CALIBRATE LTX™

WITH ADVANCED **NANOTEC** TREATMENT

atec™ INFORMED BY EOS

LATERAL INTERBODY IMPLANTS | Surgical Technique Guide

CALIBRATE LTX™

WITH ADVANCED **NANOTEC** TREATMENT

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5-15° INTERBODY SPACERS

- **Sagittal profile:** 5-15°
- **Posterior height expansion:** 6-9 mm
- **Lengths:** 45-60 mm (5 mm increments)
- **Widths:** 18 mm & 22 mm

5-20° INTERBODY SPACERS

- **Sagittal profile:** 5-20°
- **Posterior height expansion:** 6-7.5 mm
- **Lengths:** 45-60 mm (5 mm increments)
- **Widths:** 18 mm & 22 mm

8 MM, 5 – 15° INTERBODY SPACER

- **Sagittal profile:** 5-15°
- **Posterior height expansion:** 8-11 mm
- **Lengths:** 45-60 mm (5 mm increments)
- **Widths:** 18 mm & 22 mm

6 MM, 5 – 30° INTERBODY SPACER

- **Sagittal profile:** 15-30°
- **Posterior height expansion:** 6-8.7 mm
- **Lengths:** 45-60 mm (5 mm increments)
- **Widths:** 22 mm

1 Select the desired LTX or static Trial (each of the two LTX Interbody Spacers have a corresponding LTX Trial).

> **TIP:** IF USING STATIC TRIALS, IT IS RECOMMENDED TO SEQUENTIALLY INCREASE TRIAL SIZE FROM LATTRLS/ LAT15TR/LATTRLO/LIFHLTR.

2 Insert the LTX or static Trial into the disc space at its minimized height. Confirm appropriate placement of the LTX Trial using A/P fluoroscopy and lateral fluoroscopy.

3 Attach the Expansion Driver T-Handle or the LTX Expansion Driver Axial Handle to the LTX Trial by sliding the Handle over the proximal protruding shaft of the LTX Trial until it clicks into place.

> **TIP:** ASSESS THE LTX TRIAL'S POSITION BY UTILIZING THE PROXIMAL AND DISTAL CHAMFERS TO DETERMINE ENDPLATE POSITION.

> **TIP:** DETERMINE THE APPROPRIATE LENGTH OF THE LTX INTERBODY SPACER TO BE IMPLANTED BY THE FLUOROSCOPY LENGTH INDICATORS ON THE LTX TRIAL.

4 Rotate the Handle clockwise to expand the LTX Trial. Confirm appropriate expansion of the LTX Trial using A/P and lateral fluoroscopy.

> **TIP:** ASSESS POSTERIOR HEIGHT AND LORDOSIS EXPANSION OF THE LTX TRIAL VIA THE PROXIMAL INDICATOR BAND OF THE LTX TRIAL.

> **CAUTION:** TO AVOID DAMAGE TO THE VERTEBRAL ENDPLATES, DO NOT EXCESSIVELY EXPAND THE LTX TRIAL OR THE LTX INTERBODY SPACER.

5 Collapse the LTX Trial by rotating the Handle counterclockwise and remove the LTX Trial from the disc space.

> **CAUTION:** TO AVOID DAMAGE TO THE LTX TRIAL, DO NOT EXCESSIVELY COLLAPSE THE LTX TRIAL.

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1 Attach the LTX Expansion Driver T-Handle or the LTX Expansion Driver Axial Handle to the proximal end of the LTX Inserter.

2 Pack bone graft (autograft or allogenic bone graft comprised of cortical, cancellous, and/or corticocancellous bone graft) into the graft chamber of the LTX Interbody Spacer. The bone graft may be pre-packed into the cage prior to implantation and expansion, and/or post-packed after expansion.

> **TIP:** BONE GRAFT MUST CONSIST OF AUTOGRAFT AND/OR ALLOGENEIC BONE GRAFT COMPRISED OF CORTICAL, CANCELLOUS, AND/OR CORTICOCANCELLOUS BONE, AND/OR DEMINERALIZED ALLOGRAFT BONE WITH BONE MARROW ASPIRATE OR A BONE VOID FILLER AS CLEARED BY FDA FOR USE IN INTERVERTEBRAL BODY FUSION TO FACILITATE FUSION.

3 Attach the LTX Interbody Spacer to the LTX Inserter by aligning the tangs of the LTX Inserter outer sleeve with the mating pockets on the LTX Interbody Spacer. Thread the LTX Inserter into the LTX Interbody Spacer by utilizing the LTX Attachment Driver.

> **TIP:** OFFSET LEFT/RIGHT AND OFFSET MEDIAL/LATERAL LTX INSERTERS ARE ALSO AVAILABLE AND CAN BE UTILIZED DEPENDING ON THE DISC SPACE ACCESS REQUIREMENTS.

4 Insert the LTX Interbody Spacer into the disc space at its minimum height. Confirm appropriate placement of the LTX Interbody Spacer using A/P and lateral fluoroscopy.

> **TIP:** ASSESS THE POSITION OF THE LTX INTERBODY SPACER BY UTILIZING THE PROXIMAL AND DISTAL CHAMFERS TO DETERMINE ENDPLATE POSITION.

> **TIP:** THE LENGTH OF AN LTX INTERBODY SPACER IS DETERMINED BY THE LENGTH OF THE ENDPLATE AND IS NOT INCLUSIVE OF THE DISTAL/PROXIMAL HOUSING PROTRUSIONS.

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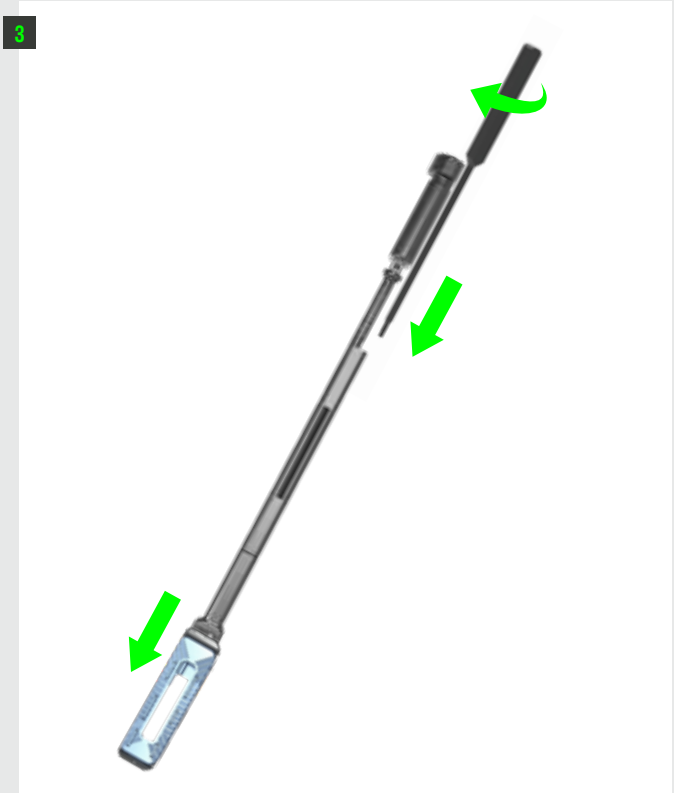


1 Attach the LTX Expansion Driver T-Handle or the LTX Expansion Driver Axial Handle to the proximal end of the LTX Inserter.

> **TIP:** THE LTX HANDLES ARE TORQUE-LIMITING, TO AID IN IDENTIFYING WHEN THE LTX INTERBODY SPACER HAS REACHED ITS MAXIMUM EXPANSION AND/OR WHEN THE MAXIMUM DISTRACTION FORCE HAS BEEN REACHED.

2 Rotate the Handle clockwise to expand the LTX Interbody Spacer. Confirm appropriate expansion of the LTX Interbody Spacer using A/P and lateral fluoroscopy.

> **TIP:** THE EXTENT OF APPROPRIATE EXPANSION OF THE LTX INTERBODY SPACER IS DETERMINED BY FLUOROSCOPY, DIRECT VISUALIZATION, AND TACTILE FEEL. GENTLY TOGGLE THE LTX INTERBODY SPACER IN THE A/P DIRECTION UNTIL THE DESIRED FIT IS ACHIEVED. REFER TO HEALTHY LEVELS ABOVE AND BELOW THE OPERATIVE LEVEL TO FURTHER AID IN DETERMINING FINAL DISC HEIGHT.

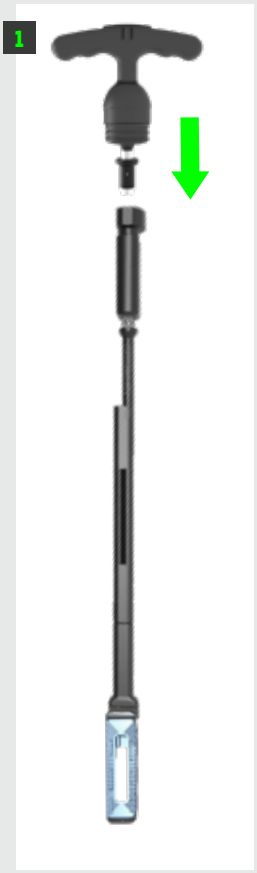
> **TIP:** USE THE LTX EXPANSION DRIVER T-HANDLE OR THE LTX EXPANSION DRIVER AXIAL HANDLE TO COUNT THE NUMBER OF ROTATIONS OF EXPANSION. REFER TO PAGE 7 FOR THE CORRELATED EXPANSION RANGES OF THE VARIOUS LTX INTERBODY SPACERS.

> **CAUTION:** TO AVOID DAMAGE TO THE VERTEBRAL ENDPLATES, DO NOT EXCESSIVELY EXPAND THE LTX TRIAL OR THE LTX INTERBODY SPACER.

3 Remove the LTX Inserter by utilizing the LTX Attachment Driver to unthread the LTX Interbody Spacer from the LTX Inserter.

> **TIP:** UTILIZE THE LTX FREEHAND EXPANSION DRIVER IF MORE LTX INTERBODY SPACER EXPANSION IS REQUIRED AFTER REMOVING THE LTX INSERTER.

> **CAUTION:** TO AVOID DAMAGE TO THE VERTEBRAL ENDPLATES, DO NOT EXCESSIVELY EXPAND THE LTX TRIAL OR THE LTX INTERBODY SPACER.



CALIBRATE LTX 5 - 15° INTERBODY SPACER EXPANSION RANGES

WIDTH	MEASURE	ROTATIONS										
		0	1	2	3	4	5	6	7	8	9	10
18 mm	Anterior Height (mm)	7.6	8.2	8.9	9.5	10.2	10.8	11.5	12.1	12.8	13.6	
	Posterior Height (mm)	6.0	6.3	6.6	6.9	7.3	7.6	7.9	8.2	8.5	8.9	
	Lordotic Angle (°)	5.0	6.1	7.1	8.2	9.3	10.4	11.4	12.5	13.6	15.0	
22 mm	Anterior Height (mm)	7.9	8.6	9.3	10.0	10.6	11.3	12.0	12.7	13.3	14.0	14.7
	Posterior Height (mm)	6.0	6.3	6.6	6.9	7.2	7.5	7.8	8.1	8.3	8.6	8.9
	Lordotic Angle (°)	5.0	6.0	7.0	8.0	9.0	10.0	11.0	12.0	13.0	14.0	15.0

CALIBRATE LTX 5 - 20° INTERBODY SPACER EXPANSION RANGES

WIDTH	MEASURE	ROTATIONS									
		0	1	2	3	4	5	6	7	8	9
18 mm	Anterior Height (mm)	7.6	8.4	9.1	9.9	10.7	11.5	12.2	13.0	13.8	
	Posterior Height (mm)	6.0	6.2	6.4	6.6	6.8	7.0	7.2	7.3	7.5	
	Lordotic Angle (°)	5.0	6.9	8.7	10.6	12.5	14.3	16.2	18.1	20.0	
22 mm	Anterior Height (mm)	7.9	8.7	9.5	10.3	11.1	11.8	12.6	13.4	14.2	15.2
	Posterior Height (mm)	6.0	6.2	6.3	6.5	6.7	6.8	7.0	7.2	7.3	7.5
	Lordotic Angle (°)	5.0	6.6	8.2	9.8	11.4	13.1	14.7	16.3	17.9	20.0

CALIBRATE LTX 5 - 15° INTERBODY SPACER EXPANSION RANGES												
WIDTH	MEASURE	ROTATIONS										
		0	1	2	3	4	5	6	7	8	9	10
18 mm	Anterior Height (mm)	9.6	10.2	10.9	11.5	12.2	12.8	13.5	14.1	14.8	15.4	
	Posterior Height (mm)	8.0	8.3	8.6	9.0	9.3	9.6	9.9	10.3	10.6	10.9	
	Lordotic Angle (º)	5.0	6.1	7.1	8.2	9.3	10.4	11.4	12.5	13.6	14.7	
22 mm	Anterior Height (mm)	9.9	10.6	11.3	12.0	12.6	13.3	14.0	14.7	15.3	16.0	16.6
	Posterior Height (mm)	8.0	8.3	8.6	8.9	9.2	9.5.	9.8	10.1	10.4	10.7	11.0
	Lordotic Angle (º)	5.0	6.0	7.0	8.0	9.0	10.0	11.0	12.0	13.0	14.0	15.0

CALIBRATE LTX 15 - 30° INTERBODY SPACER EXPANSION RANGES													
WIDTH	MEASURE	ROTATIONS											
		0	1	2	3	4	5	6	7	8	9	10	11	12
22 mm	Anterior Height (mm)	11.8	12.5	13.3	14.0	14.7	15.4	16.2	16.9	17.6	18.3	19.1	19.8	20.2
	Posterior Height (mm)	6.0	6.2	6.5	6.7	6.9	7.2	7.4	7.7	7.9	8.1	8.4	8.6	8.7
	Lordotic Angle (º)	15.0	16.3	17.6	18.9	20.2	21.4	22.7	24.0	25.3	26.6	27.9	29.2	30.0

1 Pack bone graft in and around the disc space. The bone graft may be pre-packed into the cage prior to implantatoin and expansion, and/or post-packed after expansion.

> **NOTE:** BONE GRAFT MUST CONSIST OF AUTOGRAFT AND/OR ALLOGENEIC BONE GRAFT COMPRISED OF CORTICAL, CANCELLOUS, AND/OR CORTICOCANCELLOUS BONE, AND/OR DEMINERALIZED ALLOGRAFT BONE WITH BONE MARROW ASPIRATE OR A BONE VOID FILLER AS CLEARED BY FDA FOR USE IN INTERVERTEBRAL BODY FUSION TO FACILITATE FUSION.

2 Attach the LTX Graft Funnel to the proximal end of the threaded or cone LTX Graft Tube and insert graft into the LTX Graft Tube cannula through the LTX Graft Funnel.

> **TIP:** THE LTX GRAFT TUBE HOLDS 2.4 CC OF GRAFT AND CAN BE PRE-LOADED. BONE GRAFT MATERIAL SHOULD BE MORSELIZED AND ADVANCED THROUGH THE SHAFT TO CONFIRM THAT THE SIZE OF GRAFT PARTICULATE CAN BE EASILY PUSHED THROUGH. USE THE LTX GRAFT TAMP TO PUSH BONE GRAFT MATERIAL TO THE DISTAL END OF THE LTX GRAFT TUBE, REMOVING AIR FROM THE TUBE.

3 Mate the LTX threaded or cone Graft Tube with the proximal end of the LTX Interbody Spacer graft cannula and push the graft into the disc space/LTX Interbody Spacer with the LTX Graft Tamp.

> **TIP:** REFER TO PAGE 9 FOR GRAFT VOLUME REQUIRED TO FILL THE LTX INTERBODY SPACER DEPENDING ON SIZE AND EXPANSION.

> **CAUTION:** A LTX INTERBODY SPACER MUST NOT BE COLLAPSED/RE-EXPANDED AND REUSED IF IT HAS BEEN FILLED WITH GRAFT, AS MECHANICAL FAILURE MAY OCCUR.

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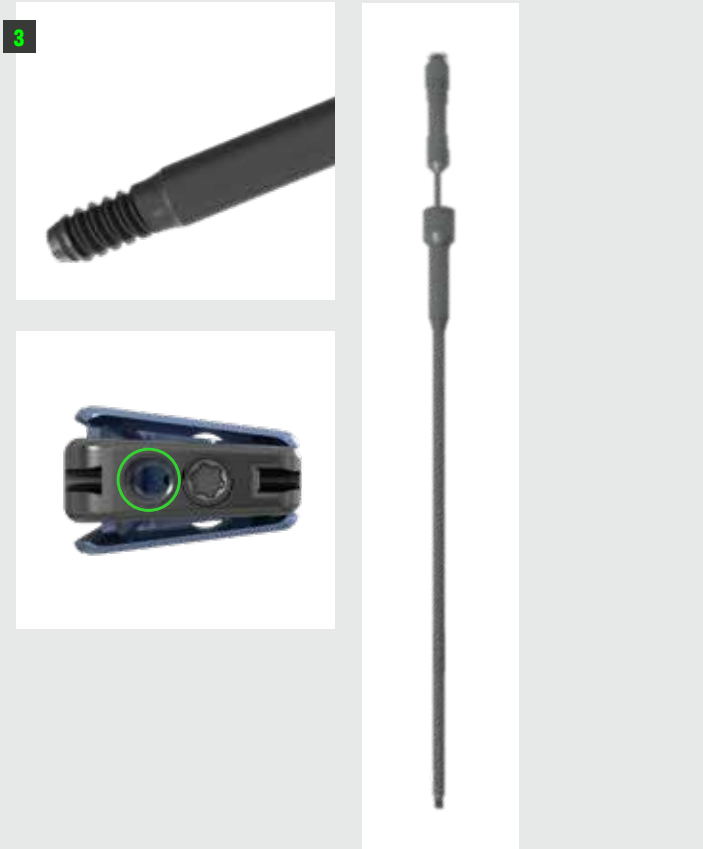

GRAFT VOLUME BY INTERBODY SPACER SIZE			
Part Number	Description	Collapsed (CC)	Expanded (CC)
261-PRO-06184515-S	6 mm x 18 mm x 45 mm, 15°	0.96	2.02
261-PRO-06185015-S	6 mm x 18 mm x 50 mm, 15°	1.19	2.40
261-PRO-06185515-S	6 mm x 18 mm x 55 mm, 15°	1.43	2.78
261-PRO-06186015-S	6 mm x 18 mm x 60 mm, 15°	1.66	3.16
261-PRO-06224515-S	6 mm x 22 mm x 45 mm, 15°	1.43	3.09
261-PRO-06225015-S	6 mm x 22 mm x 50 mm, 15°	1.78	3.68
261-PRO-06225515-S	6 mm x 22 mm x 55 mm, 15°	2.13	4.26
261-PRO-06226015-S	6 mm x 22 mm x 60 mm, 15°	2.48	4.84
261-PRO-06184520-S	6 mm x 18 mm x 45 mm, 20°	1.00	1.91
261-PRO-06185020-S	6 mm x 18 mm x 50 mm, 20°	1.23	2.27
261-PRO-06185520-S	6 mm x 18 mm x 55 mm, 20°	1.47	2.63
261-PRO-06186020-S	6 mm x 18 mm x 60 mm, 20°	1.70	2.99
261-PRO-06224520-S	6 mm x 22 mm x 45 mm, 20°	1.42	2.97
261-PRO-06225020-S	6 mm x 22 mm x 50 mm, 20°	1.76	3.53
261-PRO-06225520-S	6 mm x 22 mm x 55 mm, 20°	2.10	4.09
261-PRO-06226020-S	6 mm x 22 mm x 60 mm, 20°	2.44	4.66
261-PRO-08184515-S	8 mm x 18 mm x 45 mm, 15°	1.21	1.85
261-PRO-08185015-S	8 mm x 18 mm x 50 mm, 15°	1.50	2.30
261-PRO-08185515-S	8 mm x 18 mm x 55 mm, 15°	1.79	2.75
261-PRO-08186015-S	8 mm x 18 mm x 60 mm, 15°	2.08	3.19
261-PRO-08224515-S	8 mm x 22 mm x 45 mm, 15°	1.84	2.88
261-PRO-08225015-S	8 mm x 22 mm x 50 mm, 15°	2.29	3.58
261-PRO-08225515-S	8 mm x 22 mm x 55 mm, 15°	2.74	4.28
261-PRO-08226015-S	8 mm x 22 mm x 60 mm, 15°	3.19	4.98
261-PRO-06224530-S	6 mm x 22 mm x 45 mm, 30°	1.74	3.75
261-PRO-06225030-S	6 mm x 22 mm x 50 mm, 30°	2.18	4.46
261-PRO-06225530-S	6 mm x 22 mm x 55 mm, 30°	2.62	5.17
261-PRO-06226030-S	6 mm x 22 mm x 60 mm, 30°	3.07	5.87

1 The Calibrate LTX Implants must be used with supplemental fixation cleared by the FDA for use in the thoracolumbar spine. Implant the supplemental fixation according to the recommended surgical technique for the fixation system.

NOTE: IF UTILIZING AMP-LTX, REFER TO LIT-85691. IF UTILIZING THE LTX 15-30 (PN: 257-06XXXXX30) IMPLANT WITH INTEGRATED FIXATION, USE THE LTX INSTRUMENTATION AND FOLLOW STEPS OUTLINED IN LIT-85345. IF UTILIZING THE NANOTEC LTX 15-30 (PN: 261-PRO-06XXXXX30-S)IMPLANT WITH INTEGRATED FIXATION, USE THE AMP-LTX INSTRUMENTATION AND FOLLOW THE STEPS BELOW.

NOTE: IF USING CALIBRATE LTX HYPERLORDOTIC CAGES (PN: 257-06XXXX30) WITH INTEGRATED FIXATION, CALIBRATE LTX MUST BE USED WITH THE LTX BONE SCREWS PROVIDED AND MUST NOT BE USED WITH AMP-LTX BONE SCREWS.

NOTE: IF USING CALIBRATE NANOTEC LTX HYPERLORDOTIC CAGES (PN: 261-PRO-06XXXX30-S) WITH INTEGRATED FIXATION, CALIBRATE NANOTEC LTX MUST BE USED WITH THE AMP-LTX BONE SCREWS PROVIDED AND MUST NOT BE USED WITH LTX BONE SCREWS.

CAUTION: THE SAFETY AND EFFECTIVENESS OF THIS DEVICE HAS NOT BEEN ESTABLISHED WHEN USED IN CONJUNCTION WITH BONE CEMENT OR FOR USE IN PATIENTS WITH POOR BONE QUALITY (E.G., OSTEOPOROSIS, OSTEOPENIA).

2 After the LTX Implant has been inserted into the disc space, utilize the LTX Adjustable Awl (if using PN: 257-06XXXX30) or AMP-LTX Adjustable Awl (if using PN: 261-PRO-06XXXX30-S) and adjust the depth control to the desired depth.

1 Position the AMP-LTX Adjustable Awl in the center of the bone screw hole of the LTX Implant and verify that the tip of the guide is properly seated in the bone screw hold of the LTX Implant.

> **NOTE:** IF THE TIP OF THE AMP-LTX ADJUSTABLE AWL'S SLEEVE IS NOT FULLY SEATED, ROTATE THE AMP-LTX ADJUSTABLE AWL SLEEVE UNTIL IT BECOMES SECURED IN PLACE.

2 Advance the AMP-LTX Adjustable Awl to the desired depth. Confirm appropriate trajectory using A/P and lateral fluoroscopy. Repeat this step for the second bone screw hole.

3 Connect the Ratcheting Axial Handle to the proximal end of the AMP-LTX Bone Screwdriver by pushing the distal sleeve proximally until the Ratcheting Egg Handle and the AMP-LTX Bone Screwdriver are fully connected.

4 Load the corresponding LTX Bone Screw based off of the length determined in Step 2 onto the AMP-LTX Bone Screwdriver. Next, align the screw tip into the previously prepared pilot hole. Rotate the AMP-LTX Bone Screwdriver clockwise to insert the AMP-LTX Bone Screw into the bone.

5 Advance the AMP-LTX Bone Screw until the head is fully seated into the LTX Implant. Final positioning of the AMP-LTX Bone Screw is confirmed by utilizing the AMP-LTX Blocker Driver to turn the blocker to the locked position. Confirm appropriate placement using A/P and lateral fluoroscopy.

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NOTE: IF LTX INTERBODY SPACER REMOVAL IS REQUIRED, UTILIZE THE STEPS BELOW.

1. Attach the LTX Interbody Spacer to the LTX Inserter by aligning the tangs of the LTX Inserter outer sleeve with the mating pockets on the LTX Interbody Spacer and threading the LTX Inserter into the LTX Interbody Spacer by utilizing the LTX Attachment Driver.

2. Attach the LTX Expansion Driver T-Handle or the LTX Expansion Driver Axial Handle to the proximal end of the LTX Inserter. Rotate counterclockwise until fully collapsed. Verify that the LTX Interbody Spacer has been collapsed on A/P and lateral fluoroscopy and remove it from the disc space. If needed, remove the LTX Expansion Driver T-Handle or the LTX Expansion Driver Axial Handle to allow for slap hammering.

TIP: IF NEEDED, UTILIZE THE LTX REMOVAL TOOL FOR FURTHER LEVERAGE TO REMOVE THE LTX INTERBODY SPACER.

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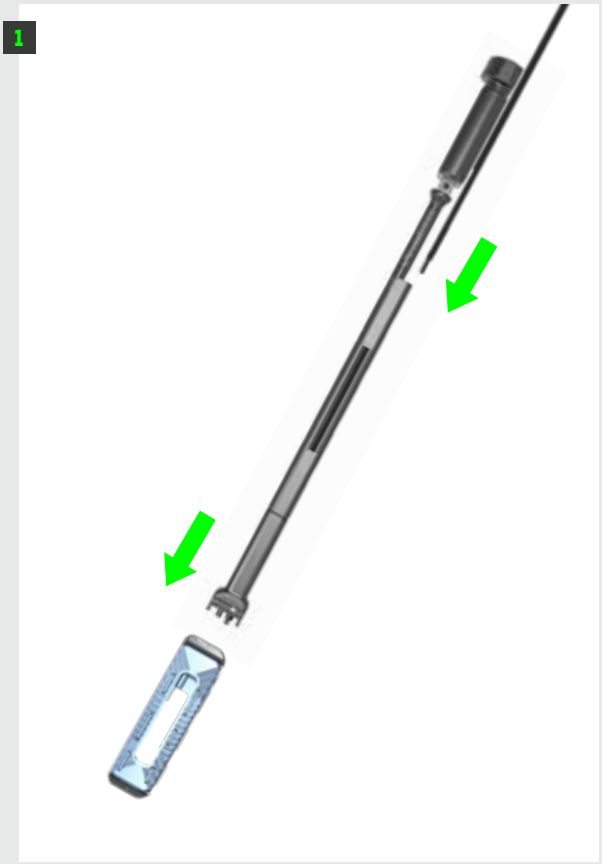

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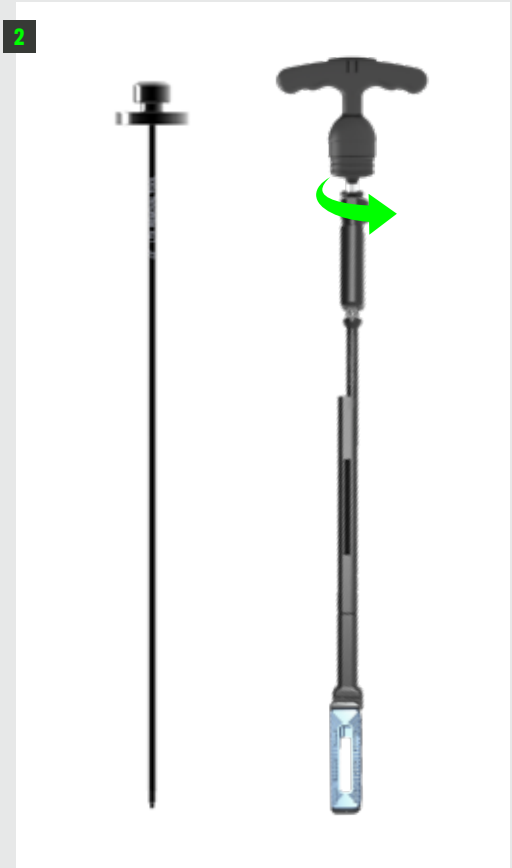

Calibrate™ NanoTec LTX™ Interbody System
INSTRUCTIONS FOR USE

GENERAL INFORMATION:
The Calibrate NanoTec LTX Interbody System is a lordotic expandable lumbar intervertebral body fusion system designed to be inserted through a lateral or anterolateral surgical approach. The Calibrate NanoTec LTX interbody spacers are manufactured from titanium alloy (Ti-6Al-4V ELI) per ASTM F136, Polyetheretherketone (PEEK) Optima LT1 per ASTM F2026, and cobalt chromium alloy (Co-28Cr-6Mo – Alloy 1) per ASTM F1537 with a nano-scale hydroxyapatite surface treatment. The bone screws are manufactured from titanium alloy (Ti-6Al-4V ELI) per ASTM F136. The Calibrate NanoTec LTX Interbody System consists of a variety of shapes and sizes of interbody spacers, bone screws, inserters, trials, and general instruments to create lordotic expansion, restore sagittal alignment, and provide indirect decompression.

Use Calibrate NanoTec LTX interbody spacers with supplemental fixation systems from Alphatec Spine such as: Zodiac® Polyaxial Spinal Fixation System, Arsenal® Spinal Fixation System, Illico® MIS Posterior Fixation System, BridgePoint® Spinous Process Fixation System, or Invictus® Spinal Fixation System.

Calibrate NanoTec LTX spacers without integrated fixation features may be used with AMP-LTXTM Anti-Migration Plate as integrated fixation in addition to supplemental fixation. Reference the AMP-LTX Anti-Migration Plate Instructions for Use for additional information pertinent to the AMP-LTX system.

INDICATIONS FOR USE:
The Calibrate LTX Interbody System with advanced NanoTec surface treatment is indicated for spinal fusion procedures from T1 to S1 in skeletally mature patients for the treatment of a symptomatic degenerative disc disease (DDD), degenerative spondylolisthesis, spinal stenosis, and/or thoracic disc herniation (myelopathy and/or radiculopathy with or without axial pain) 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.

Additionally, the Calibrate NanoTec LTX Interbody System can be used as an adjunct to fusion in patients diagnosed with multilevel degenerative scoliosis and sagittal deformity.

The Calibrate NanoTec LTX Interbody System is intended for use on patients who have had at least six months of non-operative treatment. It is intended to be used with autograft and/or allogeneic bone graft comprised of cortical, cancellous, and/or corticocancellous bone, and/or demineralized allograft bone with bone marrow aspirate, or a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion. The system is intended to be used with supplemental fixation systems that are cleared by FDA for use in the thoracic and lumbar spine.

Calibrate NanoTec LTX spacers expanded greater than 20° have integrated fixation tabs and must be used AMP-LTX provided bone screws in addition to supplemental fixation. Calibrate NanoTec LTX spacers without integrated fixation tabs may be used with AMP-LTX System as integrated fixation in addition to supplemental fixation.

CONTRAINDICATIONS:
The system is contraindicated for:
1. Patients with bone resorption related disease (e.g., osteopenia), bone and/or joint disease, or deficient soft tissue at the wound site.
2. Patients with infection, inflammation, fever, tumors, elevated white blood count, obesity, pregnancy, mental illness, and other medical conditions which would prohibit beneficial surgical outcome.
3. Patients with allergy or intolerance to titanium.
4. Patients resistant to following postoperative restrictions on movement especially in athletic and occupational activities.
5. Patients with prior fusion at the level(s) to be treated.
6. Spinal surgery cases that do not require bone grafting and/or spinal fusion.
7. Reuse or multiple uses of the implant.

WARNINGS/CAUTIONS/PRECAUTIONS:
1. Interbody implants are provided sterile.
   a. Visually inspect the packaging for signs of damage and breaches of packaging integrity prior to use. Do not use devices if package is opened, damaged, or past the expiry date.
   b. Do not re-sterilize implants.
   c. Do not use scratched or damaged devices.
2. Components of this system should not be used with components from other systems or manufacturers.
3. Do not comingle dissimilar materials (e.g., titanium and stainless steel) within the same construct.
4. All instruments are provided non-sterile and must be cleaned and sterilized prior to surgery. See CLEANING and STERILIZATION sections in this IFU. Sterile single-use instruments are disposable devices, designed for single use and should not be reused or reprocessed. Reprocessing of single use instruments may lead to instrument damage and possible improper function.
5. Implants are single use devices. Do not reuse. While an implant may appear undamaged, it may have small defects or internal stress patterns that could lead to fatigue failure. In addition, the removed implant has not been designed or validated for the decontamination of microorganisms. Reuse of this product could lead to cross-infection and/or material degradation as a result of the decontamination process.
6. These implants are used only to provide internal fixation, in conjunction with graft and supplemental fixation, during the bone fusion process. A successful result may not be achieved in every instance.
7. Potential risks identified with the use of these fusion devices, which may require additional surgery, include device component failure, loss of fixation, pseudarthrosis (i.e., non-union), fracture of the vertebra, neurological injury, and/or vascular or visceral injury.
8. Risk factors that may affect successful surgical outcomes include: alcohol abuse, obesity, patients with poor bone, muscle and/or nerve quality. Patients who use tobacco or nicotine products should be advised of the consequences that an increased incidence of non-union has been reported with patients who use tobacco or nicotine products.
9. The physician/surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc., which may affect the performance of this system.
10. Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without previous surgery.
11. Implantation should be performed only by experienced spinal surgeons with specific training in the use of this device because this is a technically demanding procedure presenting a risk of serious injury to the patient.
12. Placement and positional adjustment of implants must only be performed with system-specific instruments. They must not be used with other instrumentation unless specifically recommended by Alphatec Spine Inc., because the combination with other instrumentation may be incompatible.
13. 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.
14. Resection of the anterior longitudinal ligament (ALL) may facilitate expansion of the Calibrate NanoTec LTX implant for greater sagittal correction and aid in preventing potential endplate damage. To minimize risk to surrounding anatomy when resecting the ALL, do not extend the resection past the medial wall of the contralateral pedicle as identified on true AP fluoroscopy.
15. A Calibrate NanoTec LTX implant must not be re-expanded and reused if it has been filled with graft, as mechanical failure may occur.
16. The safety and effectiveness of this device has not been established when used in conjunction with bone cement or for use in patients with poor bone quality (e.g., osteoporosis, osteopenia).
17. To avoid damage to the vertebral endplates, do not excessively expand the LTX Trial or the LTX Interbody Spacer.
18. To avoid damage to the LTX Trial, do not excessively collapse the LTX Trial.

MRI SAFETY INFORMATION:
The Calibrate NanoTec LTX Interbody System has not been evaluated for safety and compatibility in the magnetic resonance (MR) environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of the Calibrate NanoTec LTX Interbody System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

POSSIBLE ADVERSE EFFECTS:
Possible adverse effects include:
1. Initial or delayed loosening, bending, dislocation, and/or breakage of device components.
2. Physiological reaction to implant devices due to foreign body intolerance including inflammation, local tissue reaction, seroma, and possible tumor formation.
3. Loss of desired spinal curvature, spinal correction and/or a gain or loss in height.
4. Infection and/or hemorrhaging.
5. Non-union and/or pseudarthrosis.
6. Neurological disorder, pain and/or abnormal sensations caused by improper placement of the device, and/or instruments.
7. Subsidence of the device into the vertebral body.
8. Revision surgery.
9. Death.

PREOPERATIVE MANAGEMENT:
1. Only patients meeting the criteria listed in the indications for the use section should be selected.
2. Surgeons should have a complete understanding of the surgical technique, system indications, contraindications, warnings and precautions, safety information, as well as functions and limitations of the implants and instruments.
3. Careful preoperative planning should include implantation strategy and a verification of required inventory for the case.
4. The condition of all implants and instruments should be checked prior to use. Damaged and/or worn implants and instruments should not be used.

INTRAOPERATIVE MANAGEMENT:
1. The surgical technique manual should be followed carefully.
2. To prevent possible nerve damage and associated disorders, extreme caution should be taken to avoid the spinal cord and nerve roots at all times. Fluoroscopy should be employed where view of device is obstructed.
3. Bone graft must be placed in the area to be fused and graft material must extend from the upper to the lower vertebrae being fused.

POSTOPERATIVE MANAGEMENT:
Postoperative management by the surgeon is essential. This includes instructing, warning, and monitoring the compliance of the patient.
1. Patient should be informed regarding the purpose and limitations of the implanted devices.
2. The surgeon should instruct the patient regarding the amount and time frame after surgery of any weight bearing activity. The increased risk of bending, dislocation, and/or breakage of the implanted devices, as well as an undesired surgical result are consequences of any type of early or excessive weight bearing, vibratory motion, falls, jolts or other movements preventing proper healing and/or fusion development.
3. Implanted devices should be revised or removed if bent, dislocated, or broken.
4. Immobilization should be considered in order to prevent bending, dislocation, or breakage of the implanted device in case of delayed, malunion, or nonunion of bone. Immobilization should continue until a complete bone fusion mass has developed and been confirmed.
5. Postoperative patients should be instructed not to use tobacco or nicotine products, consume alcohol, or use non-steroidal anti-inflammatory drugs and aspirin, as determined by the surgeon. Complete postoperative management to maintain the desired result should also follow implant surgery.

Excerpt from INS-174

℞Only **Caution: Federal law (USA) restricts these devices to sale by or on the order of a physician.**

SYMBOLS:
For a listing of Symbols and Explanations, see atecspine.com/eifu

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