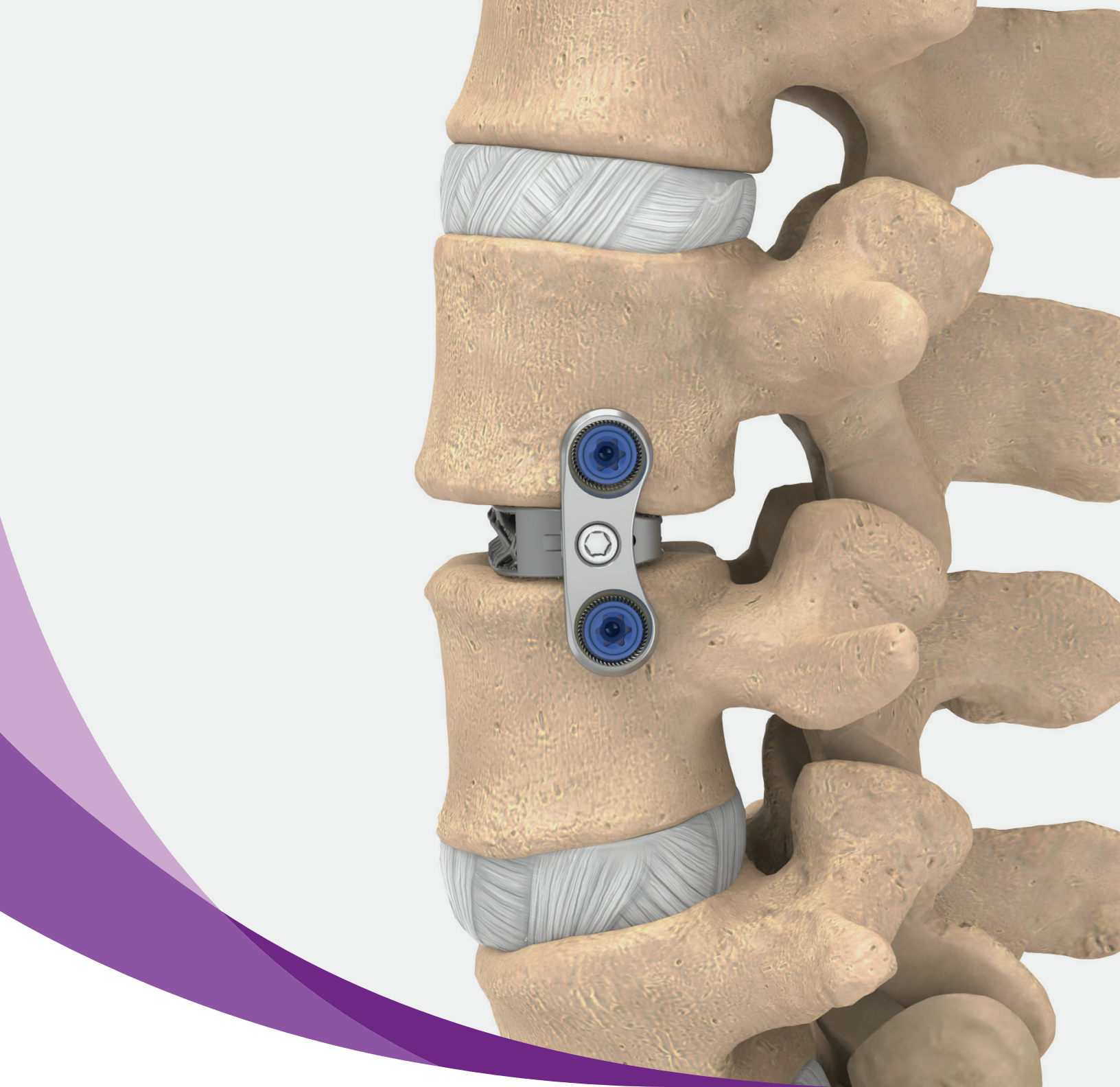




MODULUS XLIF Plate

Surgical technique guide



This surgical technique 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.

As with all surgical procedures and permanent implants, there are risks and considerations associated with surgery and use of the Modulus XLIF Plate. It may not be appropriate for all patients and all patients may not benefit.

This surgical technique guide offers guidance but, as with any such technique guide, each surgeon must consider the particular needs of each patient and make appropriate clinical decisions as required.

All non-sterile devices must be cleaned and sterilized before use. Please refer to the corresponding IFU.

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

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Modulus XLIF Plate technique guide

Equipment requirements

Patient positioning

- 3-inch tape
- Axillary roll
- Foam padding
- Radiolucent bendable surgical table

Instrumentation

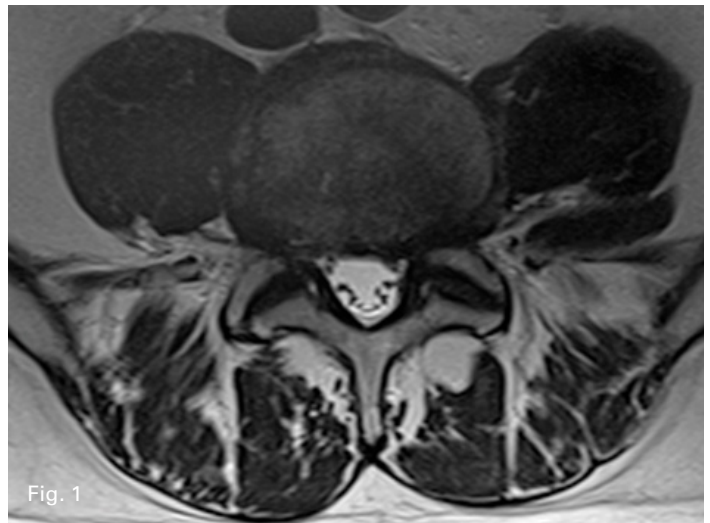
- C-arm
- Light source
- Maxcess 4 access system
- Maxcess 4 articulating arm tray
- Maxcess fixation shim kit
- XLIF instruments
- NVM5
- NVM5 electromyography (EMG) module
- NVM5 XLIF dilator kit
- XLIF Modular Plate instruments

Implants

- Modulus XLIF family of implants
- XLIF Modular Plate implants

Surgical considerations

- Psoas anatomy (*Fig. 1*)
- Iliac crest (*Fig. 2*)
- Neural anatomy (*Fig. 1*)
- Vascular anatomy (e.g., aorta, vena cava and left common iliac vein) (*Fig. 1*)
- Prior surgery



Disc removal and endplate preparation

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

Osteophyte removal (optional)

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

Plate selection: Single and dual sided options

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

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

Step 1

Plate sizing

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



Fig. 3



Fig. 4



Fig. 5

Step 3

Plate delivery

Modulus XLIF 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 Modulus 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 Modulus XLIF interbody into the disc space. Remove the inserter from the Modulus XLIF interbody. Attach the plate inserter torque handle to the distal end of the Modulus XLIF Plate inserter.

Align the plate screw with the Modulus XLIF interbody inserter feature (*Fig. 7*) and rotate the torque handle to drive the plate screw into the Modulus 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.

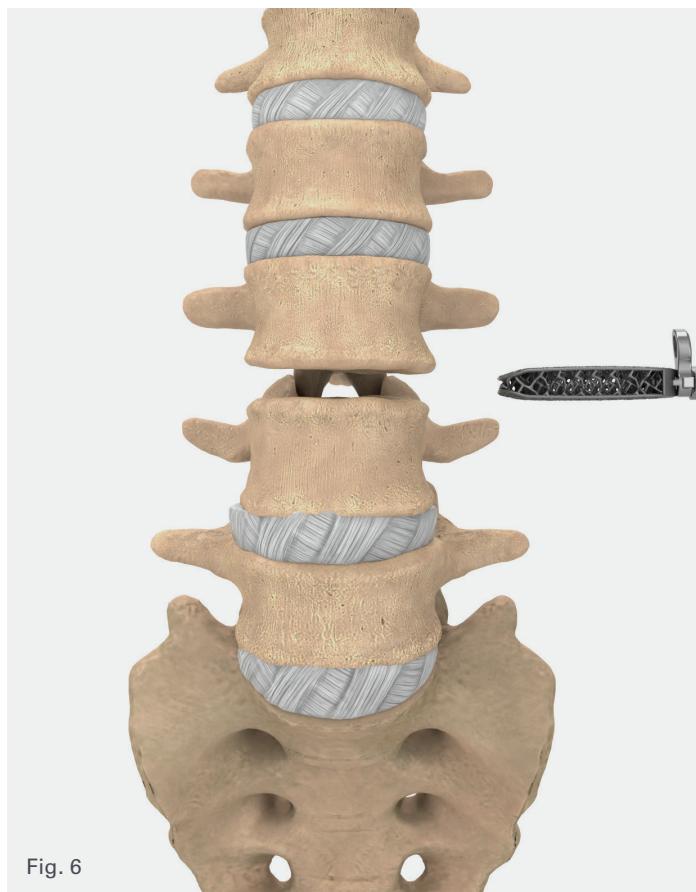


Fig. 6

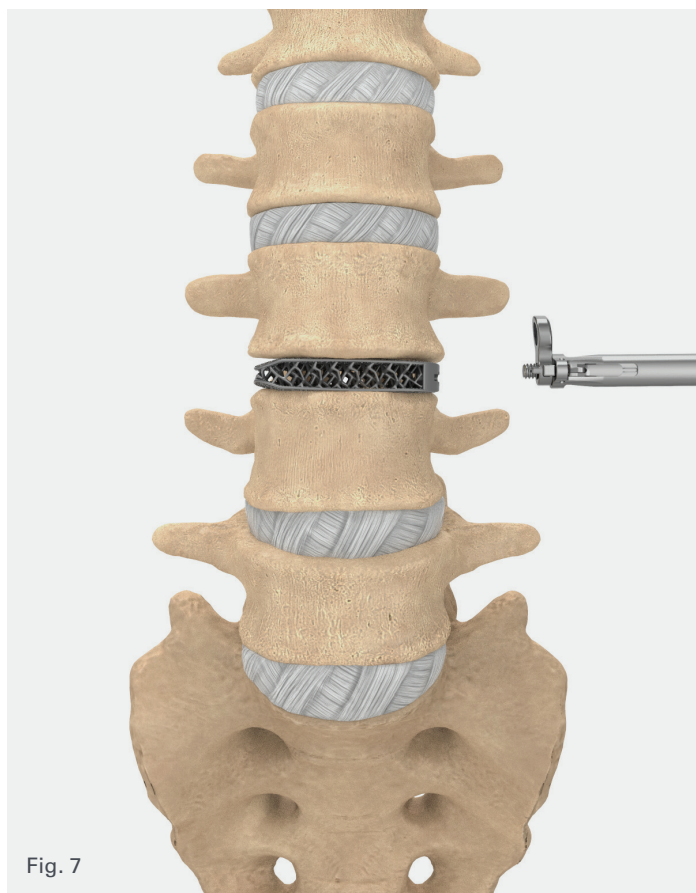


Fig. 7

Step 4

Pilot hole preparation

Single sided plate: Using the awl, prepare the pilot hole for subsequent bone screw delivery through the plate screw hole. Confirm the awl is seated firmly inside the plate screw hole before deploying. Advance the 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 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.

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*).

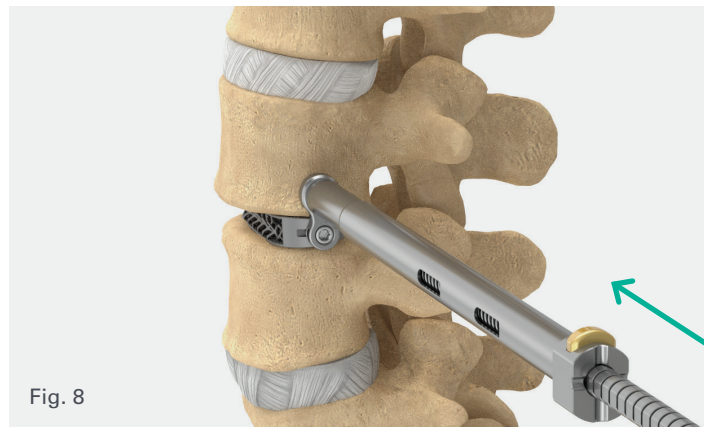


Fig. 8

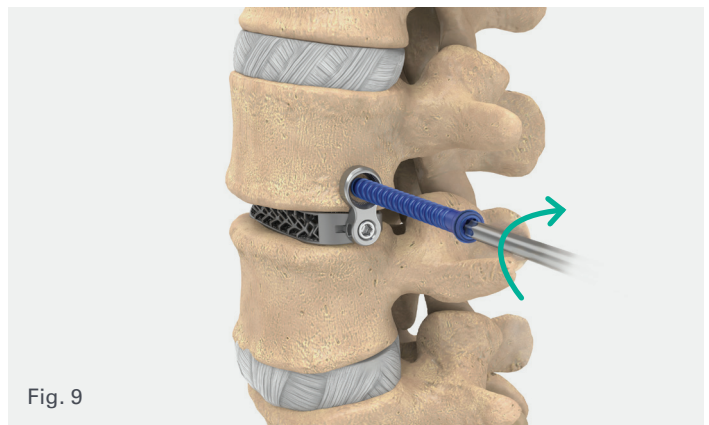


Fig. 9



Fig. 10a

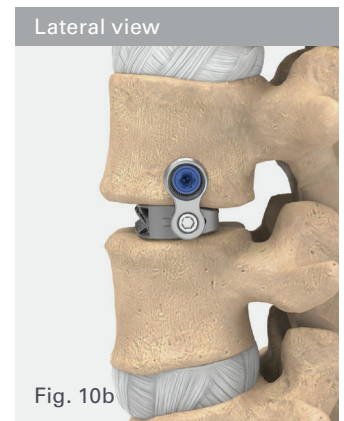


Fig. 10b



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. 13). In addition, there may be a noticeable audible click and tactile sensation upon locking.

Step 7

Supplemental spinal fixation

After bone screw insertion, place supplemental spinal fixation (Figs. 14, 15).

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.

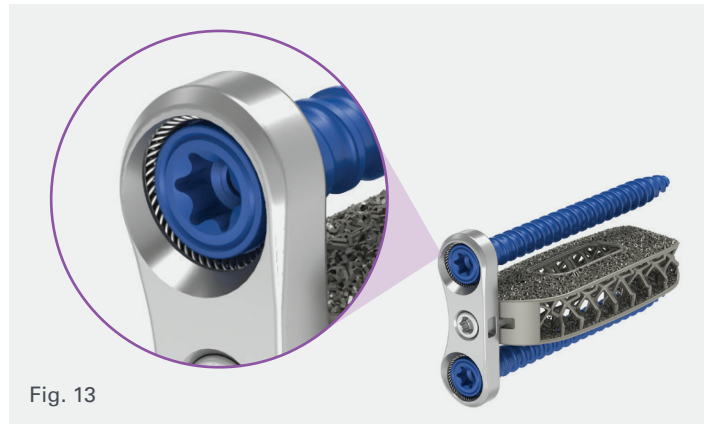


Fig. 13

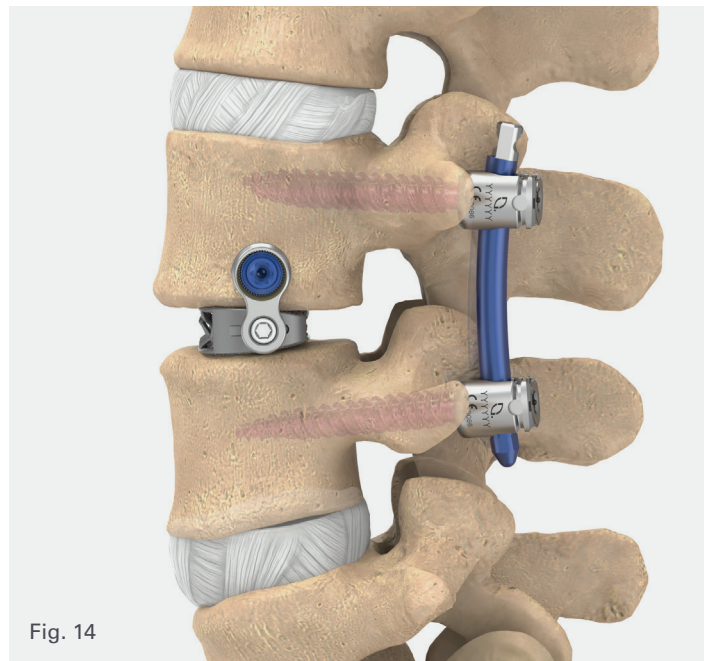


Fig. 14

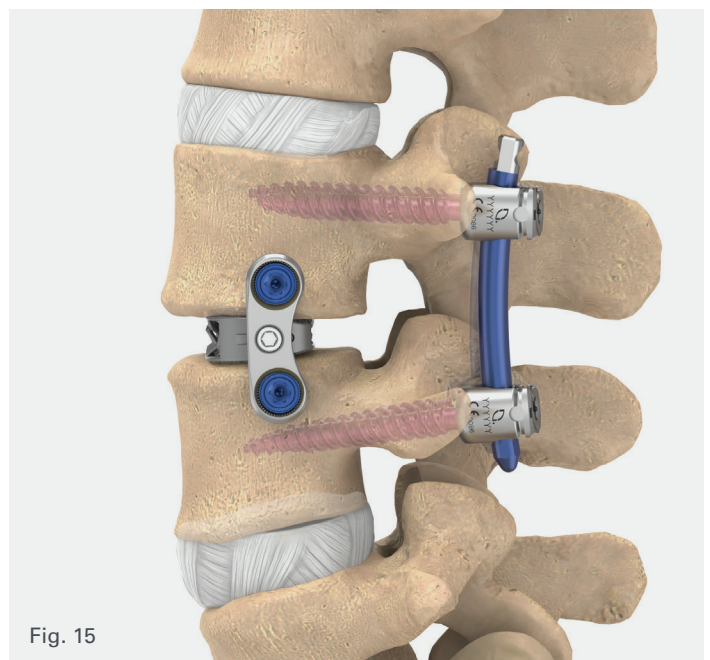


Fig. 15

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

Modulus XLIF Plate, sterile set (MDLUSPLATEIMP)

Description	Catalog no.	Qty.
Universal pelican case, sterile pack	1704712	1
Modulus XLIF Plate, 8 mm modular	1759450P2	3
Modulus XLIF Plate, 10 mm modular	1759451P2	3
Modulus XLIF Plate, 12 mm modular	1759452P2	3
Modulus XLIF Plate, 8 mm dual sided mod	1941108P2	3
Modulus XLIF Plate, 10 mm dual sided mod	1941110P2	3
Modulus XLIF Plate, 12 mm dual sided mod	1941112P2	3

Instruction for use

DESCRIPTION

The NuVasive Modulus XLIF Interbody System interbody implants and Modulus XLIF internal fixation plates and bone screws are manufactured from Ti-6Al-4V ELI conforming to ASTM F3001, ASTM F136 and ISO 5832-3. 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 of different shapes and sizes to suit the individual pathology and anatomical conditions of the patient.

INDICATIONS FOR USE

The NuVasive Modulus XLIF 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 Modulus XLIF internal fixation, the system

is intended for use with supplemental spinal fixation systems 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 Modulus XLIF Interbody System is intended for use in interbody fusions in the thoracolumbar spine from T1 to T12 and at the thoracolumbar junction (T12-L1), and for use in the lumbar spine from L1 to S1, for the treatment of symptomatic disc degeneration (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 Modulus XLIF Interbody System can also 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
8. Use with components of other systems
9. Reuse or multiple uses

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, epidural hematoma; 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 and 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.

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.

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

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.

Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without a previous surgery.

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

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

Additional care should be taken at the lower levels of the lumbar spine due to the obstruction of anatomical structures, such as the iliac crest and iliac vessels, surgical access for the subject device at these levels may not be feasible.

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

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. Resterilization may result in damage or decreased performance.

Magnetic Resonance (MR) Safety: Refer to the Modulus XLIF Interbody System IFU for MR safety information

Compatibility: Do not use the Modulus XLIF Interbody System with components of other systems. Unless stated otherwise, NuVasive devices are not to be combined with the components of another system.

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 Modulus XLIF Interbody implants. Assure highly aseptic surgical conditions, and use aseptic technique when removing the Modulus XLIF 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 Modulus XLIF Interbody 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 Modulus XLIF Interbody System IFU found at www.nuvasive.com/eifu for additional important labeling information.



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