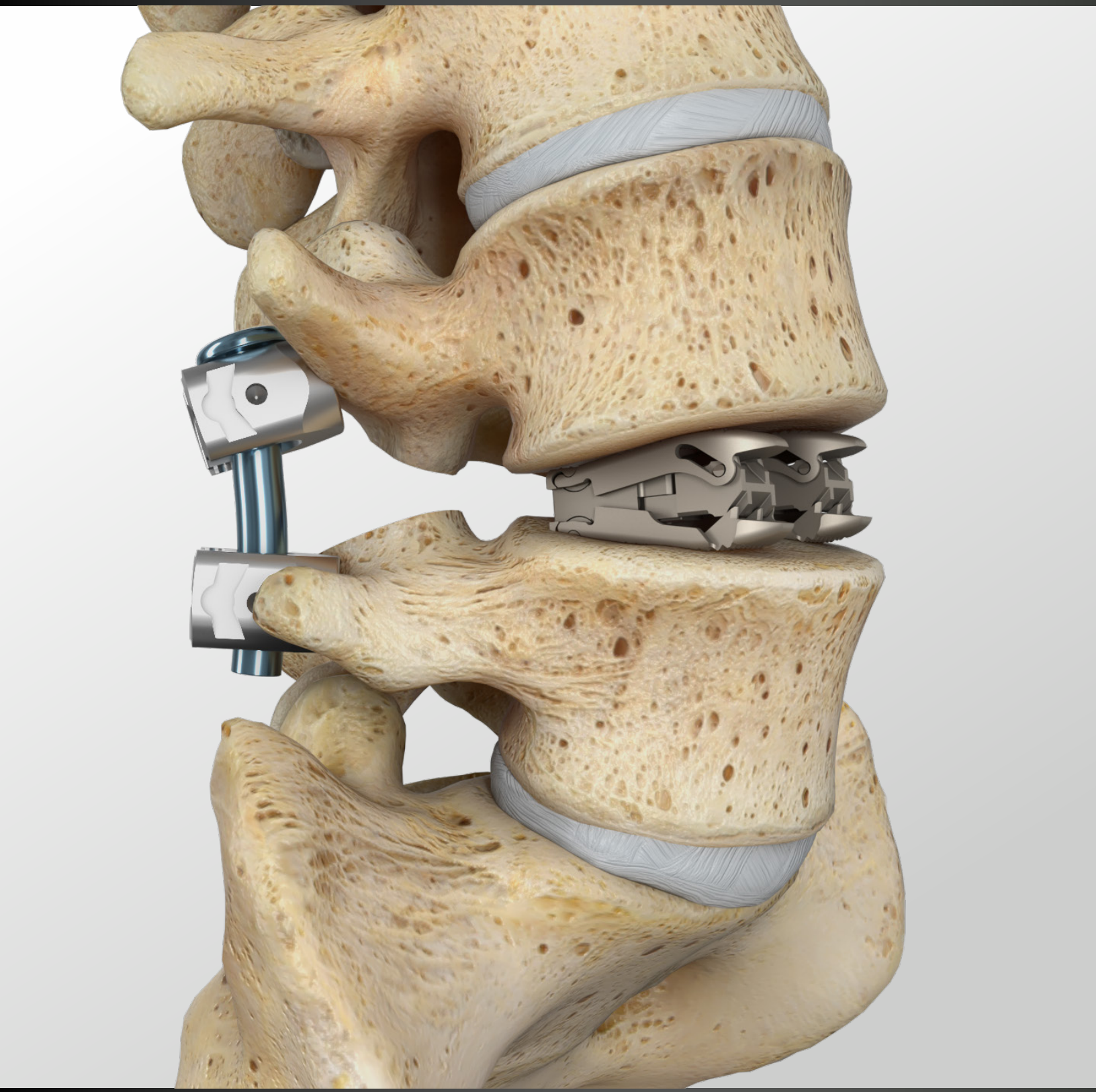
CALIBRATE PSX™

EXPANDABLE INTERBODY SYSTEM

atec™ INFORMED BY EOS



POSTERIOR INTERBODY IMPLANTS | Surgical Technique Guide

CALIBRATE PSX™

EXPANDABLE INTERBODY SYSTEM

TABLE OF CONTENTS

PATIENT POSITIONING

1 Place the patient on the operating table in prone position. Prepare and drape in a conventional manner. Uniplanar or biplanar fluoroscopy may be used. Place the necessary neuromonitoring electrodes on the patient and execute a twitch test to determine if neuromuscular blockades are clear.

INTRA-OP IMAGING

2 An open, mini-open, or minimally invasive approach may be utilized.

The facet, pars interarticularis, transverse process, and lamina on the surgical site side should be easily identified for this technique.

NOTE: DISTRACTION MAY BE ACCOMPLISHED BY ONE OF THE FOLLOWING TECHNIQUES:

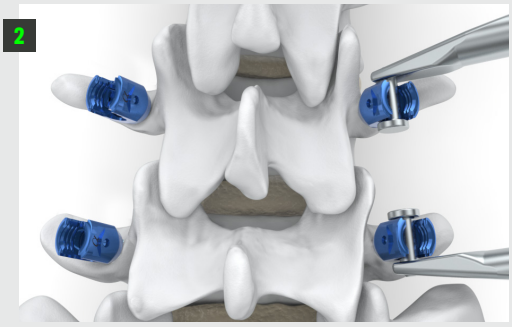
SCREW-TO-SCREW DISTRACTOR

PLACE THE SCREW-TO-SCREW DISTRACTOR ONTO THE IMPLANTED PEDICLE SCREWS WHICH MAY INCLUDE PROVISIONALLY TIGHTENED SET SCREWS. APPLY DISTRACTION ON THE PEDICLE SCREWS USING THE SCREW-TO-SCREW DISTRACTOR.

LAMINA SPREADER/DISTRACTOR

APPLY DISTRACTION ON THE BASE OF THE SPINOUS PROCESS USING A LAMINA DISTRACTOR BEFORE IMPLANTATION OF THE PEDICLE SCREWS AND RODS.

2



DECOMPRESSION AND TRANSFORAMINAL WINDOW ACCESS

1 Resect the inferior articular process of the cephalad vertebra with an Osteotome or high-speed burr. Excise the superior articular process of the caudal vertebra to the pedicle to provide entry to the disc space. Care should be taken to avoid penetration of the pedicle cortex if using a high-speed burr.

TIP: LOCAL BONE MAY BE SAVED, DECORTICATED, AND USED AS BONE GRAFT MATERIAL.

NOTE: A KERRISON RONGEUR OR DRILL MAY BE USED TO PERFORM ADDITIONAL RESECTION AS NEEDED.

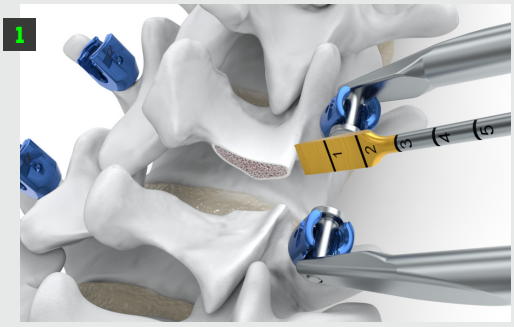
DISC SPACE PREPARATION

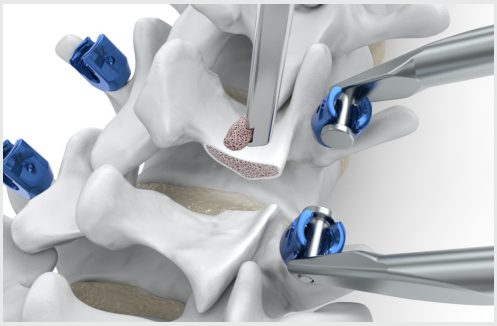
2 Place a Nerve Root Retractor to protect the exiting nerves and create an annulotomy with a scalpel. Enter and prepare the disc space using preferred tools. Insert Rotating Shavers until the cutting edge is completely within the disc space. Remove any loose disc material from the disc space with the Pituitary Rongeurs.

TIP: UP-BITING PITUITARY RONGUERS CAN ALSO FUNCTION AS DOWN-BITING PITUITARY RONGUERS.

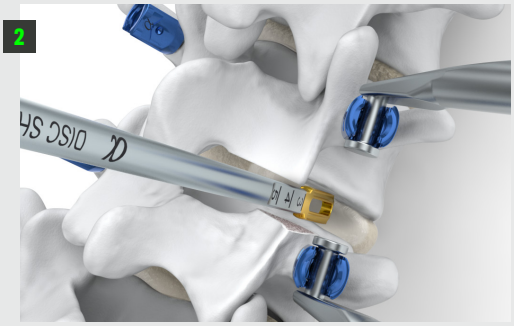
NOTE: ROTATING SHAVERS ARE INTENDED TO RESECT AND PREPARE THE DISC SPACE FOR THE INSERTION OF AN INTERBODY CAGE; THEY SHOULD NOT BE USED FOR DISTRACTION.

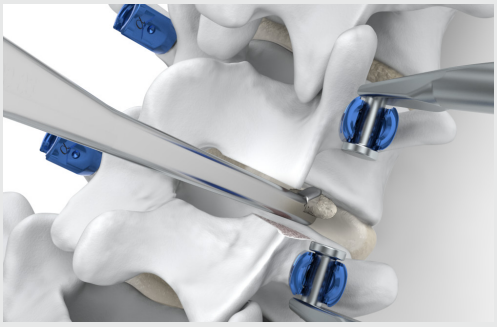
1





2

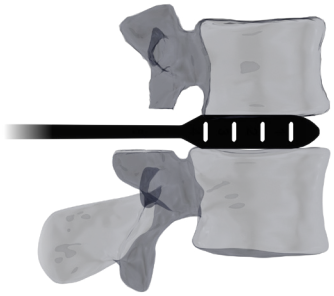




ROTATING DISTRACTION

3 Use the Rotating Distractors to distract the disc space to the desired height.

> **TIP:** FENESTRATIONS WITHIN THE ROTATING DISTRACTORS ARE VISIBLE UNDER FLUORO AND ARE 10 MM APART.

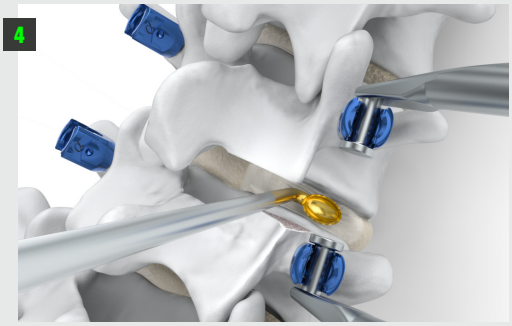


ENDPLATE PREPARATION

4 Roughen the endplates to achieve cancellous bone bleeding using disc preparation tools such as Rasps, Serrated Curettes, and teardrop-shaped Ringed Curettes.

3

4



DISTRACTOR EXPANSION

1 Verify that the Expandable Distractor is fully collapsed prior to inserting it into the disc space. If the Distractor is not fully collapsed, follow step 3.

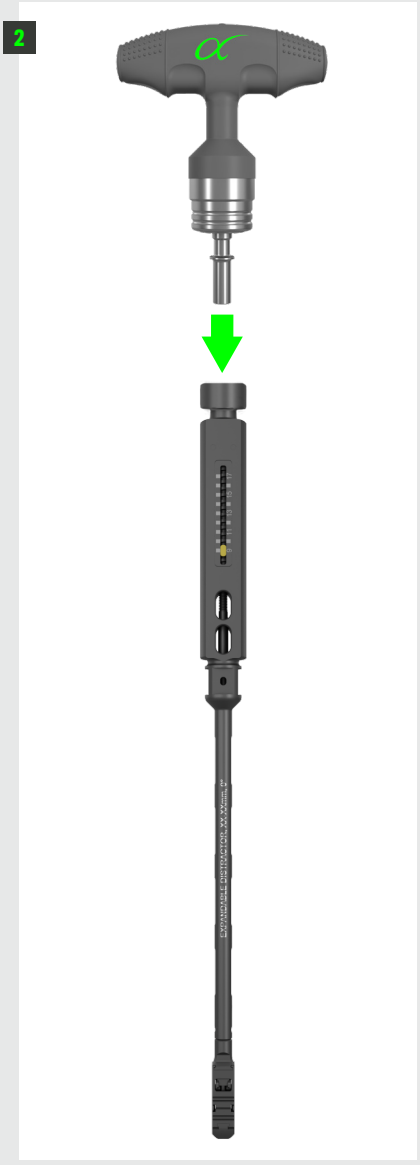
2 To expand the Distractor, insert the Grey Torque Limiting Handle into the proximal end of the Distractor.

COLLAPSING THE EXPANDABLE DISTRACTOR

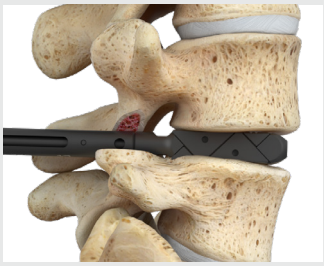
3 Once the disc space has been properly distracted, rotate the Handle counterclockwise until the Distractor returns to its collapsed state. Verify that the Distractor is fully collapsed via fluoroscopy prior to removal from the disc space.

1

2



3



TRIALING

1 Insert the selected implant Trial to confirm the correct height, footprint, lordosis, and/or location within the disc space.

A/P and/or lateral fluoroscopy can be used to confirm position.

Select the appropriately sized Calibrate PSX implant.

The implant Trials are color-coded.

- **Black** 5° implant lordosis
- **Silver** 10° implant lordosis
- **Gold** 15° implant lordosis

NOTE: IF THE IMPLANT TRIAL BECOMES LODGED IN THE DISC SPACE, CONNECT THE SLAP HAMMER TO THE TRIAL HANDLE OR DIRECTLY TO THE ¼" SQ. TO FACILITATE REMOVAL.

TIP: TRIALS ARE ALL 25 MM IN LENGTH. CUTOUTS ARE AT 30 MM FOR FLUOROSCOPIC CONFIRMATION.

TIP: EXPANDABLE IMPLANTS ARE COLOR-CODED FOR HEIGHT AND LENGTH DESIGNATION.

LENGTH	POSTERIOR HEIGHT
25 mm	7 mm
30 mm	8 mm
	10 mm
	12 mm

1

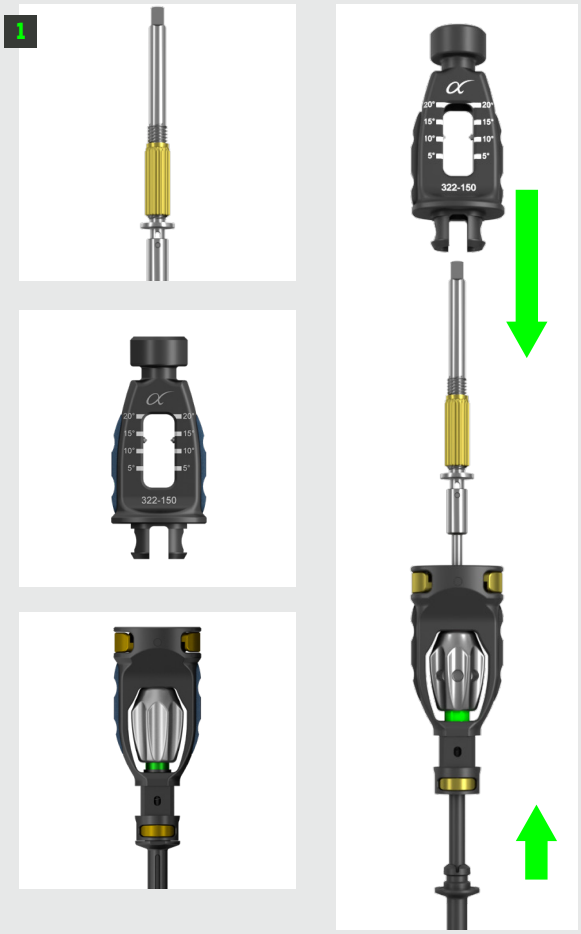
INSERTER ASSEMBLY

1 Attach the sleeve to the Inserter by sliding the sleeve over the cannula until an audible/tactile click is made, thus verifying attachment. Verify that the Expansion Shaft is in the home position. Insert the Expansion Shaft down the cannula of the Inserter on the proximal end. Attach the Impaction Cap with blue grips to the proximal portion of the Trial. Confirm that the silver arrows are aligned and slide the Impaction Cap over the Expansion Shaft until the Impaction Cap is locked within the Inserter.

IMPLANT ATTACHMENT

2 Align the prongs of the Inserter with the desired implant tracks. Put downward pressure on the implant and thumbwheel. Rotate the thumbwheel clockwise on the Inserter until the implant is fully secured. To verify that the implant is connected, the red laser-marking will be showing.

> **CAUTION:** IF IMPLANT PRE-PACKING OF BONE GRAFT IS DESIRED, THE INSERTER WITH EXPANSION SHAFT MUST BE ATTACHED TO THE IMPLANT PRIOR TO PRE-PACKING TO ALLOW FOR PROPER EXPANSION OF THE IMPLANT.



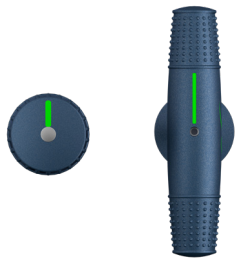
1 After interbody implantation, insert the Yellow Torque Limiting Handle (T-Handle or Axial) into the proximal end of the Inserter. Rotate the handle clockwise to expand the implant.

If more expansion of the implant is desired, insert the Blue Torque Limiting Handle into the proximal end of the Inserter. Rotate the Handle clockwise to expand the implant.

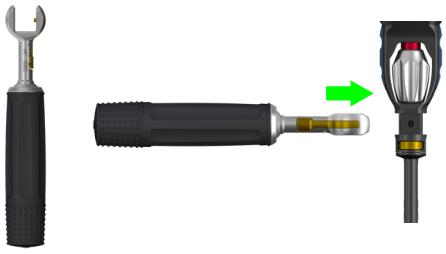
To assess lordotic expansion, locate the **BLACK** band in the window of the Impaction Cap.

The implant will be locked once the desired lordosis is achieved; no secondary lock is required.

TIP: THE INDICATOR LINE ON THE TORQUE LIMITING HANDLES CAN HELP IDENTIFY HOW MANY ROTATIONS OF THE HANDLE HAVE BEEN COMPLETED. ONE FULL TURN IS APPROXIMATELY 5° OF EXPANSION.

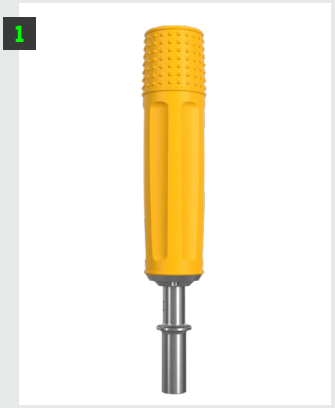


TIP: THE COUNTERTORQUE HANDLE MAY BE ATTACHED TO THE INSERTER TO HELP MITIGATE IMPLANT ROTATION DURING EXPANSION.



NOTE: ALL INTERBODY TORQUE LIMITING HANDLES (AXIAL AND T-HANDLE) ARE SET AT 20 IN-LB.

1



ATTACHING THE GRAFT DELIVERY FUNNEL

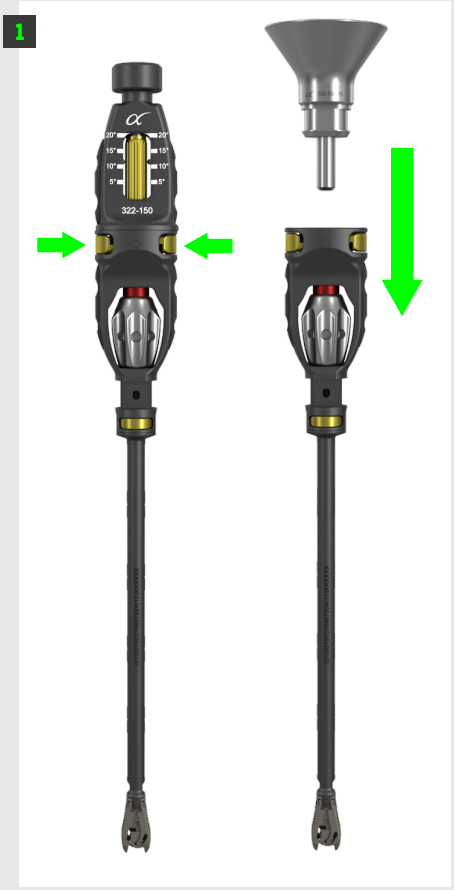
1 Press the Gold Buttons on the Inserter and remove the Impaction Cap. Remove the Expansion Shaft from the Inserter. Attach the Funnel to the proximal end of the Inserter. Verify that the Funnel is connected.

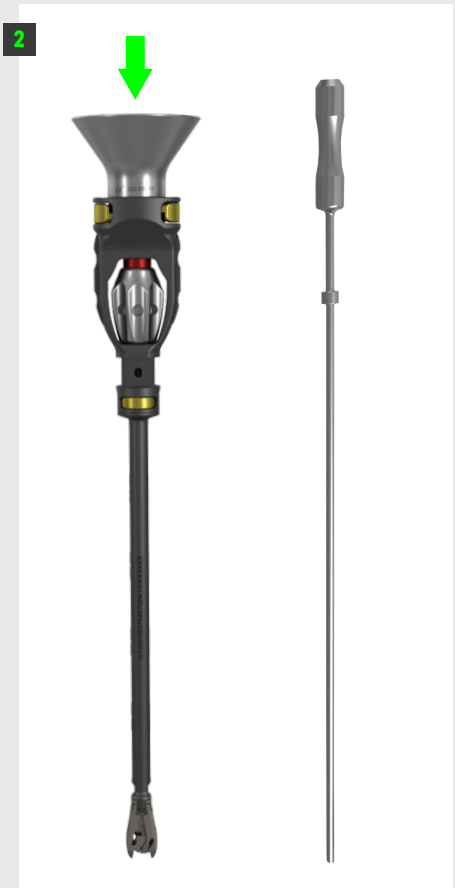
> **NOTE:** PACK BONE GRAFT (AUTOGRAFT OR ALLOGENEIC BONE GRAFT COMPRISED OF CORTICAL, CANCELLOUS, AND/OR CORTICOCANCELLOUS BONE GRAFT AND/OR DEMINERALIZED ALLOGRAFT WITH BONE MARROW ASPIRATE) IN AND AROUND THE DISC SPACE. THE BONE GRAFT MAY BE PRE-PACKED INTO THE CAGE PRIOR TO IMPLANTATION AND EXPANSION, OR POST-PACKED AFTER EXPANSION.

LOADING AND INSERTING BONE GRAFT

2 Insert desired bone graft into the Graft Funnel. Push the graft into the disc space/implant with the Graft Tamp.

> **CAUTION:** A CALIBRATE PSX IMPLANT MUST NOT BE RE-EXPANDED AND REUSED IF IT HAS BEEN FILLED WITH GRAFT, AS MECHANICAL FAILURE MAY OCCUR.





ATTACHING THE GRAFT DELIVERY ADAPTER

1 Press the Gold Buttons on the Inserter and remove the Impaction Cap. Remove the Expansion Shaft from the Inserter. Attach the Graft Delivery Adapter to the proximal end of the Inserter. Verify that the Adapter is connected.

ATTACHING THE PRE-PACKAGED BONE GRAFT

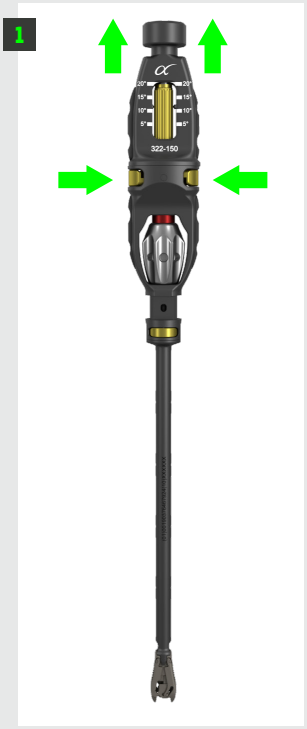
2 Remove the pre-packaged 2.5 CC Alphagraft DBM Fiber Flow Syringe from its packaging. Remove the cap on the syringe and attach the syringe to the Graft Delivery Adapter by turning it clockwise.

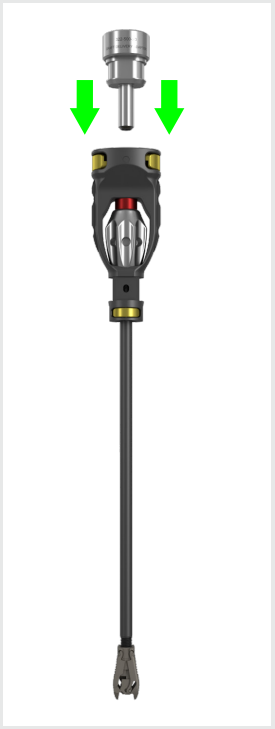
INSERTING THE PRE-PACKAGED BONE GRAFT

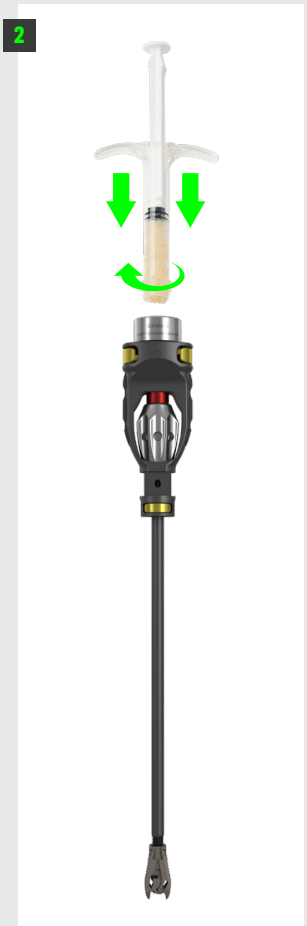
3 Press downward on the proximal handle of the syringe until a hard stop is felt. Once all the DBM Fibers have been inserted, remove the syringe by rotating it counter-clockwise. Insert the Graft Tamp into the Graft Delivery Adapter and push the remaining DBM Fibers into the interbody implant.

NOTE: IF THE ALPHAGRAFT DBM FIBER IS OVERFLOWING INTO THE DISC SPACE, STOP INSERTING THE GRAFT AND REMOVE THE GRAFT DELIVERY ADAPTER WITH THE REMAINING DBM FIBERS.

CAUTION: A PSX™ IMPLANT MUST NOT BE RE-EXPANDED AND REUSED IF IT HAS BEEN FILLED WITH GRAFT, AS MECHANICAL FAILURE MAY OCCUR.







REMOVAL OF THE INSERTER

1 To remove the Inserter from the implant, rotate the thumbwheel on the Inserter counterclockwise. Remove the Inserter from the exposure once fully disengaged. The implant is disconnected when the green laser-mark is showing.

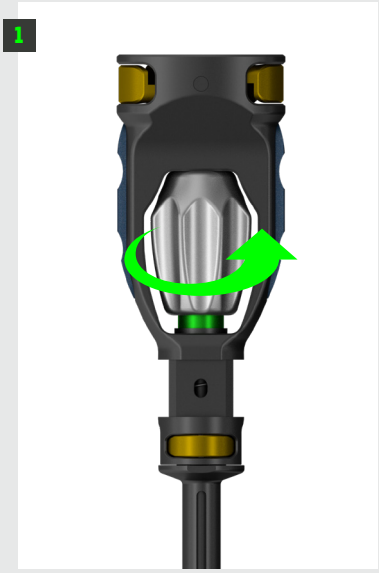
SUPPLEMENTAL FIXATION

2 The Calibrate PSX implants must be used with supplemental fixation cleared by the FDA for use in the lumbar spine. Implant the supplemental fixation according to the recommended surgical technique for the fixation system.

IMPLANT REMOVAL/RETRIEVAL

3 In case of revision, an ALIF may be performed for implant removal by using a rongeur to grasp the implant anteriorly.

1



2

Calibrate™ PSX™ Interbody System
INSTRUCTIONS FOR USE

GENERAL INFORMATION:

The CalibrateTM PSX Interbody System is a lordotic expandable lumbar intervertebral body fusion system designed to be inserted through a posterior surgical approach. The Calibrate PSX interbody spacers are manufactured from titanium alloy (Ti-6Al-4V ELI) per ASTM F136. The Calibrate PSX System consists of a variety of shapes and sizes of interbody spacers, inserters, trials, and general instruments to create lordotic expansion, restore sagittal alignment, and provide indirect decompression. The Calibrate PSX Interbody platform includes the following sub-system: Calibrate PSX Lordotic Expandable (Calibrate PSX) and PSX Lordotic Expandable (PSX).

Use Calibrate PSX 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.

INDICATIONS FOR USE:
The Calibrate PSX Interbody System is indicated for spinal fusion procedures from L1 to S1 in skeletally mature patients for the treatment of symptomatic degenerative disc disease (DDD), degenerative spondylolisthesis, and/or spinal stenosis at one or two adjacent levels. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies.

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

The Calibrate PSX Interbody System is intended for use on patients who have had at least six months of non-operative treatment. It is intended for use with autograft and/or allogenic bone graft comprised of cortical, cancellous and/or corticocancellous bone, and/or demineralized allograft bone with bone marrow aspirate and supplemental fixation systems that are cleared by FDA for use in the lumbar spine.

CONTRAINDICATIONS:
The Calibrate PSX Interbody 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. The implants of the system are provided non-sterile and must be sterilized prior to use. Refer to the CLEANING and STERILIZATION sections.
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.
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. A Calibrate PSX implant must not be re-expanded and reused if it has been filled with graft, as mechanical failure may occur.
10. If implant pre-packing with bone graft is desired, the Inserter with Expansion Shaft must be attached to the implant prior to pre-packing to allow for proper expansion of the implant.
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. 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.
14. Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without previous surgery.
15. 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.

MRI SAFETY INFORMATION:
The Calibrate PSX 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 PSX 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-143

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

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

Alphatec Spine, Inc.
1950 Camino Vida Roble
Carlsbad, CA 92008 USA
Ph: (760) 431-9286
Ph: (800) 922-1356
atecspine.com

Calibrate™ NanoTec™ PSX Interbody System
INSTRUCTIONS FOR USE
GENERAL INFORMATION:
The Calibrate NanoTec PSX Interbody System is a lordotic expandable lumbar intervertebral body fusion system designed to be inserted through a posterior surgical approach. The Calibrate NanoTec PSX interbody spacers are manufactured from titanium alloy (Ti-6Al-4V ELI) per ASTM F136 with a nano-scale hydroxyapatite surface treatment. The Calibrate NanoTec PSX System consists of a variety of shapes and sizes of interbody spacers, inserters, trials, and general instruments to create lordotic expansion, restore sagittal alignment, and provide indirect decompression.
Use Calibrate NanoTec PSX 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.

INDICATIONS FOR USE:
The Calibrate PSX Interbody System with advanced NanoTec surface treatment is indicated for spinal fusion procedures from L1 to S1 in skeletally mature patients for the treatment of symptomatic degenerative disc disease (DDD), degenerative spondylolisthesis, and/or spinal stenosis at one or two adjacent levels. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies.
Additionally, the Calibrate NanoTec PSX Interbody System can be used as an adjunct to fusion in patients diagnosed with multilevel degenerative scoliosis and sagittal deformity.
The Calibrate NanoTec PSX Interbody System is intended for use on patients who have had at least six months of non-operative treatment. It is intended for use with autograft and/or allogenic bone graft comprised of cortical, cancellous and/or corticocancellous bone, and/or demineralized allograft bone with bone marrow aspirate and supplemental fixation systems that are cleared by FDA for use in the lumbar spine.

CONTRAINDICATIONS:
The Calibrate NanoTec PSX Interbody 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.
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. A Calibrate NanoTec PSX implant must not be re-expanded and reused if it has been filled with graft, as mechanical failure may occur.
10. If implant pre-packing with bone graft is desired, the Inserter with Expansion Shaft must be attached to the implant prior to pre-packing to allow for proper expansion of the implant.
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. 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.
14. Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without previous surgery.
15. 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.

MRI SAFETY INFORMATION:
The Calibrate NanoTec PSX 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 PSX 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-161

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

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

Alphatec Spine, Inc.
1950 Camino Vida Roble
Carlsbad, CA 92008 USA
Ph: (760) 431-9286
Ph: (800) 922-1356
atecspine.com

Intervertebral Disc Preparation Instruments
INSTRUCTIONS FOR USE

GENERAL INFORMATION:
Intervertebral Disc Preparation Instruments are intended for use during surgical procedures for cutting, scraping, retracting, or similar procedures. Instruments are primarily manufactured from stainless steel per ASTM F899, titanium alloy (Ti-6Al-4V) per ASTM F136, and polymers/plastics. Instruments provided non-sterile are reusable and should be cleaned and sterilized per instructions provided below. Instruments provided sterile are single use and should not be reused.

INDICATIONS FOR USE:
Intervertebral Disc Preparation Instruments are intended to manipulate tissue or are intended for use with other devices in orthopedic and spine surgery.

CONTRAINDICATIONS:
The system is contraindicated for:
1. Infection in or around the the operative site
2. Allergy or sensitivity to instrument materials
3. Use of incompatible materials from other systems
4. Any situation not described in the indication

WARNINGS/CAUTIONS/PRECAUTIONS:
1. Non-sterile instruments of the system must be cleaned and sterilized prior to use. Refer to the CLEANING and STERILIZATION sections.
2. Single-use instruments are disposable devices, designed for single use and should not be re-used or re-processed. Reprocessing of single-use instruments may lead to instrument damage and possible improper function.
3. The instruments of Alphatec Spine product lines should not be used with any other company's products.
4. Device components should be received and accepted only in packages that have not been damaged. Damaged or worn instruments should not be used. Components must be carefully handled and stored in a manner that prevents scratches, damage, and corrosion.
5. Avoid removal of excess bony endplate to minimize risk of implant subsidence.

PREOPERATIVE MANAGEMENT:
1. 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 instruments.

INTRAOPERATIVE MANAGEMENT:
1. To prevent possible nerve damage and associated disorders, extreme caution should be taken to avoid the spinal cord and nerve roots at all times.

Excerpt from INS-139

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

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

Alphatec Spine, Inc.
1950 Camino Vida Roble
Carlsbad, CA 92008 USA
Ph: (760) 431-9286
Ph: (800) 922-1356
atecspine.com

CUSTOMER SERVICE
Toll Free: 800.922.1356
Local: 760.431.9286
atecspine.com

1950 Camino Vida Roble, Carlsbad, CA 92008

LIT-85310D | 01/09/24