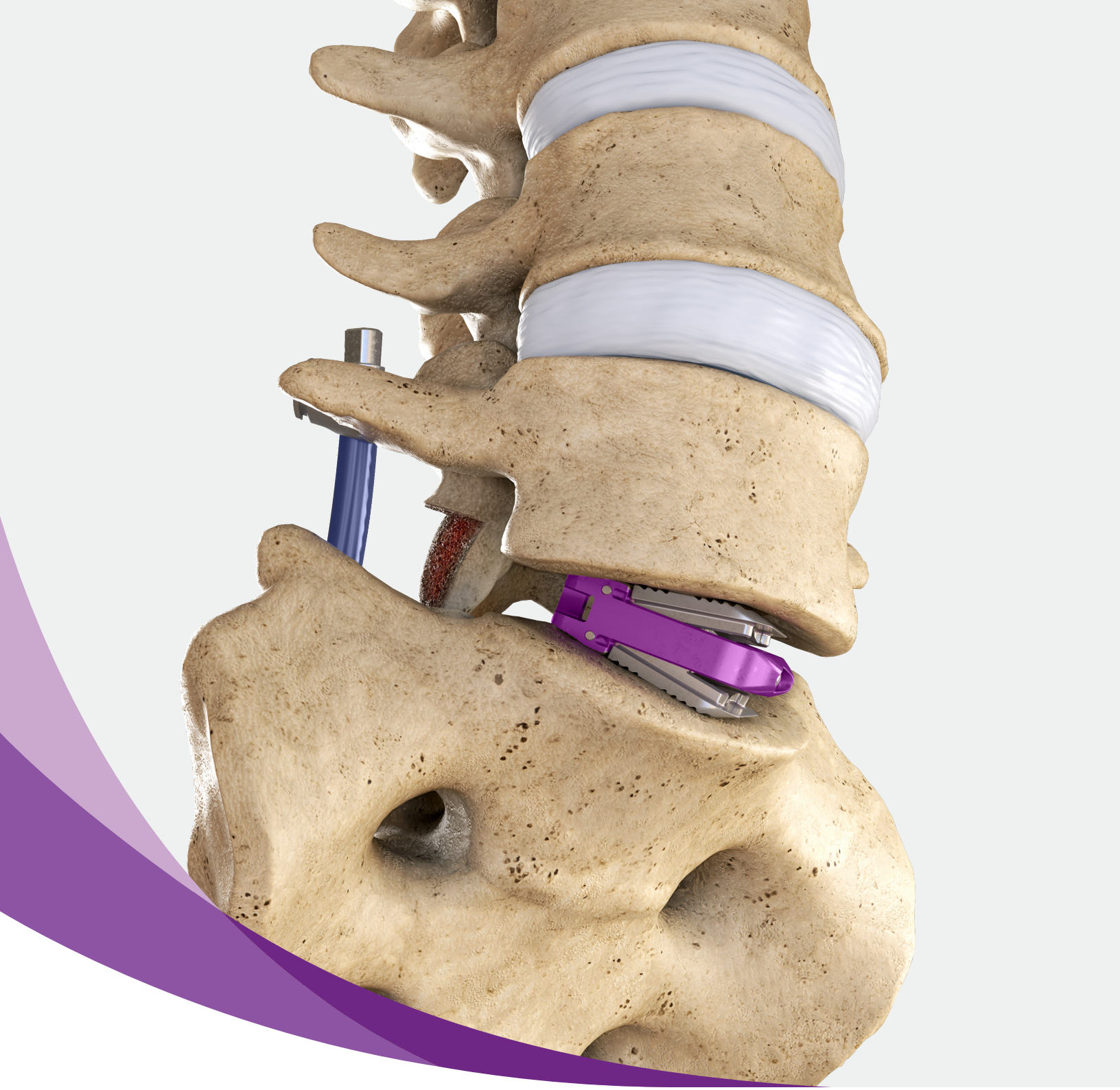


TLX 20°

Technique Guide

NuVasive

Contents

Preface

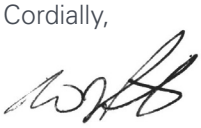
Dear Fellow Colleagues,

We are happy to introduce the TLX 20˚ Interbody System. This system was designed with the objective to enhance clinical outcomes and surgical workflow with customizable, streamlined technology. Improvement to workflow was achieved with the development of a multi-functional inserter that positions and expands the cage, and provides an easy, innovative method to deliver graft material post-expansion. Further, the implant's ability to self-lock at any point between 0 to 100% expansion allows surgeons to tailor the graft height and lordosis to each patient's unique requirements. Most important was our careful consideration of alignment in both anatomical planes when placing a lordotic cage at an oblique angle. Thus, TLX was successfully designed to expand obliquely such that the highest expansion point of the implant is at midline. This unique profile maintains coronal alignment while achieving sagittal correction.

The goal and intent of developing the TLX 20˚ system was to provide surgeons with a hyperlordotic option to achieve the maximum amount of sagittal correction and restore adequate lordosis during fusion surgery. Failure to restore adequate lumbar lordosis may result in mechanical back pain, sagittal malalignment, and adjacent segment degeneration. The TLX 20˚ instrumentation has also been optimized, offering a low profile inserter for better visualization during surgery.

TLX 20˚ is a comprehensive interbody system that improves surgical workflow with its streamlined instrumentation and multi-functional inserter. It's designed specifically to address anterior column stability and restoration of sagittal alignment through controlled, incremental expansion with up to 20° of lordosis. Its unique implant profile maintains coronal alignment while expanding in the oblique plane, while the various height and footprint options ensure a true anatomical fit.

Cordially,



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TLX Interbody System Overview

20˚ of Oblique Lordotic Expansion. Correct Sagittal Alignment. Maintain Coronal Alignment.

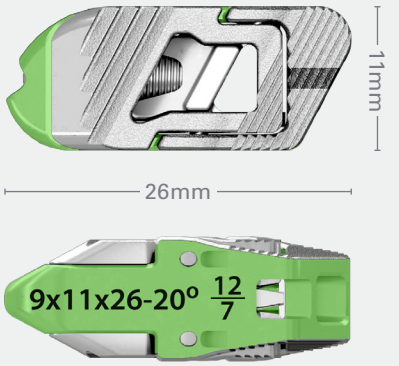
Alignment. Stability. Fusion.

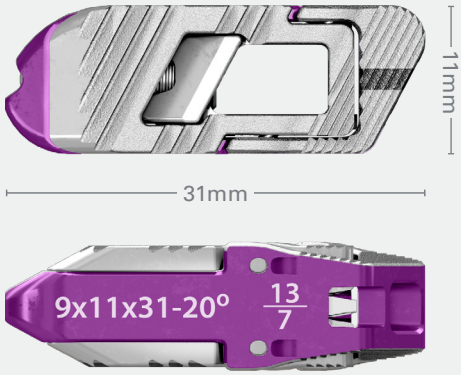
- Anterior column stability and restoration of sagittal alignment with up to 20° of customizable lordosis
- Unique implant profile maintains coronal alignment while expanding in the oblique plane
- Streamlined instrumentation allows for insertion, expansion, and post-packing through one instrument
- Reproducible verification of lordosis expansion denoted by visual gauge
- Controlled incremental expansion secured by integrated auto-lock feature

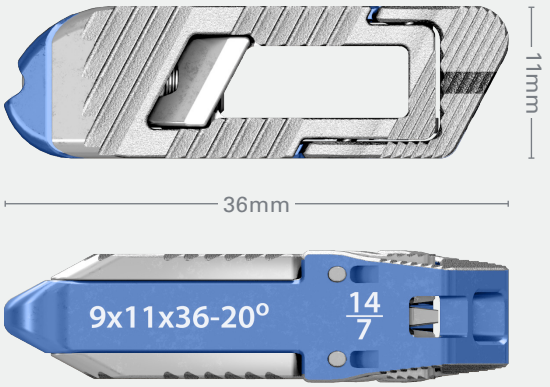
Collapsed—0˚ Lordosis

50% Expanded—10˚ Lordosis

100% Expanded—20˚ Lordosis



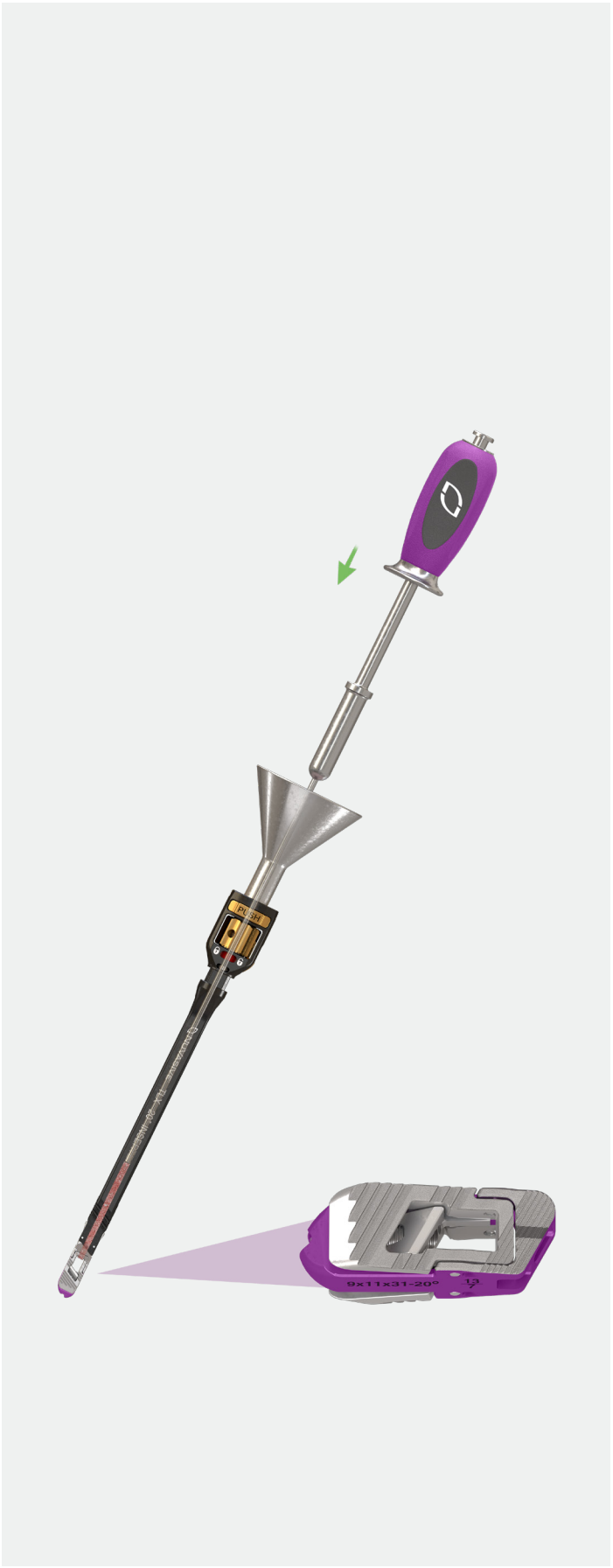




Integrated Graft Delivery

- Advanced surface technology and unimpeded central graft aperture
- Intuitive assembly enabled by quick connect attachment
- Simplified graft delivery provided by streamlined instrumentation

Estimated Autograft Volumes			
Length	Starting Anterior Height	Anterior Height Expanded	Volume
26mm	7mm	11mm	0.40cc
	8mm	11mm	0.45cc
	9mm	12mm	0.50cc
	10mm	14mm	0.50cc
	11mm	15mm	0.55cc
	12mm	16mm	0.60cc
	14mm	18mm	0.65cc
31mm	7mm	12mm	0.60cc
	8mm	13mm	0.65cc
	9mm	14mm	0.75cc
	10mm	15mm	0.85cc
	11mm	17mm	0.90cc
	12mm	18mm	0.95cc
	14mm	20mm	1.05cc
36mm	7mm	12mm	0.90cc
	8mm	12mm	1.0cc
	9mm	14mm	1.05cc
	10mm	15mm	1.2cc
	11mm	16mm	1.3cc
	12mm	17mm	1.4cc
	14mm	19mm	1.5cc



Technique Guide

Equipment Requirements

TLX20IMP

- Transforaminal Lordotic eXpandable 20° Implants set contains all 26mm and 31mm length implants

TLX20INS

- Transforaminal Lordotic eXpandable Instruments set contains trial/disc jack, inserter, torque limiting handle, and graft delivery system

TLX20IMP36 (optional)

- Transforaminal Lordotic eXpandable 20° Implants 36mm set contains all 36mm length implants

TLX20MAG (optional)

- Transforaminal lordotic expandable Graft Delivery set for use if multiple implants are needed per case

MT2ACCESS (optional)

- MAS® TLIF 2 Access set contains the MAS TLIF 2 blades, retractor body, and instrumentation

PGIINS2

- Posterior General Instrument set contains paddle sizers, shavers, curettes, and kerrisons

Fixation Options

- Reline
- Precept

Biologics

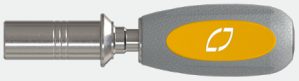
- Osteocel® Plus
- Osteocel Pro

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

Highlighted Instrumentation

Sizing and Trialing

Trial


Torque Limiting Handle

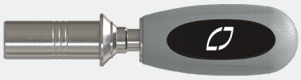
Implant Insertion and Expansion


Inner Rod

Inserter


Counter-torque


Strike Plate


Quick Connect Torque Limiting Handle

Graft Delivery


Plunger

Funnel

Loading Block

Graft Tamp

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).

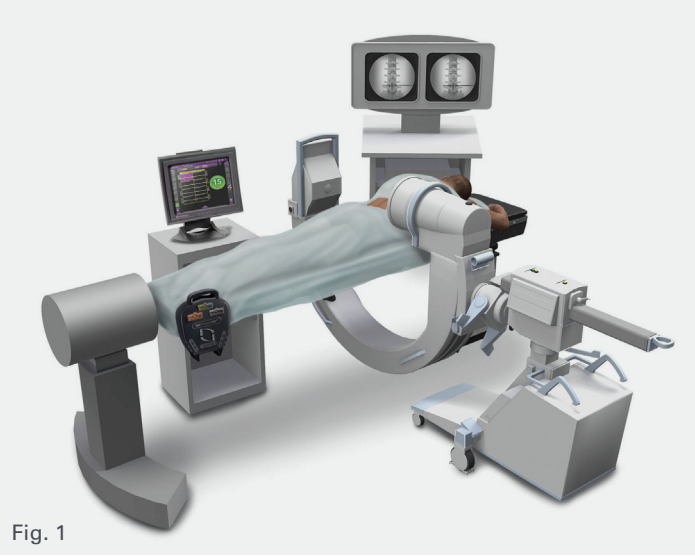


Fig. 1

Patient Prep for Lumbar Neuromonitoring with NVM5

For TLIF procedures utilizing 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).

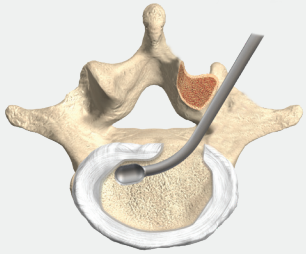


Fig. 2

NVM5: Free Run EMG

Use Free Run EMG to continuously monitor for mechanical disturbances to neural structures when using the TLX implant and inserter.

Step 4

Sizing

During discectomy, determine the appropriate implant height using a standard paddle sizer. Using an impacted or Insert and Rotate technique, sequentially increase the height until the desired disc height is achieved (Figs. 3, 4).

Note: *Paddle sizers are located in the Posterior General Instrument II set (PGIINS2).*

Tip: *Implants are labeled by their anterior height in the collapsed state. At 100% expansion, the anterior height will increase by 3-4mm for the 26mm length, 5-6mm for the 31mm length, and 4-5mm for the 36mm length. Choose the appropriate implant to achieve desired end height and lordosis in the expanded state. Be sure to reference the sizing guide to determine the most accurate implant size.*

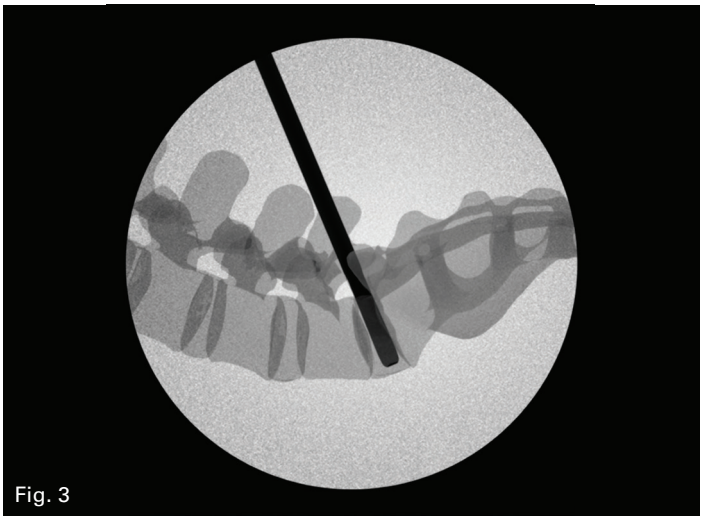


Fig. 3

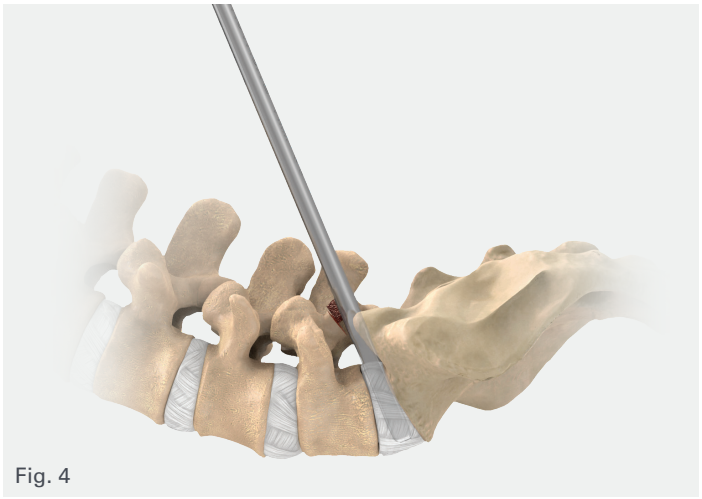


Fig. 4

Step 5

Trialing

If further trialing and distraction is required to determine the appropriate disc height, use the TLX trial. Attach the gold torque limiting handle to the gold proximal end of the trial. Attach the counter-torque to the shaft, to aid in proper alignment and provide stability (Fig. 5).

In the collapsed state, insert the trial at an oblique angle, confirming the "MEDIAL" and "LATERAL" markings are in the proper orientation. 30˚ trajectory can be confirmed visually by lining up the counter-torque handle parallel with the floor (Fig. 6).

Fig. 5

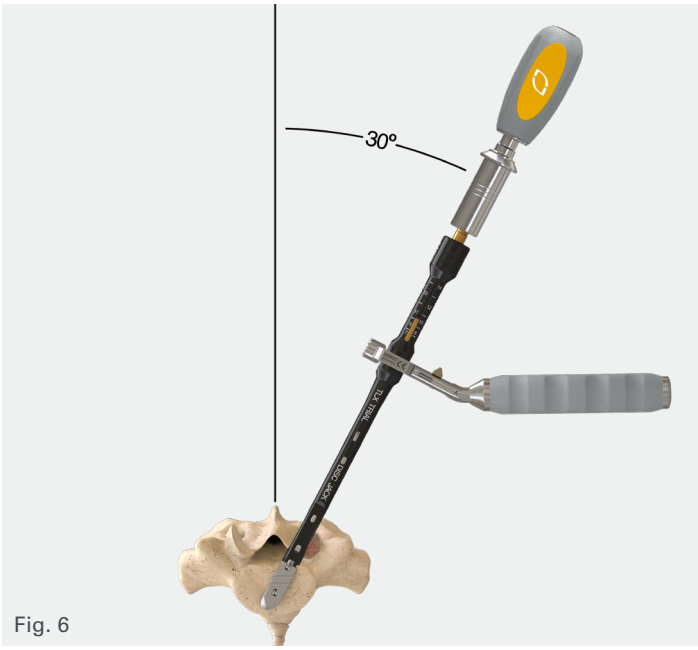


Fig. 6

Trialing (cont.)

Under lateral fluoro, verify that the distal tip is flush against the anterior annulus (Figs. 7, 8). Under A/P fluoro, confirm that the distal tip is past the spinous process. If necessary, use a surgical mallet to impact the TLX trial until it reaches the desired location.

Tip: *Proper oblique orientation of the trial can be confirmed under fluoro by aligning the notches on the trial, spaced 21 and 26mm from distal end.*

Using the counter-torque to maintain correct orientation, slowly rotate the torque limiting handle clockwise to expand the trial until the desired expansion has been achieved. Reference the gold visual indicator to verify the expanded height (Fig. 9).

Tip: *The expanding trial expands from 7 to 14mm in parallel height.*

Collapse and Removal

To remove, collapse the trial by rotating the torque limiting handle counterclockwise.

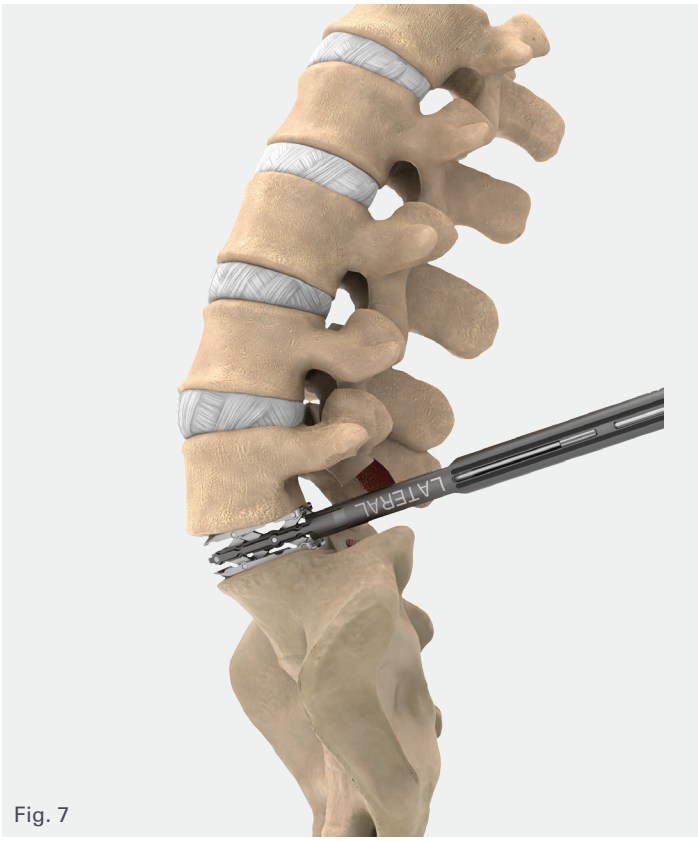


Fig. 7

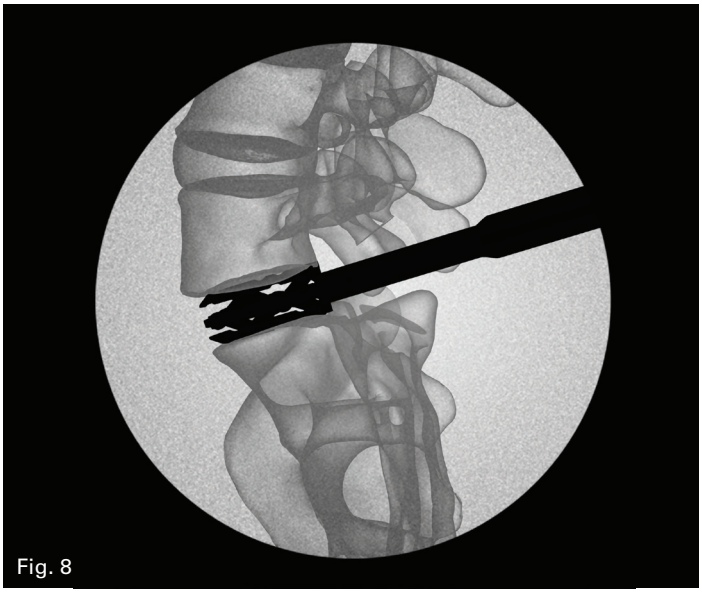


Fig. 8

Fig. 9

Step 6

Inserter Assembly

Choose the appropriate implant based on sizing/trialing of the disc space. It is important to size line to line to resist undersizing of the lordotic implant. Align the laser marked line of the implant and inserter then mate the implant to the distal face of the inserter (Fig. 10). Rotate the gold thumbwheel of the inserter clockwise until the implant is securely attached. If securely locked, the verification window will appear red (Fig. 11).

Fig. 10

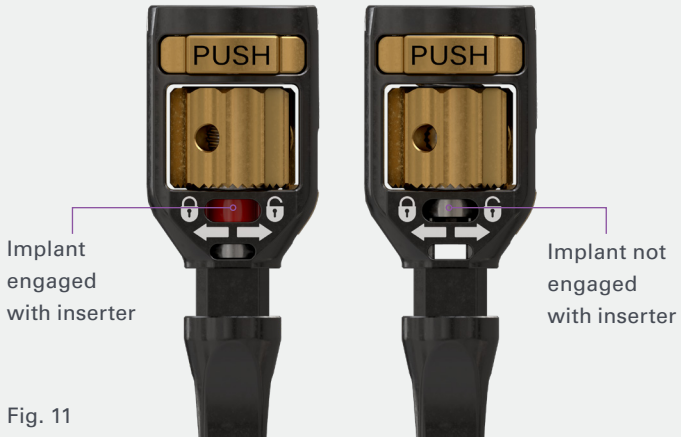
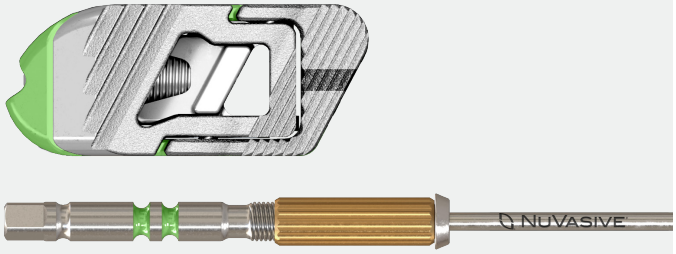


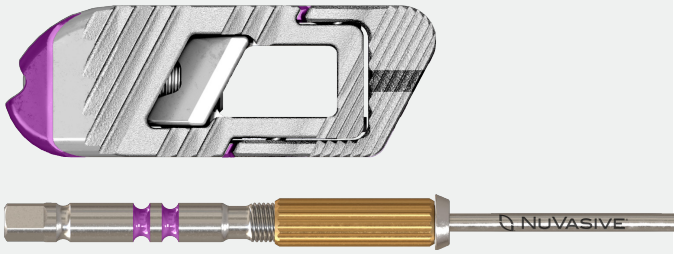
Fig. 11

Tip: *Inner rods are color coded to correlate with implant length.*

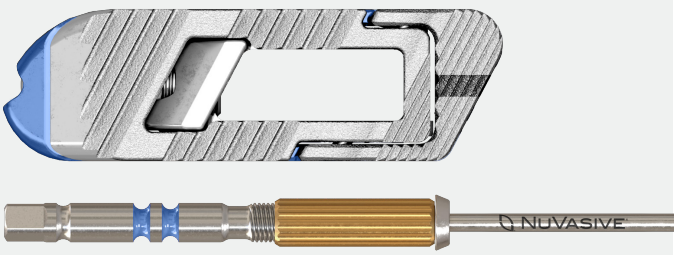
26mm: Green



31mm: Purple



36mm: Blue



Inserter Assembly (cont.)

Select the appropriate size inner rod. Rotate the gold indicator on the inner rod clockwise until it sits flush against the sliver washer (Fig. 12). Insert the inner rod into the inserter until it engages the distal screw within the implant (Fig. 13).

Fig. 12

Fig. 13

Note: *Confirm the gold indicator is sitting flush against the silver washer on the inner rod. This will allow the indicator to display an accurate measurement of expansion.*

Align the laser-marked triangle on the Strike plate with the laser-marked triangle on the inserter (Fig. 14). Slide the strike plate over the inner rod and engage with the inserter.

Fig. 14

Step 7

Implant Insertion and Expansion

Attach the counter-torque to the inserter with the handle in the lateral position (Fig. 15).

In the collapsed state, insert the implant at a 30° oblique angle, ensuring that the MEDIAL and LATERAL laser markings are in the proper orientation. Gently impact the implant, using the counter-torque to aid in proper alignment and provide stability.

Under lateral fluoro, confirm proper placement of the implant against the annulus. Under A/P fluoro, verify that the distal tip of the implant is past midline (Fig. 16).

Note: *Distance between the most anterior and posterior points of the implant at 30° oblique angle*

Implant Length	A/P Distance at 30˚ Trajectory
26mm	22.5mm
31mm	26.8mm
36mm	31.1mm

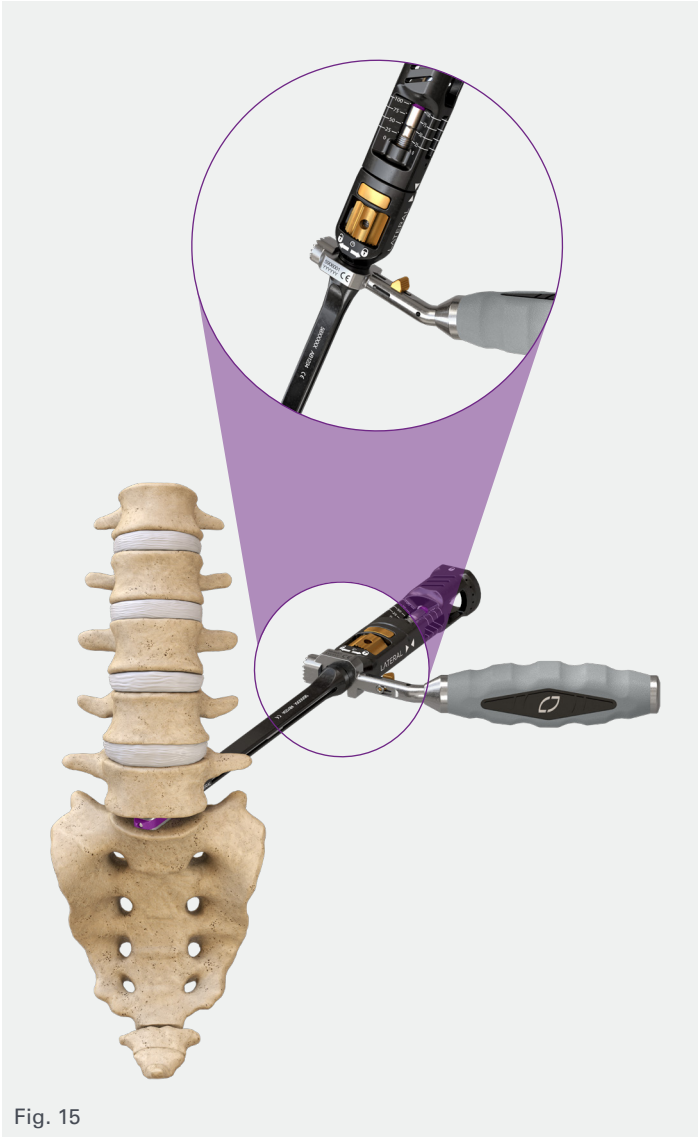
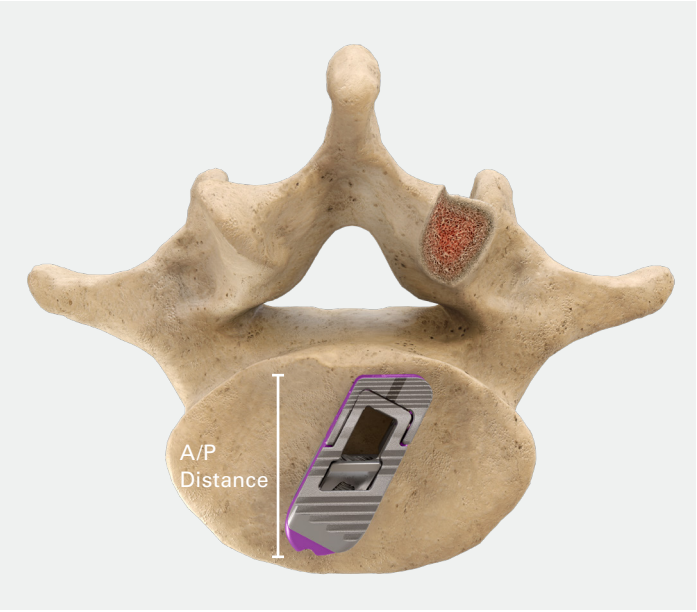


Fig. 15



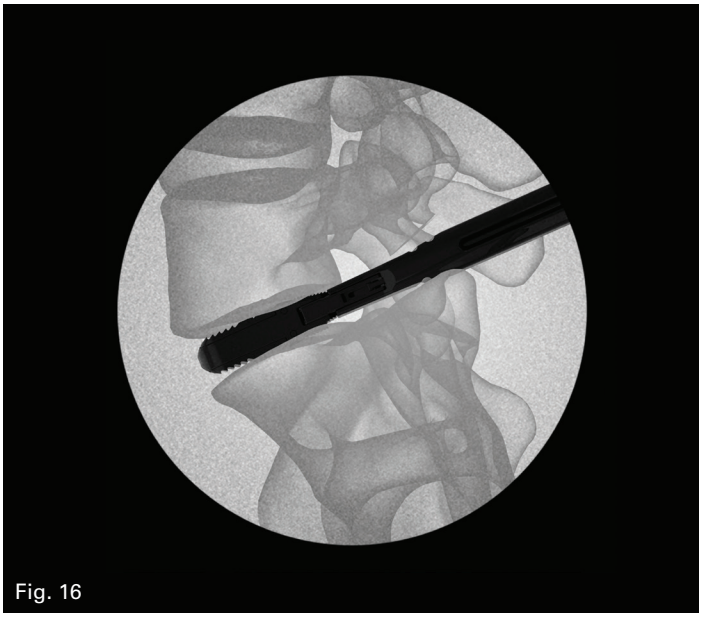
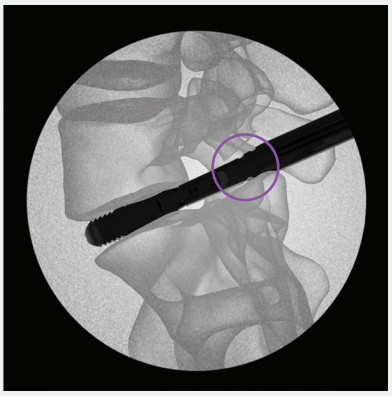


Fig. 16

Implant Insertion and Expansion (cont.)

Tip: *Proper oblique orientation of the implant can be confirmed under lateral fluoro by vertically aligning the alignment notches on the inserter, spaced 15 and 20mm from the distal end.*



Note: *The strike plate is designed to withstand impaction. If impaction is required, mallet on the strike plate. Do not attach and mallet on the torque limiting handle.*

Attach the black torque limiting handle to the inner rod (Fig. 17). Expand the implant by slowly rotating the torque limiting handle clockwise. Expand the implant until desired lordosis has been achieved and tactile resistance is felt.

Height expansion can be confirmed under fluoro and by the visual indicator on the Strike Plate (Fig. 18).

Note: *The torque limiting handle will break off at 25 in/lbs.*

Repositioning

Rotate the torque limiting handle counterclockwise to collapse the implant. If impaction is necessary for repositioning, remove the torque limiting handle and mallet on the strike plate.

After adequate adjustment, re-attach the torque limiting handle and expand the implant.

Caution: *Check implant placement under fluoro prior to packing graft. A TLX implant must not be re-expanded and reused after it has been filled with autograft, as mechanical failure may occur.*

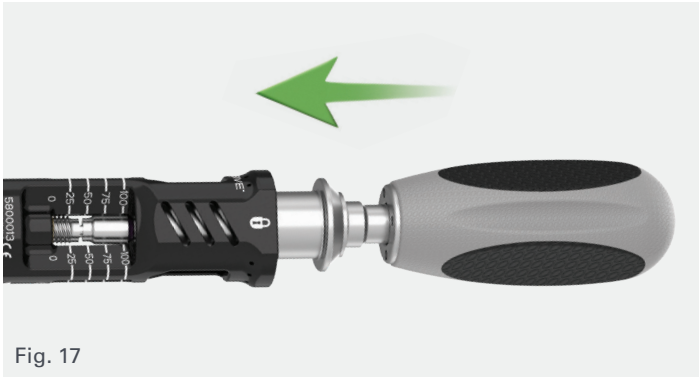
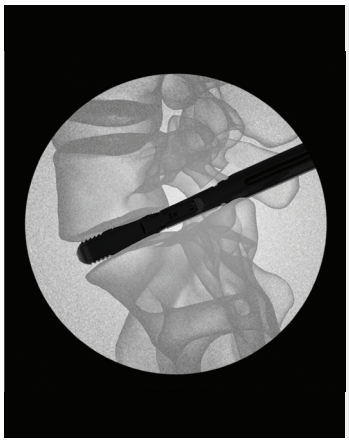
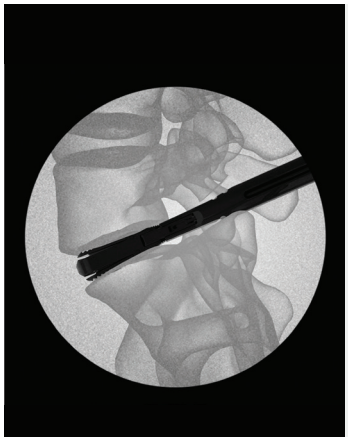


Fig. 17





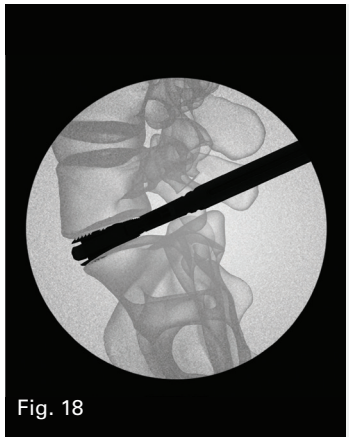


Fig. 18

Step 8

Graft Delivery Assembly

Place the funnels on the loading block. Using the spoon end of the graft material tamp, measure 1cc of graft material and place into a funnel (1 heaping scoop is approximately 1cc).

Using the opposite end of the tamp, tamp the graft material into the neck of the funnel (Fig. 19). Repeat these steps until the neck of the funnel is full of graft material.

Tip: *The neck of the funnel is designed to hold approximately 2cc of graft material. Avoid over packing the funnel. Pack the funnel during discectomy, prior to attaching the funnel to the inserter.*

Fig. 19

Step 9

Graft Delivery

After the implant has been expanded, press the gold button labeled "PUSH" and pull up on the torque limiting handle (Fig. 20). The strike plate and inner rod will disengage and pull out alongside the torque limiting handle.

Attach the funnel to the inserter by lining up the arrow on the funnel with the inserter and pressing down for a quick connect attachment.

While stabilizing the inserter, drive the graft plunger into the funnel (Fig. 22). Continue until the plunger bottoms out on the funnel. Cage is fully packed when the plunger no longer bottoms out on the funnel.

Caution: *When packing graft through a funnel, do not use the adjustable graft plunger in its fully extended state ("MAG" position) as damage to the TLX implant may occur.*


Fig. 20


Fig. 21


Fig. 22

Graft Delivery (cont.)

If use of the MAG Graft Delivery system is desired, load the silver cartridge into the black tray, then slide the tray into the tray base (Fig. 23). Using the spatula side of the multi tool (Fig. 24), pack up to 5cc of graft material into the cartridge, within the base. Avoid over packing.

Note: *If the tray does not slide easily into the tray base use the hex portion of the multi tool to rotate the hex of the base slightly then slide the tray into the tray base. Ensure the multi tool is removed from the base prior to re-inserting the tray.*

Once the cartridge is fully packed, insert the hex end of the multi tool (Fig. 25) into the hex on the tray base (Fig. 26). Rotate the multi tool clockwise to dispel the cartridge from the base (Fig. 27), so that excess graft material is removed.

Note: *The MAG Graft Delivery System must be ordered separately (TLX20MAG).*

Fig. 23

Fig. 24

Fig. 25

Fig. 26

Fig. 27

Step 9

Graft Delivery (cont.)

Remove the cartridge and attach the cartridge lid (Fig. 28), sealing the graft material within the fully assembled cartridge. Verify the cartridge lid sits flush on the cartridge.

Tip: *Ensure that there is no graft material sitting between the cartridge lid and cartridge preventing the two from fully mating.*

Insert the cartridge into the receiver (Figs. 29, 30). The numerical laser marking should be aligned with the through window and set at position 1 (Fig. 30).

Align the "LATERAL" laser markings on the receiver, with the "LATERAL" laser markings on the inserter. Attach the receiver to the proximal end of the inserter (Fig. 31).

Using the adjustable graft plunger, compress the "PUSH" button if necessary and set to the "MAG" location, deliver the graft material into the implant. Remove the graft plunger and advance the cartridge assembly to the next station by rotating the wheel on the top of the receiver (Fig. 31) and again deliver the graft material into the implant. The implant is fully packed when the adjustable graft plunger no longer bottoms out on the receiver.

Fig. 29

Fig. 30

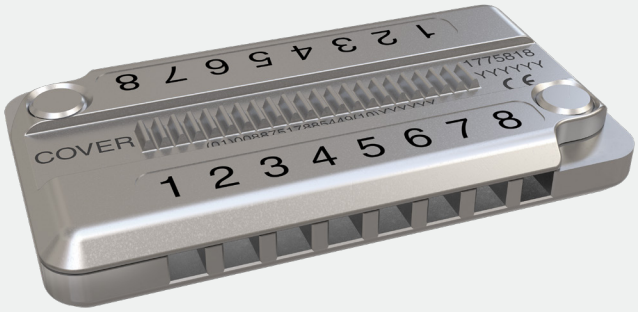


Fig. 28

Fig. 31

Step 10

Inserter Release

Remove the funnel or MAG from the inserter by pressing the gold button labeled "PUSH". Turn the gold thumbwheel counterclockwise until you feel a hard stop to disengage and remove the inserter from the implant (Fig. 32).

Tip: *Should there be any difficulty removing the inserter from the implant, lightly wag the inserter lateral to help disengage the inserter arms from the implant. Ensure the thumbwheel has been fully rotated in the CCW direction.*

Tip: *Should re-attachment of the inserter to the implant be required prior to packing graft, use the alignment tool as a guide. Insert the alignment tool into the implant, then slide the ratcheting inserter over the alignment tool until the inserter engages the proximal end of the implant.*

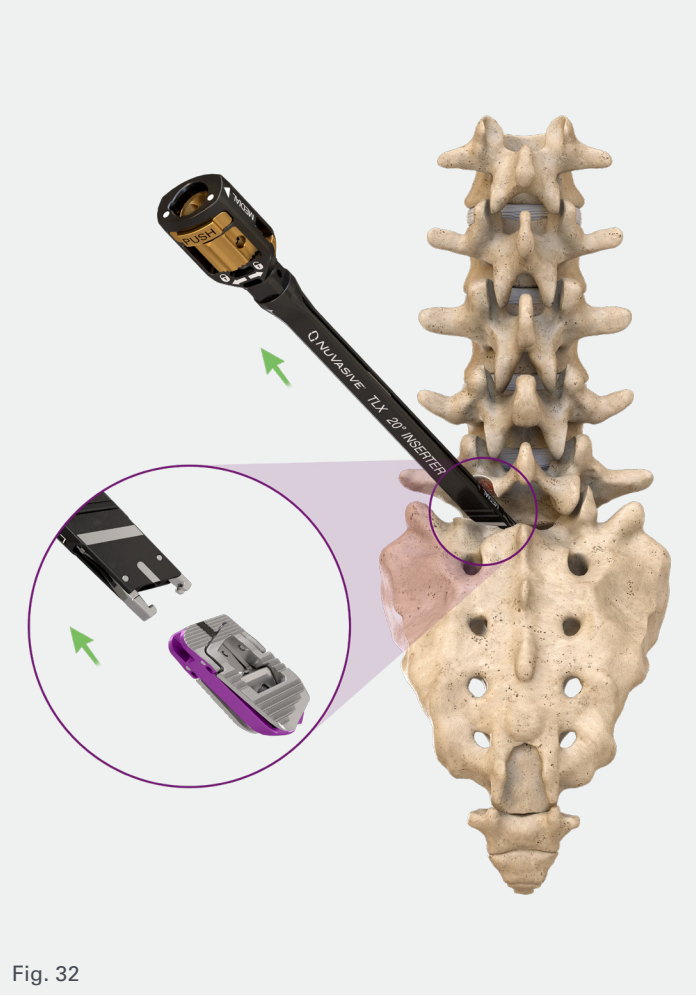
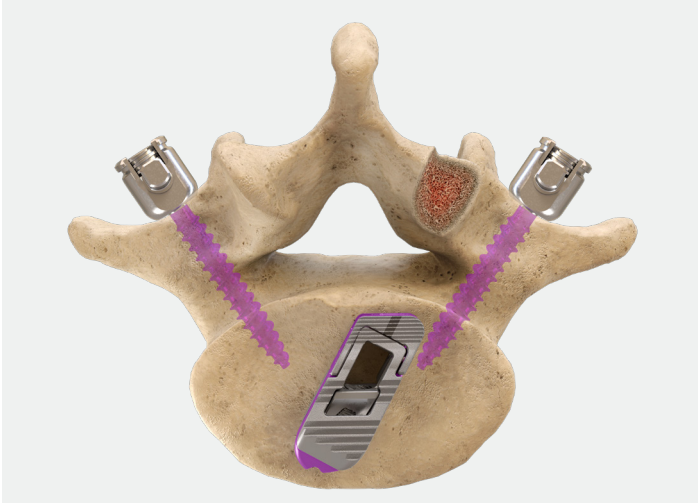


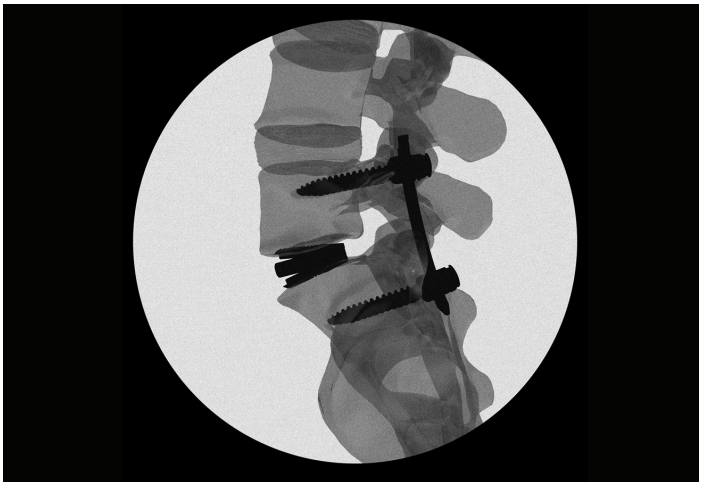
Fig. 32

Step 11

Fixation

Place the desired fixation system, such as Reline® or Precept® (Fig 33).





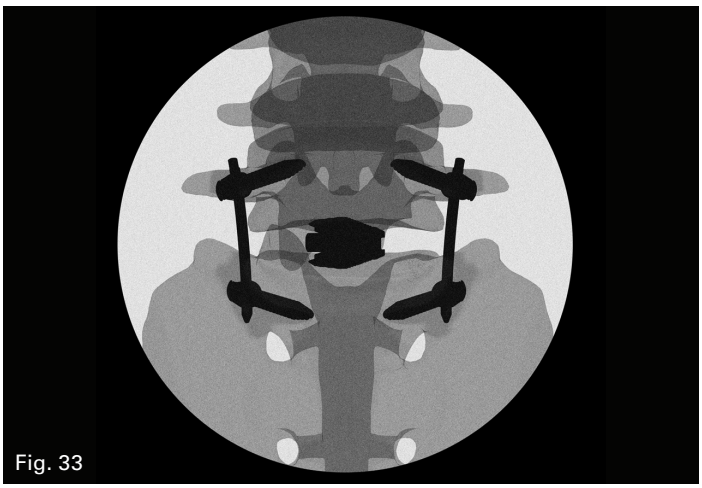


Fig. 33

Implant Removal

Should implant removal be required prior to post-packing the implant, use the TLX inserter and inner rod to collapse and remove the implant.

Should implant removal be required after post-packing the implant, an ALIF may be performed.

If it is necessary to remove the implant from a posterior approach, after post-packing, attach the ratcheting inserter to the proximal end of the implant. With the inserter attached, slide the drill into the inserter. Rotate the drill clockwise until the drill meets the distal end of the implant (Fig. 34).

Once enough graft material has been cleared, re-attach the appropriate size inner rod, strike plate, and torque limiting handle. Rotate the torque limiting handle counterclockwise to collapse the implant.

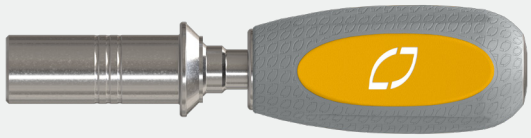
Tip: *If use of a slap hammer is necessary, attach the Hudson adapter to the proximal end of the strike plate.*

Fig. 34

TLX 20° System

TLX Instruments

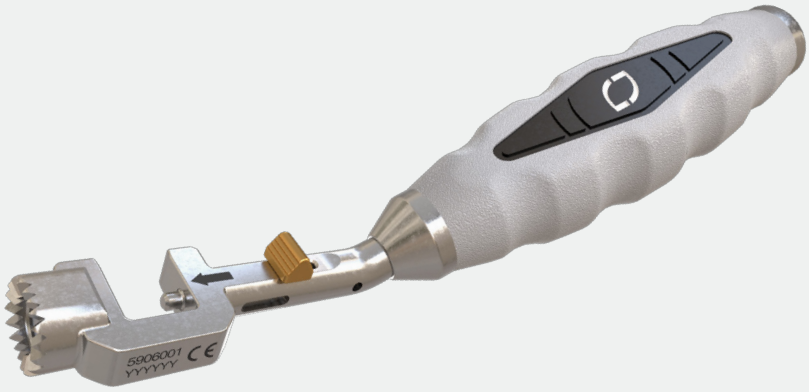
TLX Torque Limiting Handle



TLX Quick Connect Torque Limiting Handle

TLX 20° Inserter

TLX Counter-torque



TLX Strike Plate

TLX Instruments

TLX Expanding Trial, 7-14mm

TLX Inner Rod, 26mm

TLX Inner Rod, 31mm

TLX Inner Rod, 36mm

TLX Plunger, Graft Delivery

TLX Tamp

TLX Instruments

TLX Graft Material Loading Block

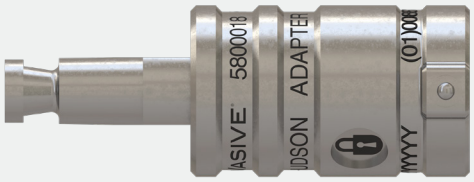
TLX Graft Material Tamp

TLX Funnel, Graft Delivery

TLX Alignment Tool

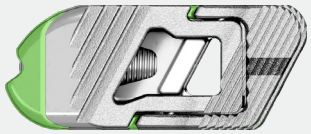
TLX Drill

TLX Hudson Adapter

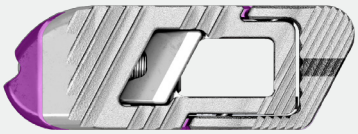


TLX Implants

TLX Implant, 26mm, 20°



TLX Implant, 31mm, 20°



TLX Implant, 36mm, 20°

Sizing Guide

Implants and rods are color coded by length.

26mm

Part Number	Percent Expanded	Anterior Height (mm)	Posterior Height (mm)	Lordosis	Anterior Height Increase
5902726P2 7x11x26mm	0%	7	5	0°	4
	25%	8	5	5°	
	50%	9	5	10°	
	75%	10	5	15°	
	100%	11	5	20°	
5902826P2 8x11x26mm	0%	8	6	0°	4
	25%	9	6	5°	
	50%	10	6	10°	
	75%	11	6	15°	
	100%	12	6	20°	
5902926P2 9x11x26mm	0%	9	7	0°	4
	25%	10	7	5°	
	50%	11	7	10°	
	75%	12	7	15°	
	100%	13	7	20°	
5902026P2 10x11x26mm	0%	10	8	0°	4
	25%	11	8	5°	
	50%	12	8	10°	
	75%	13	8	15°	
	100%	14	8	20°	
5902126P2 11x11x26mm	0%	11	9	0°	4
	25%	12	9	5°	
	50%	13	9	10°	
	75%	14	9	15°	
	100%	15	9	20°	
5902226P2 12x11x26mm	0%	12	10	0°	4
	25%	13	10	5°	
	50%	14	10	10°	
	75%	15	10	15°	
	100%	16	10	20°	
5902426P2 14x11x26mm	0%	14	12	0°	4
	25%	15	12	5°	
	50%	16	12	10°	
	75%	17	12	15°	
	100%	18	12	20°	

Sizing Guide

Implants and rods are color coded by length.

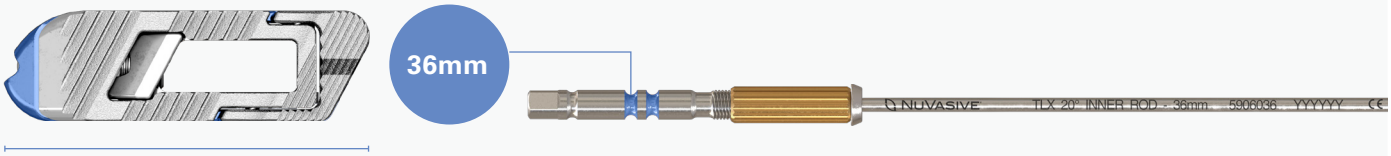
31mm

Part Number	Percent Expanded	Anterior Height	Posterior Height	Lordosis	Anterior Height Increase
5902731P2 7x11x31mm	0%	7	5	0°	5
	25%	8	5	5°	
	50%	9	5	10°	
	75%	10	5	15°	
	100%	12	5	20°	
5902831P2 8x11x31mm	0%	8	6	0°	5
	25%	9	6	5°	
	50%	10	6	10°	
	75%	11	6	15°	
	100%	13	6	20°	
5902931P2 9x11x31mm	0%	9	6	0°	5
	25%	10	6	5°	
	50%	11	6	10°	
	75%	12	6	15°	
	100%	14	6	20°	
5902031P2 10x11x31mm	0%	10	7	0°	5
	25%	11	7	5°	
	50%	12	7	10°	
	75%	13	7	15°	
	100%	15	7	20°	
5902131P2 11x11x31mm	0%	11	9	0°	6
	25%	12	9	5°	
	50%	13	9	10°	
	75%	15	9	15°	
	100%	17	9	20°	
5902231P2 12x11x31mm	0%	12	9	0°	6
	25%	13	9	5°	
	50%	14	9	10°	
	75%	16	9	15°	
	100%	18	9	20°	
5902431P2 14x11x31mm	0%	14	12	0	6
	25%	15	12	5°	
	50%	16	12	10°	
	75%	18	12	15°	
	100%	20	12	20°	

Sizing Guide

Implants and rods are color coded by length.

36mm



Part Number	Percent Expanded	Anterior Height (mm)	Posterior Height (mm)	Lordosis	Anterior Height Increase
5903736P2 7x11x36mm	0%	7	6	0°	5
	25%	8	6	3°	
	50%	9	6	6°	
	75%	10	6	10°	
	100%	12	6	13°	
5903836P2 8x11x36mm	0%	8	6	0°	5
	25%	9	6	3°	
	50%	10	6	6°	
	75%	11	6	10°	
	100%	13	6	13°	
5905936P2 9x11x36mm	0%	9	7	0°	5
	25%	10	7	4°	
	50%	11	7	7°	
	75%	12	7	11°	
	100%	14	7	15°	
5905036P2 10x11x36mm	0%	10	8	0°	5
	25%	11	8	4°	
	50%	12	8	7°	
	75%	13	8	11°	
	100%	15	8	15°	
5905136P2 11x11x36mm	0%	11	9	0°	5
	25%	12	9	4°	
	50%	13	9	7°	
	75%	14	9	11°	
	100%	16	9	15°	
5905236P2 12x11x36mm	0%	12	10	0°	5
	25%	13	10	4°	
	50%	14	10	7°	
	75%	15	10	11°	
	100%	17	10	15°	
5905436P2 14x11x36mm	0%	14	12	0°	5
	25%	15	12	4°	
	50%	16	12	7°	
	75%	17	12	11°	
	100%	19	12	15°	

Catalog

TLX 20˚ Implants (TLX20IMP)	
Description	Catalog #
Universal Pelican Case, Sterile Pack	1704712
TLX20 Implant, 7x11x26mm 20°	5902726P2
TLX20 Implant, 8x11x26mm 20°	5902826P2
TLX20 Implant, 9x11x26mm 20°	5902926P2
TLX20 Implant, 10x11x26mm 20°	5902026P2
TLX20 Implant, 11x11x26mm 20°	5902126P2
TLX20 Implant, 12x11x26mm 20°	5902226P2
TLX20 Implant, 7x11x31mm 20°	5902731P2
TLX20 Implant, 8x11x31mm 20°	5902831P2
TLX20 Implant, 9x11x31mm 20°	5902931P2
TLX20 Implant, 10x11x31mm 20°	5902031P2
TLX20 Implant, 11x11x31mm 20°	5902131P2
TLX20 Implant, 12x11x31mm 20°	5902231P2
TLX Interbody System IFU	9402203

TLX 20˚ MAG System (TLX20MAG)	
Description	Catalog #
NuVasive Generic Tray Lid	8801300
TLX Cartridge, Magazine Graft	1775799
TLX Cover, Magazine Graft Cartridge	1775818
TLX Delivery System, Mag Graft Cart	1775550
TLX Base, Magazine Graft Loading	1775800
TLX Tray, Magazine Graft Loading	1775810
TLX20 Base, Graft Delivery Tray	5906004
TLX20 Nipple Mat, Tray	5906005
TLX Multi Tool, Graft Packing	1788390
TLX Graft Plunger, Adjustable	1788380
TLX Interbody System IFU	9402203

TLX 20˚ Instruments (TLX20INS)	
Description	Catalog #
NuVasive Generic Tray Lid	8801300
TLX Trial, 7-14mm 20° Expandable	1780200
TLX20 Counter Torque	5906001
TLX20 Inserter	5906000
TLX Handle, Torque Limiting Quick Conn	5800022
TLX Handle, Torque Limiting	5800000
TLX20 Strike Plate, Inserter	5800013
TLX20 Inner Rod, 26mm	5906026
TLX20 Inner Rod, 31mm	5906031
TLX20 Inner Rod, 36mm	5906036
TLX20 Plunger, Graft Delivery	5800016
TLX Loading Block, Graft	5800020
TLX20 Funnel, Graft Delivery	5906002
TLX Hudson Adapter	5800018
TLX Tamp	5800023
TLX Alignment Tool	5800019
TLX Drill	5890020
TLX Nipple Mat, Tray	5890022
TLX Top, Tray	5890024
TLX Bottom, Tray	5890023
TLX Tamp, Graft	5800021
TLX Base, Instrument Tray	5890021
TLX Interbody System IFU	9402203

TLX 20˚ Implants 36mm (TLX20IMP36)	
Description	Catalog #
Universal Pelican Case, SP 2.0 12CT	1704725
TLX20 Implant, 7x11x36mm 13°	5903736P2
TLX20 Implant, 8x11x36mm 13°	5903836P2
TLX20 Implant, 9x11x36mm 15°	5905936P2
TLX20 Implant, 10x11x36mm 15°	5905036P2
TLX20 Implant, 11x11x36mm 15°	5905136P2
TLX20 Implant, 12x11x36mm 15°	5905236P2
TLX Interbody System IFU	9402203

Instructions for Use

INDICATIONS FOR USE
The NuVasive® TLX 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 TLX Interbody System is intended for use in interbody fusions in the thoracic spine from T1 to T12 and at the thoracolumbar junction (T12-L1), and is intended for use in the lumbar spine, from L1 to S1, for the treatment of symptomatic disc degeneration (DDD) or degenerative spondylolisthesis at one or two adjacent levels, including thoracic disc herniation (with myelopathy and/or radiculopathy with or without axial pain). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The NuVasive TLX Interbody System can be used as an adjunct to fusion in patients diagnosed with multilevel degenerative scoliosis.

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.

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. 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.

Additional care should be taken to ensure a thorough discectomy is completed in order to correctly size, place, and expand the device. An incomplete discectomy may result in difficulty to fully deploy and place the device in its intended position.

A TLX implant must not be re-expanded and reused if it has been filled with graft, as mechanical failure may occur.

When packing graft through a funnel, do not use the Adjustable Graft Plunger in its fully extended state ("MAG" position) as damage to the TLX implant may occur.

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 Information: The TLX 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 TLX Interbody System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

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

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

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

Please refer to the *TLX Interbody System* eIFU 9402203 at **www.nuvasive.com/eIFU** for complete labeling information.

Notes

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