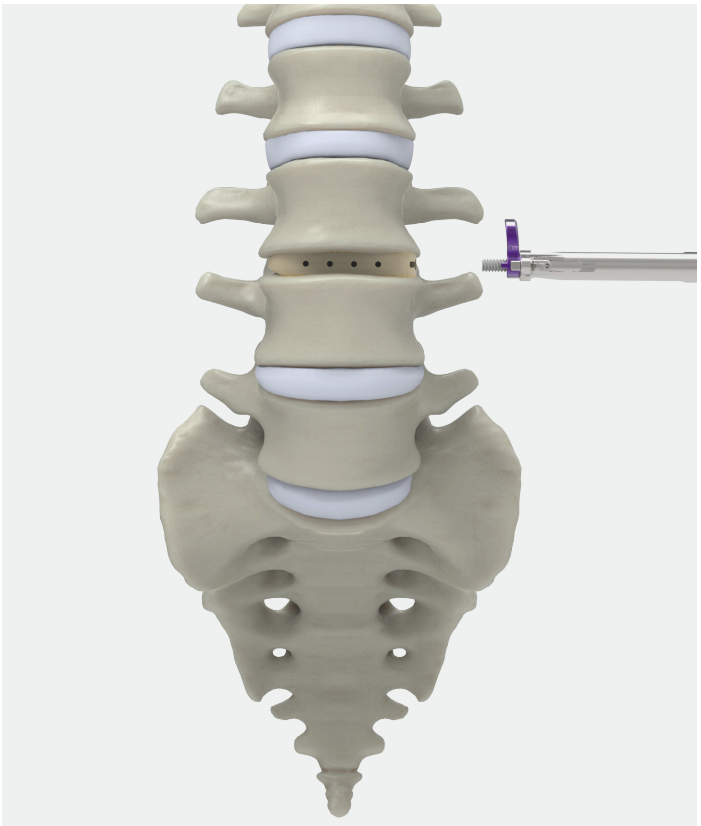

Fig. 7

Step 4

Pilot hole preparation

Single sided plate: Using the drill or awl, prepare the pilot hole for subsequent bone screw delivery through the plate screw hole. Confirm the drill or awl is seated firmly inside the plate screw hole before deploying. Advance the drill or awl into the vertebral body until the desired depth is reached *(Fig. 8)*.

Dual sided plate: Utilize the technique described above for the dual sided plate. It is recommended to only create one pilot hole at a time, placing the subsequent screw before deploying the drill or awl in the second plate screw hole.

Note: *In order to confirm desired screw trajectory, use A/P fluoroscopy during initial drill or awl advancement for visual confirmation of the pilot hole path.*

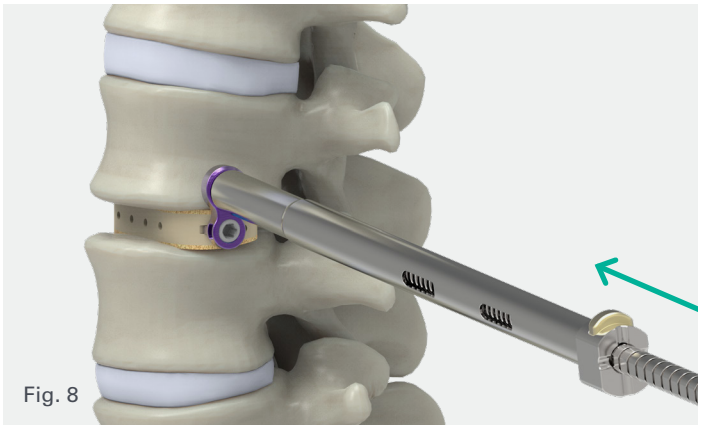
Fig. 8

Step 5

Screw placement

Bone screw length is determined using interbody graft length and pilot hole depth for reference. Additional length may be needed if bicortical purchase is desired. Select the desired length variable 5.5 or 6.5 mm screw and insert the tip of the starter screwdriver into the hexalobe engagement feature on the screw head. Turn the knurled section on the starter screwdriver clockwise to thread the screwdriver into the screw and secure it into position.

Single side plate: Begin driving the screw through the plate screw hole *(Fig. 9)*. Once the screw has advanced 3/4 of its path, detach the starter screwdriver and use the final screwdriver to advance the screw to its final position *(Figs. 10a, 10b)*. The final screwdriver provides increased strength and tactile response for final screw placement and coil lock confirmation.

Dual sided plate: Begin driving the first screw through the plate screw hole. Once the screw has advanced 3/4 of its path, detach the starter screwdriver and follow the same steps to place the second screw in the remaining plate screw hole. Once both screws are driven 3/4 into the vertebral body, use the final screwdriver to advance the screws to their final position *(Fig. 11)*.

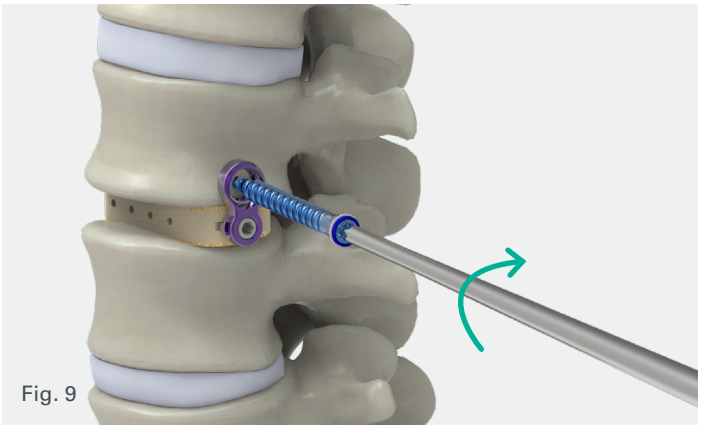
Fig. 9

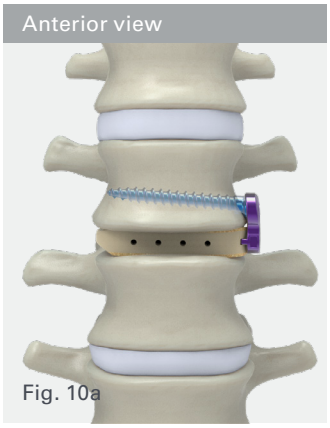
Anterior view

Fig. 10a

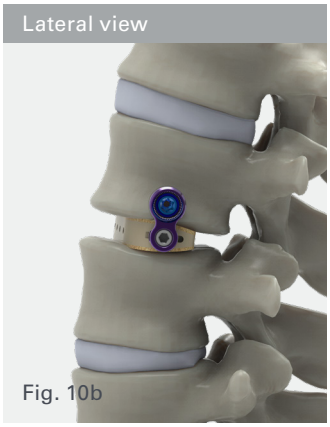
Lateral view

Fig. 10b

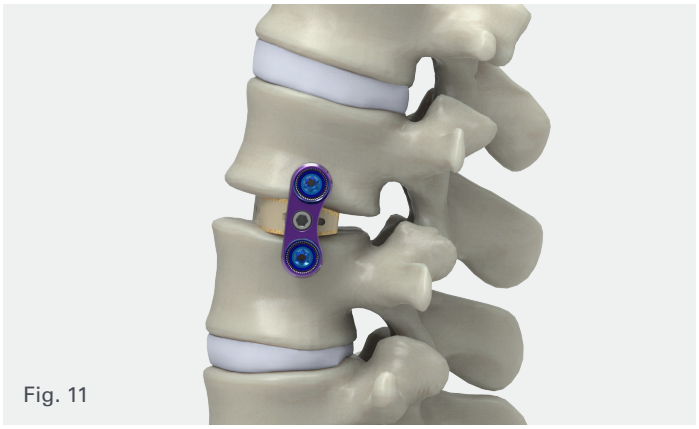
Fig. 11

Step 6

Final locking confirmation

Proper bone screw locking is confirmed by the canted coil covering the entire circumference of the screw head *(Fig. 12)*. In addition, there may be a noticeable audible click and tactile sensation upon locking.

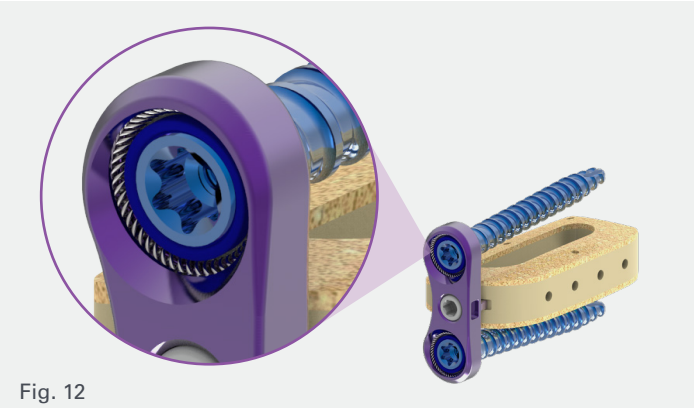

Fig. 12

Step 7

Supplemental spinal fixation

After bone screw insertion, place supplemental spinal fixation *(Figs. 13, 14)*.

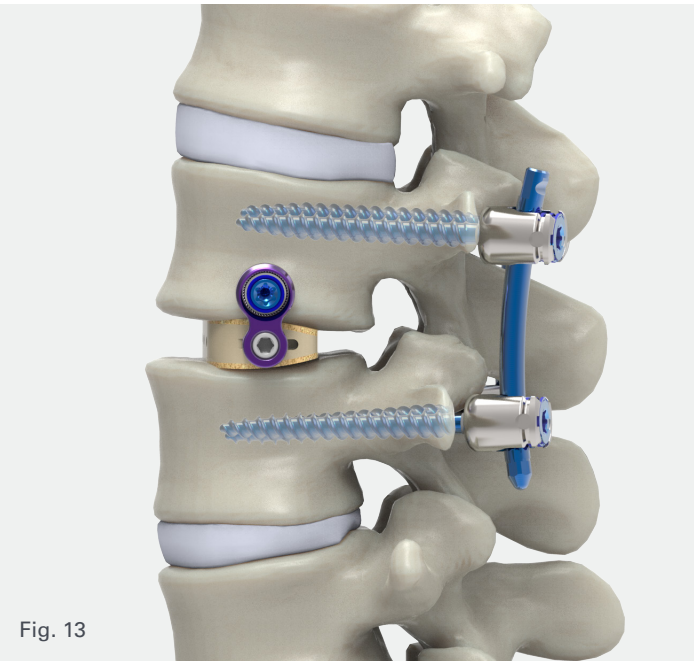

Fig. 13

Step 8

Screw and implant removal

If screw removal is necessary, use the screw extractor to safely extract the screw from the vertebral body. The implant can also be removed from the intervertebral space using the Modulus XLIF Plate inserter and a slap hammer.

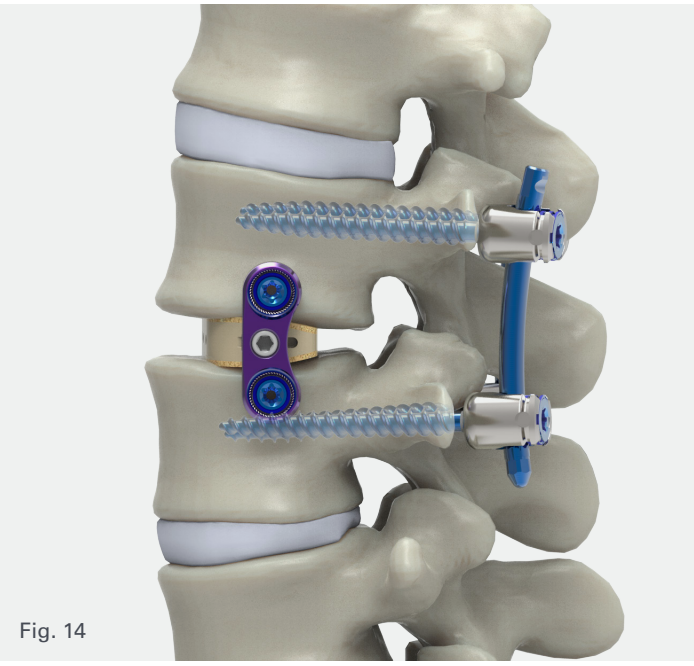

Fig. 14

Catalog

Modulus XLIF Plate instrument set (MDLUSPLATEINS)

Description	Catalog no.	Qty.
NuVasive generic tray lid	8801300	1
Modulus XLIF Modulus Plate screw caddy	1720322	1
Coroent XLF screw, 5.5x25 mm, variable	5485525	3
Coroent XLF screw, 5.5x40 mm, variable	5485540	3
Coroent XLF screw, 5.5x45 mm, variable	5485545	3
Coroent XLF screw, 5.5x50 mm, variable	5485550	3
Coroent XLF screw, 5.5x55 mm, variable	5485555	3
Coroent XLF screw, 5.5x60 mm, variable	5485560	3
Coroent XLF screw, 6.5x25 mm, variable	5486525	2
Coroent XLF screw, 6.5x40 mm, variable	5486540	2
Coroent XLF screw, 6.5x45 mm, variable	5486545	2
Coroent XLF screw, 6.5x50 mm, variable	5486550	2
Coroent XLF screw, 6.5x55 mm, variable	5486555	2
Universal torque handle, 22 in-lbs	3321830	2
Coroent XL-FW drill, self-centering	6180015	1
Universal handle, quick connect straight	7240010	1
Universal screwdriver, Coroent XL-F	5450065	1
Coroent XL-F awl, fixed self-centering	5450028	1
Universal driver, final Coroent XL-F	5450031	1
Universal screw extractor, Coroent XL-F	5450032	1
Modulus XLIF handle, inserter	1720252	1
Modulus XLIF inserter, plate modular	1720230	2
Modulus XLIF modular plate base, tray	1720321	1

XLIF AMS Plate sterile set (AMSPLATEIMP)

Description	Catalog no.	Qty.
Universal pelican case, sterile pack	1704712	1
XLIF AMS Plate, 8 mm, single-sided	1910108P2	3
XLIF AMS Plate, 10 mm, single-sided	1910110P2	3
XLIF AMS Plate, 12 mm, single-sided	1910112P2	3
XLIF AMS Plate, 8 mm, dual-sided	1910208P2	3
XLIF AMS Plate, 10 mm, dual-sided	1910210P2	3
XLIF AMS Plate, 12 mm, dual-sided	1910212P2	3

Instruction for use

DESCRIPTION

The NuVasive Cohere Thoracolumbar Interbody System consists of an interbody, internal fixation plate and bone screws manufactured from manufactured from PEEK Scoria (Polyether-ether-ketone), and Titanium Alloy (Ti-6Al-4V ELI) conforming to ASTM F136/ ISO 5832-3 and 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) per 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) 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.

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.

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.

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.

POSTOPERATIVE 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.

Please refer to the Cohere Thoracolumbar Interbody System IFU found at nuvasive.com/eifu for additional important labeling information.

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