MODULUS ALIF

Surgical 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 ALIF. 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.

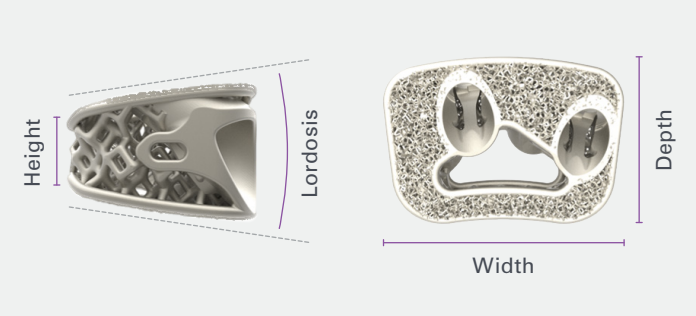
This surgical technique guide provides information supplemental to information provided in the individual system instructions for use (IFU) regarding the products referenced herein.

Contents

Modulus ALIF overview

Sizing

- **Range of posterior heights:** 6–12 mm in 2 mm increments
- **Lordosis options:** 10°, 15° and 20° standalone; 25° and 30° require supplemental posterior fixation

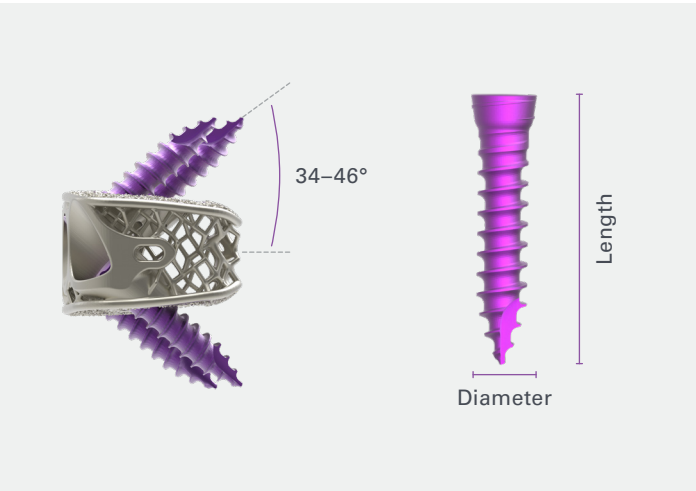


Footprint	Posterior height	Lordosis
34x24 mm		
38x28 mm	6, 8, 10, 12 mm*	10°, 15°, 20°, 25°, 30°
42x32 mm		
34x28 mm	6, 8, 10 mm	10°, 15°, 20°

*30° is not available in 12 mm height

Bolts

- Screws have 12° cone of variability during insertion.
- Screw angulation trajectory can range 34–46° from midline.



Diameter	Length**
5.0 mm (magenta) **6.0 mm (green)**	15 mm
	17.5 mm
	20 mm
	22.5 mm
	25 mm
	27.5 mm
	30 mm

**Length measurement indicates length of screw in bone

Instrumentation overview

Inserters

Straight

Antero lateral grasping

Cranial-caudal

Lateral footed

Drivers

Straight

U-joint

Ball tipped

U-joint ball

Fixed angle

U-joint removal

Removal

Presurgical preparation

Equipment requirements

To perform the anterior lumbar interbody fusion (ALIF) procedure with Modulus ALIF, the following patient positioning supplies, instruments, implants and fixation options are required.

Retractor/access

Supine ALIF approach

- MASALIFACCESS
- LATALIFARM (x2)

XALIF approach

- XALIFACCESS
- LATALIFARM
- M4AARM

Disc prep

- ALIFDISCPREP1
- ALIFDISCPREP2

Core Modulus ALIF sets

Modulus ALIF instruments

- AMSALIFINS1
- AMSALIFINS2
- MDLUSALIFAWLNTRIAL

Modulus ALIF interbodies (sterile packed)

- MDLUSALIFIMP3424
- MDLUSALIFIMP3828
- MDLUSALIFIMP4232

Modulus ALIF bolts (non-sterile)

- MDLUSALIFBOLT

Disposables

- MAS ALIF access kit (catalog #6973450)

Fixation

- Posterior fixation of choice

Biologics

- Autogenous and/or allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft

Reference the applicable technique guide(s) or reference manual(s), and/or IFU for additional important labeling information. IFUs can be referenced at ***nuvasive.com/eIFU***

Modulus ALIF surgical technique

The below technique refers to the Supine ALIF technique.

Step 1

Patient positioning and OR setup

Room setup

Place the patient in the supine position on the radiolucent surgical table centered in the room *(Fig. 1)*.

Patient preparation

Mark out the operative levels on the skin of the patient to locate the proper skin incision locations. Finally, drape the patient using standard drapes and techniques, and place the articulating arms onto the bed *(Fig. 2)*.

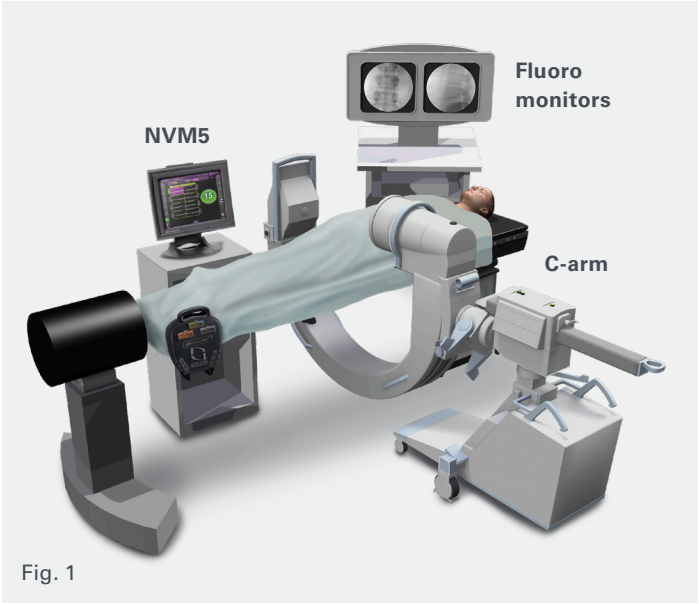


Fig. 1

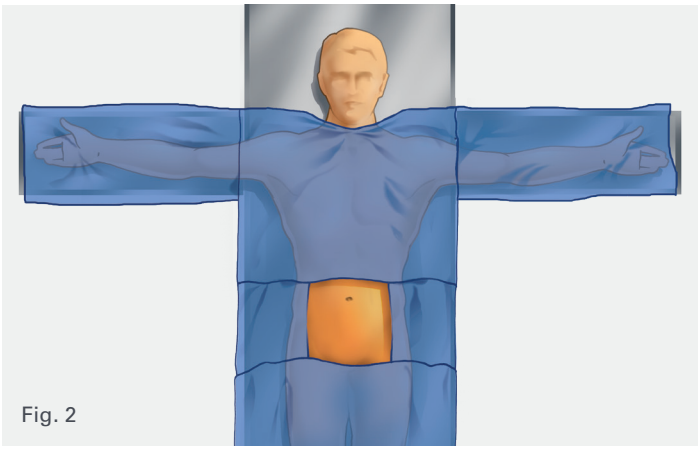


Fig. 2

Step 2

Access

Utilize the Supine ALIF retractor (MASALIFACCESS) *(Fig. 3)* set to perform a Supine ALIF exposure approach to the lumbar spine, per surgeon preference. Expose the intervertebral disc such that there is sufficient space on either side of the vertebral midline.

Radiographically confirm disc midline location *(Fig. 4)*.


Fig. 3


Fig. 4

Step 3

Annulotomy and disc removal

The annulus is incised and a conventional discectomy is performed. Cobbs, pituitaries, curettes, disc cutters, end plate scrapers and other conventional disc preparation instruments can be used to thoroughly evacuate the disc, release the contralateral annulus and prepare the endplates for fusion *(Fig. 5)*.

Note: *The Modulus ALIF system also has an initiator to help prepare the disc space before trialing (Fig. 6).*

- *Anterior height: 8 mm*
- *Lordosis: 15°*
- *Depth marking: 24 mm*

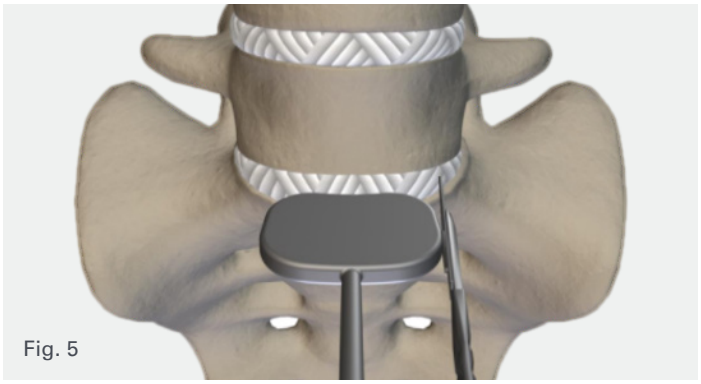


Fig. 5

Fig. 6

Step 4

Trialing

Connect the selected trial by aligning the distal cut outs to the inserter and spinning the thumbwheel clockwise to engage *(Fig. 7)*. Under lateral fluoroscopy, gently impact the trial into the disc space. Use sequential trialing within the disc space to help prevent endplate damage. Proper midline positioning of final trial placement should be verified using A/P fluoroscopy. Under lateral fluoroscopy, use the circle to verify orientation *(Fig. 8)*. Trialing is used to determine the desired sized Modulus ALIF interbody.

Note: *The trial is able to be attached direct anterior or at a 35° offset (Fig. 9).*

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

Fig. 7

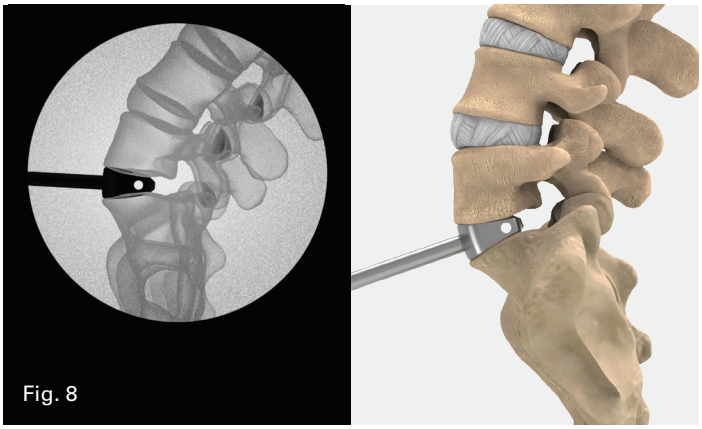


Fig. 8

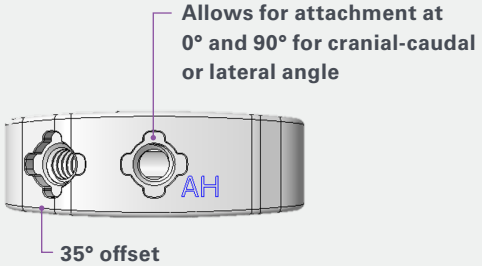


Fig. 9

Step 5

Implant placement

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

For surgical technique purposes, we will be describing the technique with the straight inserter *(Fig. 10*).

Next, select the straight inserter and attach the gold ALIF T-handle to the top of the inserter. Confirm the distal tongue of the inserter is in the unlocked position by aligning it vertically *(Figs. 11a, 11b)*.

Insert the distal insertion tongue into the center rectangular hole of the implant. Turn the thumbwheel clockwise until the implant is firmly locked onto the inserter. The surgeon may now insert the implant into the disc space.

Note: *The straight inserter allows for both pilot hole prep and bolt insertion with the inserter connected. The instrument is designed to leave the inserter connected to the implant, but can be removed prior if surgeon prefers.*

Step 6

Pilot hole preparation

When implant is in position, select the desired awl (straight or angled) based on the access to the bolt holes on the implant. Confirm the depth stop is in the locked position and place awl into the bolt pocket, confirming the distal portion is seated below the latch lock *(Fig. 12)*. Once it's properly positioned, the surgeon can move it to the active position and deploy the tip *(Fig. 13)*.

The awl has variable angulation from 34–46° *(Fig. 14)*. It is recommended to angle the awl flush against the bolt tube to allow for the maximum angulation of 46°. Confirm depth and trajectory on lateral fluoro imaging.

Fig. 10

Unlocked
Distal tip vertical

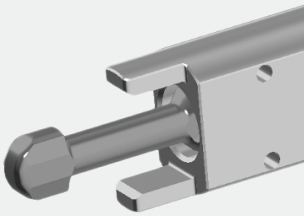


Fig. 11a

Locked
Distal tip horizontal

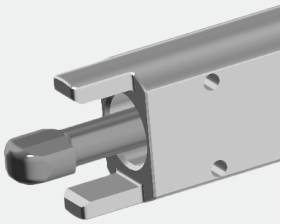


Fig. 11b

Confirm distal portion of the awl is seated below the latch lock.

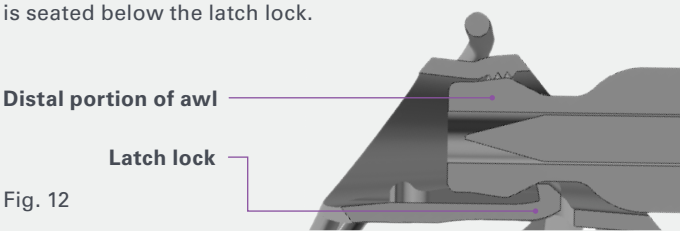


Fig. 12

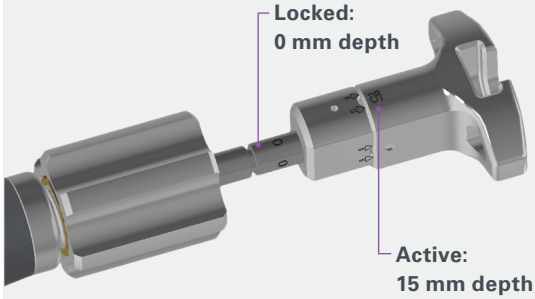


Fig. 13

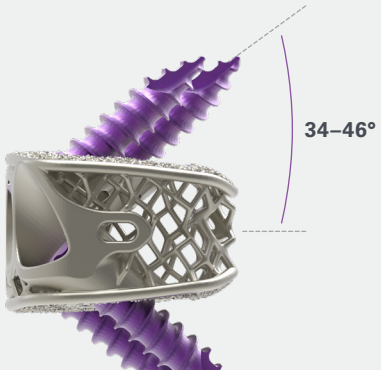


Fig. 14

Pilot hole preparation (cont.)

Both straight *(Fig. 15a)* and angled *(Fig. 15b)* awls have a threaded backout feature for controlled removal of awl tip.

Note: *The awl is designed to perforate the cortex of bone and enable self-drilling/self-tapping bolts to pull into bone with minimal effort. The length of the awl in bone is 15 mm.*

Fig. 15a

Fig. 15b

Step 7

Bolt placement

Once the pilot hole is made, select the desired bolt driver (straight, angled or U-joint) *(Fig. 16)* and place desired handle (straight or T-handle) *(Fig. 17)* on the proximal end of the bolt driver shaft.

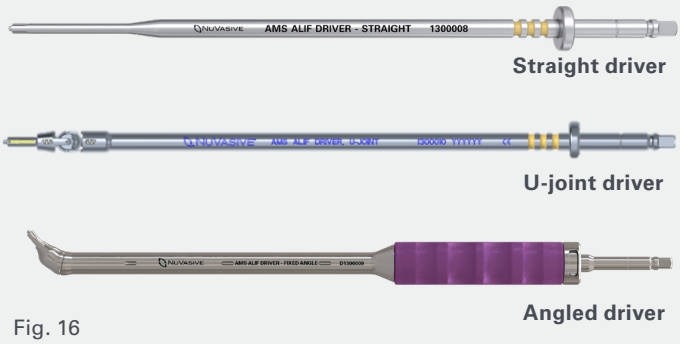


Fig. 16

Next, select desired length 5.0 mm bolt and confirm desired length with bolt measurement tool, found on the side of the bolt caddy. Attach the bolt to the driver with a stab and grab motion.

Carefully insert the bolt tip into the desired bolt hole and turn the handle clockwise to drive the bolt into bone past the latch lock anti-backout feature. Once the bolt head advances fully into the bolt pocket, the surgeon will feel a tactile torque spike, and it will become more difficult to advance the bolt. The bolt is now fully seated in the bolt pocket. Remove the driver and visually confirm the bolt is advanced beyond the latch lock *(Fig. 18)*.

Proceed with the same bolt placement technique for the remaining bolts.

Fig. 17

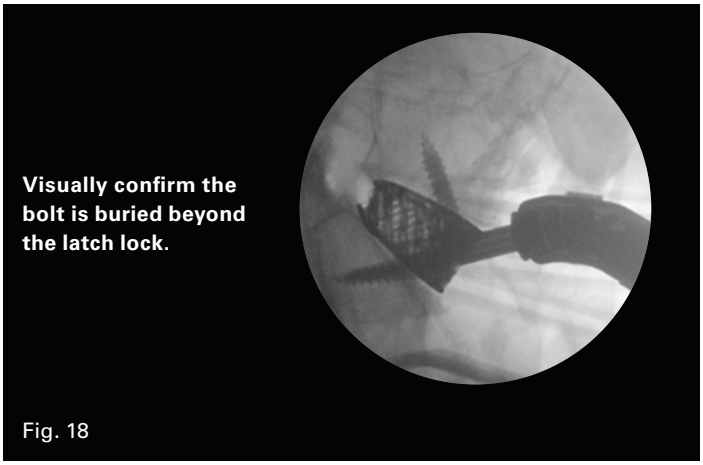


Fig. 18

Supplemental fixation

For 25–30° lordotic implants or constructs used with less than three bolts, complete the surgery with supplemental internal spinal fixation systems for use in the lumbar spine *(Fig. 19)*. See the system corresponding IFU and surgical technique for instructions.

Bolt removal

If bolt removal is necessary, utilize the straight *(Fig. 20a)* or U-joint *(Fig. 20b)* bolt removal tool denoted by red bands. Align the distal tip shaft with the bolt tri-lobe and turn it counterclockwise to engage. Turn the instrument handle counterclockwise until the bolt is removed from the implant. The distal cam surface of the driver will deflect the latch lock to allow removal. Repeat until all necessary bolts are removed.

Implant removal

If necessary, the interbody implant can be removed with the use of the implant inserters. The straight implant inserter is recommended. Reattach the inserter to the implant. Press the button on the top of the slap mallet to release the shaft. Slide the shaft into the T-handle and carefully back slap to remove the implant *(Fig. 21)*. Care should be exercised to avoid neural and vascular elements during removal.

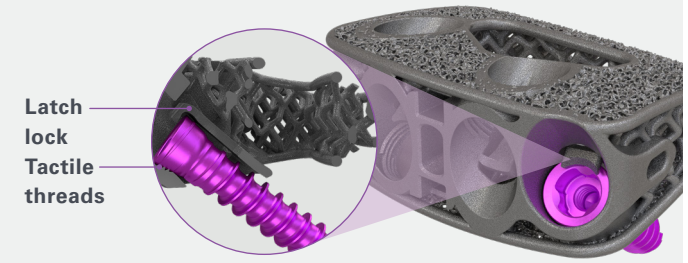


Fig. 19

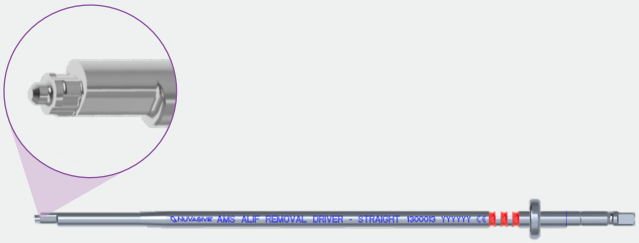


Fig. 20a

Fig. 20b

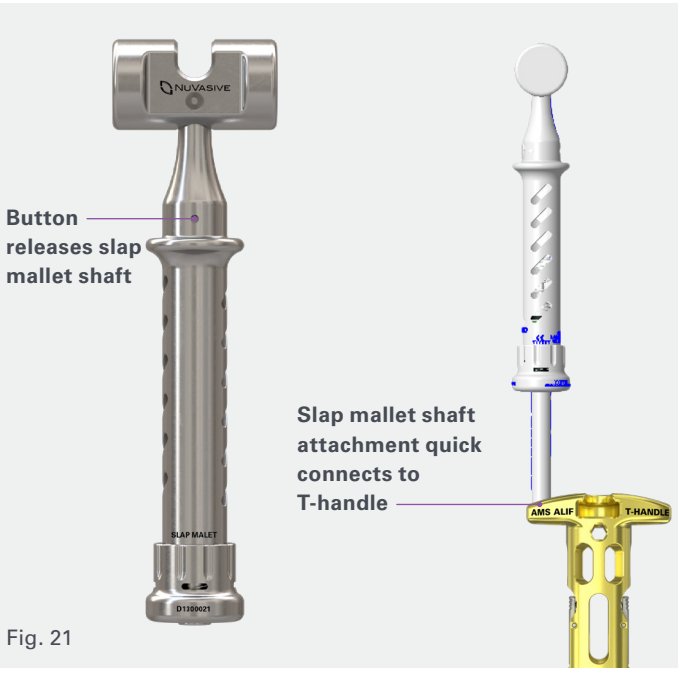


Fig. 21

Modulus ALIF system

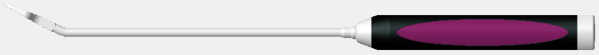
Initiator, straight

T-handle

Trial inserter, straight

Inserter, straight

Initiator, cranial-caudal



Trial inserter, cranial-caudal

Inserter, cranial-caudal

Inserter, Antero lateral (AL) grasping

Driver, straight

Driver, U-joint

Driver, ball end

Driver, U-joint ball end

T-handle

Handle, straight

Driver, fixed angle

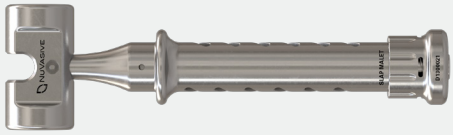
Removal driver, straight

Removal driver, U-joint

Inserter, lateral footed

Adapter, quick connect

Slap mallet



Awl, straight

Awl, angled

Catalog

Modulus ALIF interbody 34x24 mm set (MDLUSALIFIMP3424)

Description	Catalog no.	Qty.
Modulus ALIF, 6x34x24 mm, 10°	1921001P2	2
Modulus ALIF, 8x34x24 mm, 10°	1921002P2	2
Modulus ALIF, 10x34x24 mm, 10°	1921003P2	2
Modulus ALIF, 6x34x24 mm, 15°	1921005P2	2
Modulus ALIF, 8x34x24 mm, 15°	1921006P2	2
Modulus ALIF, 10x34x24 mm, 15°	1921007P2	1
Modulus ALIF, 6x34x24 mm, 20°	1921009P2	2
Modulus ALIF, 8x34x24 mm, 20°	1921010P2	2

Modulus ALIF interbody 42x32 mm set (MDLUSALIFIMP4232)

Description	Catalog no.	Qty.
Modulus ALIF, 6x42x32 mm, 10°	1921081P2	1
Modulus ALIF, 8x42x32 mm, 10°	1921082P2	2
Modulus ALIF, 10x42x32 mm, 10°	1921083P2	1
Modulus ALIF, 6x42x32 mm, 15°	1921085P2	1
Modulus ALIF, 8x42x32 mm, 15°	1921086P2	2
Modulus ALIF, 6x42x32 mm, 20°	1921089P2	1

Modulus ALIF interbody 38x28 mm set (MDLUSALIFIMP3828)

Description	Catalog no.	Qty.
Modulus ALIF, 6x38x28 mm, 10°	1921041P2	2
Modulus ALIF, 8x38x28 mm, 10°	1921042P2	2
Modulus ALIF, 10x38x28 mm, 10°	1921043P2	2
Modulus ALIF, 6x38x28 mm, 15°	1921045P2	2
Modulus ALIF, 8x38x28 mm, 15°	1921046P2	2
Modulus ALIF, 10x38x28 mm, 15°	1921047P2	1
Modulus ALIF, 6x38x28 mm, 20°	1921049P2	2
Modulus ALIF, 8x38x28 mm, 20°	1921050P2	2

Modulus ALIF bolt tray (MDLUSALIFBOLT)

Description	Catalog no.	Qty.
Modulus ALIF fixation bolt, Ø5.0x15 mm	1450150	6
Modulus ALIF fixation bolt, Ø5.0x17.5 mm	1450175	8
Modulus ALIF fixation bolt, Ø5.0x20 mm	1450200	8
Modulus ALIF fixation bolt, Ø5.0x22.5 mm	1450225	8
Modulus ALIF fixation bolt, Ø5.0x25 mm	1450250	6
Modulus ALIF fixation bolt, Ø6.0x15 mm	1460150	2
Modulus ALIF fixation bolt, Ø6.0x17.5 mm	1460175	2
Modulus ALIF fixation bolt, Ø6.0x20 mm	1460200	2
Modulus ALIF fixation bolt, Ø6.0x22.5 mm	1460225	2
Modulus ALIF fixation bolt, Ø6.0x25 mm	1460250	2

Advanced Materials Science (AMS) ALIF instrument tray 1 (AMSALIFINS1)

Description	Catalog no.	Qty.
NuVasive generic tray lid	8801300	1
AMS ALIF initiator	1300019	1
AMS ALIF trial inserter	D1300004	2
AMS ALIF inserter, straight	D1300000	2
AMS ALIF inserter, T-handle	1300095	2
AMS ALIF initiator, cranial-caudal	1300020	1
AMS ALIF trial inserter, cranial-caudal	D1300005	1
AMS ALIF inserter, cranial-caudal	D1300002	1
AMS ALIF inserter, AL grasping	D1300003	1

AMS ALIF instrument tray 2 (AMSALIFINS2)

Description	Catalog no.	Qty.
NuVasive generic tray lid	8801300	1
AMS ALIF driver, straight	1300008	2
AMS ALIF driver, straight ball end	1300011	1
AMS ALIF driver, U-joint	1300010	1
AMS ALIF driver, U-joint ball end	1300012	1
AMS ALIF driver, fixed angle	D1300009	1
MAS PLIF handle, ratcheting straight long	7070020	1
Universal T-handle	7070202	1
AMS ALIF removal driver, straight	1300013	1
AMS ALIF removal driver, U-joint	1300014	1
AMS ALIF adapter, quick connect	1882062	1
AMS ALIF slap mallet	D1300021	1

Modulus ALIF awl and trial tray (MDLUSAWLNTRIAL)

Description	Catalog no.	Qty.
Modulus ALIF trial, 6x34x24 mm, 10°, small	1982101	1
Modulus ALIF trial, 8x34x24 mm, 10°, small	1982102	1
Modulus ALIF trial, 10x34x24 mm, 10°, small	1982103	1
Modulus ALIF trial, 12x34x24 mm, 10°, small	1982104	1
Modulus ALIF trial, 6x34x24 mm, 15°, small	1982105	1
Modulus ALIF trial, 8x34x24 mm, 15°, small	1982106	1
Modulus ALIF trial, 10x34x24 mm, 15°, small	1982107	1
Modulus ALIF trial, 12x34x24 mm, 15°, small	1982108	1
Modulus ALIF trial, 6x34x24 mm, 20°, small	1982109	1

Modulus ALIF awl and trial tray (MDLUSAWLNTRIAL) (cont.)

Description	Catalog no.	Qty.
Modulus ALIF trial, 8x34x24 mm, 20°, small	1982110	1
Modulus ALIF trial, 10x34x24 mm, 20°, small	1982111	1
Modulus ALIF trial, 12x34x24 mm, 20°, small	1982112	1
Modulus ALIF trial, 6x38x28 mm, 10°, medium	1982141	1
Modulus ALIF trial, 8x38x28 mm, 10°, medium	1982142	1
Modulus ALIF trial, 10x38x28 mm, 10°, medium	1982143	1
Modulus ALIF trial, 12x38x28 mm, 10°, medium	1982144	1
Modulus ALIF trial, 6x38x28 mm, 15°, medium	1982145	1
Modulus ALIF trial, 8x38x28 mm, 15°, medium	1982146	1
Modulus ALIF trial, 10x38x28 mm, 15°, medium	1982147	1
Modulus ALIF trial, 12x38x28 mm, 15°, medium	1982148	1
Modulus ALIF trial, 6x38x28 mm, 20°, medium	1982149	1
Modulus ALIF trial, 8x38x28 mm, 20°, medium	1982150	1
Modulus ALIF trial, 10x38x28 mm, 20°, medium	1982151	1
Modulus ALIF trial, 12x38x28 mm, 20°, medium	1982152	1
Modulus ALIF trial, 6x42x32 mm, 10°, large	1982181	1
Modulus ALIF trial, 8x42x32 mm, 10°, large	1982182	1
Modulus ALIF trial, 10x42x32 mm, 10°, large	1982183	1
Modulus ALIF trial, 12x42x32 mm, 10°, large	1982184	1
Modulus ALIF trial, 6x42x32 mm, 15°, large	1982185	1
Modulus ALIF trial, 8x42x32 mm, 15°, large	1982186	1
Modulus ALIF trial, 10x42x32 mm, 15°, large	1982187	1
Modulus ALIF trial, 6x42x32 mm, 20°, large	1982189	1
Modulus ALIF trial, 8x42x32 mm, 20°, large	1982190	1
Modulus ALIF trial, 10x42x32 mm, 20°, large	1982191	1
Modulus ALIF trial, 12x42x32 mm, 20°, large	1982192	1
Modulus ALIF awl, straight	D1300006	1
Modulus ALIF awl, angled	D1300007	1
Modulus ALIF inserter, lateral footed	D1300001	1

AMS ALIF rigid drivers tray (AMSALIFRIGIDDRIVER)

Description	Catalog no.	Qty.
AMS ALIF rigid driver, straight	D1300096	1
AMS ALIF rigid driver, fixed angle	D1300097	1

Modulus ALIF hyperlordotic (HL) trial tray (MDLUSALIFHLTRIAL)

Description	Catalog no.	Qty.
Modulus ALIF HL trial caddy, HL trial tray	1300163	1
Modulus ALIF HL trial, 6x34x24 mm, 25°	1982113	1
Modulus ALIF HL trial, 8x34x24 mm, 25°	1982114	1
Modulus ALIF HL trial, 10x34x24 mm, 25°	1982115	1
Modulus ALIF HL trial, 6x34x24 mm, 30°	1982117	1
Modulus ALIF HL trial, 8x34x24 mm, 30°	1982118	1
Modulus ALIF HL trial, 10x34x24 mm, 30°	1982119	1
Modulus ALIF HL trial, 6x38x28 mm, 25°	1982153	1
Modulus ALIF HL trial, 8x38x28 mm, 25°	1982154	1
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Modulus ALIF HL trial, 6x38x28 mm, 30°	1982157	1
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Modulus ALIF HL trial, 8x42x32 mm, 25°	1982194	1
Modulus ALIF HL trial, 10x42x32 mm, 25°	1982195	1
Modulus ALIF HL trial, 6x42x32 mm, 30°	1982197	1
Modulus ALIF HL trial, 8x42x32 mm, 30°	1982198	1

Modulus ALIF 34x28 trial tray (MDLUSALIFTRIAL3428)

Description	Catalog no.	Qty.
Modulus ALIF trial, 6x34x28 mm, 10°, small deep	1982121	1
Modulus ALIF trial, 8x34x28 mm, 10°, small deep	1982122	1
Modulus ALIF trial, 10x34x28 mm, 10°, small deep	1982123	1
Modulus ALIF trial, 6x34x28 mm, 15°, small deep	1982125	1
Modulus ALIF trial, 8x34x28 mm, 15°, small deep	1982126	1
Modulus ALIF trial, 10x34x28 mm, 15°, small deep	1982127	1
Modulus ALIF trial, 6x34x28 mm, 20°, small deep	1982129	1
Modulus ALIF trial, 8x34x28 mm, 20°, small deep	1982130	1
Modulus ALIF trial, 10x34x28 mm, 20°, small deep	1982131	1

Modulus ALIF HL trial rasp tray (MDLUSALIFHLTRIALR)

Description	Catalog no.	Qty.
Modulus ALIF HL trial rasp, 6x34x24 mm, 25°	1300113	1
Modulus ALIF HL trial rasp, 8x34x24 mm, 25°	1300114	1
Modulus ALIF HL trial rasp, 10x34x24 mm, 25°	1300115	1
Modulus ALIF HL trial rasp, 6x34x24 mm, 30°	1300117	1
Modulus ALIF HL trial rasp, 8x34x24 mm, 30°	1300118	1
Modulus ALIF HL trial rasp, 10x34x24 mm, 30°	1300119	1
Modulus ALIF HL trial rasp, 6x38x28 mm, 25°	1300153	1
Modulus ALIF HL trial rasp, 8x38x28 mm, 25°	1300154	1
Modulus ALIF HL trial rasp, 10x38x28 mm, 25°	1300155	1
Modulus ALIF HL trial rasp, 6x38x28 mm, 30°	1300157	1
Modulus ALIF HL trial rasp, 8x38x28 mm, 30°	1300158	1
Modulus ALIF HL trial rasp, 6x42x32 mm, 25°	1300193	1
Modulus ALIF HL trial rasp, 8x42x32 mm, 25°	1300194	1
Modulus ALIF HL trial rasp, 10x42x32 mm, 25°	1300195	1
Modulus ALIF HL trial rasp, 6x42x32 mm, 30°	1300197	1
Modulus ALIF HL trial rasp, 8x42x32 mm, 30°	1300198	1

Instructions for use

DESCRIPTION

The NuVasive Modulus ALIF System interbody implants and bone screws are manufactured from Ti-6Al-4V ELI conforming to ASTM F3001, ASTM F136 and ISO 5832-3. The implants are available in a variety of different shapes and sizes to suit the individual pathology and anatomical conditions of the patient. The Modulus ALIF System 10° - 20° lordotic cages may be used as a standalone system. The Modulus ALIF System 25° - 30° lordotic cages must be used with supplemental internal spinal fixations systems (e.g. posterior pedicle screw and rod system) that are cleared by the FDA for use in the lumbar spine.

US INDICATIONS FOR USE

The NuVasive Modulus ALIF System is indicated for spinal fusion procedures in skeletally mature patients. The Modulus ALIF System 10° - 20° lordotic cages may be used as a standalone system. The Modulus ALIF System 25° - 30° lordotic cages must be used with supplemental internal spinal fixation systems (e.g. posterior pedicle screw and rod system) that are cleared by the FDA for use in the lumbar spine. The System is designed for use with autogenous and/or allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft to facilitate fusion. The devices are to be used in patients who have had at least six months of non-operative treatment.

The NuVasive Modulus ALIF System is intended for use in interbody fusions in the lumbar spine from L2 to S1, following discectomy in the treatment of symptomatic degenerative disc disease (DDD), degenerative spondylolisthesis, and/or spinal stenosis at one or two adjacent levels. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The Modulus ALIF System implants can also be used as an adjunct to fusion in patients diagnosed with multilevel degenerative scoliosis and sagittal deformity; however, when used in these patients at multiple levels and for patients with degenerative spondylolistheses and spinal stenosis at one or two adjacent levels, the Modulus ALIF System must be used with a supplemental internal spinal fixation system (e.g., pedicle screw system) cleared by FDA for use in the lumbar spine in addition to the integrated screws.

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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
- Proximal junctional kyphosis (PJK)
- Neurological, vascular or visceral injury
- Metal sensitivity or allergic reaction to a foreign body
- Tissue reactions including macrophage and foreign body reactions adjacent to implants
- Infection
- Decrease in bone density due to stress shielding

- Degenerative changes or instability of segments adjacent to fused vertebral levels
- Malalignment of anatomical structures (i.e. loss of normal spinal contours or change in height)
- Pain, discomfort or abnormal sensations due to the presence of the device
- Nerve damage due to surgical trauma
- Bursitis
- Dural leak
- Paralysis
- Death

WARNINGS, CAUTIONS AND PRECAUTIONS

The subject device is intended for use only as indicated. The implantation of spinal systems should be performed only by experienced spinal surgeons with specific training in the use of this spinal system because this is a technically demanding procedure presenting a risk of serious injury to the patient.

Correct selection of the implant is extremely important. The potential for success is increased by the selection of the proper size of the implant. While proper selection can minimize risks, the size and shape of human bones present limitations on the size and strength of implants. Metallic internal fixation devices cannot withstand the activity levels and/or loads equal to those placed on normal, healthy bone.

These devices are not designed to withstand the unsupported stress of full weight or load bearing alone.

When implanted at adjacent levels, it is important to select the appropriate length NuVasive Modulus ALIF

System bolt and confirm trajectory under intraoperative fluoroscopy in order to avoid potential screw impingement.

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.

If fewer than 3 bolts are used, then the system is intended to be used with additional supplemental fixation (cleared by the FDA) for use in the lumbar spine.

These devices can break when subjected to the increased load associated with delayed union or nonunion. Internal fixation appliances are load-sharing devices that hold bony structures in alignment until healing occurs. If healing is delayed, or does not occur, the implant may eventually loosen, bend, or break. Loads on the device produced by load bearing and by the patient's activity level will dictate the longevity of the implant.

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.made aware that implant components may bend, break or loosen even though restrictions in activity are followed.

Based on fatigue testing results, when using the Modulus ALIF 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.

Care should be taken to ensure 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 Information: Refer to the Modulus ALIF System IFU for MRI Safety Information.

Compatibility: Do not use the Modulus ALIF 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 ALIF 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 ALIF 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 ALIF implants if there is any evidence of damage.
4. Refer to Cleaning and Sterilization Instructions below for all non-sterile parts.
5. Care should be used during surgical procedures to prevent damage to the device(s) and injury to the patient.

POSTOPERATIVE WARNINGS

During the postoperative phase it is of particular importance that the physician keeps the patient well informed of all procedures and treatments.

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

Please refer to the Modulus ALIF System IFU found at nuvasive.com/eIFU for additional important labeling information.

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