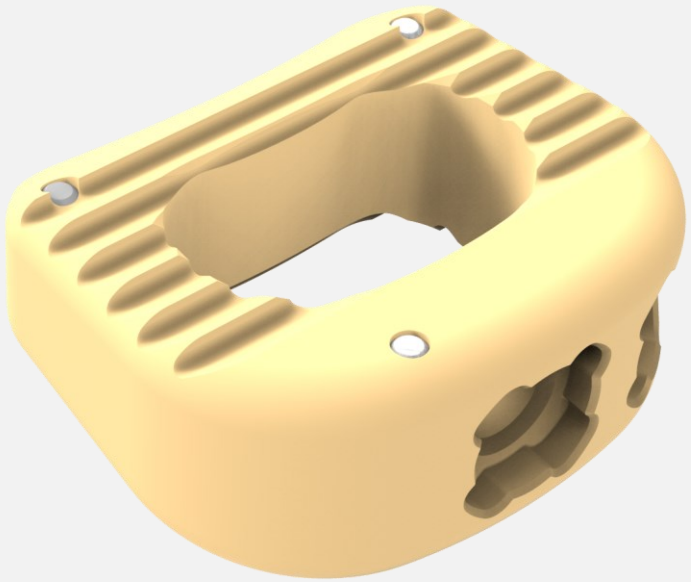


CoRoent XLR Surgical Technique Guide

NuVasive®

CoRoent XLR Surgical Technique Guide

This document is intended exclusively for physicians.

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

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

As with all surgical procedures and permanent implants, there are risks and considerations associated with surgery and the implant, including the use of CoRoent XLR. 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.

CoRoent XLR Footprints

26 x 22mm (CORXLR26X22)	
Description	**Part Number**
6 x 26 x 22mm 10°	6960662
8 x 26 x 22mm 10°	6960862
10 x 26 x 22mm 10°	6961062

34 x 24mm (CORXLR)	
Description	**Part Number**
10 x 34 x 24mm 8°	6921044
12 x 34 x 24mm 8°	6921244
14 x 34 x 24mm 8°	6921444
16 x 34 x 24mm 8°	6921644
18 x 34 x 24mm 8°	6921844
20 x 34 x 24mm 8°	6922044

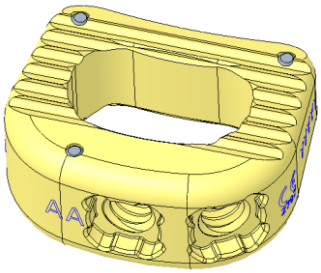
38 x 28mm (CORXLR)	
Description	**Part Number**
10 x 38 x 28mm 8°	6921088
12 x 38 x 28mm 8°	6921288
14 x 38 x 28mm 8°	6921488
16 x 38 x 28mm 8°	6921688
18 x 38 x 28mm 8°	6921888
20 x 38 x 28mm 8°	6922088
12 x 38 x 28mm 15°	6931288
14 x 38 x 28mm 15°	6931488
16 x 38 x 28mm 15°	6931688
18 x 38 x 28mm 15°	6931888
20 x 38 x 28mm 15°	6932088

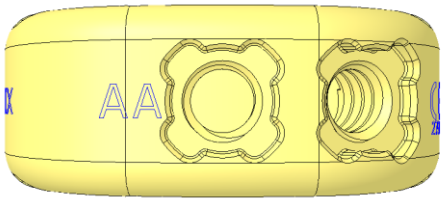
CoRoent XLR Line Extension: 26x22mm

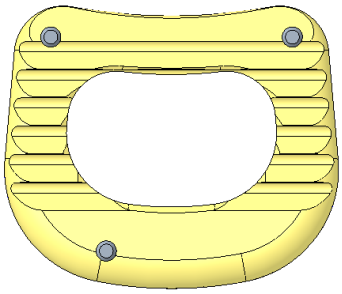
Smaller footprint to address:

- TLIF/PLIF revisions done anteriorly
- Small patient anatomy
- Limited access provided by the access surgeon

New Size Offerings	
Widths (mm)	26
Depths (mm)	22
Heights (mm)	6, 8, 10
Lordosis	10°

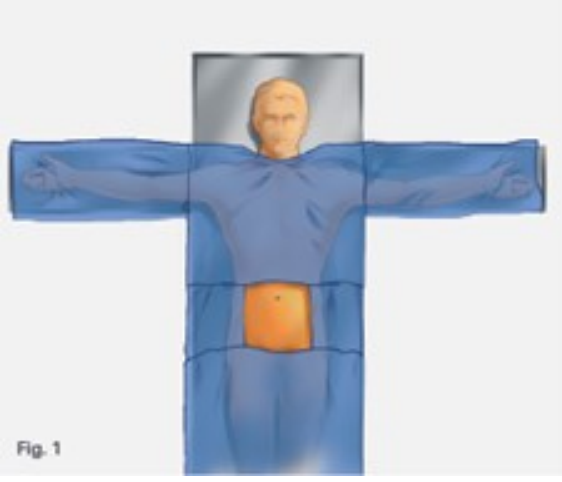






Patient Positioning and OR Setup

Place the patient on a radiolucent operating table in the supine position. Prepare and drape in the conventional manner ***(Fig. 1)*.** The fluoroscope should have adequate access to the surgical field for both the lateral and anteroposterior views.



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Step 1:

Access

Utilize the Supine ALIF Retractor (MASALIFACCESS) set to perform a supine ALIF exposure approach to the lumbar spine, per surgeon preference. Expose the intervertebral disc such that there is sufficient space on either side of the vertebral midline. Radiographically confirm disc midline location ***(Fig. 2).***

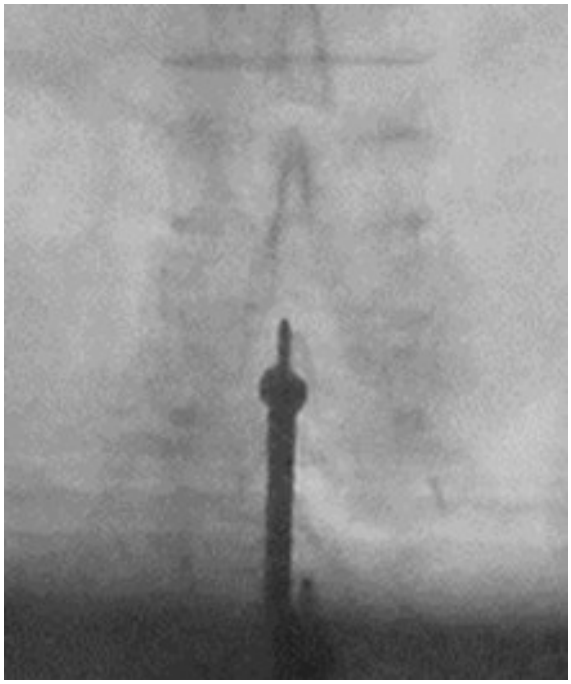

Figure 2: Identify midline

Step 2:

Annulotomy & disc removal

The annulus is incised and a conventional discectomy is performed. Cobbs, pituitaries, curettes, disc cutters, endplate scrapers and other conventional disc preparation instruments can be used to thoroughly evacuate the disc, release the contralateral annulus, and prepare the endplates for fusion ***(Fig. 3).***

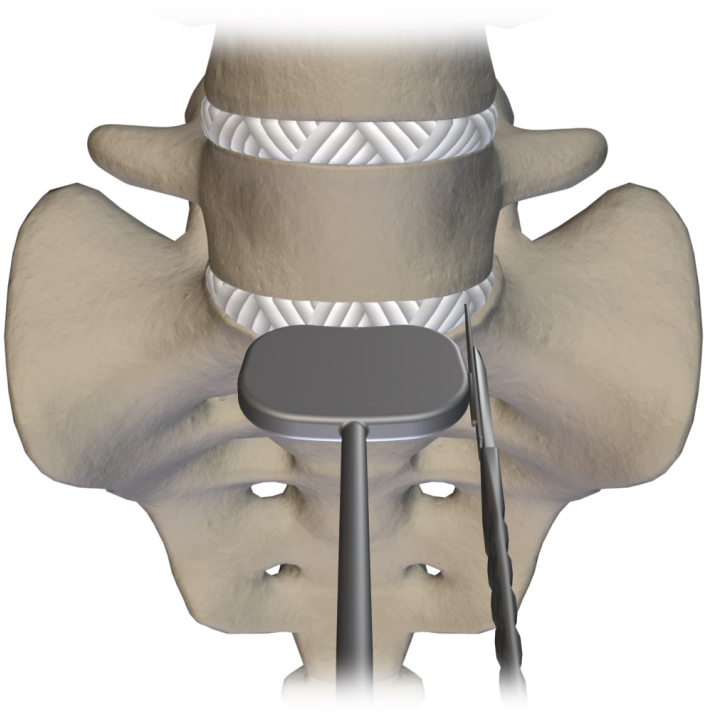

Figure 3: Disc removal

Step 3:

Trialing

Connect the selected trial to the Inserter found in ALIFDISCPREP1 ***(Fig. 4).*** Under lateral fluoroscopy, gently impact the trial into the disc space **(Fig. 5).** Use sequential trialing within the disc space to help prevent endplate damage. Proper midline positioning of final trial placement should be verified using A/P fluoroscopy. Trialing is used to determine the appropriately sized CoRoent XLR interbody.

Figure 4 : Attach trial to inserter

Trial inserter (D6970005)

NOTE:

It is important to place the trial flush to the anterior lip of the vertebral body, in order to mimic proper implant placement.

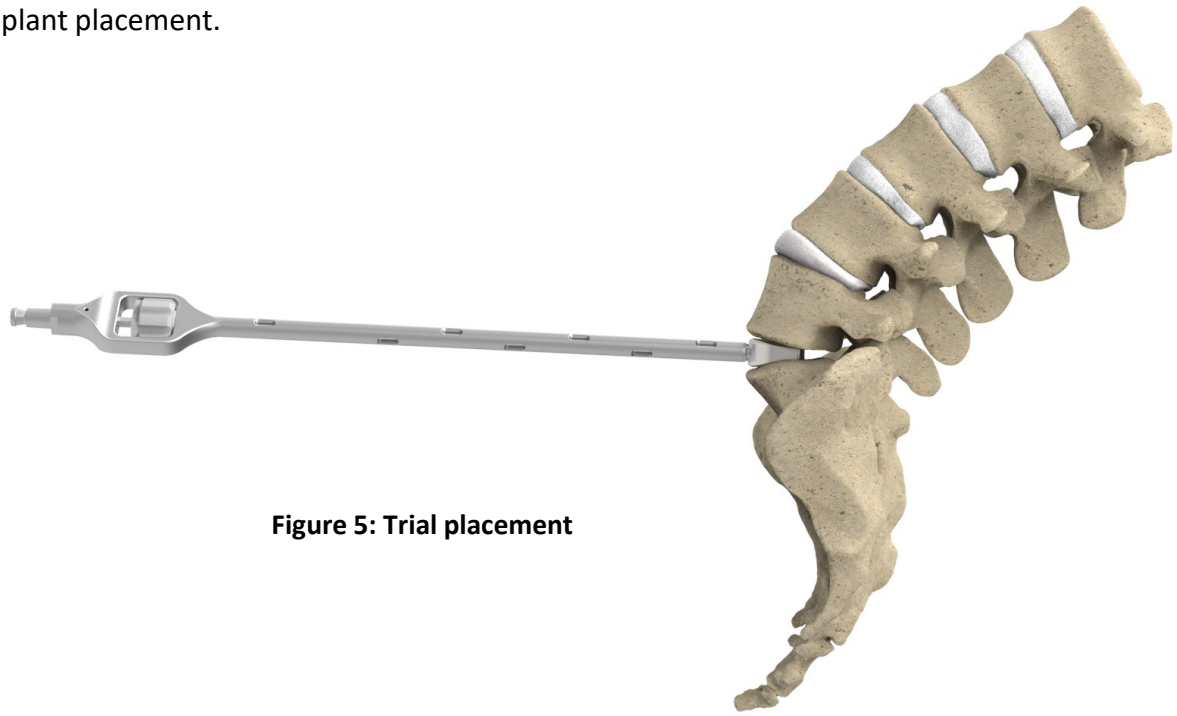

Figure 5: Trial placement

Step 4:

Implant placement

When placement and fit of the trial are satisfactory, the corresponding implant should be selected and filled with graft material.

Next, select the implant inserter (same instrument as trial inserter). Insert the distal insertion feature into the desired connection point on the implant. Turn the thumbwheel clockwise until the implant is firmly locked onto the inserter ***(Fig. 6).*** The surgeon may now insert the implant into the disc space ***(Fig. 7).***

Figure 6: Implant Inserter (D6970005)

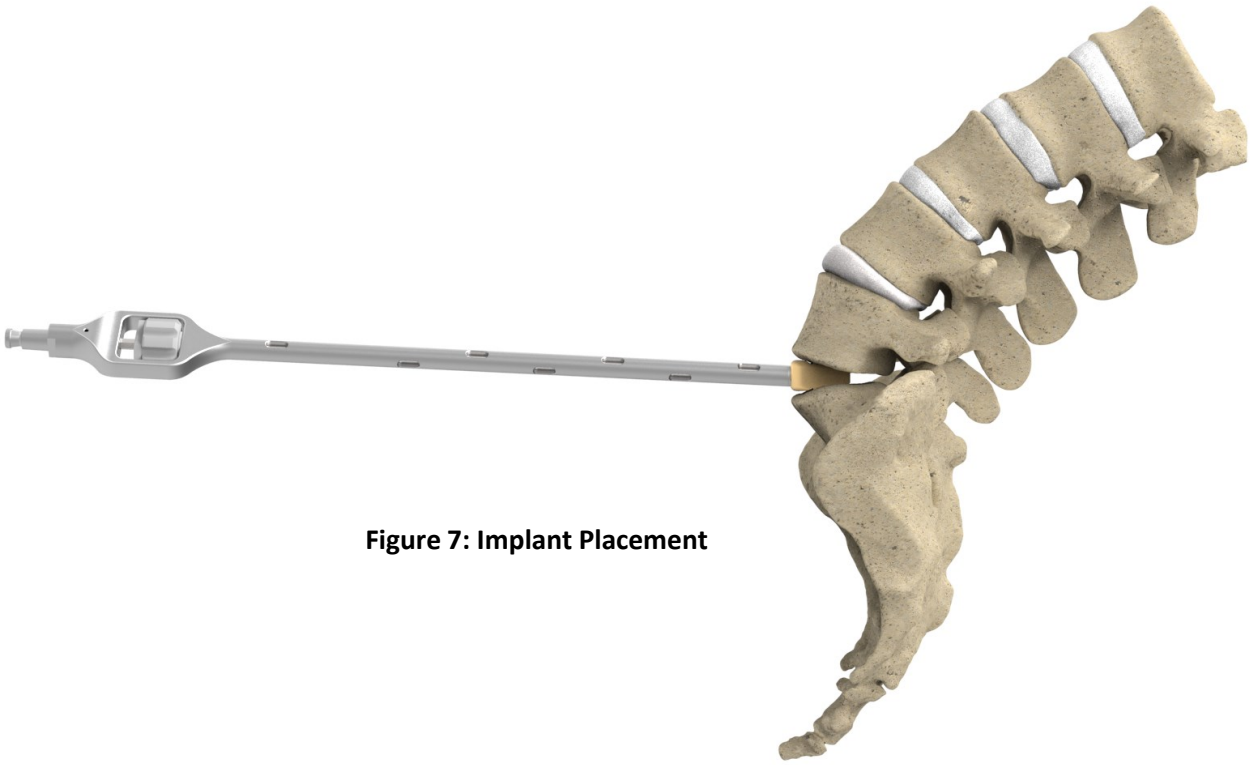

Figure 7: Implant Placement

Supplemental Fixation

Complete the surgery with supplemental internal spinal fixation systems that are cleared for use in the lumbar spine. See the system IFU and surgical technique for instructions.

Implant removal

If necessary, the interbody implant can be removed with the use of the implant inserters. Reattach the inserter to the implant and remove gently. Care should be exercised to avoid neural and vascular elements during removal.

Instructions for use

DESCRIPTION

The *NuVasive CoRoent Thoracolumbar System* is manufactured from PEEK-Optima LT-1 (Polyetheretherketone) conforming to ASTM F2026, commercially pure titanium (CP Ti) conforming to ASTM F1580, 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 implants are available in a variety of sizes to suit the individual pathology and anatomical conditions of the patient.

INDICATIONS FOR USE

The *NuVasive CoRoent Thoracolumbar 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 and supplemental internal 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 CoRoent XL platforms* are intended for use in interbody fusions in the thoracic spine, from T1 to T12, and at the thoracolumbar junction (T12-L1), and the *CoRoent Thoracolumbar System (L and XL platforms) implants* are intended for use 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 CoRoent Thoracolumbar System (L and XL platforms)* can be used as an adjunct to fusion in patients diagnosed with multilevel degenerative scoliosis.

The *CoRoent Ti-C System* is intended for use at either one level or two contiguous levels in the lumbar spine, from L2 to S1, for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The lumbar devices are to be used in patients who have had at least six months of non-operative treatment. The System is intended to be used with supplemental internal spinal fixation systems that use in the lumbar spine.

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.

Instructions for use

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.

Instructions for use

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 inconjunction with each other.

Based on fatigue testing results, when using the *CoRoent Thoracolumbar 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 *CoRoent Anterior TLIF 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 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.

Magnetic Resonance (MR) Safety: Refer to the NuVasive CoRoent Thoracolumbar System eIFU for MR safety information.

Instructions for use

Compatibility: Do not use *CoRoent Thoracolumbar 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 *CoRoent 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 *CoRoent 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 *CoRoent 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.

INFORMATION

Please, refer to the NuVasive CoRoent Thoracolumbar System IFU found at www.nuvasive.com/eifu for additional important labeling information.

To order, please contact your NuVasive Sales Consultant or Customer Service Representative today at:

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