MODULUS TLIF-O

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 the use of Modulus TLIF-O. 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.

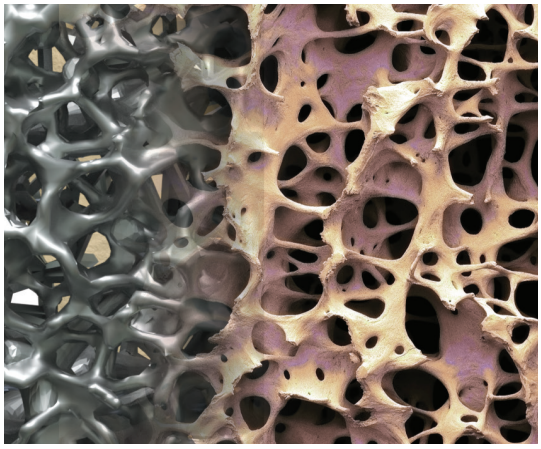
This surgical technique guide provides information supplemental to information provided in the individual system instructions for use (IFU) regarding the products referenced herein.

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**.

Contents

Modulus TLIF-O system overview

Surface



Porous surface designed to participate in fusion

Modulus endplate porosity provides a favorable environment for bone in-growth,[1] demonstrating the greatest integration strength by 12 weeks compared to alternative implant materials in a preclinical study.[1]

Fully porous, roughened endplate design promotes new bone on-growth and in-growth at four weeks.[1]

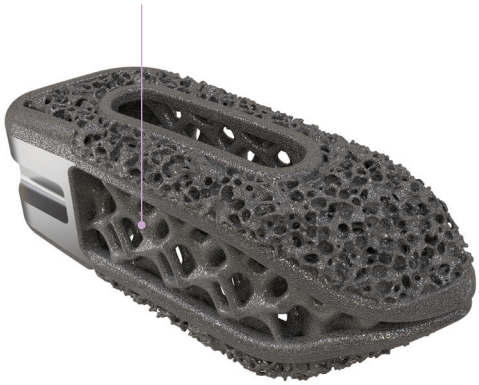
Through surface topography and porous design, Modulus titanium (Ti) exhibits more wicking ability compared to traditional smooth implants.

Increased resistance to expulsion

Roughened endplate surface maximizes bone-to-implant contact, increasing expulsion resistance.[2]

Structure

Lattice architecture individually optimized to each implant geometry



Optimized lattice structure

The microporous endplates are designed to exhibit effective stiffness profiles similar to bone.[3]

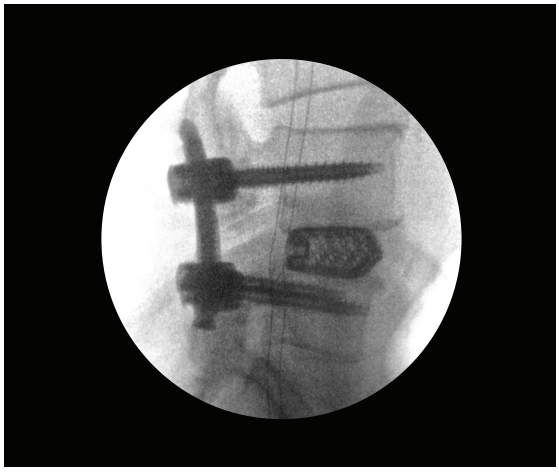
Modulus Ti implants are designed with an optimized balance between strength and stiffness to minimize stress shielding[5] and subsidence.[5]

Strong, durable implant material

Modulus Ti optimization algorithm and design methodology balance implant porosity and strength.

High-strength Ti lattice structure is uniquely engineered to each implant size.

Imaging



Enhanced imaging characteristics for visualization of fusion

Proprietary design and manufacturing process enables enhanced radiographic visualization in a variety of imaging modalities compared to many solid Ti interbody implants.

Technique guide

Equipment requirements

MDLUSTLIFOCOREIMP

- Modulus TLIF-O implant set contains all core implant sizes.

MDLUSTLIFOCOREINS

- Modulus TLIF-O instrument set contains trials, inserters, T-handles, graft packer and tamp.

MDLUSTLIFOOUTIMP1 and MDLUSTLIFOTRIAL1

- Modulus TLIF-O outlier one sets contains 7 mm and 14 mm tall implants and Modulus TLIF-O outlier trial one set contains the associated trials.

MDLUSTLIFOOUTIMP2 and MDLUSTLIFOTRIAL2

- Modulus TLIF-O outlier two sets contains 14 mm wide and 35 mm long implants and Modulus TLIF-O outlier trial two set contains the associated trials.

MT2ACCESS (optional)

- MAS TLIF 2 access set contains the MAS TLIF 2 blades, retractor body and instrumentation.

EXGENINS, EXDISCPREPSTRT or EXDISCPREPBAY

- Excavation sets contain paddle sizers, shavers, curettes and Kerrisons.

Fixation options

- Reline

Biologics

- Osteocel Plus
- Osteocel Pro
- Graft Delivery System

For a complete list of intended uses, indications, device description, contraindications, warnings and precautions, please refer to the IFU in the back of this technique guide.

Highlighted instrumentation

Sizing and trialing

Trial

Implant insertion

Cam lock inserter

Graft preparation

TLIF-O graft packer

Patient positioning and OR setup

Place the patient on the operating table in a prone position. Prepare and drape in a conventional manner. Fluoroscope should have easy access to the surgical field for both A/P and lateral views. Fluoroscopic monitors and NVM5 unit should be placed in clear view *(Fig. 1)*.

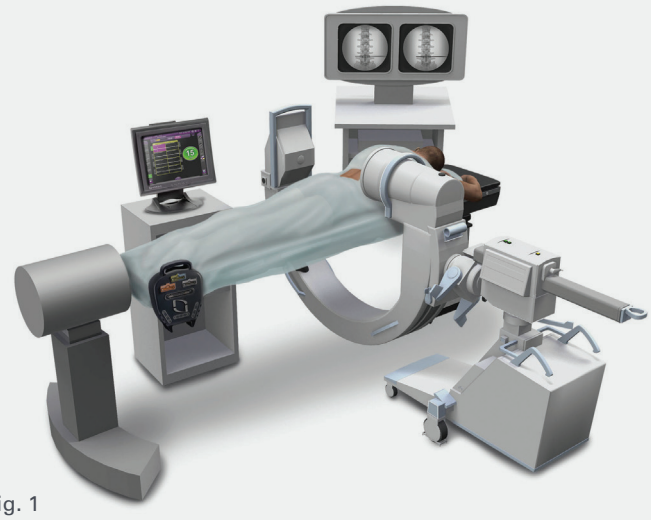


Fig. 1

Patient prep for lumbar neuromonitoring with NVM5

For TLIF procedures utilizing electromyography (EMG) neuromonitoring, place the EMG electrodes on the patient prior to positioning and orient the NVM5 screen toward the operative surgeon. Refer to the NVM5 electrode patient prep guides for more information.

Once electrodes are properly placed, execute a twitch test to detect the presence of neuromuscular blocking agents, which can impact the accuracy of EMG monitoring.

Step 1

Anatomical landmark identification and initial incisions

Localize the disc space using fluoroscopy in the A/P and lateral views. Target the pedicles above and below the affected level and mark the location of each pedicle. Make a skin incision between the pedicle markings, sized appropriately for the retractor being used.

Step 2

Exposure

Using finger dissection, a cobb or curette, release tissue from the facet joint, as necessary, at the affected level.

Step 3

Discectomy

After achieving access to the target anatomy and completing a decompression, perform the necessary thorough annulotomy and discectomy *(Fig. 2)*.

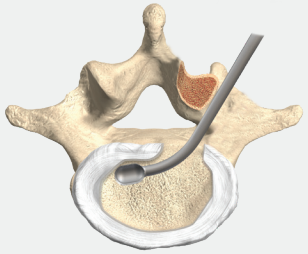


Fig. 2

NVM5: Free run EMG

Use free run EMG to continuously monitor for mechanical disturbances to neural structures when using the Modulus TLIF-O implant and inserter.

Step 4

Sizing

Once the discectomy at the desired level has been completed, determine the appropriate height and width required, using the provided trials *(Fig. 3)*.

Note: *Trial width and height match the true width and height of the implant.*

Attach T-handle to trial and insert on its side into the disc space at an oblique angle *(Fig. 4)*. Sequentially increase trial size until the desired disc height is established. Use A/P and lateral fluoro to confirm the proper placement and trajectory.

Tip: *The corresponding height and lordotic angle are labeled on the proximal end.*

Tip: *Insert trial into the disc space at 30° to achieve proper lordosis in the sagittal plane.*

Once across midline, rotate the T-handle up to height, confirming that the "**medial**" and "**lateral**" markings on the proximal end of the trial are in the proper orientation *(Fig. 5)*. The angle can be verified via fluoroscopy in the sagittal plane if you can clearly identify a triangle anterior and posterior with a rectangle in the middle.

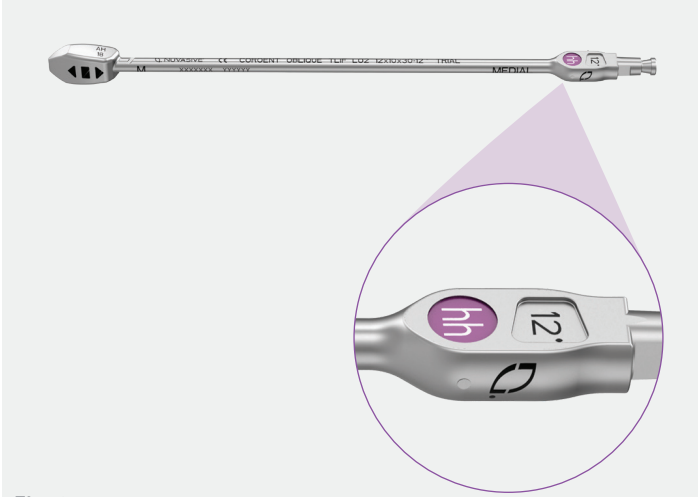


Fig. 3

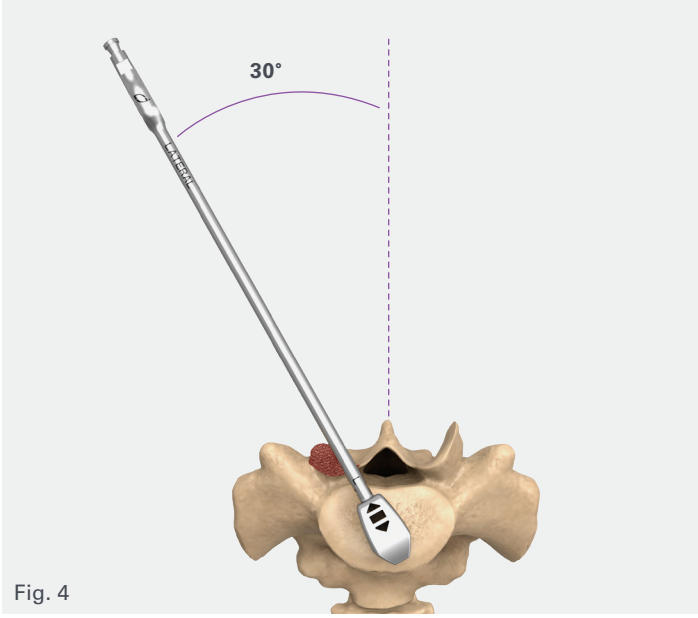


Fig. 4

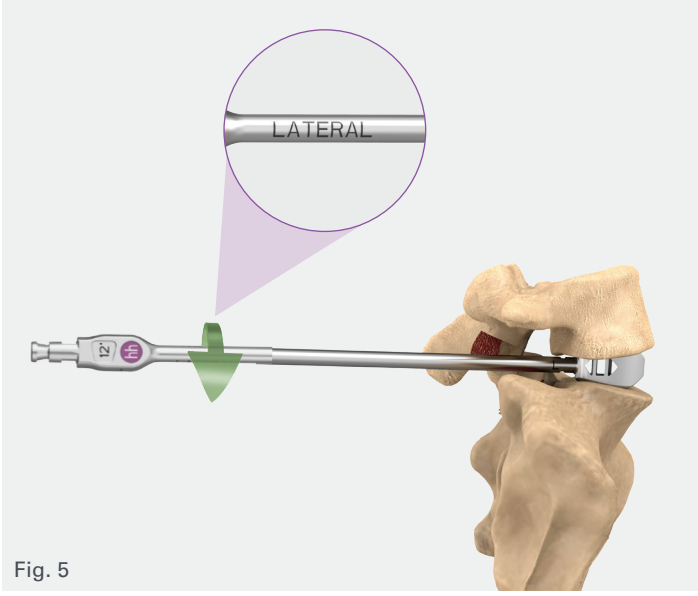


Fig. 5

Sizing (cont.)

If the anterior triangle is larger than the posterior triangle *(Fig. 6)*, adjust hand medially until anterior and posterior triangles are the same size.

If the posterior triangle is larger than the anterior triangle *(Fig. 7)*, adjust hand laterally until posterior and anterior triangles are the same size.

Note: *Additional length measurements can be assessed by referencing the notch proximal to the windows.*

On the 25 mm trials, the notch represents 30 mm in length (Fig. 8).

On the 30 mm trials, the notch represents 35 mm in length (Fig. 9).

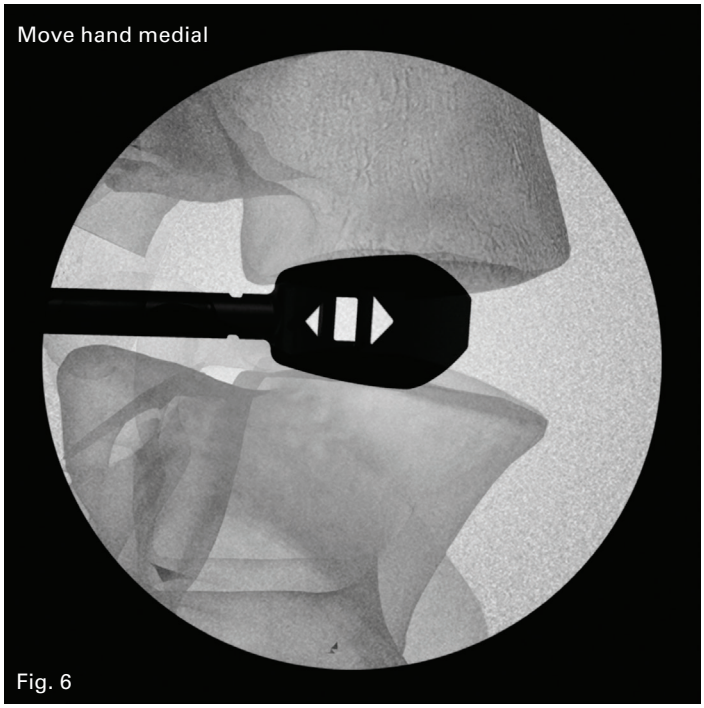


Fig. 6

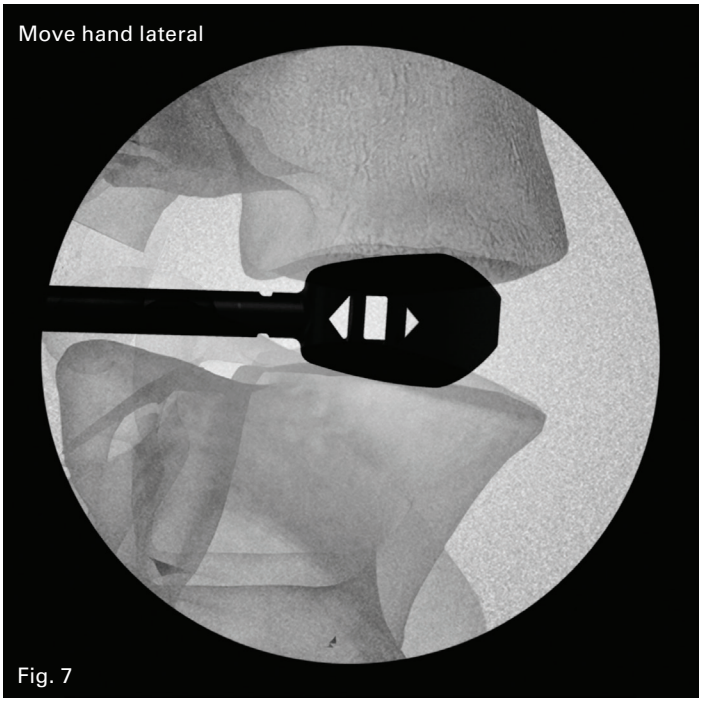


Fig. 7

NVM5: Nerve root monitoring

During the sizing and implant insertion steps, the free run EMG modality on NVM5 provides immediate surgeon-directed notification of spontaneous EMG activity and potential nerve root impingement.

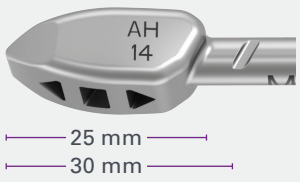


Fig. 8

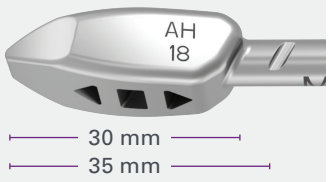


Fig. 9

Step 5

Inserter and implant attachment

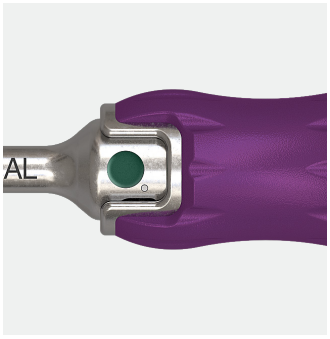
Prior to attaching the implant to the inserter, verify that the inserter is in the unlocked position. This can be confirmed when the green dot is visible *(Fig. 10b)*. If the green dot is not visible, rotate the silicone handle clockwise.

To attach the implant to the inserter, match the black laser line on the implant to the black laser line located on the distal end of the inserter *(Fig. 10a)*.

To lock the implant in place, push the silicone handle forward and rotate counterclockwise *(Fig. 11b)*.

In the locked position, a laser-marked lock symbol will be visible *(Fig. 11a)*.

Tip: *When the green dot is visible, the implant can be attached or removed from the inserter.*



Tip: *When the lock symbol is visible, the implant is locked to the inserter.*

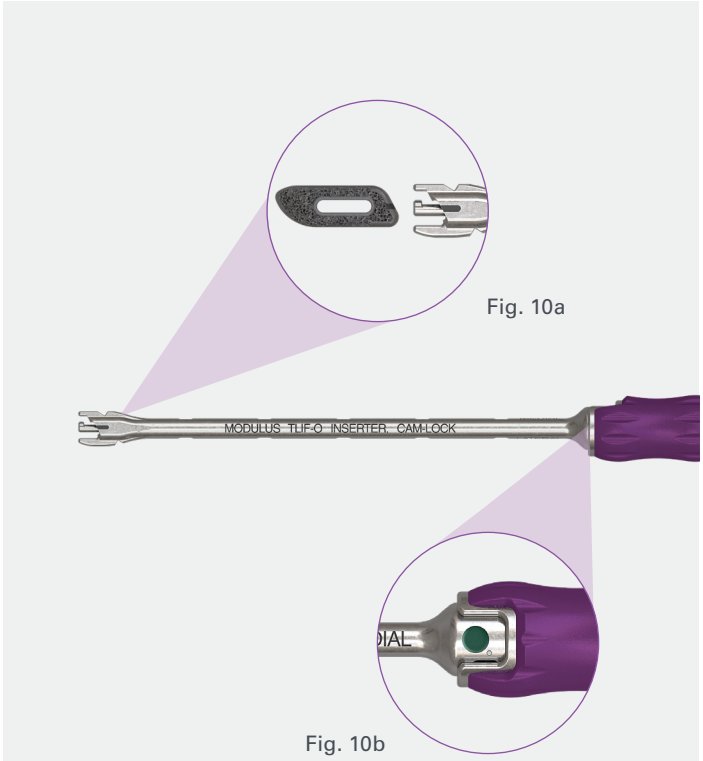


Fig. 10a

Fig. 10b

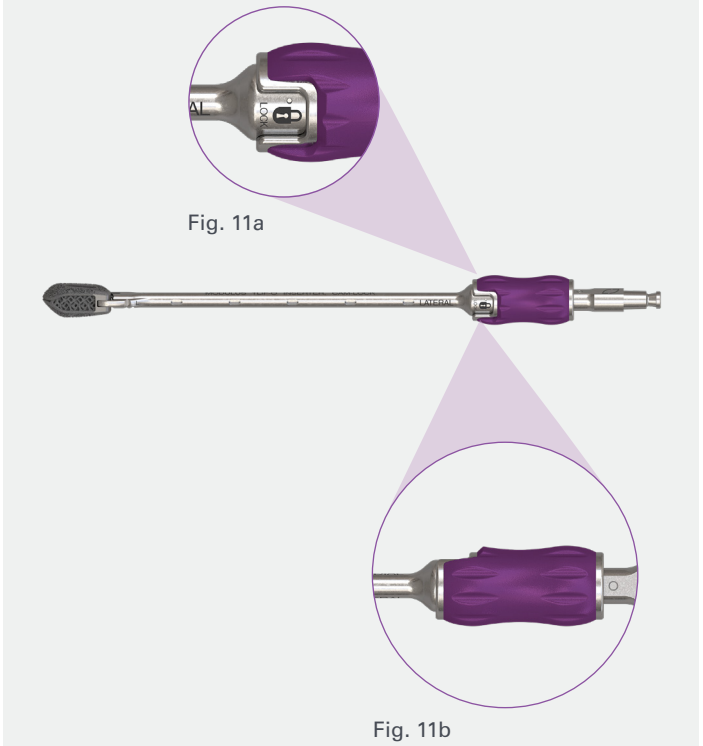


Fig. 11a

Fig. 11b

Step 6

Implant insertion

Impaction technique

Tip: *10 mm-wide implant—impaction technique recommended for implants that are shorter than or equal to 10 mm in anterior height.*

14 mm-wide implant—always impact.

This method of implant insertion provides slight distraction upon insertion into the disc space. The implant should be inserted at the same angle as the implant trial to allow for proper placement and crossing of midline.

Impact the implant until the posterior aspect of the cage is seated fully in the disc space *(Fig. 12)*.

Note: *Under fluoro in the lateral view, alignment marker cutouts on the inserter will help confirm proper 30° trajectory.*

If repositioning is necessary, remove and reinsert the implant and inserter from the disc space and adjust hand medially or laterally until the anterior and posterior triangles are the same size (Fig. 13).

An A/P fluoro shot should also be taken to confirm that the distal end of the implant is across midline.

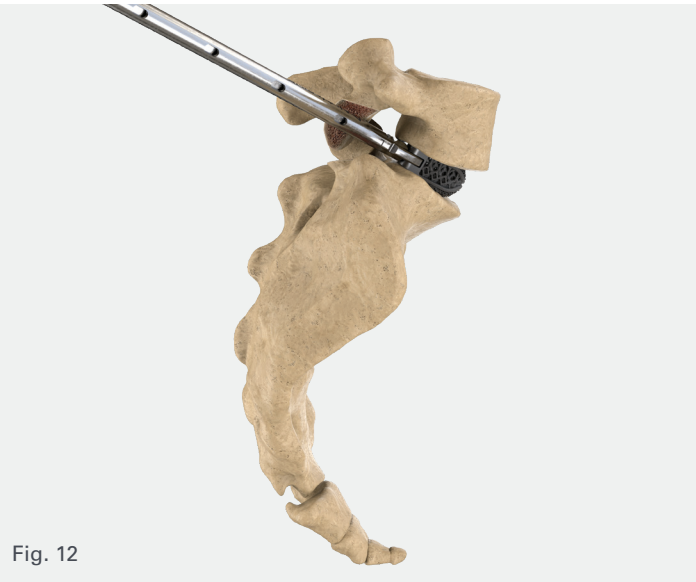


Fig. 12

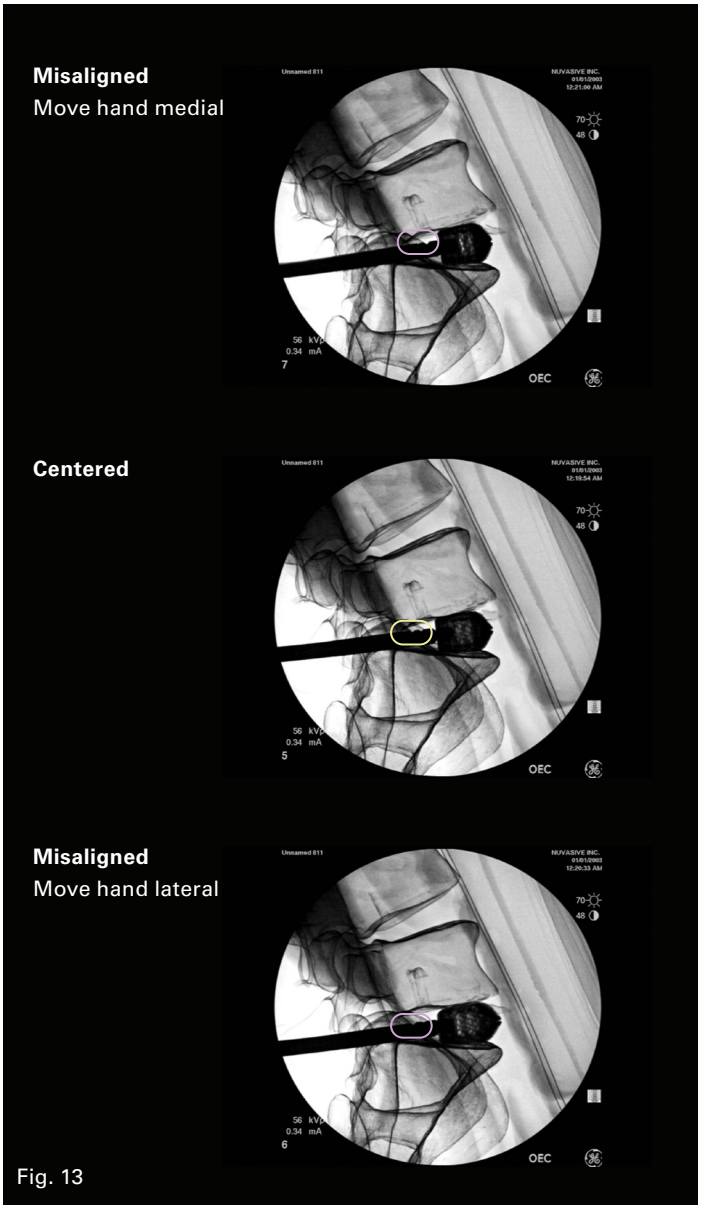


Fig. 13

Step 6 (cont.)

Implant insertion

Insert and rotate technique

Note: *10 mm-wide implant—insert and rotate technique recommended for implants with an anterior height taller than 10 mm.*

The insert and rotate technique is designed to provide maximum control and height restoration. This method will allow repositioning of the implant, as deemed appropriate, prior to rotating up to height.

Insert the implant on its side with the tapered nose facing cephalad. Impact the implant until the posterior aspect of the cage is seated fully in the disc space *(Fig. 14)*.

Note: *Prior to rotation, an A/P fluoro shot should be taken to confirm that the distal end of the implant is across midline.*

Once the desired placement of the implant has been achieved, rotate up to height, confirming that the "**medial**" and "**lateral**" markings on the proximal end of the inserter are in the proper orientation *(Fig. 15)*.

If further manipulation is required, disengage the implant from the inserter and utilize the oblique TLIF tamp (provided in the set) to impact the proximal aspect of the implant.

Note: *Under lateral fluoro, the anterior alignment marker cutout and the distal alignment marker cutout provides an additional 5 mm depth indication (Fig. 16).*

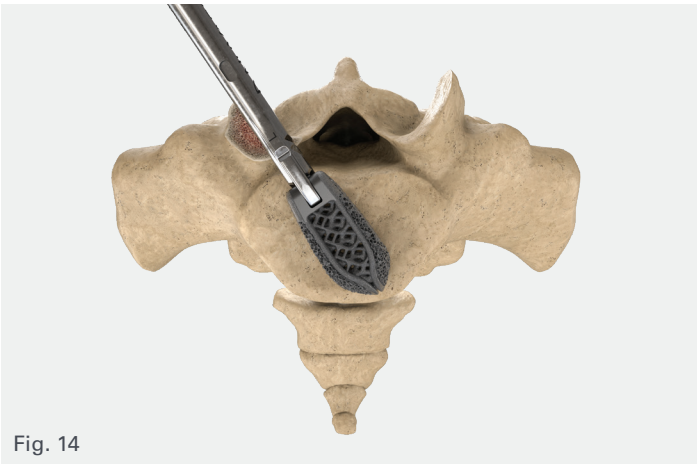


Fig. 14

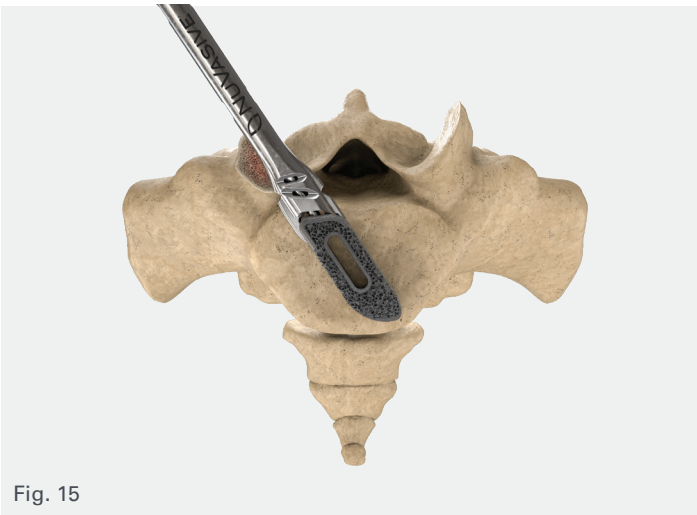


Fig. 15

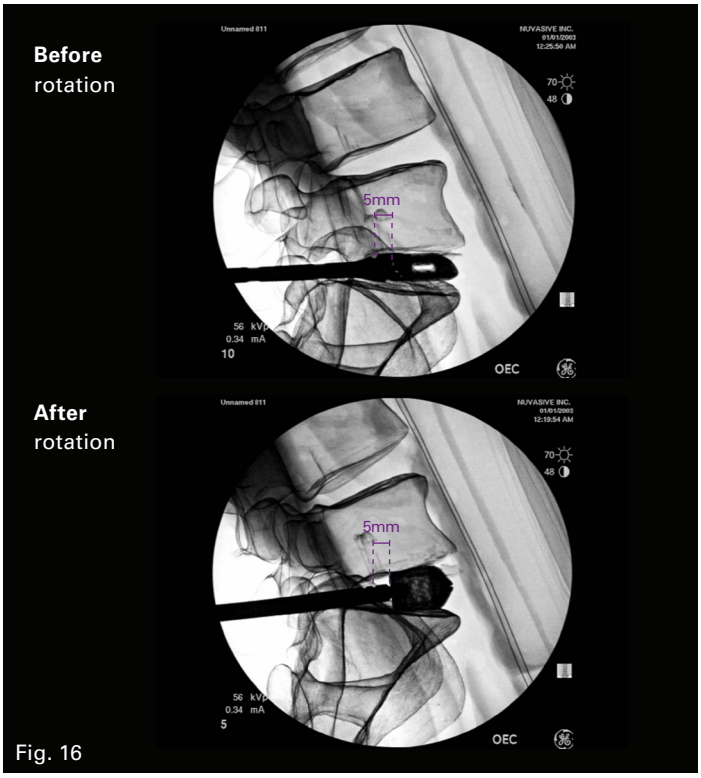


Fig. 16

Step 7

Final placement and inserter release

Final position of the implant can be verified under fluoroscopy. To release the implant from the inserter, push the silicone handle forward and rotate clockwise. In the unlocked position, the green dot will be visible *(Figs. 17, 18)*.

Step 8

Graft delivery

Graft material can then be filled posterior, utilizing the MAS graft delivery system *(Fig. 19)*.

Note: *The MAS graft delivery system will allow up to 10 cc of graft material to be delivered per pass. Once the graft tube has been loaded with Osteocel, the distal tip of the graft tube is inserted into the disc space (Fig. 19), and the threaded applicator gradually moves graft material through the graft tube into the disc space at a controlled pace. See the MAS graft delivery system technique guide for assembly instructions (document #9501278).*

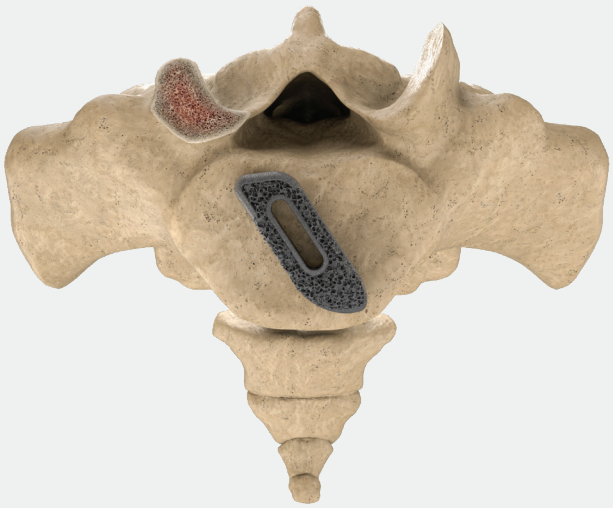


Fig. 18

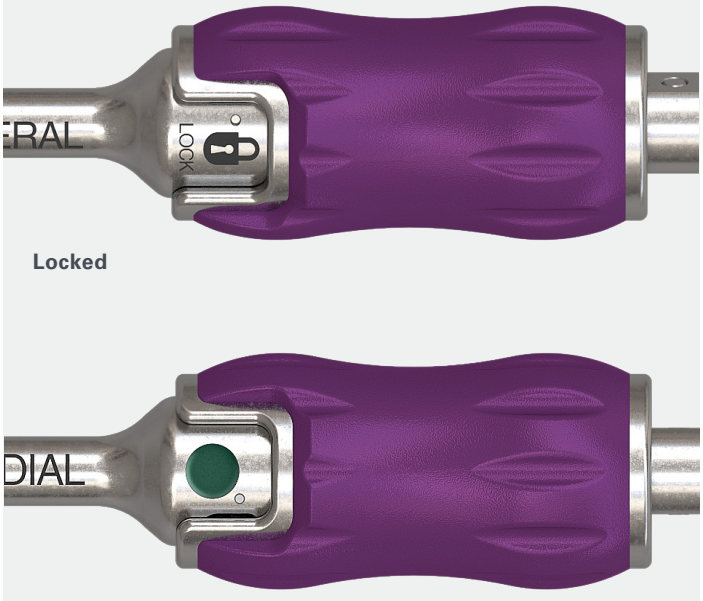


Fig. 17

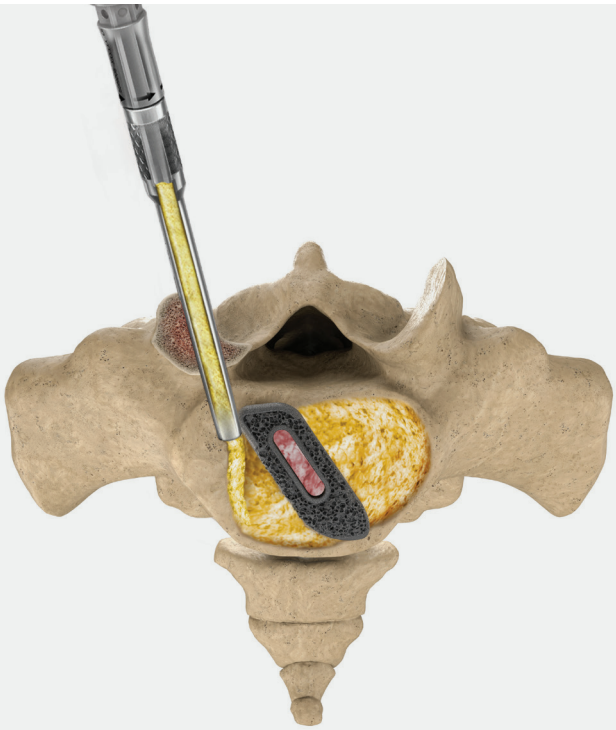


Fig. 19

Step 9

Fixation

Place the desired fixation system, such as Reline *(Fig. 20)*.

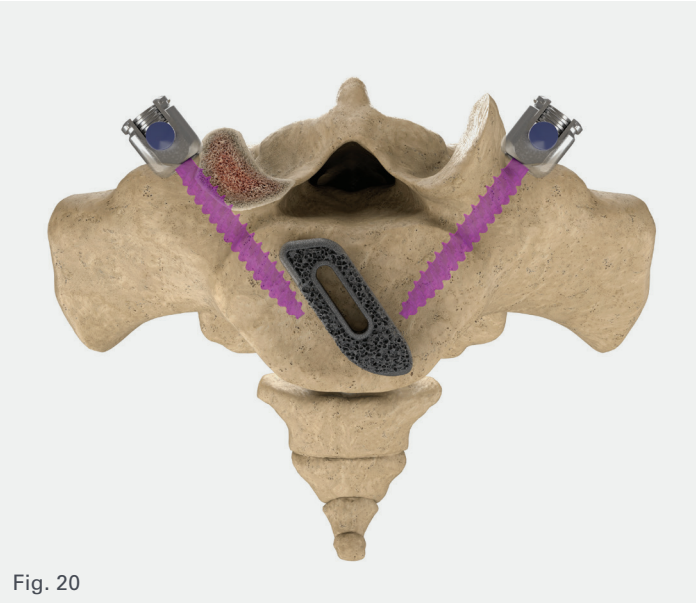
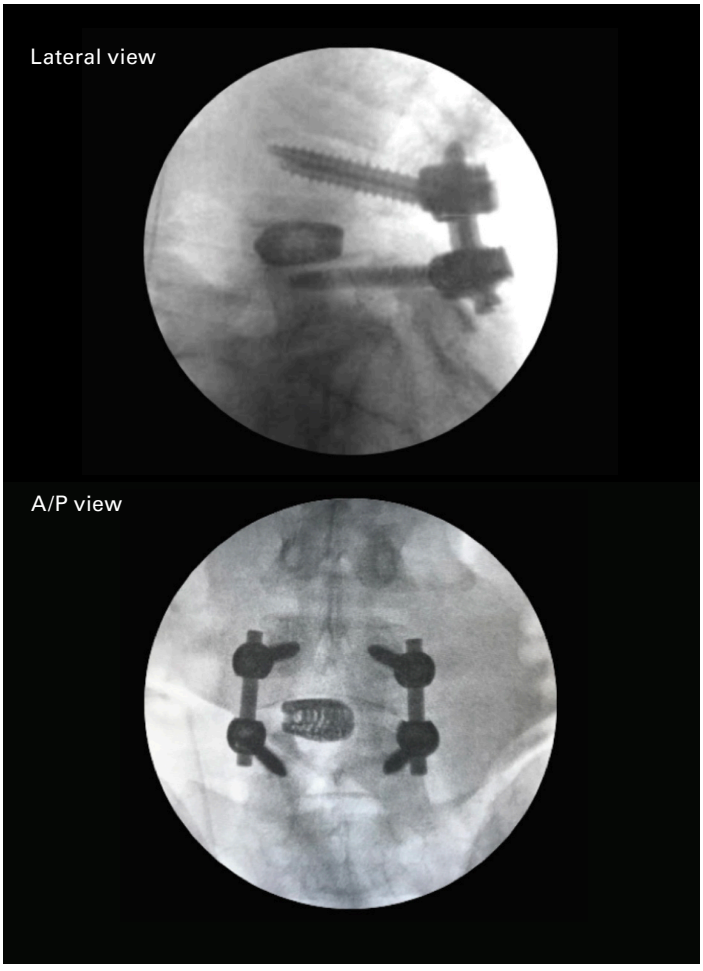


Fig. 20



Step 10

Implant removal

Exposure is performed in the same fashion as the primary surgery. Prior to implant removal, the spinal fixation system must first be removed following instructions provided in the system surgical technique.

If the implant must be removed, verify that the inserter is in the unlock position. This can be confirmed when the green dot is visible. If the green dot is not visible, rotate the silicone handle counterclockwise. Engage the forks onto the implant and lock the inserter onto the implant by rotating the silicone handle clockwise. In the lock position, a laser-marked lock symbol will be visible. The implant can now be removed by pulling back on the inserter.

Care should be exercised to avoid neural elements during removal.

Modulus TLIF-O system

Modulus TLIF-O instruments

Modulus TLIF-O inserter, cam lock

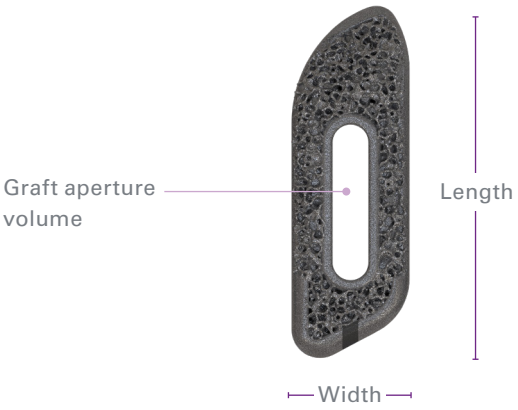
Oblique TLIF tamp

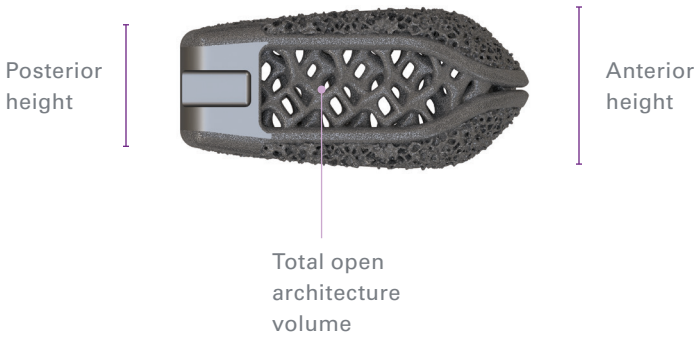
Oblique TLIF Ti trial

Universal T-handle with Hudson

Modulus TLIF-O graft packer

Sizing guide





Important: *Labeled implant footprint height references posterior height. Refer to the table below to determine the anterior height of the implant.*

Anterior/posterior height relationship

	Footprint (WxL)			
Lordosis	10x25 mm	10x30 mm	10x35 mm	14x30 mm
4°	+2 to PH	+2 to PH	+2.5 to PH	+2 to PH
8°	+3 to PH	+3.5 to PH	–	–
12°	+3.5 to PH	+4.5 to PH	–	–

Core configuration

Catalog no.	PHxWxL	Posterior height (mm)	Anterior height (mm)	Graft aperture volume (cc)	Open architecture volume (cc)*
2080254P2	8x10x25 mm, 4°	8	10	0.26	0.76
2100254P2	10x10x25 mm, 4°	10	12	0.31	1.09
2120254P2	12x10x25 mm, 4°	12	14	0.36	1.27
2080258P2	8x10x25 mm, 8°	8	11	0.28	0.82
2100258P2	10x10x25 mm, 8°	10	13	0.33	1.13
2120258P2	12x10x25 mm, 8°	12	15	0.38	1.27
2080252P2	8x10x25 mm, 12°	8	11.5	0.29	0.88
2100252P2	10x10x25 mm, 12°	10	13.5	0.34	1.20

**Includes graft aperture*

Core configuration (cont.)

Catalog no.	PHxWxL	Posterior height (mm)	Anterior height (mm)	Graft aperture volume (cc)	Open architecture volume (cc)*
2120252P2	12x10x25 mm, 12°	12	15.5	0.40	1.42
2080304P2	8x10x30 mm, 4°	8	10	0.38	1.12
2100304P2	10x10x30 mm, 4°	10	12	0.46	1.49
2120304P2	12x10x30 mm, 4°	12	14	0.54	1.81
2080308P2	8x10x30 mm, 8°	8	11.5	0.41	1.23
2100308P2	10x10x30 mm, 8°	10	13.5	0.49	1.59
2120308P2	12x10x30 mm, 8°	12	15.5	0.57	1.92
2080302P2	8x10x30 mm, 12°	8	12.5	0.44	1.37
2100302P2	10x10x30 mm, 12°	10	14.5	0.52	1.76
2120302P2	12x10x30 mm, 12°	12	16.5	0.60	2.05

Outlier 1 configuration (optional)

Catalog no.	PHxWxL	Posterior height (mm)	Anterior height (mm)	Graft aperture volume (cc)	Open architecture volume (cc)*
2070254P2	7x10x25 mm, 4°	7	9	0.23	0.64
2070258P2	7x10x25 mm, 8°	7	10	0.25	0.71
2070252P2	7x10x25 mm, 12°	7	10.5	0.27	0.52
2070304P2	7x10x30 mm, 4°	7	9	0.35	0.98
2070308P2	7x10x30 mm, 8°	7	10.5	0.37	1.10
2070302P2	7x10x30 mm, 12°	7	11.5	0.40	1.18
2140254P2	14x10x25 mm, 4°	14	16	0.42	1.50
2140258P2	14x10x25 mm, 8°	14	17	0.43	1.53
2140252P2	14x10x25 mm, 12°	14	17.5	0.45	1.63
2140304P2	14x10x30 mm, 4°	14	16	0.61	2.09
2140308P2	14x10x30 mm, 8°	14	17.5	0.64	2.20
2140302P2	14x10x30 mm, 12°	14	18.5	0.67	2.31

**Includes graft aperture*

Outlier 2 configuration (optional)

Catalog no.	PHxWxL	Posterior height (mm)	Anterior height (mm)	Graft aperture volume (cc)	Open architecture volume (cc)*
2080354P2	8x10x35 mm, 4°	8	10.5	0.51	1.45
2100354P2	10x10x35 mm, 4°	10	12.5	0.56	1.95
2120354P2	12x10x35 mm, 4°	12	14.5	0.60	2.33
2084304P2	8x14x30 mm, 4°	8	10	0.38	1.54
2104304P2	10x14x30 mm, 4°	10	12	0.46	2.09
2124304P2	12x14x30 mm, 4°	12	14	0.53	2.59

**Includes graft aperture*

Catalog

Modulus TLIF-O core instrument set MDLUSTLIFOCOREINS	
Description	Catalog no.
Generic NuVasive tray lid	1660500
Universal T-Handle, with Hudson	5155035
Oblique TLIF Ti trial, 8x10x25 mm, 4°	1713612
Oblique TLIF Ti trial, 10x10x25 mm, 4°	1713614
Oblique TLIF Ti trial, 12x10x25 mm, 4°	1713616
Oblique TLIF Ti trial, 8x10x25 mm, 8°	1713621
Oblique TLIF Ti trial, 10x10x25 mm, 8°	1713623
Oblique TLIF Ti trial, 12x10x25 mm, 8°	1713625
Oblique TLIF Ti trial, 8x10x25 mm, 12°	1713630
Oblique TLIF Ti trial, 10x10x25 mm, 12°	1713632
Oblique TLIF Ti trial, 12x10x25 mm, 12°	1713634
Modulus TLIF-O top, case	2144409
Modulus TLIF-O pin mat, top	2060265
Oblique TLIF Ti trial, 8x10x30 mm, 4°	1713657
Oblique TLIF Ti trial, 10x10x30 mm, 4°	1713659
Oblique TLIF Ti trial, 12x10x30 mm, 4°	1713661
Oblique TLIF Ti trial, 8x10x30 mm, 8°	1713666
Oblique TLIF Ti trial, 10x10x30 mm, 8°	1713668
Oblique TLIF Ti trial, 12x10x30 mm, 8°	1713670
Oblique TLIF Ti trial, 8x10x30 mm, 12°	1713675
Oblique TLIF Ti trial, 10x10x30 mm, 12°	1713677
Oblique TLIF Ti trial, 12x10x30 mm, 12°	1713679
Oblique TLIF tamp	1657590
Modulus TLIF-O graft packer	2060262
Modulus TLIF-O inserter, cam lock	D2060241
Modulus TLIF-O bottom, case	2144410
Modulus TLIF-O pin mat, bottom	2060266
Modulus TLIF-O base, case	2144411

Modulus TLIF-O core implant set MDLUSTLIFOCOREIMP	
Description	Catalog no.
Universal pelican case, SP 2 sm 40CT	1704726
MDLUSTLOIMP sterile IMP size key	9000001
Modulus TLIF-O, 8x10x25 mm, 4°	2080254P2
Modulus TLIF-O, 10x10x25 mm, 4°	2100254P2
Modulus TLIF-O, 12x10x25 mm, 4°	2120254P2
Modulus TLIF-O, 8x10x30 mm, 4°	2080304P2
Modulus TLIF-O, 10x10x30 mm, 4°	2100304P2
Modulus TLIF-O, 12x10x30 mm, 4°	2120304P2
Modulus TLIF-O, 8x10x25 mm, 8°	2080258P2
Modulus TLIF-O, 10x10x25 mm, 8°	2100258P2
Modulus TLIF-O, 12x10x25 mm, 8°	2120258P2
Modulus TLIF-O, 8x10x30 mm, 8°	2080308P2
Modulus TLIF-O, 10x10x30 mm, 8°	2100308P2
Modulus TLIF-O, 12x10x30 mm, 8°	2120308P2
Modulus TLIF-O, 8x10x25 mm, 12°	2080252P2
Modulus TLIF-O, 10x10x25 mm, 12°	2100252P2
Modulus TLIF-O, 12x10x25 mm, 12°	2120252P2
Modulus TLIF-O, 8x10x30 mm, 12°	2080302P2
Modulus TLIF-O, 10x10x30 mm, 12°	2100302P2
Modulus TLIF-O, 12x10x30 mm, 12°	2120302P2

Modulus TLIF-O 7 and 14 mm tall implant set MDLUSTLIFOOUTIMP1 (optional)	
Description	Catalog no.
Universal pelican case, SP 2 12CT	1704725
MDLUSTLOOUT1–Sterile IMP size key	9000002
Modulus TLIF-O, 7x10x25 mm, 4°	2070254P2
Modulus TLIF-O, 7x10x25 mm, 8°	2070258P2
Modulus TLIF-O, 7x10x25 mm, 12°	2070252P2
Modulus TLIF-O, 7x10x30 mm, 4°	2070304P2
Modulus TLIF-O, 7x10x30 mm, 8°	2070308P2
Modulus TLIF-O, 7x10x30 mm, 12°	2070302P2
Modulus TLIF-O, 14x10x25 mm, 4°	2140254P2
Modulus TLIF-O, 14x10x25 mm, 8°	2140258P2
Modulus TLIF-O, 14x10x25 mm, 12°	2140252P2
Modulus TLIF-O, 14x10x30 mm, 4°	2140304P2
Modulus TLIF-O, 14x10x30 mm, 8°	2140308P2
Modulus TLIF-O, 14x10x30 mm, 12°	2140302P2

Modulus TLIF-O 7 and 14 mm tall trial set MDLUSTLIFOTRIAL1 (optional)	
Description	Catalog no.
Generic NuVasive half lid, medin tray	1660363
Oblique TLIF Ti trial, 7x10x25 mm, 4°	1713611
Oblique TLIF Ti trial, 7x10x25 mm, 8°	1713620
Oblique TLIF Ti trial, 7x10x25 mm, 12°	1713629
Oblique TLIF Ti trial, 7x10x30 mm, 4°	1713656
Oblique TLIF Ti trial, 7x10x30 mm, 8°	1713665
Oblique TLIF Ti trial, 7x10x30 mm, 12°	1713674
Oblique TLIF Ti trial, 14x10x25 mm, 4°	1713618
Oblique TLIF Ti trial, 14x10x25 mm, 8°	1713627
Oblique TLIF Ti trial, 14x10x25 mm, 12°	1713636
Oblique TLIF Ti trial, 14x10x30 mm, 4°	1713663
Oblique TLIF Ti trial, 14x10x30 mm, 8°	1713672
Oblique TLIF Ti trial, 14x10x30 mm, 12°	1713681
Modulus TLIF-O 7 and 14 tall trial tray	2060243

Modulus TLIF-O outlier implant set MDLUSTLIFOOUT2 (optional)	
Description	Catalog no.
Universal pelican case, sp 2 12CT	1704725
MDLUSTLIFOOUTIMP2–Sterile IMP size key	9000003
Modulus TLIF-O, 8x10x35 mm, 4°	2080354P2
Modulus TLIF-O, 8x14x30 mm, 4°	2084304P2
Modulus TLIF-O, 10x10x35 mm, 4°	2100354P2
Modulus TLIF-O, 10x14x30 mm, 4°	2104304P2
Modulus TLIF-O, 12x10x35 mm, 4°	2120354P2
Modulus TLIF-O, 12x14x30 mm, 4°	2124304P2

Modulus TLIF-O outlier trial set MDLUSTLIFOTRIAL2 (optional)	
Description	Catalog no.
Generic NuVasive half lid, medin tray	1660363
Oblique TLIF Ti trial, 8x10x35 mm, 4°	1713693
Oblique TLIF Ti trial, 10x10x35 mm, 4°	1713695
Oblique TLIF Ti trial, 12x10x35 mm, 4°	1713697
Oblique TLIF Ti trial, 8x14x30 mm, 4°	1713738
Oblique TLIF Ti trial, 10x14x30 mm, 4°	1713740
Oblique TLIF Ti trial, 12x14x30 mm, 4°	1713742
Modulus TLIF-O outlier trial tray	2060242
Modulus TLIF-O nipple mat, base	2060253

Instructions for use

DESCRIPTION

The NuVasive Modulus Interbody System interbody implants and Modulus XLIF internal fixation plate and bone screws are manufactured from Ti-6Al-4V ELI conforming to ASTM F3001, ASTM F136 and ISO 58323. 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), degenerative spondylolisthesis, and/or spinal stenosis 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 and sagittal deformity.

Modulus TLIF interbody system:

The NuVasive Modulus TLIF Interbody System is indicated for intervertebral body fusion of the spine inskeletally 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), degenerative spondylolisthesis, and/or spinal stenosis 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 and sagittal deformity.

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.

CONTRAINDICTIONS

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, and
9. reuse or multiple 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, 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 lower interbody fusion rate compared to one- and two-level interbody fusions.

POTENTIAL ADVERSE EVENTS AND COMPLICATIONS

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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, and
- 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 t his 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.

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.

MRI safety unformation: The Modulus interbody system has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of the Modulus interbody system in the MR environment is unknown. Scanning a patient who has this device may results in patient injury.

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.

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 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.

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 weight-bearing structures can give rise to loosening of the components, dislocation and migration, as well as other complications. To confirm the earliest possible detection of such catalysts of device dysfunction, the devices must be checked periodically postoperatively, using appropriate radiographic techniques.

This instructions for use document is intended for the US market only. For OUS instructions for use, please refer to document #9402668 for sterile implants.

References

1. Preclinical data on file. Data may not be representative of clinical results. TR 9604787
2. Preclinical data on file. Data may not be representative of clinical results. TR 9603905
3. Preclinical data on file. Data may not be representative of clinical results. TR 9604781.
4. Chatham LS, Patel VV, Yakacki CM, et al. Interbody spacer material properties and design conformity for reducing subsidence during lumbar interbody fusion. *J Biomech Eng* 2017;139(5):051005.
5. Preclinical Data on File. Data may not be representative of clinical results. TR 9603972.

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