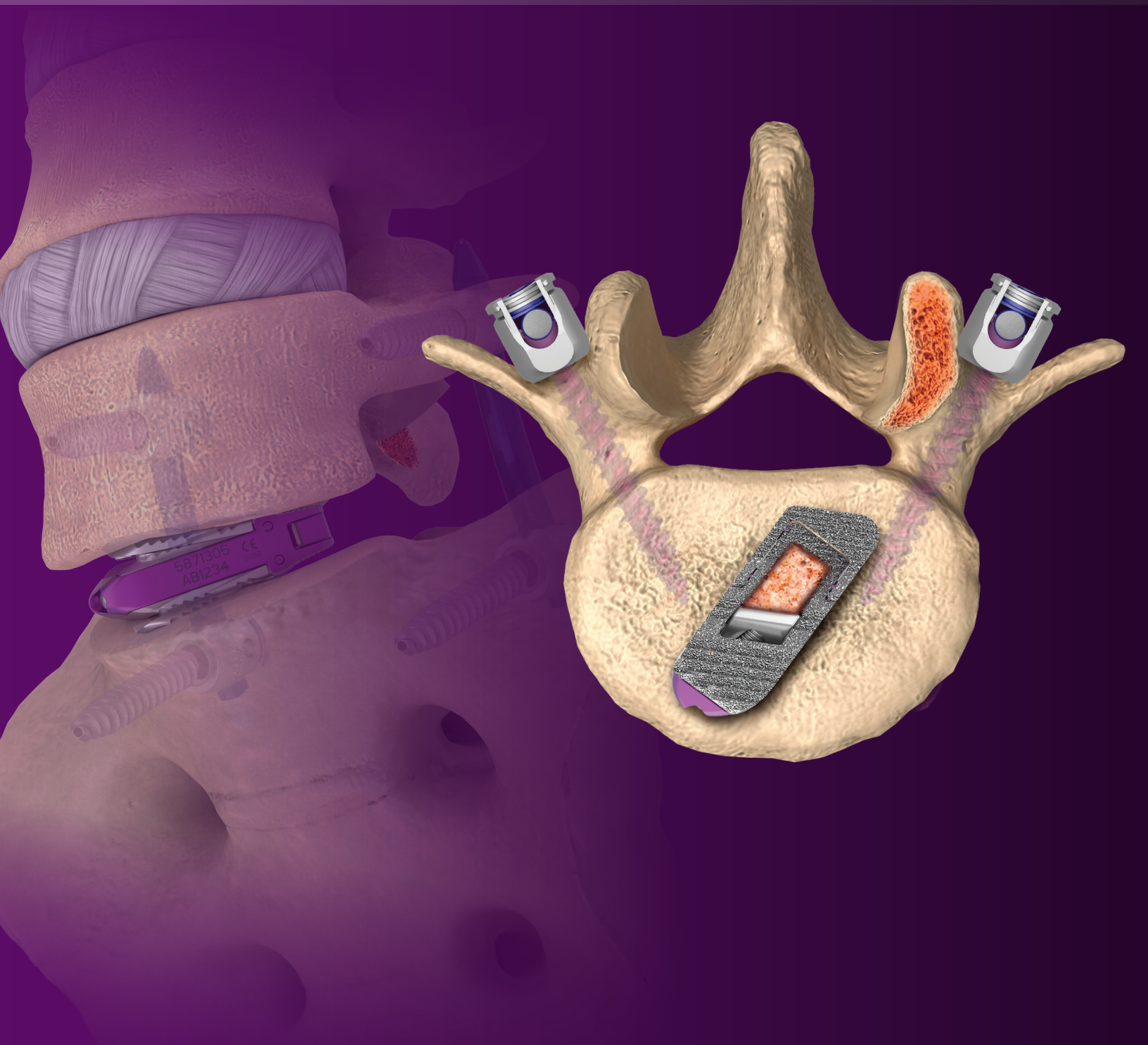
NuVasive®

TLX™

Technique Guide



TLX™

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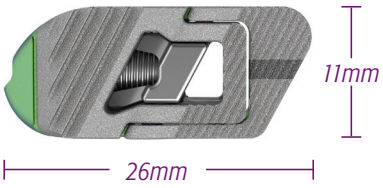
TLX™ INTERBODY SYSTEM OVERVIEW

REDUCED DISRUPTION. CONTROLLED LORDOTIC EXPANSION.

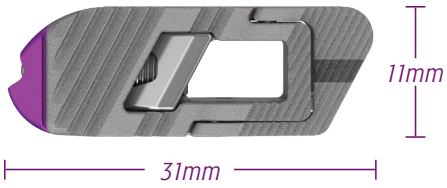
Alignment. Stability. Fusion.

- Seamless insertion and minimized impaction provided by low-profile, tapered design
- Guided distraction restores natural disc height
- True anatomical fit enabled by various heights, footprints, and lordotic options

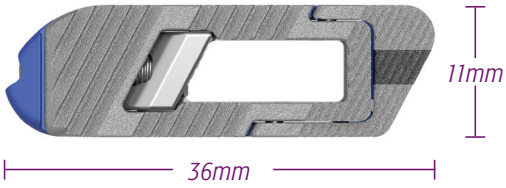
26mm: *Green*



31mm: *Purple*



36mm: *Blue*



- Anterior column stability and restoration of sagittal alignment with up to 15° of customizable lordosis
- Reproducible verification of lordosis expansion denoted by visual gauge
- Controlled incremental expansion secured by integrated auto-lock feature

VISUAL GAUGE

COLLAPSED

0° LORDOSIS

50% EXPANDED

7° LORDOSIS

EXPANDED

15° LORDOSIS

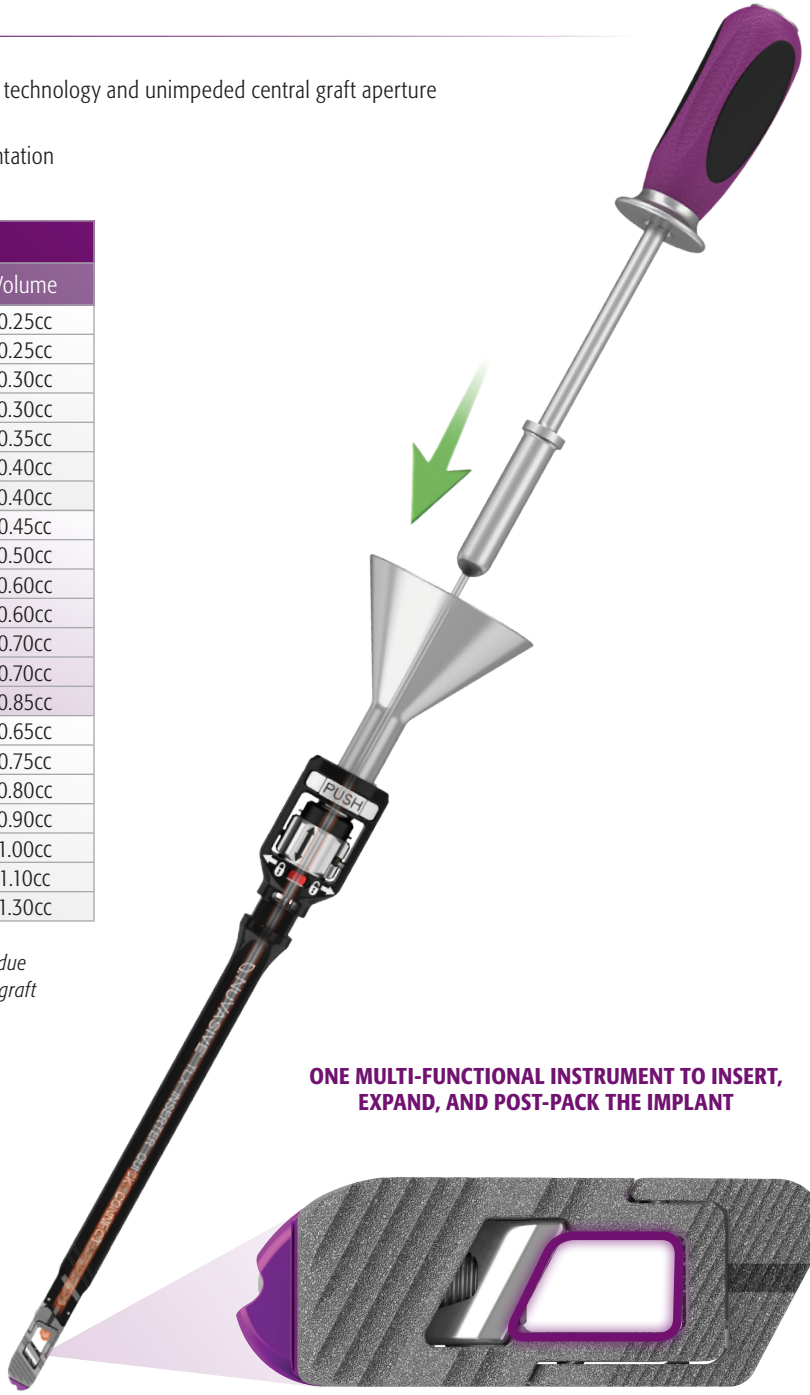
INTEGRATED GRAFT DELIVERY.

Alignment. Stability. Fusion.

- Maximum fusion opportunity induced by 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	Posterior Height	Anterior Height Expanded	Volume
26mm	5mm	10mm	0.25cc
	6mm	11mm	0.25cc
	7mm	12mm	0.30cc
	8mm	13mm	0.30cc
	9mm	14mm	0.35cc
	10mm	15mm	0.40cc
	12mm	17mm	0.40cc
31mm	5mm	11mm	0.45cc
	6mm	12mm	0.50cc
	7mm	13mm	0.60cc
	8mm	14mm	0.60cc
	9mm	15mm	0.70cc
	10mm	16mm	0.70cc
	12mm	18mm	0.85cc
36mm	5mm	11mm	0.65cc
	6mm	12mm	0.75cc
	7mm	14mm	0.80cc
	8mm	15mm	0.90cc
	9mm	16mm	1.00cc
	10mm	17mm	1.10cc
	12mm	19mm	1.30cc

Typically add 1 to 2cc as actual autograft volumes may be different due to varying patient anatomy (such as concavity of the endplate) and graft compression ratio.



ONE MULTI-FUNCTIONAL INSTRUMENT TO INSERT, EXPAND, AND POST-PACK THE IMPLANT

TLX™ TECHNIQUE GUIDE

EQUIPMENT REQUIREMENTS

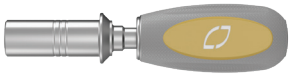
- TLXIMP
  - Transforaminal Lordotic eXpandable Implants set contains all Implants
- TLXINS
  - Transforaminal Lordotic eXpandable Instruments set contains Trial, Inserter, Torque Limiting Handle, and Graft Delivery system
- PGIINS
  - Posterior General Instrument set contains paddle sizers, shavers, curettes, and kerrisons
- M2TACCESS
  - MAS® TLIF 2 Access set contains the MAS TLIF 2 blades, retractor body, and instrumentation
- Fixation Options
  - Reline®
  - Precept®
- Biologics

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

Counter-torque

Quick Connect Torque Limiting Handle

Inserter

Strike Plate

GRAFT DELIVERY

Plunger

Graft Tamp

Funnel

Loading Block

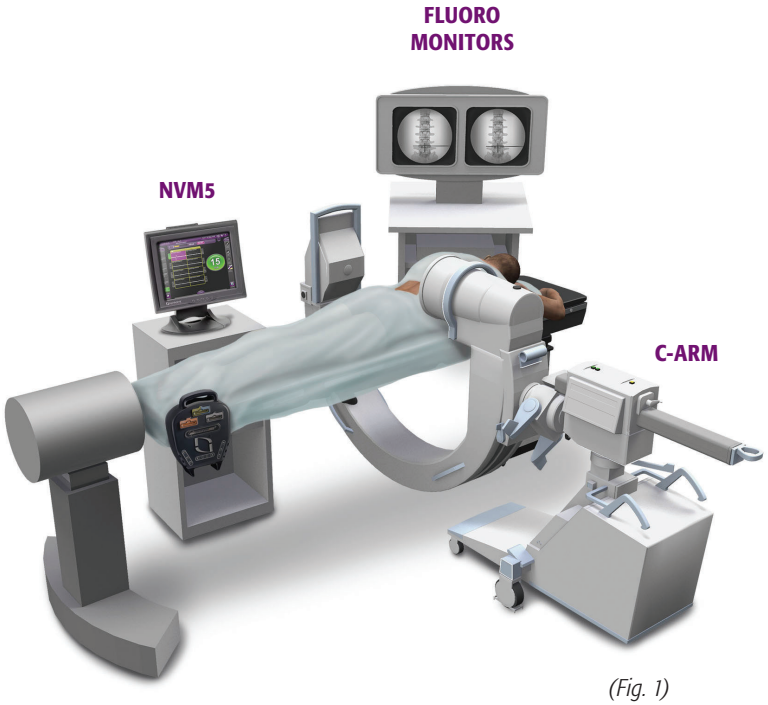
PATIENT POSITIONING AND O.R. SETUP

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)*.

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.



(Fig. 1)

TLX™ TECHNIQUE GUIDE

STEP 1:
DISCECTOMY

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

NVM5®: FREE RUN EMG

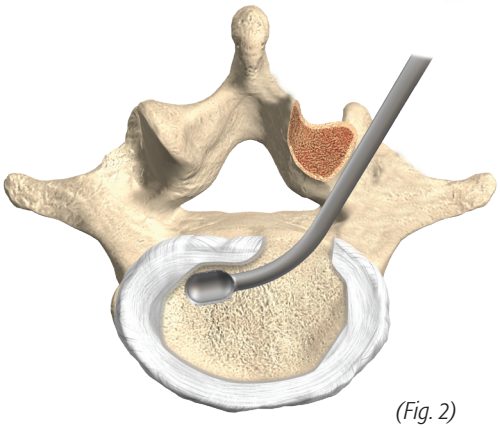
Use Free Run EMG to continuously monitor for mechanical disturbances to neural structures when using the TLX Implant and Inserter.

STEP 2:
SIZING

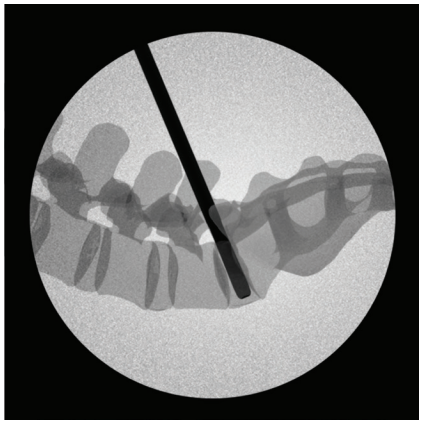
During discectomy, determine the appropriate Implant height using a standard paddle sizer. Using an impacted or Insert and Rotate technique, sequentially increase the height until the desired disc height is achieved *(Figs. 3, 4)*.

Note

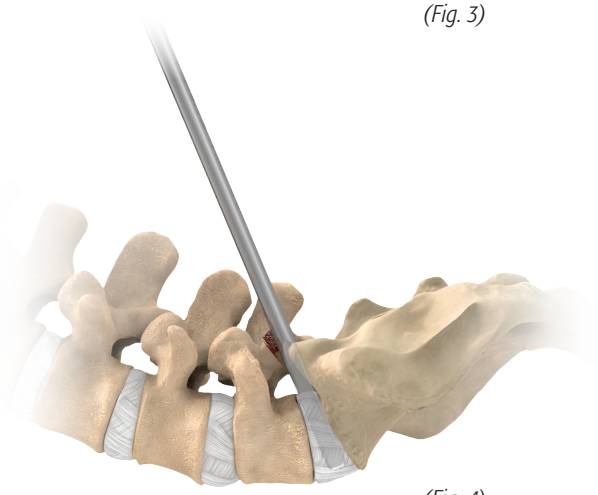
Paddle sizers are located in the Posterior General Instrument set (PGIINS).



(Fig. 2)



(Fig. 3)

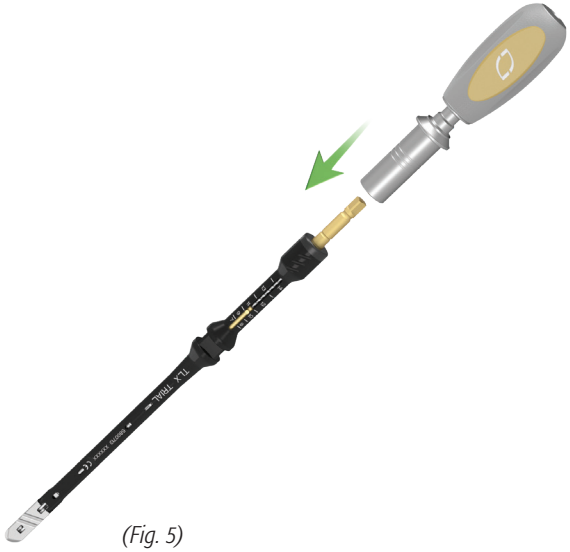


(Fig. 4)

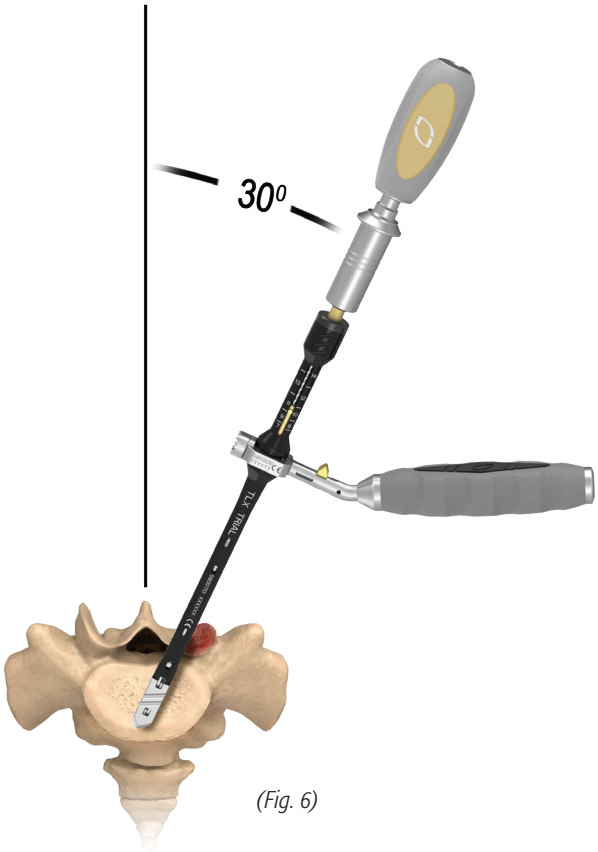
STEP 3:
TRIALING

If further trialing and distraction is required to determine the appropriate disc height, use the Expanding 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 *(Fig. 6)*.



(Fig. 5)



(Fig. 6)

TLX™ TECHNIQUE GUIDE

STEP 3:
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.

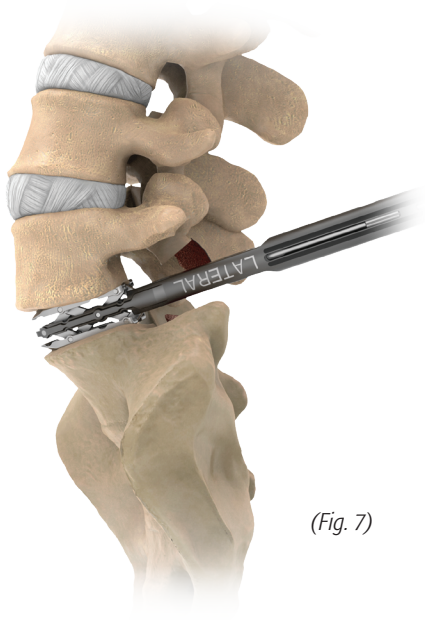
> ***Tip***
>
> *Proper oblique orientation of the Trial can be confirmed under fluoro by aligning the notches on the Trial, spaced 21 and 26mm from distal end.*

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)*.

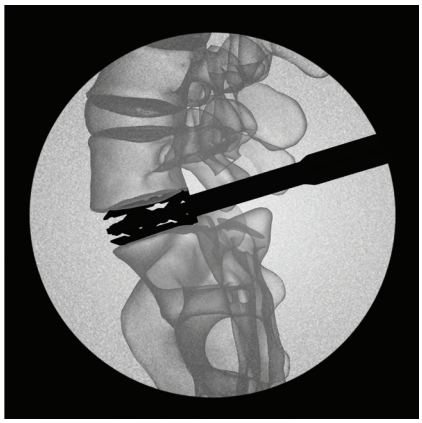
> ***Tip***
>
> *The Expanding Trial expands from 7 to 14mm in parallel height.*

Collapse and Removal

To remove, collapse the Trial by rotating the Torque Limiting Handle counterclockwise.



(Fig. 7)



(Fig. 8)

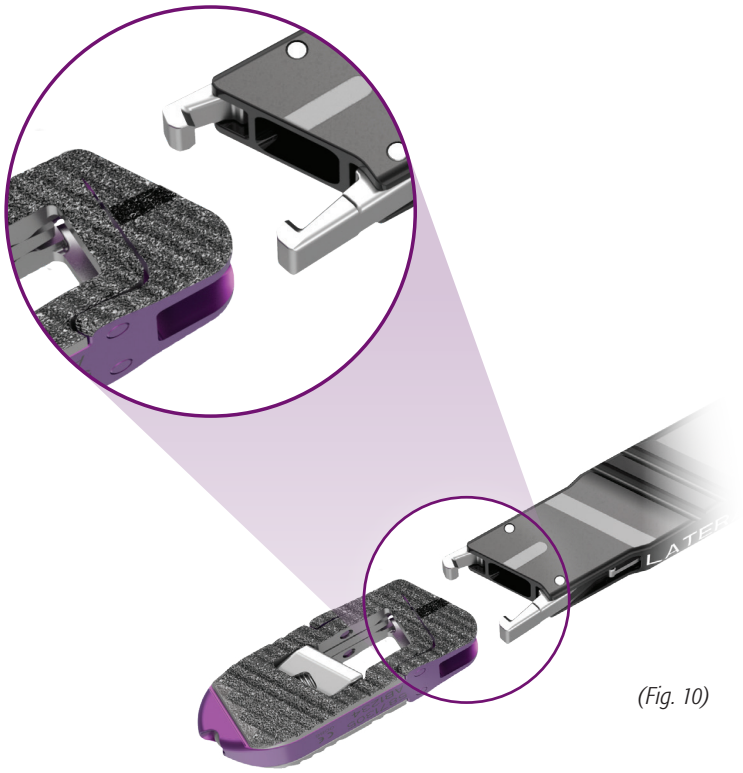
(Fig. 9)

STEP 4:
INSERTER ASSEMBLY

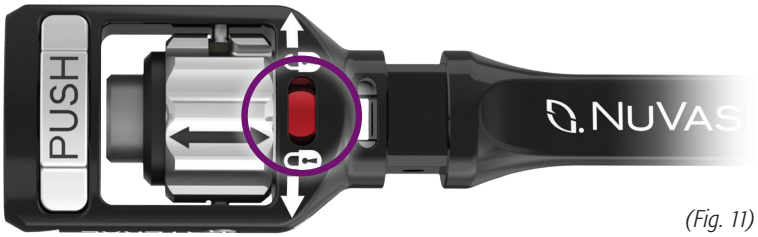
Choose the appropriate Implant based on sizing/trialing of the disc space. It is important to size line to line to resist undersizing of the lordotic Implant. Align the laser line on the Implant with the laser line on the Inserter *(Fig. 10)*. Lock the Implant to the Inserter by pushing the silver thumbwheel forward and turning it clockwise. If properly locked, the verification window will appear red *(Fig. 11)*.

> ***Note***
>
> *Implants are labeled by their anterior height in the collapsed state, not by the true posterior height. Be sure to reference the Implant sizing guide to determine the most accurate Implant size.*

> ***Tip***
>
> *If using the Ratcheting Inserter, lock the Implant to the Inserter by rotating the gold thumbwheel clockwise. If securely locked, the verification window will appear red.*



(Fig. 10)



(Fig. 11)

TLX™ TECHNIQUE GUIDE

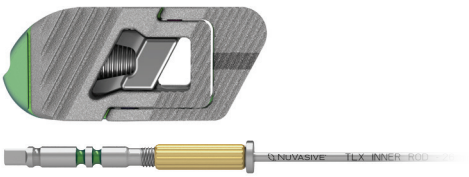
STEP 4:
INSERTER ASSEMBLY (CONT.)

Select the appropriate size Inner Rod. Rotate the gold indicator on the Inner Rod clockwise until it sits flush against the silver washer *(Fig. 12)*. Insert the Inner Rod into the Inserter until it engages the distal screw within the Implant *(Fig. 13)*.

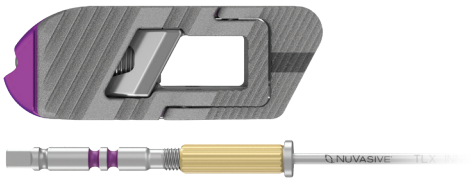
Tip

Inner Rods are color coded to correlate with Implant length.

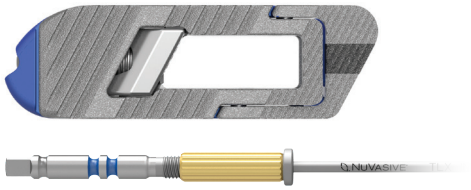
26mm: *Green*



31mm: *Purple*



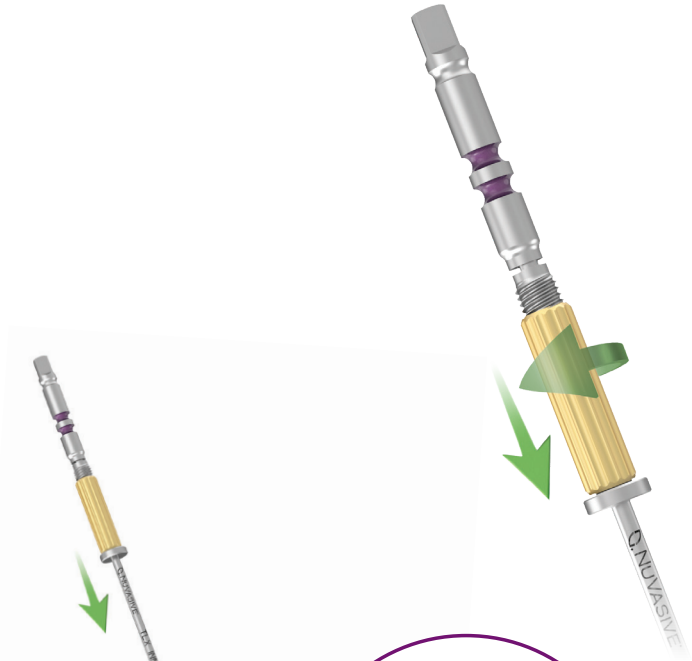
36mm: *Blue*



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. 12)

(Fig. 13)

(Fig. 14)

STEP 5:
IMPLANT INSERTION AND EXPANSION

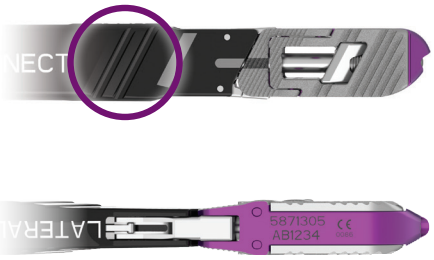
Attach the Counter-torque to the Inserter with the handle in the lateral position *(Fig. 15)*.

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.

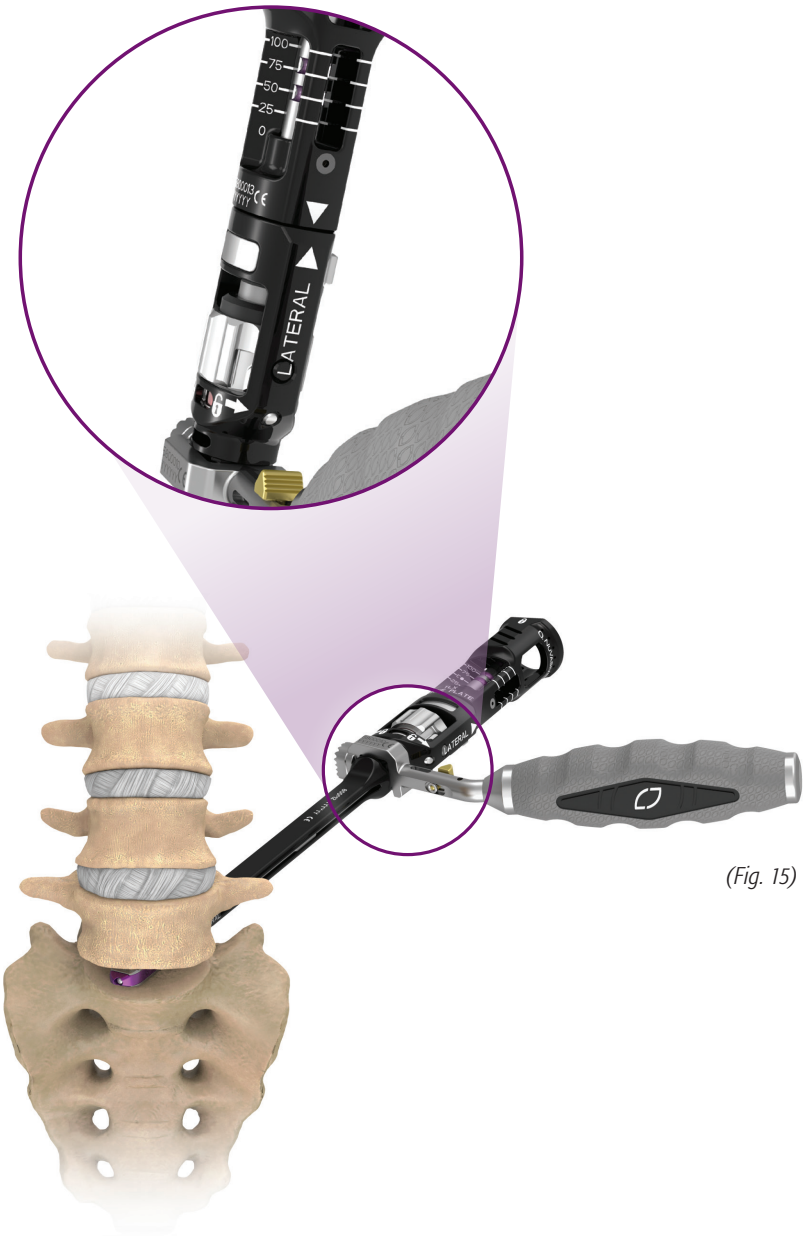
Tip

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.



(Fig. 15)

STEP 5:
IMPLANT INSERTION AND EXPANSION (CONT.)

Attach the black Torque Limiting Handle to the Inner Rod *(Fig. 16)*. Expand the Implant by slowing rotating the Torque Limiting Handle clockwise. Expand the Implant until proper 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. 17)*.

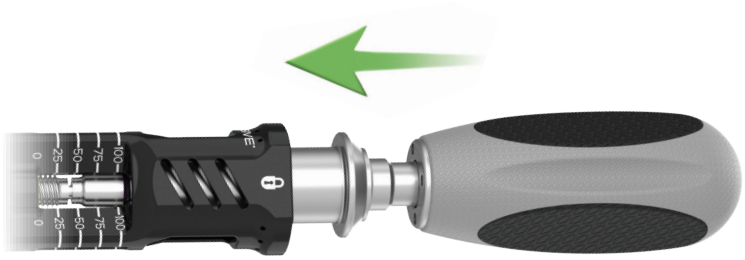
> ***Note***
> *The Torque Limiting Handle will break off at 25 in./lb.*

Repositioning

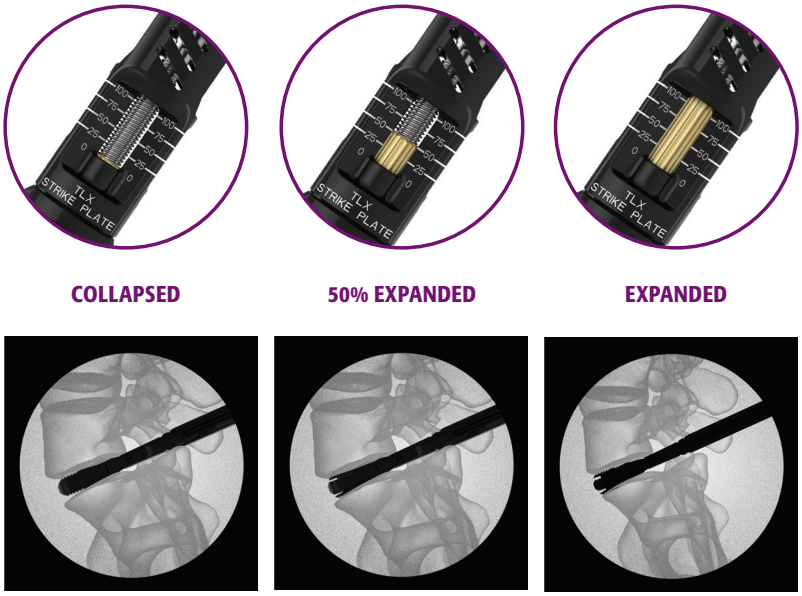
Rotate the Torque Limiting Handle counterclockwise to collapse the Implant. If impaction is necessary for repositioning, remove the Torque Limiting Handle and mallet on the Strike Plate.

After adequate adjustment, re-expand the Implant by repeating Step 5.

> **CAUTION**
> **A TLX Implant must not be re-expanded and reused after it has been filled with autograft, as mechanical failure may occur.**



(Fig. 16)



(Fig. 17)

STEP 6:
GRAFT DELIVERY ASSEMBLY

Place the Funnels on the Loading Block. Using the spoon end of the Graft Material Tamp, measure 1cc of graft material (1 heaping scoop is equivalent to 1cc) and place into a Funnel. Using the opposite end of the Tamp, tamp the graft material into the neck of the Funnel *(Fig. 18)*. Repeat these steps until the neck of the Funnel is full of graft material.

> ***Tip***
>
> *The neck of the Funnel is designed to hold a large amount of graft material. Pack the Funnel during discectomy, prior to attaching the Funnel to the Inserter.*

(Fig. 18)

TLX™ TECHNIQUE GUIDE

STEP 7:
GRAFT DELIVERY

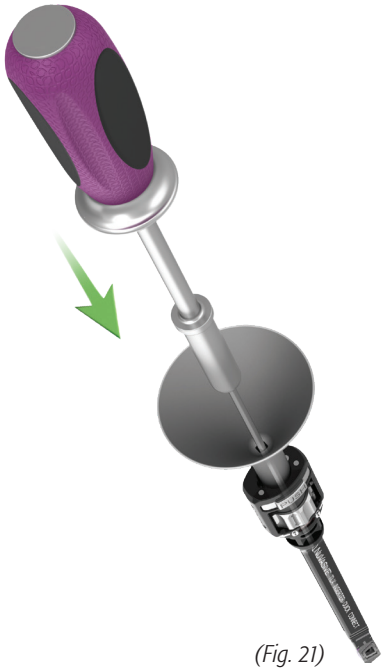
After the Implant has been expanded, press the silver button labeled "PUSH" and pull up on the Torque Limiting Handle *(Fig. 19)*.

Attach the Funnel to the Inserter *(Fig. 20)*.

While stabilizing the Inserter, drive the Graft Plunger into the Funnel *(Fig. 21)*. Continue until the Plunger bottoms out on the Funnel.

(Fig. 19)

(Fig. 20)

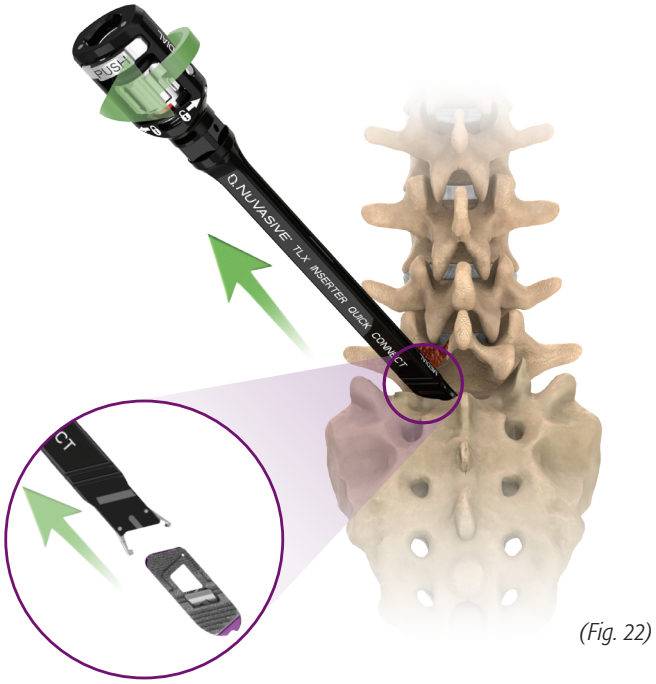


(Fig. 21)

STEP 8:
INSERTER RELEASE

Remove the Funnel from the Inserter by pressing the silver button labeled "PUSH." Turn the silver thumbwheel counterclockwise until the thumbwheel is released to remove the Implant from the Inserter *(Fig. 22)*.

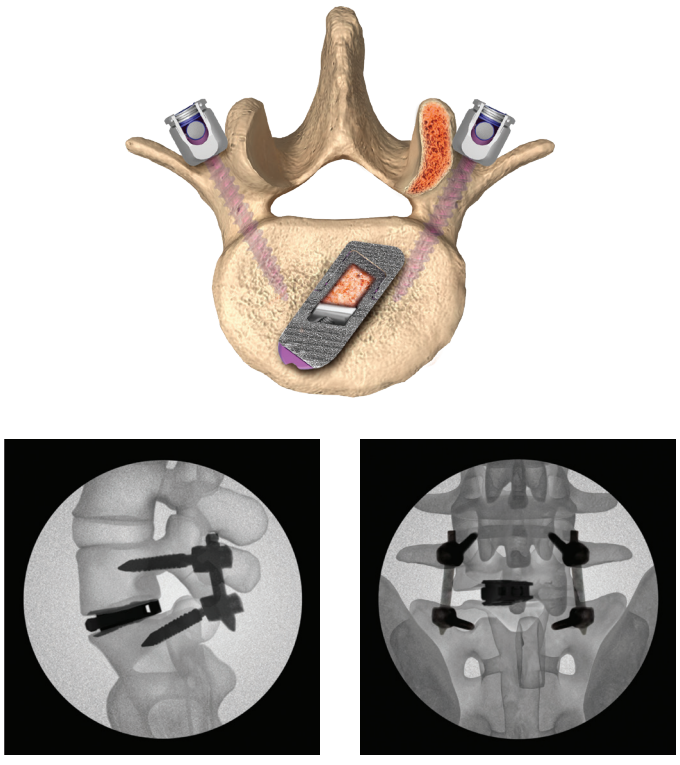
> ***Tip***
>
> *Should re-attachment of the Inserter to the Implant be required, use the Alignment Tool as a guide. Insert the Alignment Tool into the Implant, then slide the Ratcheting Inserter over the Alignment Tool until the Inserter engages the proximal end of the Implant.*



(Fig. 22)

STEP 9:
FIXATION

Place the desired fixation system, such as Reline® or Precept® *(Fig. 23)*.



(Fig. 23)

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.

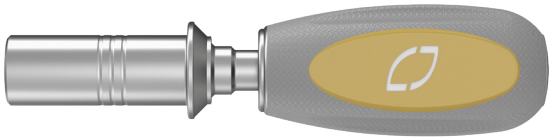
Should Implant removal be required after post-packing the Implant, an ALIF may be performed.

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. 24)*. 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.

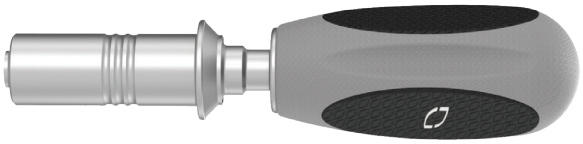
(Fig. 24)

TLX INSTRUMENTS

TLX TORQUE LIMITING HANDLE



TLX QUICK CONNECT TORQUE LIMITING HANDLE



TLX INSERTER

TLX INSERTER, QUICK CONNECT

TLX COUNTER-TORQUE

TLX STRIKE PLATE

TLX™ SYSTEM

TLX INSTRUMENTS

TLX EXPANDING TRIAL, 7-14mm

TLX INNER ROD, 26mm

TLX INNER ROD, 31mm

TLX INNER ROD, 36mm

TLX PLUNGER, GRAFT DELIVERY

TLX INSTRUMENTS

TLX TAMP

TLX GRAFT MATERIAL LOADING BLOCK

TLX GRAFT MATERIAL TAMP

TLX FUNNEL, GRAFT DELIVERY

TLX ALIGNMENT TOOL

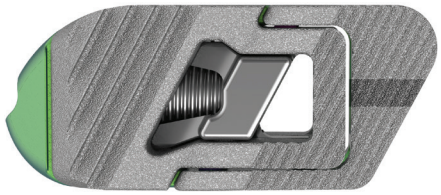
TLX DRILL

TLX HUDSON ADAPTER

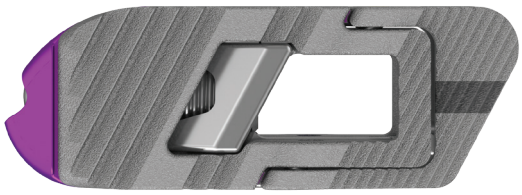
TLX™ SYSTEM

TLX IMPLANTS

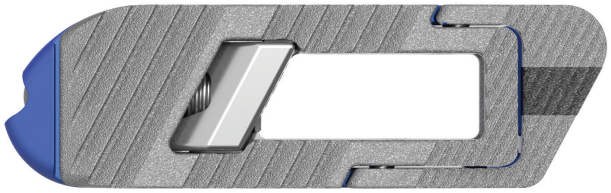
TLX IMPLANT, 26mm, 15°



TLX IMPLANT, 31mm, 15°

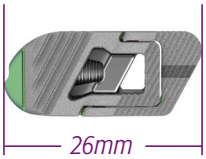


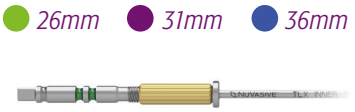
TLX IMPLANT, 36mm, 15°

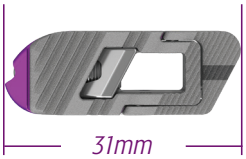


SIZING GUIDE

IMPLANTS AND INNER RODS ARE COLOR CODED BY LENGTH





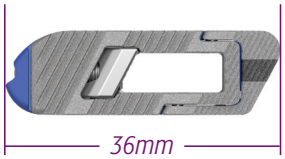


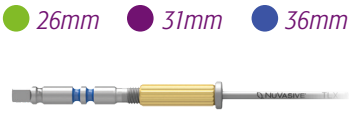
PART NUMBER	PERCENT EXPANDED	ANTERIOR HEIGHT	POSTERIOR HEIGHT	LORDOSIS
5871255 7 x 11 x 26mm	0%	7mm	5mm	0°
	25%	8mm	5mm	3°
	50%	8.5mm	5mm	7°
	75%	9mm	5mm	11°
	100%	10mm	5mm	15°
5881255 8 x 11 x 26mm	0%	7mm	6mm	0°
	25%	8.5mm	6mm	3°
	50%	9mm	6mm	7°
	75%	10mm	6mm	11°
	100%	11mm	6mm	15°
5891255 9 x 11 x 26mm	0%	8mm	7mm	0°
	25%	9mm	7mm	4°
	50%	10mm	7mm	7°
	75%	11mm	7mm	11°
	100%	12mm	7mm	15°
5801255 10 x 11 x 26mm	0%	10mm	8mm	0°
	25%	10.5mm	8mm	4°
	50%	11mm	8mm	7°
	75%	12mm	8mm	11°
	100%	13mm	8mm	15°
5811255 11 x 11 x 26mm	0%	11mm	9mm	0°
	25%	11.5mm	9mm	4°
	50%	12mm	9mm	7°
	75%	13.5mm	9mm	11°
	100%	14mm	9mm	15°
5821255 12 x 11 x 26mm	0%	12mm	10mm	0°
	25%	12.5mm	10mm	4°
	50%	13mm	10mm	7°
	75%	14mm	10mm	11°
	100%	15mm	10mm	15°
5841255 14 x 11 x 26mm	0%	14mm	12mm	0°
	25%	14.5mm	12mm	4°
	50%	15mm	12mm	7°
	75%	16mm	12mm	11°
	100%	17mm	12mm	15°

PART NUMBER	PERCENT EXPANDED	ANTERIOR HEIGHT	POSTERIOR HEIGHT	LORDOSIS
5871305 7 x 11 x 31mm	0%	7mm	5mm	0°
	25%	8mm	5mm	4°
	50%	9mm	5mm	7°
	75%	10mm	5mm	11°
	100%	11mm	5mm	15°
5881305 8 x 11 x 31mm	0%	8mm	6mm	0°
	25%	9mm	6mm	4°
	50%	10mm	6mm	7°
	75%	11mm	6mm	10°
	100%	12mm	6mm	15°
5891305 9 x 11 x 31mm	0%	9mm	7mm	0°
	25%	10mm	7mm	4°
	50%	11mm	7mm	7°
	75%	12mm	7mm	11°
	100%	13mm	7mm	15°
5801305 10 x 11 x 31mm	0%	10mm	8mm	0°
	25%	11mm	8mm	4°
	50%	12mm	8mm	7°
	75%	13mm	8mm	11°
	100%	14mm	8mm	15°
5811305 11 x 11 x 31mm	0%	11mm	9mm	0°
	25%	12mm	9mm	3°
	50%	13mm	9mm	7°
	75%	14mm	9mm	11°
	100%	15mm	9mm	15°
5821305 12 x 11 x 31mm	0%	12mm	10mm	0°
	25%	13mm	10mm	4°
	50%	14mm	10mm	7°
	75%	15mm	10mm	11°
	100%	16mm	10mm	15°
5841305 14 x 11 x 31mm	0%	14mm	12mm	0°
	25%	15mm	12mm	4°
	50%	16mm	12mm	7°
	75%	17mm	12mm	11°
	100%	18mm	12mm	15°

SIZING GUIDE

IMPLANTS AND INNER RODS ARE COLOR CODED BY LENGTH





PART NUMBER	PERCENT EXPANDED	ANTERIOR HEIGHT	POSTERIOR HEIGHT	LORDOSIS
5871352 7 x 11 x 36mm	0%	7mm	5mm	0°
	25%	8mm	5mm	3°
	50%	9mm	5mm	6°
	75%	10mm	5mm	9°
	100%	11mm	5mm	12°
5881352 8 x 11 x 36mm	0%	8mm	6mm	0°
	25%	9mm	6mm	3°
	50%	10mm	6mm	6°
	75%	11mm	6mm	9°
	100%	12mm	6mm	12°
5891355 9 x 11 x 36mm	0%	9mm	7mm	0°
	25%	10mm	7mm	4°
	50%	11mm	7mm	7°
	75%	13mm	7mm	11°
	100%	14mm	7mm	15°
5801355 10 x 11 x 36mm	0%	10mm	8mm	0°
	25%	11mm	8mm	4°
	50%	12mm	8mm	7°
	75%	14mm	8mm	11°
	100%	15mm	8mm	15°
5811355 11 x 11 x 36mm	0%	11mm	9mm	0°
	25%	12mm	9mm	4°
	50%	13mm	9mm	7°
	75%	15mm	9mm	11°
	100%	16mm	9mm	15°
5821355 12 x 11 x 36mm	0%	12mm	10mm	0°
	25%	13mm	10mm	4°
	50%	14mm	10mm	7°
	75%	16mm	10mm	11°
	100%	17mm	10mm	15°
5841355 14 x 11 x 36mm	0%	14mm	12mm	0°
	25%	15mm	12mm	4°
	50%	16mm	12mm	7°
	75%	17mm	12mm	11°
	100%	19mm	12mm	15°

TLX™ INSTRUMENTS

DESCRIPTION	CATALOG #
Generic NuVasive® Tray Lid	8801300
TLX Expanding Trial, 7-14mm	5800713
TLX Inserter, Quick Connect	5800012
TLX Inserter	5800011
TLX Torque Limiting Handle	5800000
TLX Quick Connect Torque Limiting Handle	5800022
TLX Strike Plate	5800013
TLX Inner Rod, 26mm	5890026
TLX Inner Rod, 31mm	5890031
TLX Inner Rod, 36mm	5890036
TLX Counter-torque	5800010
TLX Graft Material Tamp	5800021
TLX Graft Material Loading Block	5800020
TLX Plunger, Graft Delivery	5800016
TLX Funnels, Graft Delivery	5800015
TLX Hudson Adapter	5800018
TLX Tamp	5800023
TLX Alignment Tool	5800019
TLX Drill	5800017
TLX Nipple Mat	5800006
TLX Top Insert	5800002
TLX Bottom Insert	5800003
TLX Tray Base	5800001

TLX IMPLANTS

DESCRIPTION	CATALOG #
TLX Implant, 7 x 11 x 26mm, 15°	5871255
TLX Implant, 7 x 11 x 31mm, 15°	5871305
TLX Implant, 7 x 11 x 36mm, 12°	5871352
TLX Implant, 8 x 11 x 26mm, 15°	5881255
TLX Implant, 8 x 11 x 31mm, 15°	5881305
TLX Implant, 8 x 11 x 36mm, 12°	5881352
TLX Implant, 9 x 11 x 26mm, 15°	5891255
TLX Implant, 9 x 11 x 31mm, 15°	5891305
TLX Implant, 9 x 11 x 36mm, 15°	5891355
TLX Implant, 10 x 11 x 26mm, 15°	5801255
TLX Implant, 10 x 11 x 31mm, 15°	5801305
TLX Implant, 10 x 11 x 36mm, 15°	5801355
TLX Implant, 11 x 11 x 26mm, 15°	5811255
TLX Implant, 11 x 11 x 31mm, 15°	5811305
TLX Implant, 11 x 11 x 36mm, 15°	5811355
TLX Implant, 12 x 11 x 26mm, 15°	5821255
TLX Implant, 12 x 11 x 31mm, 15°	5821305
TLX Implant, 12 x 11 x 36mm, 15°	5821355
TLX Implant, 14 x 11 x 26mm, 15°	5841255
TLX Implant, 14 x 11 x 31mm, 15°	5841305
TLX Implant, 14 x 11 x 36mm, 15°	5841355
TLX Implant Caddy, 26mm	5800026
TLX Implant Caddy, 31mm	5800031
TLX Implant Caddy, 36mm	5800036
Generic NuVasive Tray Lid	8801300
TLX Implant Tray, Base	5800008

INSTRUCTIONS FOR USE

INDICATIONS

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 bone graft to facilitate fusion.

The TLX Interbody System is intended for use at either one level or two contiguous levels in the lumbar spine, from L2 to S1, for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. Patients must have undergone a regimen of at least six (6) months of non-operative treatment prior to being treated with the TLX Interbody System. The TLX Interbody System is intended to be used with supplemental internal spinal fixation systems that are cleared by the FDA for use in the lumbar spine.

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.

Potential risks identified with the use of this device system, which may require additional surgery, include: device component fracture, loss of fixation, non-union, fracture of the vertebra, neurological injury, and vascular or visceral injury.

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 non-union. 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.

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: 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.

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

Magnetic Resonance (MR) Safety: The TLX Interbody System has not been evaluated for safety and compatibility in the MR environment. The TLX Interbody System has not been tested for heating or migration in the MR environment.

Compatibility: Do not use the 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 implants. The implants should not be scratched or damaged. Implants and instruments should be protected during storage and from corrosive environments.
4. All non-sterile parts should be cleaned and sterilized before use.
5. Devices should be inspected for damage prior to implantation.
6. 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 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* Package Insert (Electronic Instructions for Use 9402203) for complete labeling information.

NOTES

To order, please contact your NuVasive Sales Consultant or Customer Service Representative today at:
NuVasive, Inc. 7475 Lusk Blvd., San Diego, CA 92121 USA • phone: 800-475-9131 fax: 800-475-9134
EC REP **NuVasive Netherlands B.V.** Jachthavenweg 109A, 1081 KM Amsterdam, The Netherlands • phone: 31-20-72-33-000

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