MODULUS Cervical

Technique guide

NUVASIVE

As with all surgical procedures and permanent implants, there are risks and considerations associated with surgery and use of Modulus Cervical. 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. Multi-component instrument assemblies must be disassembled prior to cleaning. Please refer to the corresponding instructions for use (IFU).

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

Please refer to the corresponding IFU for important product information, including, but not limited to, indications, contraindications, warnings, precautions and potential adverse effects.

Contents

Preface **3**

ACDF procedural solutions **4**

Modulus Cervical technique guide **5–11**

Patient positioning 5

Access and approach 5

Discectomy and decompression 6

Interbody sizing 7

Inserter configuration 8

Implant attachment 9

Interbody placement 10

Plate fixation 11

Device removal **12**

Modulus Cervical system **13–14**

Catalog **15–16**

Instructions for use **17–18**

Preface

Fellow colleagues,

There has been growing interest from clinicians for spinal interbody implants capable of achieving direct fixation through osseointegration. More than 30 years of research has demonstrated that implant surface topography is the main driver of enhanced osteogenic response at the cell level and greater osseointegration at the implant level. Traditional PEEK and titanium implants are limited by the materials from which they are created, often requiring surgeons to make compromises when selecting a spinal implant, sacrificing radiolucency for durability or favorable osteogenic properties for a bone-like construct.

Modulus Cervical was designed with the intent to overcome these limitations by adhering to the three core principles of Advanced Materials Science: surface, structure and imaging. Modulus Cervical is a fully porous titanium cervical interbody designed to provide a favorable environment for bone in-growth[1] while enhancing visualization compared to traditional titanium interbody implants.

Backed by extensive research, a pioneering design and manufacturing methods that combine the inherent benefits of porosity with the advantageous material properties of titanium, Modulus Cervical represents the future of porous anterior cervical discectomy and fusion (ACDF) implant technologies.

We are pleased to announce the release of our new cervical Advanced Materials Science option, Modulus Cervical.

Best Regards,

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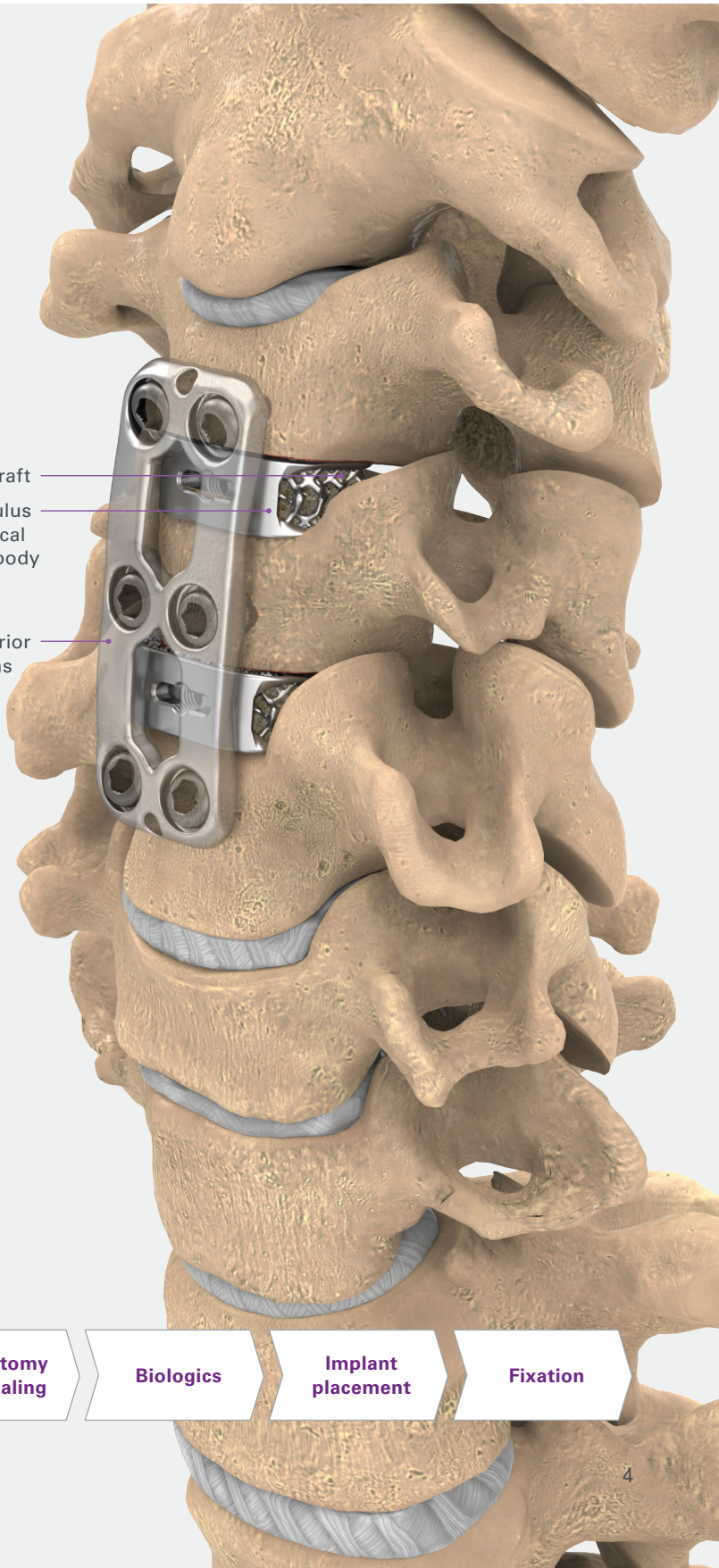
ACDF procedural solution

Powered by Surgical Intelligence technologies

Pulse integrated
OR platform



Cios Spin integrated
3D mobile C-arm

Surgical planning | **Positioning the patient** | **Accessing the spine** | **Discectomy and trialing** | **Biologics** | **Implant placement** | **Fixation**

Modulus Cervical technique guide

Step 1

Patient positioning

Position the patient on a radiolucent operating table in the supine position, with the head in slight extension and chin in an "up" position. Prepare and drape the patient in a conventional manner *(Fig. 1)*.

Using fluoroscopy in the A/P and lateral views, locate the operative level and assess the bony anatomy *(Figs. 2, 3)*.

Step 2

Access and approach

Carry out an anterior approach to the appropriate level of the cervical spine in the usual manner. Direct anterior access to the disc and adjacent vertebral bodies is necessary.

Using fluoroscopy in the A/P and lateral views, locate the operative level and assess the bony anatomy *(Figs. 2, 3)*.

Fig. 1

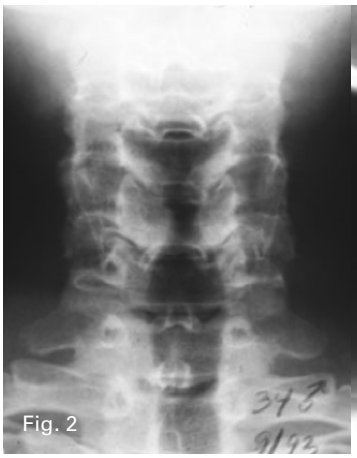


Fig. 2

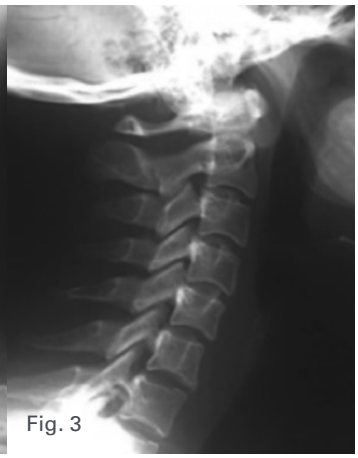


Fig. 3

Step 3

Discectomy and decompression

The Maxcess-C retractor system, through its table fixation feature, allows the surgeon to expose only what is necessary for a complete anterior cervical procedure. Illumination provided by the light source creates an additional level of visibility when the surgeon is working in challenging exposures *(Fig. 4)*.

Perform a complete discectomy and decompression. After a thorough removal of the disc material, remove the cartilaginous endplates with standard curettes or drill. A rasp may be used to help flatten the endplates *(Fig. 5)*.

If appropriate, remove the overhanging osteophytes to improve visualization and access to the disc space.

Tip: *During removal of the cartilage from the endplates, be careful to avoid overly aggressive removal of the bony cortical endplates.*

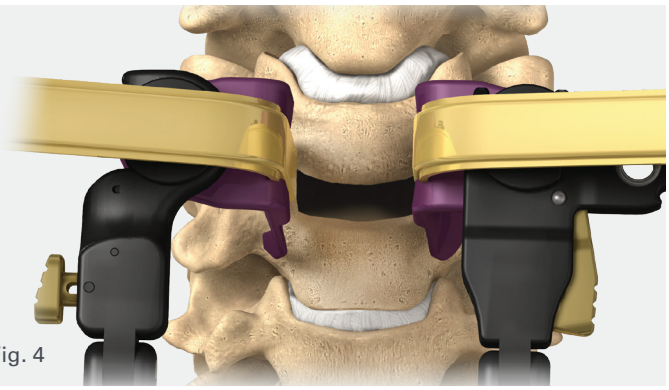


Fig. 4

Fig. 5

Step 4

Interbody sizing

First, select the desired trial from the multiple options available *(Fig. 6)*. Determine the interbody height by sequentially increasing the height of the trial until it fits firmly in the disc space, while maintaining full endplate contact *(Fig. 7)*. When sizing for the interbody, confirm the endplates are making good contact with the trial to allow for an optimized graftloading environment. Confirm the appropriate height by radiographic imaging.

Note: *The corresponding height and lordotic angle are labeled on the proximal end. The color band(s) on the proximal end refer to both the degree of lordosis and footprint size.*

		7°	10°
15x12 mm	Small		
17x14 mm	Medium		
19x16 mm	Large		

Tip: *"Measuring the anterior-posterior depth of the disc space on the preoperative sagittal MRI or CT images can help the surgeon anticipate the desired footprint (small=12 mm, medium=14 mm, large=16 mm) and depth of insertion." Charles Crawford, M.D.*

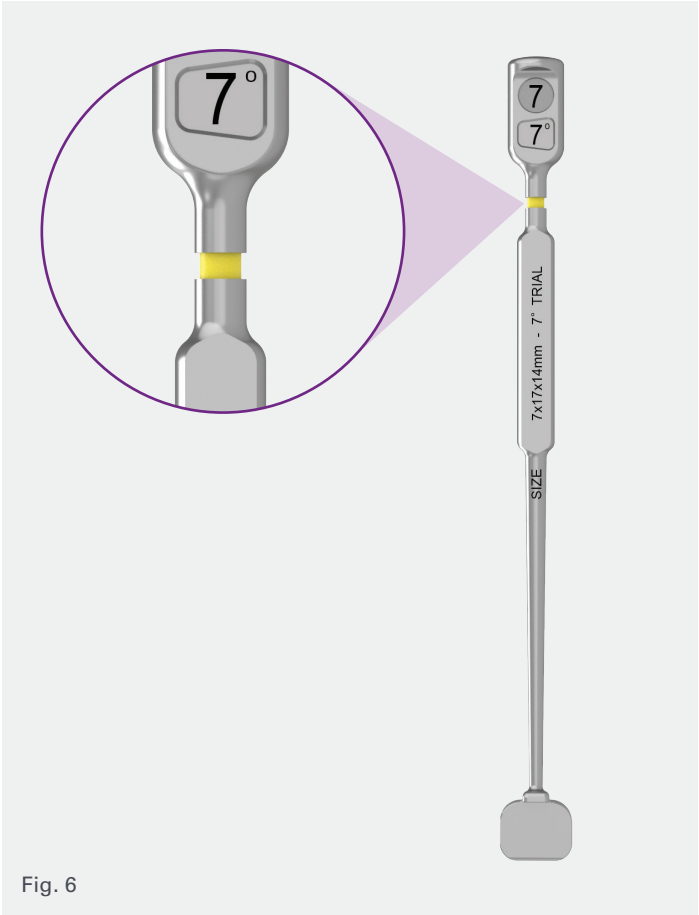


Fig. 6

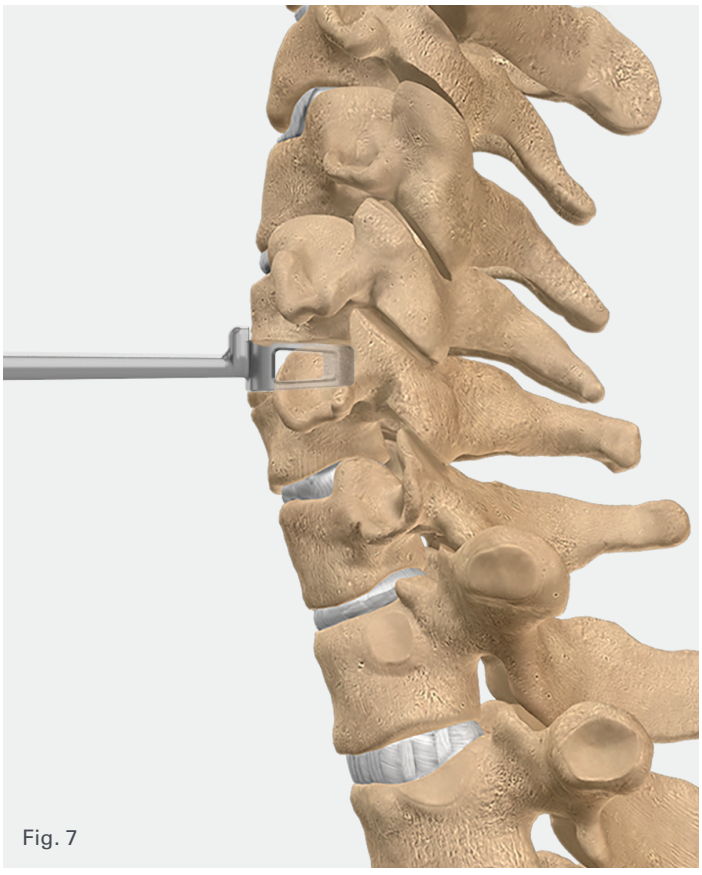


Fig. 7

Step 5

Inserter configuration

Select the desired Inserter shaft from the two options available.

- **Option 1:** Freehand (no depth stop)—Freehand allows for unrestricted placement of the interbody, especially useful in cases where the large disc space required the interbody to be placed further back from the anterior of the disc space.
- **Option 2:** Depth stop (13 mm)—Depth stop allows for controlled placement of the interbody in the disc space by limiting the interbody placement to 0.5 mm subflush from the anterior of the disc space.

Thread the inserter retention rod into the desired inserter shaft by turning the retention rod clockwise until it threads through the shaft *(Fig. 8)*. At this point you will see the retention rod protruding at the distal tip of the instrument.

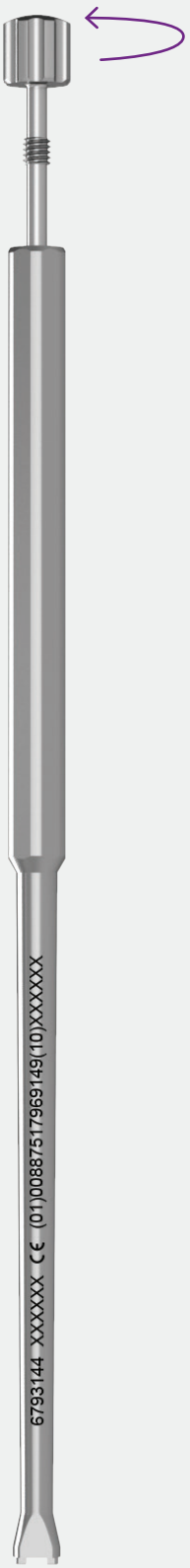


Fig. 8

Step 6

Interbody attachment

The preferred length, width and height of the implant are determined through use of the trials. Align the anti-rotation boss on the inserter with the anti-rotation groove on the interbody *(Fig. 9)*. Rotate the thumbwheel clockwise to attach the interbody to the Inserter *(Fig. 10)*. Continue rotating the thumbwheel until bottomed out. Confirm that the interbody is secure and will not come off the inserter before proceeding.

Fig. 9

Fig. 10

Step 7

Interbody placement

Insert the desired interbody into the disc space *(Fig. 11)*. Confirm position with fluoroscopy as needed. Detach the inserter from the interbody by rotating the thumbwheel counterclockwise *(Fig. 12)*. If additional manipulation is appropriate, the tamp and mallet can be used to gently tap the interbody into place. Detach the inserter from the interbody by rotating the thumbwheel counterclockwise.

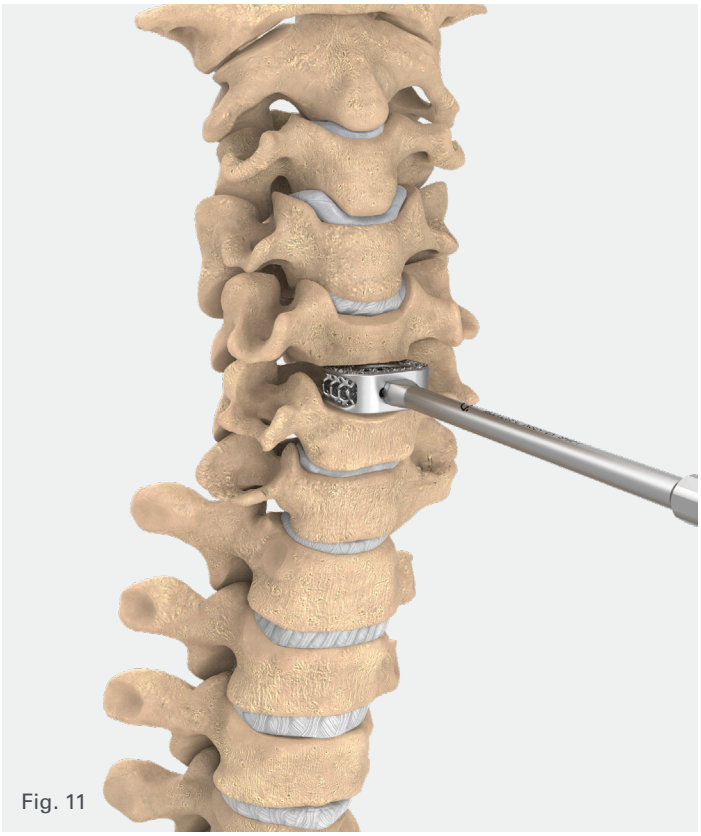


Fig. 11

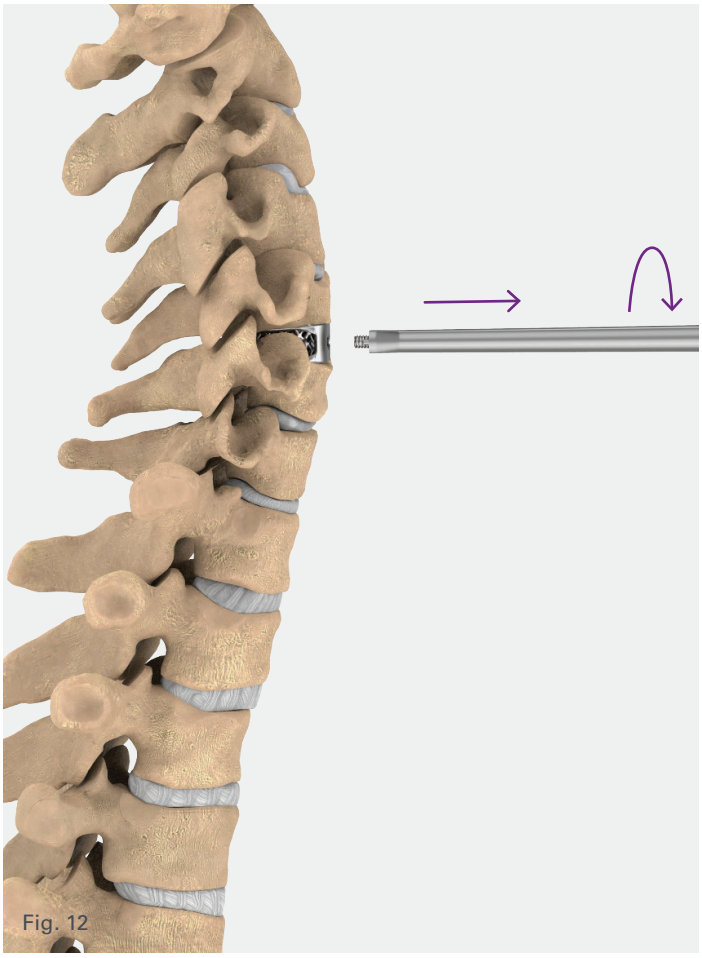


Fig. 12

Step 8

Plate fixation

Complete the surgery with the desired supplemental fixation in the form of an anterior cervical plate *(Fig. 13)*.

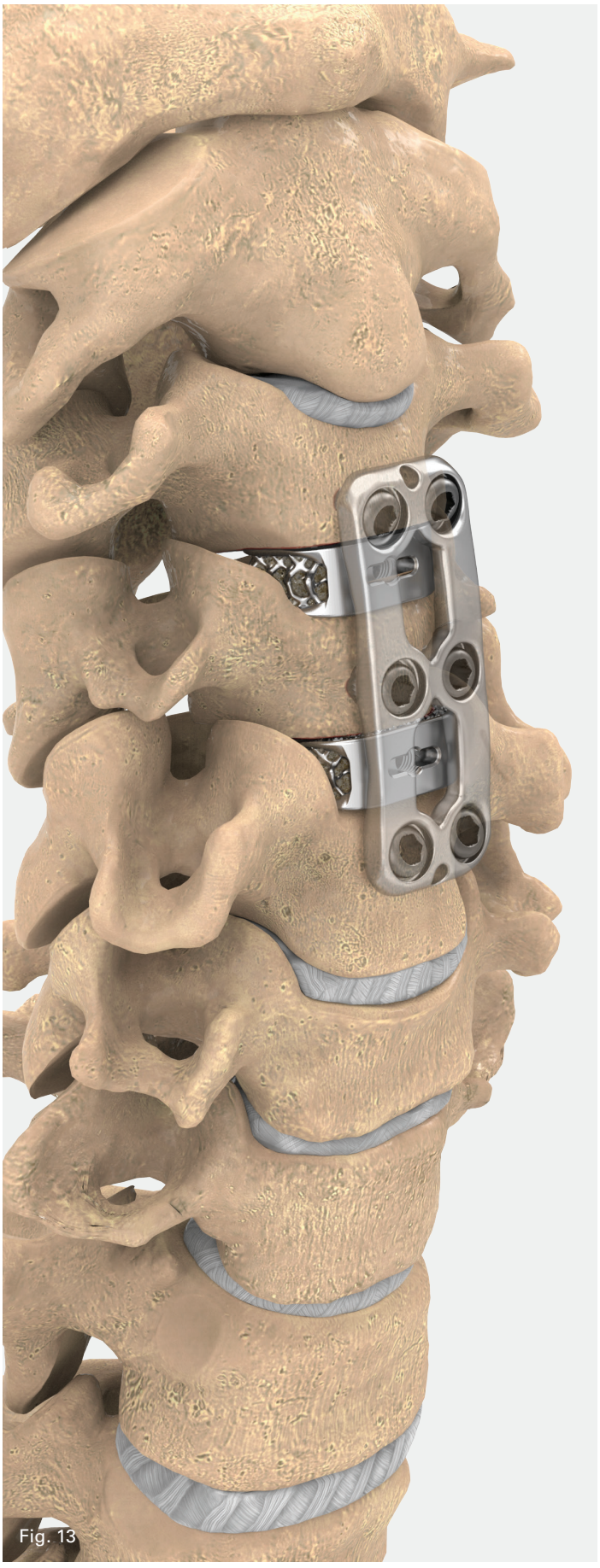


Fig. 13

Device removal

If the implant must be removed, first remove the supplemental fixation anterior to the interbody cage per its surgical technique guide. Align the anti-rotation boss on the inserter with the anti-rotation groove on the interbody. Rotate the thumbwheel clockwise to attach the interbody to the inserter *(Fig. 14)*. Continue rotating the thumbwheel until it bottoms out. Confirm the interbody is secure and will not come off the Inserter before proceeding. Carefully remove interbody from disc space.

Tip: *"It may be helpful to use distraction pins and a small osteotome (similar to total disc removal device) when necessary." Charles Crawford, M.D.*

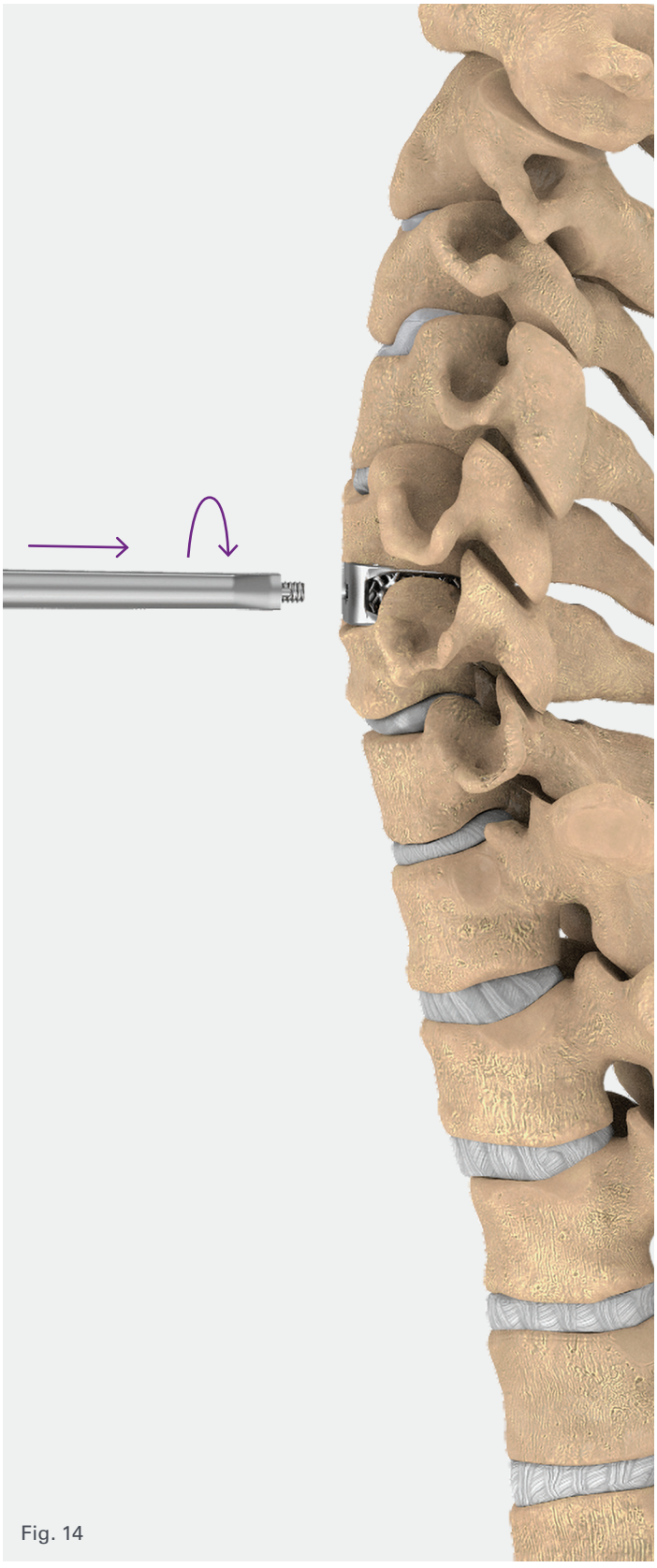
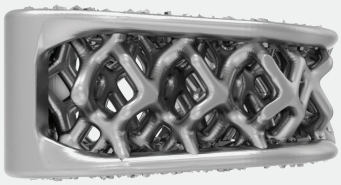


Fig. 14

Modulus Cervical system

Modulus Cervical implants



Lateral view

Footprint	Lordosis	Anterior height (mm)	5	6	7	8	9	10
15x12 mm	7°	Posterior (mm)	3.5	4.5	5.5	6.5	7.5	8.5
		Graft aperture volume (CC)	0.14	0.17	0.20	0.23	0.26	0.29
		Open architecture volume (CC)*	0.41	0.52	0.65	0.74	0.84	0.95
	10°	Posterior (mm)	3	4	5	6	7	8
		Graft aperture volume (CC)	0.13	0.16	0.19	0.19	0.25	0.28
		Open architecture volume (CC)*	0.39	0.49	0.58	0.70	0.78	0.92
17x14 mm	7°	Posterior (mm)	3	4	5	6	7	8
		Graft aperture volume (CC)	0.24	0.29	0.35	0.4	0.46	0.51
		Open architecture volume (CC)*	0.58	0.75	0.9	1.06	1.20	1.37
	10°	Posterior (mm)	–	3.5	4.5	5.5	6.5	7.5
		Graft aperture volume (CC)	N/A	0.28	0.33	0.39	0.44	0.5
		Open architecture volume (CC)*	N/A	0.68	0.84	0.99	1.14	1.31
19x16 mm	7°	Posterior (mm)	3	4	5	6	7	8
		Graft aperture volume (CC)	0.37	0.45	0.54	0.63	0.71	0.8
		Open architecture volume (CC)*	0.78	1	1.21	1.43	1.64	1.86
	10°	Posterior (mm)	–	3	4	5	6	7
		Graft aperture volume (CC)	–	0.42	0.51	0.6	0.68	0.77
		Open architecture volume (CC)*	–	0.9	1.12	1.33	1.54	1.76

*Open architecture volume includes graft aperture volume.

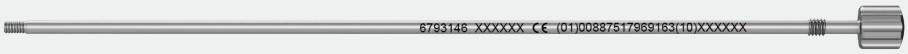
Trial

Rasp

Inserter

Inserter with stop

Inserter retention shaft



Inserter retention wrench

Universal mallet

Tamp

Catalog

Modulus Cervical implants	
Description	**Catalog no.**
Modulus Cervical, 6x15x12 mm 7°	67940001P2
Modulus Cervical, 7x15x12 mm 7°	67940002P2
Modulus Cervical, 8x15x12 mm 7°	67940003P2
Modulus Cervical, 9x15x12 mm 7°	67940004P2
Modulus Cervical, 6x15x12 mm 10°	67940013P2
Modulus Cervical, 7x15x12 mm 10°	67940014P2
Modulus Cervical, 8x15x12 mm 10°	67940015P2
Modulus Cervical, 9x15x12 mm 10°	67940016P2
Modulus Cervical, 6x17x14 mm 7°	67940036P2
Modulus Cervical, 7x17x14 mm 7°	67940037P2
Modulus Cervical, 8x17x14 mm 7°	67940038P2
Modulus Cervical, 9x17x14 mm 7°	67940039P2
Modulus Cervical, 6x17x14 mm 10°	67940047P2
Modulus Cervical, 7x17x14 mm 10°	67940048P2
Modulus Cervical, 8x17x14 mm 10°	67940049P2
Modulus Cervical, 9x17x14 mm 10°	67940050P2
Modulus Cervical, 6x19x16 mm 7°	67940069P2
Modulus Cervical, 7x19x16 mm 7°	67940070P2
Modulus Cervical, 8x19x16 mm 7°	67940071P2
Modulus Cervical, 9x19x16 mm 7°	67940072P2
Modulus Cervical, 6x19x16 mm 10°	67940080P2
Modulus Cervical, 7x19x16 mm 10°	67940081P2
Modulus Cervical, 8x19x16 mm 10°	67940082P2
Modulus Cervical, 9x19x16 mm 10°	67940083P2
Modulus Cervical, 5x15x12 mm 7°	67940000P2

Modulus Cervical implants	
Description	**Catalog no.**
Modulus Cervical, 10x15x12 mm 7°	67940005P2
Modulus Cervical, 5x15x12 mm 10°	67940012P2
Modulus Cervical, 10x15x12 mm 10°	67940017P2
Modulus Cervical, 5x17x14 mm 7°	67940035P2
Modulus Cervical, 10x17x14 mm 7°	67940040P2
Modulus Cervical, 10x17x14 mm 10°	67940051P2
Modulus Cervical, 5x19x16 mm 7°	67940068P2
Modulus Cervical, 10x19x16 mm 7°	67940073P2
Modulus Cervical, 10x19x16 mm 10°	67940084P2

Modulus Cervical instruments	
Description	**Catalog no.**
Universal mallet, cervical	1006278
Modulus Cervical inserter shaft	6793144
Modulus Cervical inserter shaft, depth stop	6793145
Modulus Cervical inserter retention	6793146
Modulus Cervical inserter retention wrench	6793147
CoRoent Small ACR tamp	6721710
CoRoent Small ACR rasp, 15x12	6721500
Modulus-C nipple mat	6790022
Modulus-C bottom level, tray	6790023
Modulus-C trial, 5x15x12 mm 7° hard stop	67950000
Modulus-C trial, 6x15x12 mm 7° hard stop	67950001
Modulus-C trial, 7x15x12 mm 7° hard stop	67950002
Modulus-C trial, 8x15x12 mm 7° hard stop	67950003
Modulus-C trial, 9x15x12 mm 7° hard stop	67950004
Modulus-C trial, 10x15x12 mm 7° hard stop	67950005
Modulus-C trial, 5x15x12 mm 10° hard stop	67950012
Modulus-C trial, 6x15x12 mm 10° hard stop	67950013
Modulus-C trial, 7x15x12 mm 10° hard stop	67950014
Modulus-C trial, 8x15x12 mm 10° hard stop	67950015
Modulus-C trial, 9x15x12 mm 10° hard stop	67950016
Modulus-C trial, 10x15x12 mm 10° hard stop	67950017
Modulus-C trial, 5x17x14 mm 7° hard stop	67950035
Modulus-C trial, 6x17x14 mm 7° hard stop	67950036
Modulus-C trial, 7x17x14 mm 7° hard stop	67950037
Modulus-C trial, 8x17x14 mm 7° hard stop	67950038
Modulus-C trial, 9x17x14 mm 7° hard stop	67950039
Modulus-C trial, 10x17x14 mm 7° hard stop	67950040
Modulus-C trial, 6x17x14 mm 10° hard stop	67950047

Modulus Cervical instruments (cont.)	
Description	**Catalog no.**
Modulus-C trial, 7x17x14 mm 10° hard stop	67950048
Modulus-C trial, 8x17x14 mm 10° hard stop	67950049
Modulus-C trial, 9x17x14 mm 10° hard stop	67950050
Modulus-C trial, 10x17x14 mm 10° hard stop	67950051
Modulus-C trial, 5x19x16 mm 7° hard stop	67950068
Modulus-C trial, 6x19x16 mm 7° hard stop	67950069
Modulus-C trial, 7x19x16 mm 7° hard stop	67950070
Modulus-C trial, 8x19x16 mm 7° hard stop	67950071
Modulus-C trial, 9x19x16 mm 7° hard stop	67950072
Modulus-C trial, 10x19x16 mm 7° hard stop	67950073
Modulus-C trial, 6x19x16 mm 10° hard stop	67950080
Modulus-C trial, 7x19x16 mm 10° hard stop	67950081
Modulus-C trial, 8x19x16 mm 10° hard stop	67950082
Modulus-C trial, 9x19x16 mm 10° hard stop	67950083
Modulus-C trial, 10x19x16 mm 10°hard stop	67950084
Modulus-C trial, 5x19x16 mm 7°	67950068
Modulus-C trial, 6x19x16 mm 7°	67950069
Modulus-C trial, 7x19x16 mm 7°	67950070
Modulus-C trial, 8x19x16 mm 7°	67950071
Modulus-C trial, 9x19x16 mm 7°	67950072
Modulus-C trial, 10x19x16 mm 7°	67950073
Modulus-C trial, 6x19x16 mm 10°	67950080
Modulus-C trial, 7x19x16 mm 10°	67950081
Modulus-C trial, 8x19x16 mm 10°	67950082
Modulus-C trial, 9x19x16 mm 10°	67950083
Modulus-C trial, 10x19x16 mm 10°	67950084

Instructions for use

DESCRIPTION
The NuVasive Modulus 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
MODULUS XLIF INTERBODY SYSTEM
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 Modulus XLIF internal fixation, the system is intended for use with supplemental spinal fixation system 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 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.

MODULUS TLIF INTERBODY SYSTEM
The NuVasive Modulus TLIF 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 and supplemental internal 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 Modulus TLIF 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 TLIF Interbody System can also be used as an adjunct to fusion in patients diagnosed with multilevel degenerative scoliosis.

MODULUS-C INTERBODY SYSTEM
The NuVasive Modulus-C Interbody System is indicated for intervertebral body fusion of the spine in skeletally mature patients. The Modulus-C Interbody System is intended for use for anterior cervical interbody fusion in patients with cervical disc degeneration and/or cervical spinal instability, as confirmed by imaging studies (radiographs, CT, MRI), that results in radiculopathy, myelopathy, and/or pain at multiple contiguous levels from C2 - T1. The System is intended to be used with supplemental fixation. The System is designed for use with autogenous and/or allogeneic bone graft comprised of cancellous, cortical and/or corticocancellous bone graft to facilitate fusion.

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.

The Modulus-C interbody devices are required to be used with an anterior cervical plate as the form of supplemental fixation.

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.

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 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.

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 the these levels may not be feasible.

For Modulus 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 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 Modulus Interbody System IFU for MR safety information.

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

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 Modulus 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 Modulus 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 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 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.
- 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.**

Please refer to the Modulus Interbody System IFU found at **www.nuvasive.com/eifu** for additional important labeling information.

Reference

1. Preclinical data on file. Data may not be representative of clinical results. TR 9604787.

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