MODULUS TLIF-A

Technique guide

NuVasive

As with all surgical procedures and permanent implants, there are risks and considerations associated with surgery and use of the Modulus TLIF-A. 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).

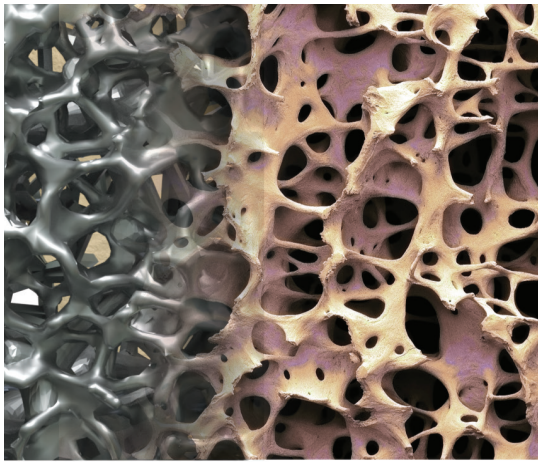
It is the surgeon's responsibility to discuss all relevant risks with the patient prior to surgery.

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

Contents

Modulus TLIF-A 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]

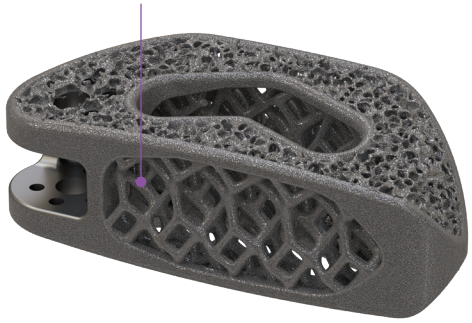
Through surface topography and porous design, Modulus titanium (Ti) exhibits more wicking ability compared to traditional smooth implants.[2]

Increased resistance to expulsion

Roughened endplate surface maximizes bone-to-implant contact, increasing expulsion resistance.[3]

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.[4]

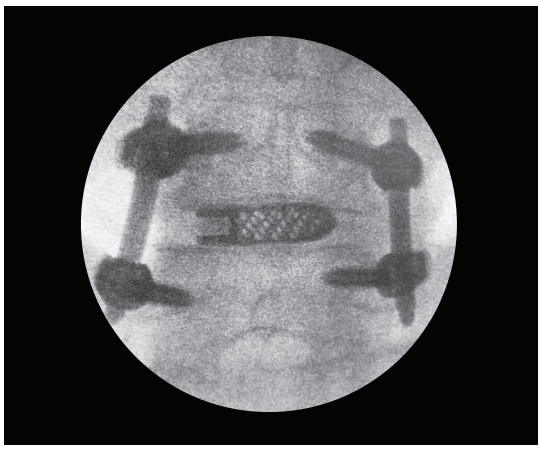
Modulus Ti implants are designed with an optimized balance between strength and stiffness to minimize stress shielding[5] and subsidence.[6]

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

MDLUSTLIFACOREIMP or MDLUSTLIFAXLIMP

- Modulus transforaminal lumbar interbody fusion (TLIF)-A core implant set contains core implants and Modulus TLIF-A XL set contains XL implants.

MDLUSTLIFACOREINS or MDLUSTLIFAXLINS

- Modulus TLIF-A instrument sets contain pivoting trials, inserters, tamps, a graft packer and a removal tool.

MDLUSTLIFAOUTIMP (optional)

- Modulus TLIF-A outlier implant sets contain 14x30/14x34–8° outlier implants.

MDLUSTLIFAOUTTRIAL (optional)

- Modulus TLIF-A outlier trial sets contain pivoting trials for 14x30/14x34–8° outlier implant families.

MT2ACCESS or MASPLIFACCESS (optional)

- Access sets contain blades, retractor bodies and instrumentation.

EXGENINS and EXDISCPREPSTRT or EXDISCPREPBAY

- Excavation sets contain decompression and disc prep instrumentation including paddle sizers, shavers, curettes and Kerrisons.

Fixation options

- Reline
- Reline MAS Midline

Biologics

- Osteocel Plus
- Osteocel Pro
- Graft Delivery System (GDS)

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

Modulus pivoting trial inserter

Pivoting trial

Implant insertion

Modulus TLIF-A inserter, inline

Modulus TLIF-A inserter, offset

Implant positioning

Modulus TLIF-A forked tamp

Graft preparation

TLIF-A graft packer

Implant removal

Removal clip

Modulus TLIF-A with MAS TLIF 2 technique

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)*.

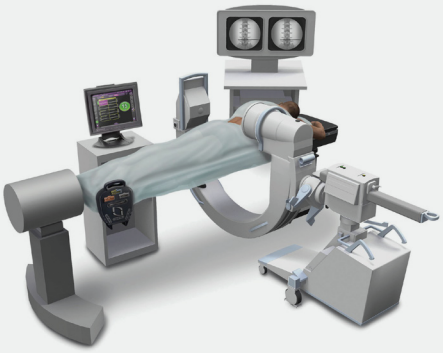


Fig. 1

Patient preparation 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

Decompression and discectomy

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

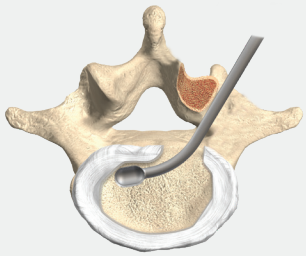


Fig. 2

NVM5: Free-run EMG

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

Step 4

Sizing

Once the discectomy at the desired level has been completed, determine the desired height and width required, using the Modulus TLIF-A pivoting trials.

Select a trial shaft and insert it into the distal end of the trial inserter confirming the trial shaft is in the appropriate orientation by referencing the laser mark on the distal end of the trial inserter. Rotate the thumbwheel on the trial inserter clockwise to bring the trial to the locked position for initial insertion *(Fig. 3)*.

Note: *Confirm that the thumbwheel is fully rotated until a hard stop is felt prior to impacting the trial. A red indicator will appear in the proximal window of the trial inserter to indicate the trial body is in the locked position. The red indicator will disappear when the trial body is able to pivot.* ***Only impact on the trial inserter when the trial tip is locked in the inline position and the red indicator is visible. When removing the trial from the disc space, confirm that the red indicator is not visible.***

Impact the assembled trial inserter into the disc space at an oblique angle *(Fig. 4)*. Once the distal tip of the trial is at the contralateral anterior annulus, rotate the thumbwheel counter clockwise, until the red indicator is no longer visible, to bring the assembled trial inserter to the pivot position. The trial will remain connected to the trial inserter but will now be free to pivot up to 90° from the distal portion of the inserter *(Fig. 5)*. Position hand and trial inserter handle medial to assist with pivoting the trial body and impact until trial body is positioned to the anterior one-third of the disc space.

Sequentially increase the trial size until the desired disc height is established. Use A/P and lateral fluoro to confirm the proper placement and trajectory.

Note: *Trial body height, width, length and lordosis match the true height, width, length and lordosis of the implant. The "M" laser marking on the trial should face medial and the "L" laser marking should face lateral.*

Note: *To disassemble the trial shaft from the trial inserter, depress the gold button on the trial inserter and rotate the thumbwheel counter clockwise. The trial shaft will begin to release from the trial inserter. Continue rotating the thumbwheel until the trial shaft is fully released (Fig. 6).*

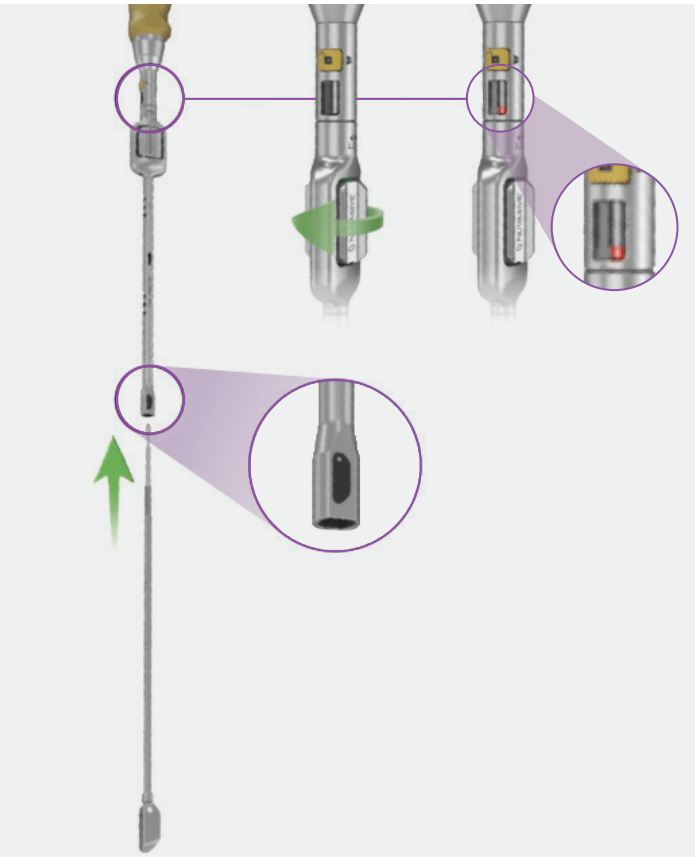


Fig. 3

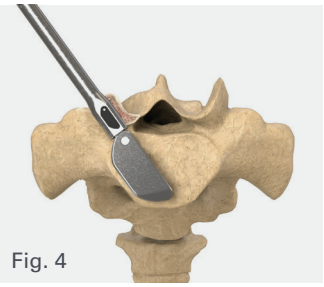


Fig. 4

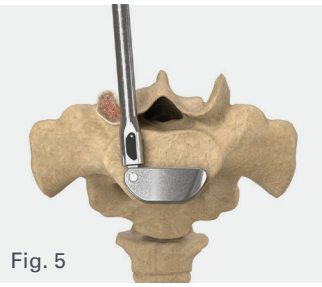


Fig. 5

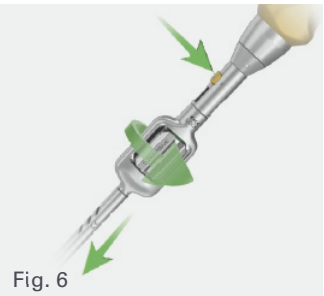


Fig. 6

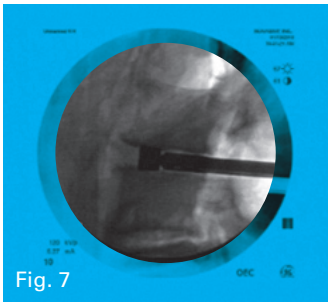


Fig. 7

Tip: *Confirm the trial is articulated 90° when a small radiolucent gap is visible between the distal end of the trial inserter shaft and articulated trial body (Fig. 7).*

Step 5

Inserter selection

Select either the inline *(Fig. 8)* or offset inserter *(Fig. 9)*.

Inserter and implant attachment

Confirm that the inserter is in the unlocked position by depressing the paddle marked with the green pivot symbol. This will release the proximal lever to the pivot position. Next, depress the red button etched with the unlock symbol to prepare the inserter for attachment *(Fig. 10)*.

Align the interbody so it is oriented to the laser etched marking on the distal end of the inserter. Attach the distal aspect of the inserter to the inserter feature of the interbody *(Fig. 11)*.

Depress the proximal lever on the inserter so it sits flush with the inserter *(Fig. 12)*.

Tip: *Confirm that the lever is fully seated under the collar to confirm the lock position.*

When in the lock position, the implant is rigid and in line with the inserter and unable to articulate *(Fig. 13)*.

Tip: *Both the inline and offset inserters allow up to 90° of articulation.*

Tip: *Confirm that the interbody is oriented to the laser etched marking on the distal end of the inserter (Fig. 14).*

Fig. 8

Fig. 9

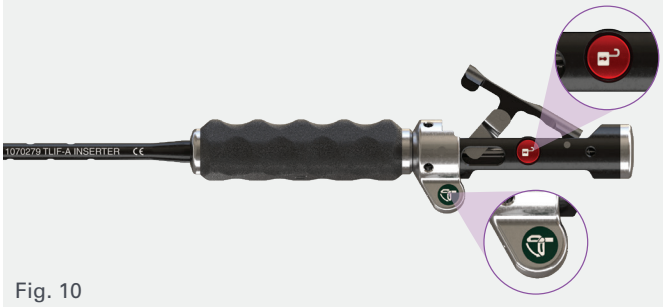


Fig. 10

Fig. 11

Fig. 12

Fig. 13

Fig. 14

Step 6

Implant insertion

With the inserter in the lock position, insert the implant into the disc space at a 30° oblique trajectory to achieve proper placement and crossing of midline *(Fig. 15)*.

Once the distal tip of the implant is at the contralateral anterior annulus, proper depth has been achieved. Depress the paddle marked with the green pivot symbol to place the inserter into pivot mode. The interbody will remain connected to the inserter but will now be free to pivot up to 90° from the distal portion of the inserter. Position hand and inserter handle medial to assist with pivoting the implant *(Fig. 16)*. Continue to impact until the implant reaches the anterior one-third of the disc space.

To release the implant from the inserter, depress the red button etched with the unlock symbol. The inserter can now be disengaged from the implant *(Fig. 17)*.

Note: *The "M" laser marking on the inserter should face medial and the "L" laser marking should face lateral.*

Note: *Confirm the interbody selection is sized line-to-line with selected trial.*

Reminder: *The offset inserter's torsion lock rotates the opposite direction of the inline inserter. The surgeon will "pull" the torsion lock laterally instead of "push" (Fig. 18).*

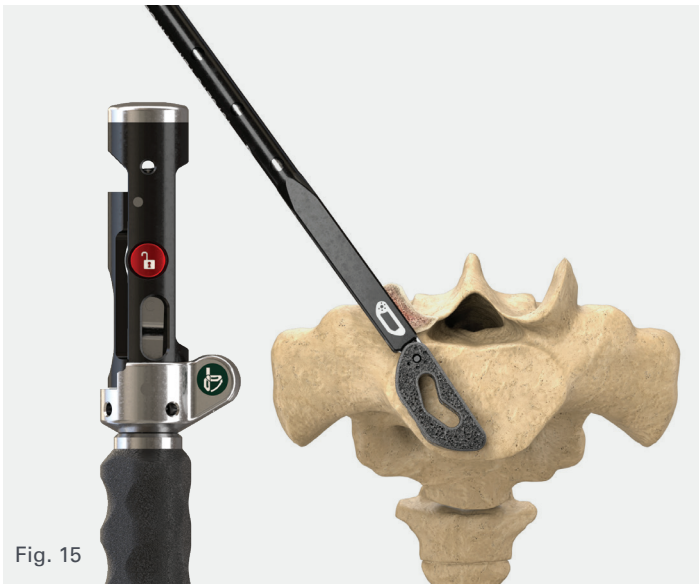


Fig. 15

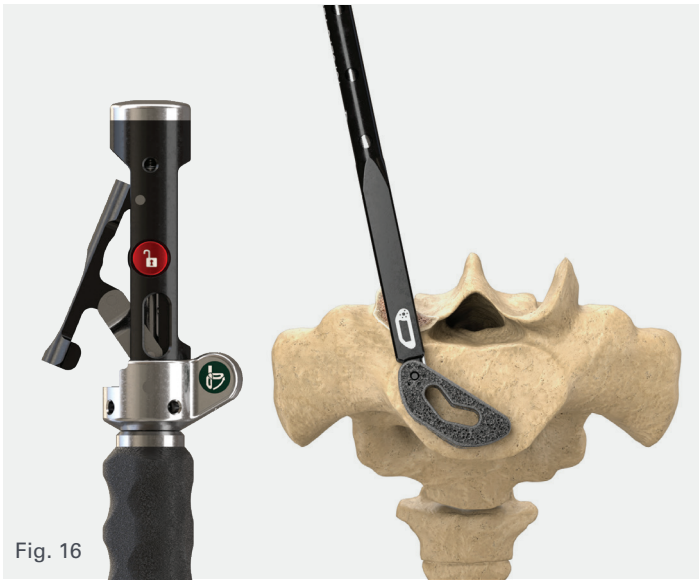


Fig. 16

Fig. 18

Fig. 17

Step 7

Implant manipulation

If further manipulation is required, utilize either the straight or forked tamp. Place either tamp into the inserter feature of the implant and mallet until the implant is in the ideal position against the anterior annulus *(Fig. 19)*.

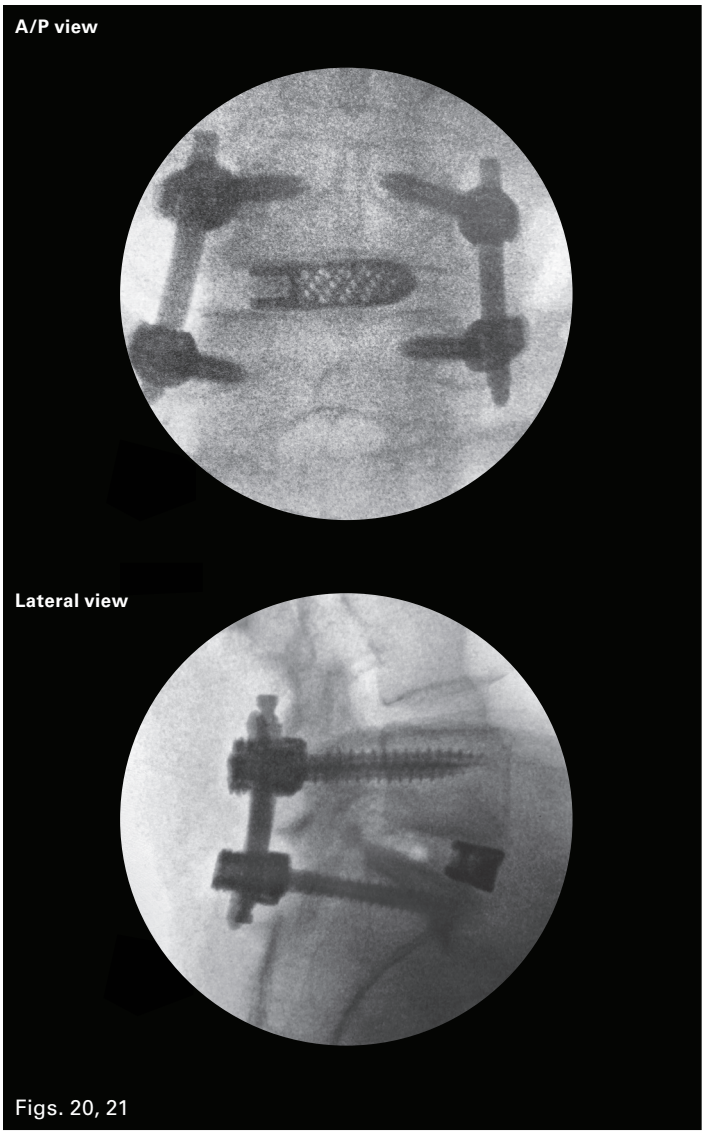
Note: *Tamps should not be used on the body lattice.*

Step 8

Final placement and graft delivery

Final position of the implant can be confirmed under fluoroscopy *(Figs. 20, 21)*. The implant should rest in the anterior third of the disc space. Graft material can then be filled posteriorly, utilizing the maximum access surgery (MAS) graft delivery system *(Fig. 22)*.

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 bone graft, the distal tip of the graft tube is inserted into the disc space, 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).*



Figs. 20, 21

Fig. 19

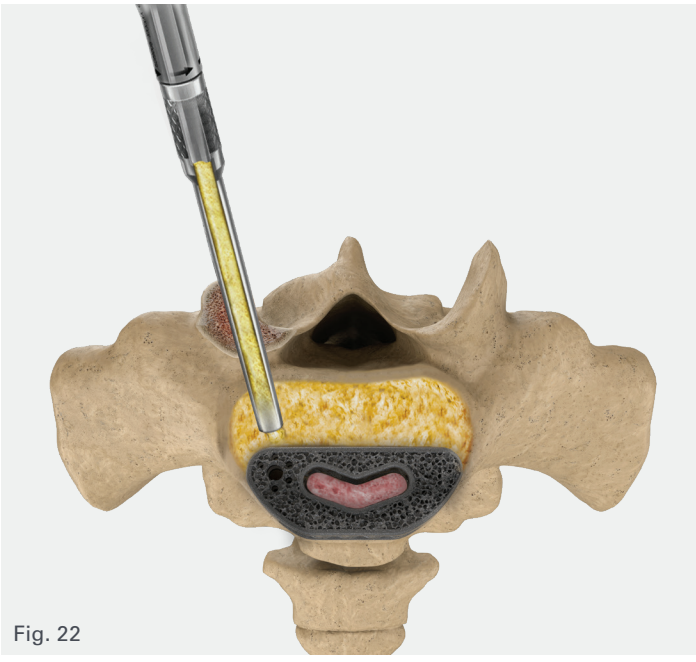


Fig. 22

Step 9

Fixation

Place desired fixation option, such as Reline *(Fig. 23)*. See the supplemental fixation system IFU and surgical technique guide for instructions.

Step 10

Implant removal

For implant removal, either inserter may be used. Confirm that the inserter is in the unlocked position and orient the removal clip so the distal clip stop is positioned through the proximal gap between the lever and lever housing. The proximal end of the clip should align with the Hudson adapter threads on the proximal end of the inserter. Thread the adapter through the clip and into the inserter to secure the clip *(Fig. 24)*.

Keeping the inserter in the unlocked position, place the inserter tip into the engagement feature of the implant. Depress the lever until it transitions from unlock to pivot. Confirmation of a successful transition will be audible, tactile, and visual (reference the position pin). Attach a slap-hammer and remove.

Note: *Always use removal clip during implant removal to prevent the inserter from re-engaging the implant in the locked position.*

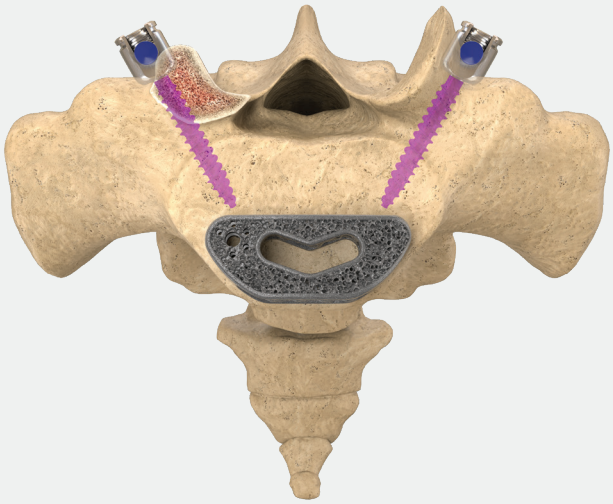


Fig. 23

Fig. 24

Modulus TLIF-A with MAS Midline technique

Step 1

Decompression and discectomy

Reference the MAS PLIF and Reline MAS Midline surgical technique guides for steps leading to interbody implantation.

Step 2

Sizing

Once the discectomy at the desired level has been completed, determine the desired height and width required, using the Modulus TLIF-A pivoting trials.

Select a trial shaft and insert it into the distal end of the trial inserter confirming the trial shaft is in the appropriate orientation by referencing the laser mark on the distal end of the trial inserter. Rotate the thumbwheel on the trial inserter clockwise to bring the trial to the locked position for initial insertion *(Fig. 1)*.

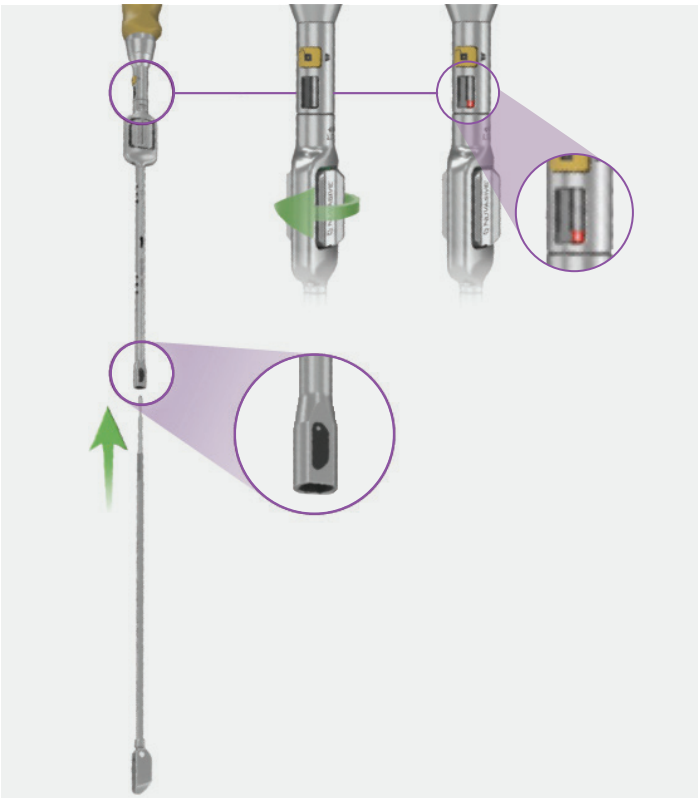


Fig. 1

Note: *Confirm that the thumbwheel is fully rotated until a hard stop is felt prior to impacting the trial. A red indicator will appear in the proximal window of the trial inserter to indicate the trial body is in the locked position. The red indicator will disappear when the trial body is able to pivot.* ***Only impact on the trial inserter when the trial tip is locked in the inline position and the red indicator is visible. When removing the trial from the disc space, confirm that the red indicator is not visible.***

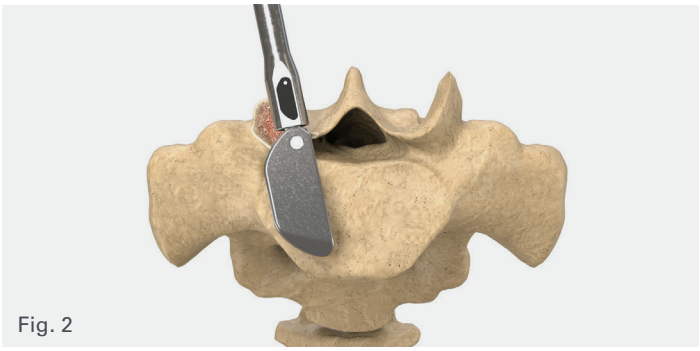


Fig. 2

Impact the assembled trial inserter into the disc space at a slight angle *(Fig. 2)*. Once the posterior aspect of the trial is past the posterior margin of the vertebral body, rotate the thumbwheel counter clockwise to bring the assembled trial inserter to the pivot position. The trial will remain connected to the trial inserter but will now be free to pivot up to 90° from the distal portion of the inserter. Position hand and trial inserter handle medial to assist with pivoting the trial body and impact until trial body is positioned to the anterior one-third of the disc space *(Fig. 3)*.

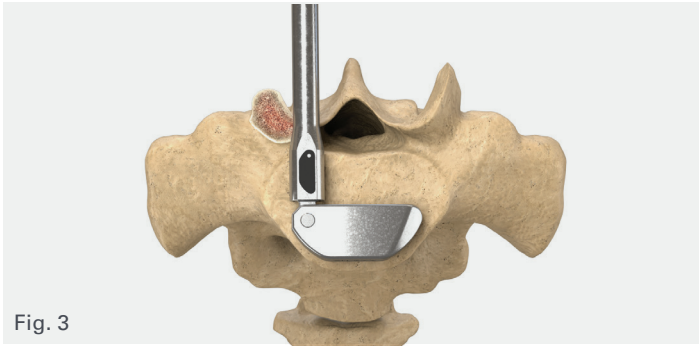


Fig. 3

Sizing (cont.)

Sequentially increase the trial size until the desired disc height is established. Use A/P and lateral fluoro to confirm the proper placement and trajectory.

Note: *Trial body height, width, length and lordosis match the true height, width, length and lordosis of the implant. The "M" laser marking on the trial should face medial and the "L" laser marking should face lateral.*

Note: *To disassemble the trial shaft from the trial inserter, depress the gold button on the trial inserter and rotate the thumbwheel counter clockwise. The trial shaft will begin to release from the trial inserter. Continue rotating the thumbwheel until the trial shaft is fully released (Fig. 4).*

Tip: *Confirm the trial is articulated 90° when a small radiolucent gap is visible between the distal end of the trial inserter shaft and articulated trial body (Fig. 5).*

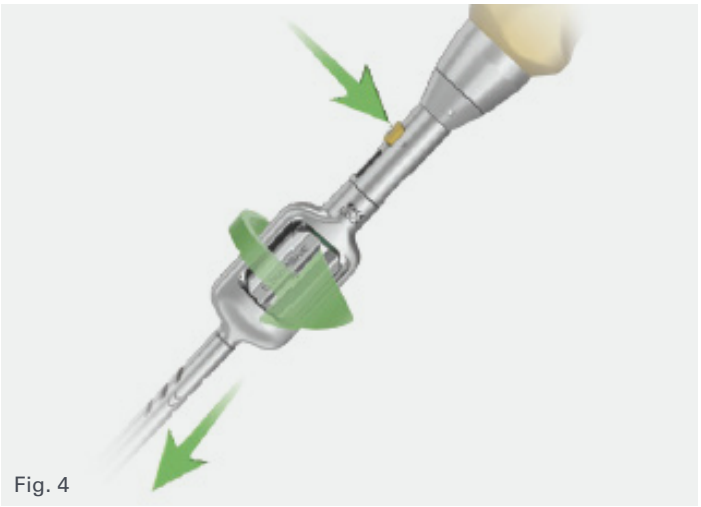


Fig. 4

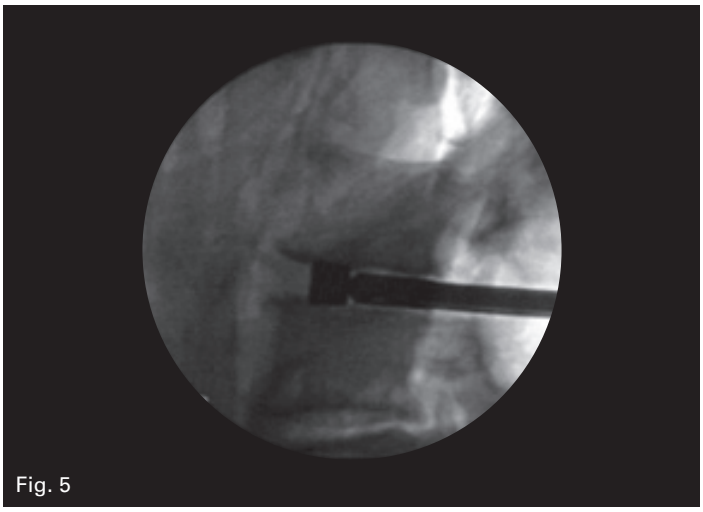


Fig. 5

Step 3

Inserter selection

Select an inserter. For this example, the inline inserter is used. Reference step five above for inserter and implant attachment of the MAS TLIF 2 technique.

Step 4

Implant insertion

With the inserter in the lock position, insert the implant into the disc space at a slight angle *(Fig. 6)*.

Once the posterior aspect of the implant is past the posterior margin of the vertebral body, proper depth has been achieved. Push the rotating paddle to place the inserter into pivot mode. The implant will remain connected to the inserter but will now be free to pivot up to 90° from the distal portion of the inserter. The contour of the ipsilateral annulus will assist with pivoting the implant during impaction *(Fig. 7)*. Position hand and inserter handle medial and continue impaction until the implant is positioned in the anterior one-third of the disc space and bisects the spinous process confirmed by lateral and A/P fluoroscopy.

To release the implant from the inserter, depress the red button etched with the unlock symbol. The inserter can now be disengaged from the implant *(Fig. 8)*.

Tip: *Confirm the interbody selection is sized line-to-line with selected trial.*

Reminder: *The offset inserter's torsion lock rotates the opposite direction than the Inline Inserter. The surgeon will pull the torsion lock flange laterally instead of push (Fig. 9).*

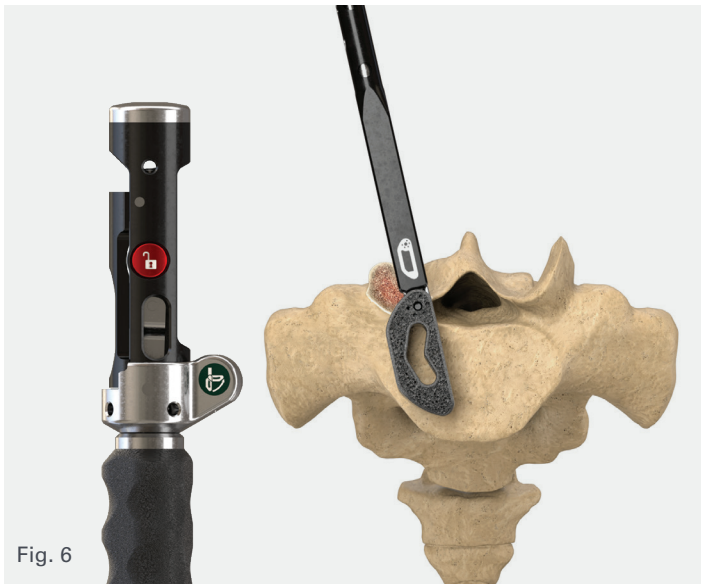


Fig. 6

Fig. 7

Fig. 9

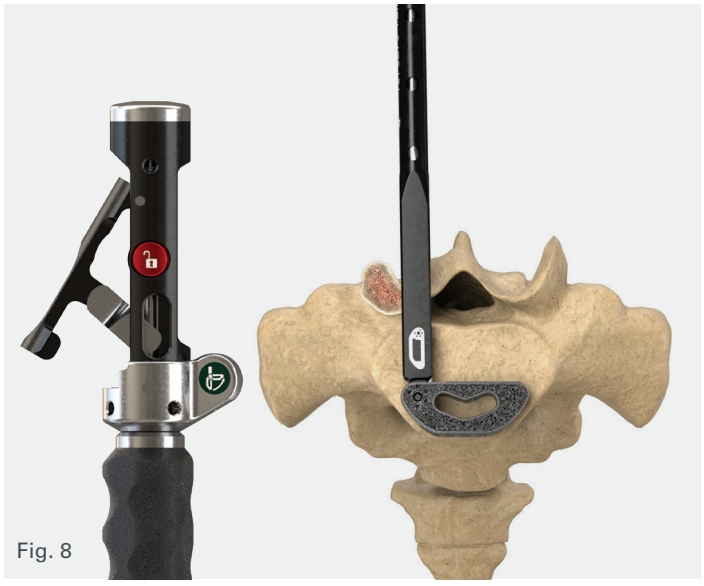


Fig. 8

Step 5

Implant manipulation

If further manipulation is required, utilize either the straight or forked tamp. Place either tamp into the inserter feature of the implant and mallet until the implant is in the ideal position against the anterior annulus *(Fig. 10)*.

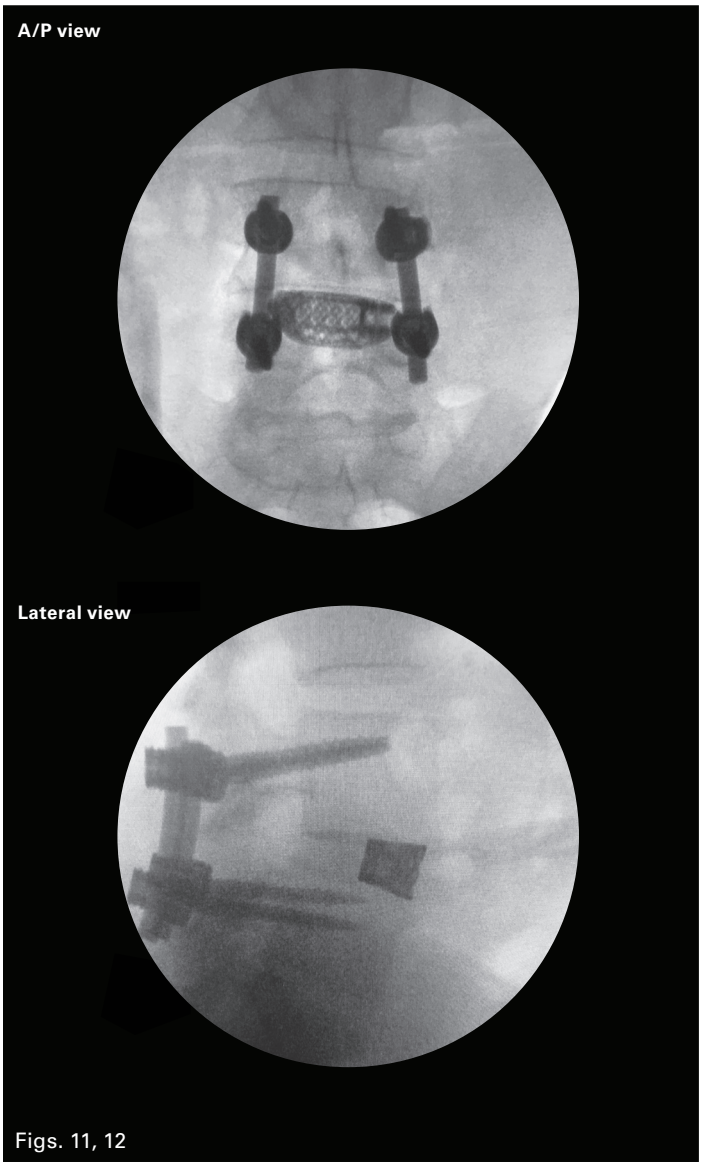
Note: *Tamps should not be used on the body lattice.*

Step 6

Final placement and graft delivery

Final position of the implant can be confirmed under fluoroscopy *(Figs. 11, 12)*. The implant should rest in the anterior third of the disc space. Graft material can then be filled posteriorly, utilizing the MAS *Graft Delivery System (Fig. 13)*.

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 bone graft, the distal tip of the graft tube is inserted into the disc space, 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).*



Figs. 11, 12

Fig. 10

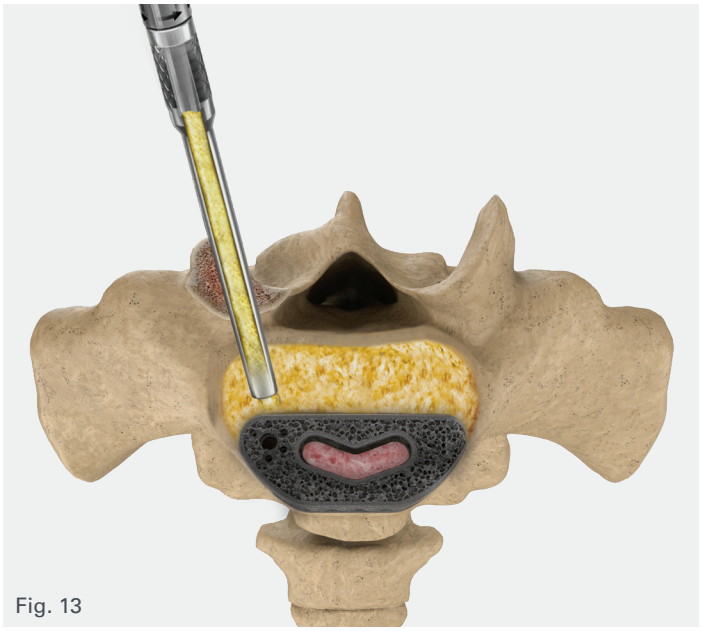


Fig. 13

Step 7

Fixation

Reference the Reline MAS Midline surgical technique for completing the construct *(Fig. 14).*

Step 8

Implant removal

For implant removal, either inserter may be used. Confirm that the inserter is in the unlocked position and orient the removal clip so the distal clip stop is positioned through the proximal gap between the lever and lever housing. The proximal end of the clip should align with the Hudson adapter threads on the proximal end of the inserter. Thread the adapter through the clip and into the inserter to secure the clip *(Fig. 15).*

Keeping the inserter in the unlocked position, place the inserter tip into the engagement feature of the implant. Depress the lever until it transitions from unlock to pivot. Confirmation of a successful transition will be audible, tactile and visual (reference the position pin). Attach a slap-hammer and remove.

Note: *Always use removal clip during implant removal to prevent the inserter from reengaging the implant in the locked position.*

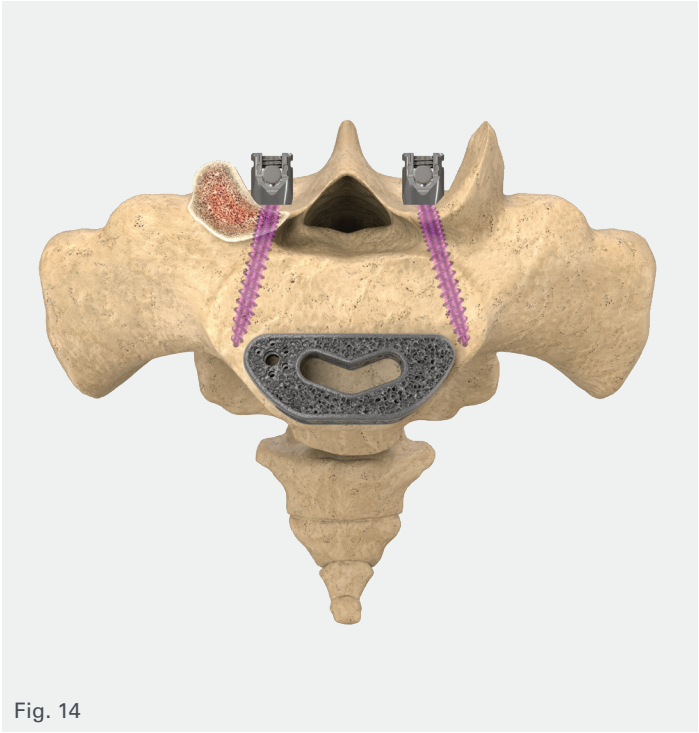


Fig. 14

Fig. 15

Modulus TLIF-A system

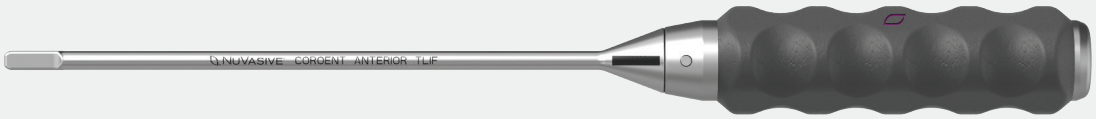
Instruments

Modulus TLIF-A inserter, inline

Modulus TLIF-A inserter, offset

Modulus TLIF-A removal clip

Straight tamp



Modulus TLIF-A forked tamp

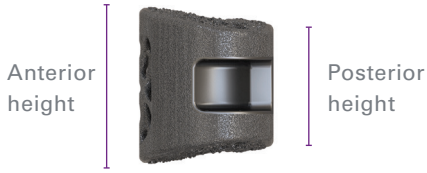
Graft packer

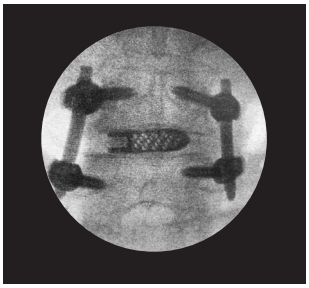
Modulus pivoting trial inserter

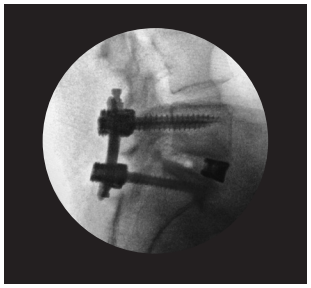
Modulus pivoting trial

Hudson adapter

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	9x30 mm	11x30 mm	14x30 mm	11x34 mm	14x34 mm	11x40 mm	14x40 mm
8°	+1.5 to PH	+1.5 to PH	+2 to PH	+1.5 to PH	+2 to PH	+1.5 to PH	+2 to PH
15°	–	+3 to PH	–	+3 to PH	+3.5 to PH	+3 to PH	+3.5 to PH

Core configuration

Catalog no.	HxWxL	Posterior height (mm)	Anterior height (mm)	Graft aperture volume (cc)	Open architecture volume (cc)*
1089308P2	8x9x30 mm, 8°	8	9.5	0.20	0.84
1099308P2	9x9x30 mm, 8°	9	10.5	0.22	0.92
1109308P2	10x9x30 mm, 8°	10	11.5	0.25	1.02
1119308P2	11x9x30 mm, 8°	11	12.5	0.27	1.16
1129308P2	12x9x30 mm, 8°	12	13.5	0.29	1.30
1081308P2	8x11x30 mm, 8°	8	9.5	0.31	1.11
1091308P2	9x11x30 mm, 8°	9	10.5	0.35	1.23
1101308P2	10x11x30 mm, 8°	10	11.5	0.38	1.32
1111308P2	11x11x30 mm, 8°	11	12.5	0.42	1.52
1121308P2	12x11x30 mm, 8°	12	13.5	0.45	1.67
1081305P2	8x11x30 mm, 15°	8	11	0.33	1.19
1091305P2	9x11x30 mm, 15°	9	12	0.37	1.32
1101305P2	10x11x30 mm, 15°	10	13	0.40	1.42
1101305P2	11x11x30 mm, 15°	11	14	0.44	1.67
1121305P2	12x11x30 mm, 15°	12	15	0.48	1.77

**Includes graft aperture*

XL configuration

Catalog co.	HxWxL	Posterior height (mm)	Anterior height (mm)	Graft aperture volume (cc)	Open architecture volume (cc)*
1081348P2	8x11x34 mm, 8°	8	9.5	0.41	1.39
1101348P2	10x11x34 mm, 8°	10	11.5	0.50	1.68
1121348P2	12x11x34 mm, 8°	12	13.5	0.59	2.07
1081345P2	8x11x34 mm, 15°	8	11	0.44	1.50
1101345P2	10x11x34 mm, 15°	10	13	0.53	1.80
1121345P2	12x11x34 mm, 15°	12	15	0.62	2.18
1084345P2	8x14x34 mm, 15°	8	11.5	0.70	2.13
1104345P2	10x14x34 mm, 15°	10	13.5	0.82	2.54
1124345P2	12x14x34 mm, 15°	12	15.5	0.96	3.07
1081408P2	8x11x40 mm, 8°	8	9.5	0.56	1.80
1101408P2	10x11x40 mm, 8°	10	11.5	0.67	2.14
1121408P2	12x11x40 mm, 8°	12	13.5	0.80	2.60
1084405P2	8x14x40 mm, 15°	8	11.5	0.94	2.47
1104405P2	10x14x40 mm, 15°	10	13.5	1.10	3.18
1124405P2	12x14x40 mm, 15°	12	15.5	1.30	3.79

Outlier configuration

Catalog no.	HxWxL	Posterior height (mm)	Anterior height (mm)	Graft aperture volume (cc)	Open architecture volume (cc)*
1084308P2	8x14x30 mm, 8°	8	10	0.49	1.58
1104308P2	10x14x30 mm, 8°	10	12	0.60	1.91
1124308P2	12x14x30 mm, 8°	12	14	0.71	2.40
1084348P2	8x14x34 mm, 8°	11	12.5	0.63	1.90
1104348P2	10x14x34 mm, 8°	12	13.5	0.77	2.31
1124348P2	12x14x34 mm, 8°	8	9.5	0.91	2.86

**Includes graft aperture*

Catalog

Modulus TLIF-A core instrument set (MDLUSTLIFACOREINS)	
Description	Catalog no.
Generic NuVasive tray lid	1660500
Modulus inserter, dism trial	D1265965
Modulus pivoting trial, 8x9x30 mm, 8°	1265861
Modulus pivoting trial, 9x9x30 mm, 8°	1265862
Modulus pivoting trial, 10x9x30 mm, 8°	1265863
Modulus pivoting trial, 11x9x30 mm, 8°	1265864
Modulus pivoting trial, 12x9x30 mm 8°	1265865
Modulus pivoting trial, 8x11x30 mm, 8°	1265873
Modulus pivoting trial, 9x11x30 mm, 8°	1265874
Modulus pivoting trial, 10x11x30 mm, 8°	1265875
Modulus pivoting trial, 11x11x30 mm, 8°	1265876
Modulus pivoting trial, 12x11x30 mm, 8°	1265877
Modulus pivoting trial, 8x11x30 mm, 15°	1265885
Modulus pivoting trial, 9x11x30 mm, 15°	1265967
Modulus pivoting trial, 10x11x30 mm, 15°	1265886
Modulus pivoting trial, 11x11x30 mm, 15°	1265968
Modulus pivoting trial, 12x11x30 mm, 15°	1265887
Modulus TLIF-A top, core ins case	1070266
Modulus TLIF-A, inserter	1070279
Modulus TLIF-A inserter, offset	1070275
Universal adapter, threaded hudson	5001901
Modulus TLIF-A removal clip	1070265
Coroent ant TLIF tamp	5195115
Modulus TLIF-A tamp, forked	1070277
Modulus TLIF-A graft packer	1070278
Modulus TLIF-A bottom, core ins case	1070267
Modulus TLIF-A base, core ins case	1070268
Modulus interbody system IFU	9402506

Modulus TLIF-A core implant set (MDLUSTLIFACOREIMP)	
Description	Catalog no.
Universal pelican case, SP 2 sm 40CT	1704726
MDLUSTLIFACOREIMP–sterile IMP size key	9000004
Modulus TLIF-A, 8x9x30 mm, 8°	1089308P2
Modulus TLIF-A, 9x9x30 mm, 8°	1099308P2
Modulus TLIF-A, 10x9x30 mm, 8°	1109308P2
Modulus TLIF-A, 11x9x30 mm, 8°	1119308P2
Modulus TLIF-A, 12x9x30 mm, 8°	1129308P2
Modulus TLIF-A, 8x11x30 mm, 8°	1081308P2
Modulus TLIF-A, 9x11x30 mm, 8°	1091308P2
Modulus TLIF-A, 10x11x30 mm, 8°	1101308P2
Modulus TLIF-A, 11x11x30 mm, 8°	1111308P2
Modulus TLIF-A, 12x11x30 mm, 8°	1121308P2
Modulus TLIF-A, 8x11x30 mm, 15°	1081305P2
Modulus TLIF-A, 9x11x30 mm, 15°	1091305P2
Modulus TLIF-A, 10x11x30 mm, 15°	1101305P2
Modulus TLIF-A, 11x11x30 mm, 15°	1111305P2
Modulus TLIF-A, 12x11x30 mm, 15°	1121305P2
Modulus interbody system IFU	9402506

Modulus TLIF-A XL instrument set (MDLUSTLIFAXLINS)	
Description	Catalog no.
Generic NuVasive tray lid	1660362
Modulus inserter, dism trial	D1265965
Modulus pivoting trial, 8x11x34 mm, 8°	1265889
Modulus pivoting trial, 10x11x34 mm, 8°	1265891
Modulus pivoting trial, 12x11x34 mm, 8°	1265893
Modulus pivoting trial, 8x11x34 mm, 15°	1265901
Modulus pivoting trial, 10x11x34 mm, 15°	1265902
Modulus pivoting trial, 12x11x34 mm, 15°	1265903
Modulus pivoting trial, 8x14x34 mm, 15°	1265947
Modulus pivoting trial, 10x14x34 mm, 15°	1265948
Modulus pivoting trial, 12x14x34 mm, 15°	1265949
Modulus pivoting trial, 8x11x40 mm, 8°	1265905
Modulus pivoting trial, 10x11x40 mm, 8°	1265907
Modulus pivoting trial, 12x11x40 mm, 8°	1265909
Modulus pivoting trial, 8x14x40 mm, 15°	1265961
Modulus pivoting trial, 10x14x40 mm, 15°	1265962
Modulus pivoting trial, 12x14x40 mm, 15°	1265963
Modulus TLIF-A top, XL ins case	1070269
Modulus TLIF-A, inserter	1070279
Modulus TLIF-A inserter, offset	1070275
Modulus TLIF-A removal clip	1070265
Universal adapter, threaded Hudson	5001901
Coroent ant TLIF tamp	5195115
Modulus TLIF-A tamp, forked	1070277
Modulus TLIF-A graft packer	1070278
Modulus TLIF-A bottom, XL ins case	1070270
Modulus TLIF-A base, XL ins case	1070271
Modulus interbody system IFU	9402506

Modulus TLIF-A XL implant set (MDLUSTLIFAXLIMP)	
Description	Catalog no.
Universal pelican case, SP 2 sm 40CT	1704726
Modulus TLIF-A XL IMP size key	9000005
Modulus TLIF-A, 8x11x34 mm, 8°	1081348P2
Modulus TLIF-A, 10x11x34 mm, 8°	1101348P2
Modulus TLIF-A, 12x11x34 mm, 8°	1121348P2
Modulus TLIF-A, 8x11x34 mm, 15°	1081345P2
Modulus TLIF-A, 10x11x34 mm, 15°	1101345P2
Modulus TLIF-A, 12x11x34 mm, 15°	1121345P2
Modulus TLIF-A, 8x14x34 mm, 15°	1084345P2
Modulus TLIF-A, 10x14x34 mm, 15°	1104345P2
Modulus TLIF-A, 12x14x34 mm, 15°	1124345P2
Modulus TLIF-A, 8x11x40 mm, 8°	1081408P2
Modulus TLIF-A, 10x11x40 mm, 8°	1101408P2
Modulus TLIF-A, 12x11x40 mm, 8°	1121408P2
Modulus TLIF-A, 8x14x40 mm, 15°	1084405P2
Modulus TLIF-A, 10x14x40 mm, 15°	1104405P2
Modulus TLIF-A, 12x14x40 mm, 15°	1124405P2
Modulus interbody system IFU	9402506

Modulus TLIF-A outlier trial set (MDLUSTLIFAOUTTRIAL)–optional	
Description	Catalog no.
NuVasive generic tray lid-half	1660363
Modulus pivoting trial, 8x14x30 mm, 8°	1265919
Modulus pivoting trial, 10x14x30 mm, 8°	1265921
Modulus pivoting trial, 12x14x30 mm, 8°	1265923
Modulus pivoting trial, 8x14x34 mm, 8°	1265935
Modulus pivoting trial, 10x14x34 mm, 8°	1265937
Modulus pivoting trial, 12x14x34 mm, 8°	1265939
Pin mat	1265978
Modulus TLIF-A outlier trial tray	1265971
Modulus interbody system IFU	9402506

Modulus TLIF-A outlier implant set (MDLUSTLIFAOUTIMP)–optional	
Description	Catalog no.
Universal pelican case, SP 2.0 12CT	1704725
MDLUSTLIFAOUTIMP-sterile IMP size key	9000006
Modulus TLIF-A, 8x14x30 mm, 8°	1084308P2
Modulus TLIF-A, 10x14x30 mm, 8°	1104308P2
Modulus TLIF-A, 12x14x30 mm, 8°	1124308P2
Modulus TLIF-A, 8x14x34 mm, 8°	1084348P2
Modulus TLIF-A, 10x14x34 mm, 8°	1104348P2
Modulus TLIF-A, 12x14x34 mm, 8°	1124348P2
Modulus interbody system IFU	9402506

Instructions for use

DESCRIPTION

The 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 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), 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.

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 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.

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.

POTENTIAL ADVERSE EVENTS AND COMPLICATIONS

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 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: TR9604724.
3. Preclinical data on file. Data may not be representative of clinical results. TR 9603905.
4. Preclinical data on file. Data may not be representative of clinical results. TR 9604781.
5. 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.
6. Preclinical data on file. Data may not be representative of clinical results. TR 9603972.

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