IdentiTi™ ALIF

Standalone Interbody System

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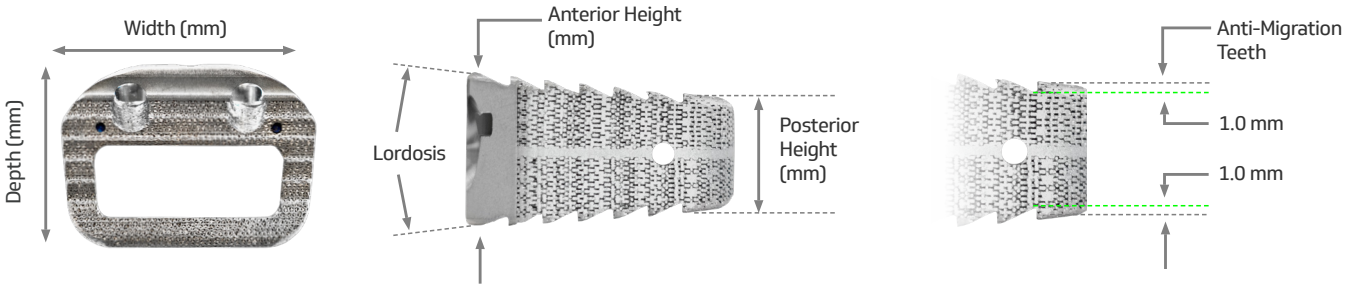
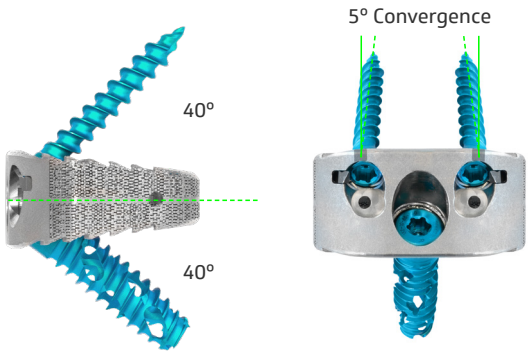
IMPLANT OVERVIEW

IdentiTi ALIF Standalone Interbody Spacers are made of commercially pure titanium and titanium alloy, and are available in three different footprints, multiple lordotic options, and a range of heights.



INTERBODY SPACER SIZES

SCREW ANGLES



SCREW/BOLT SIZES

All Screw/Bolt options are available in 25, 30, and 35 mm lengths and utilize a T25 hex size with the exception of the Ø9.0 Graft bolt which utilizes a T40 hex.

STANDARD

Graft Bolt: Ø8.5 mm

Center and Lateral Screw: Ø5.0 mm

RESCUE

Graft Bolt: Ø9.0 mm*

Center and Lateral Screw: Ø6.0 mm

**The Ø9.0 graft bolt is fully cannulated.*

DETERMINE APPROACH

1 Use a retroperitoneal or transperitoneal approach to expose the operative level(s).

DISCECTOMY

2 Remove disc material using available pituitary rongeurs, curettes, and other select instruments.

3 Remove any anterior or posterior osteophytes and prepare both the superior and inferior endplates for fusion.

> **TIP:** IN PATIENTS WITH VERY DENSE OR SCLEROTIC BONE, ADDITIONAL ENDPLATE PREPARATION MAY BE REQUIRED.

2

TRIALING

1 The Trial Handles provided are used to attach anteriorly or anterolaterally to the Trials to determine proper implant sizing.

> **NOTE:** TRIAL SIZING IS MEASURED LINE-TO-LINE WITH THE SPACER.

> **TIP:** TRIALS ARE COLOR-CODED BY LORDOSIS.

2 Thread the Trial Handle into the desired attachment hole of the Trial.

IMPLANT INSERTION

3 Assemble the Inserter by attaching the Impact Cap or desired handle to the proximal end.

4 To unlock the Inserter, push the slide feature forward and rotate the thumbwheel counterclockwise. The slide feature will automatically reengage the thumbwheel once fully unlocked.

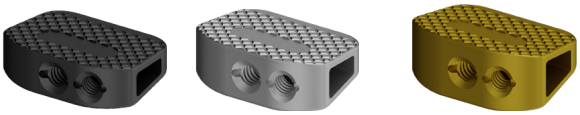
5 Using the selected Spacer, engage the Inserter prongs with the slots located within the lateral screw holes of the Spacer.

6 To lock the Inserter, confirm that the prongs are engaged with the Spacer and rotate the thumbwheel clockwise until the connection is rigid.

> **NOTE:** CONFIRM THAT THE RATCHETING TEETH OF THE SLIDE FEATURE ARE ENGAGED WITH THE THUMBWHEEL AND THERE IS NO GAP BETWEEN THEM WHILE LOADING THE SPACER. THE SPACER SHOULD FIT SNUGLY AGAINST THE INSERTER.

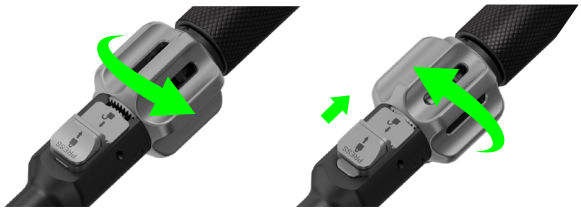
7 Insert the Spacer at the indicated level.

2



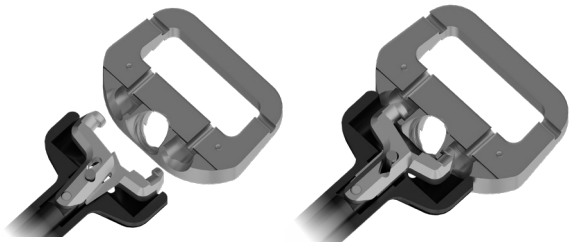
10° 15° 20° & 30°

4



UNLOCKING INSERTER LOCKING INSERTER

5



UNLOCKED LOCKED

IMPLANT INSERTION WITH ANTEROLATERAL INSERTER (OPTIONAL)

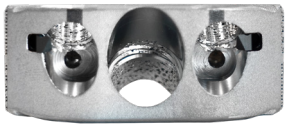
NOTE: AN ANTEROLATERAL INSERTER (15° OFFSET FROM MIDLINE) IS AVAILABLE AS AN OPTIONAL INSTRUMENT IN SITUATIONS WHERE ANATOMY MAY NOT PERMIT THE USE OF THE STRAIGHT INSERTER.

1 Assemble the Inserter by attaching the Impact Cap or desired handle to the proximal end.

2 To unlock the Inserter, push the slide feature forward and rotate the thumbwheel counterclockwise. The slide feature will automatically reengage the thumbwheel once fully unlocked.

3 Using the selected Spacer, hook the fixed prong of the Anterolateral Inserter onto the shelf of the lateral screw hole across the midline of the Spacer.

NOTE: TWO LASER MARKS ON THE SPACER INDICATE THE DIRECTION THAT THE LATERAL SCREWS WILL EXIT THE SPACER. CONSIDER ORIENTATION WHEN ATTACHING TO THE INSERTER.



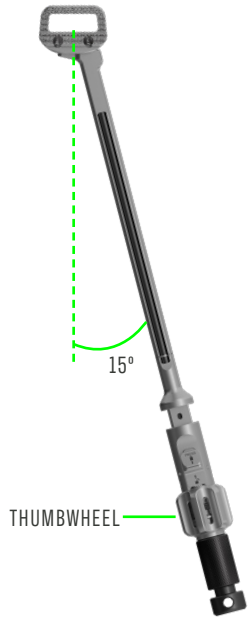
4 To lock the Spacer to the Inserter, confirm that the prongs are engaged with the Spacer and rotate the thumbwheel clockwise until the connection is rigid.

NOTE: CONFIRM THAT THE RATCHETING TEETH OF THE SLIDE FEATURE ARE ENGAGED WITH THE THUMBWHEEL AND THERE IS NO GAP BETWEEN THEM WHILE LOADING THE SPACER. THE SPACER SHOULD FIT SNUGLY AGAINST THE INSERTER.

5 Insert the Spacer at the indicated level.

NOTE: ATTACH THE OFFSET HANDLE FOR IMPROVED LEVERAGE.

1



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UNLOCKING INSERTER LOCKING INSERTER

3
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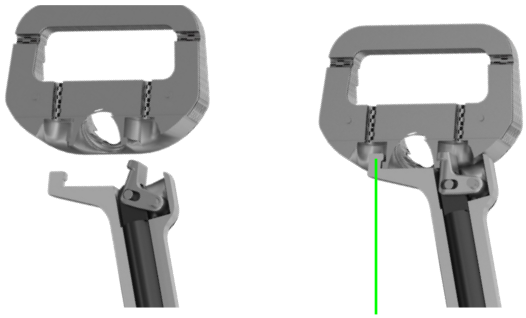
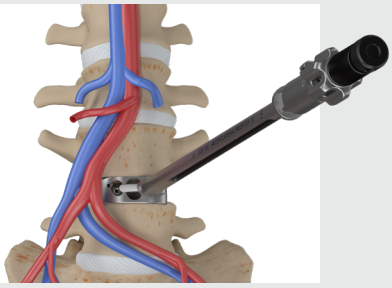
UNLOCKING INSERTER LOCKING INSERTER



FIXED PRONG HOOKED ONTO LATERAL SCREW HOLE SHELF

5



IMPLANT INSERTION WITH CRANIAL INSERTER
(OPTIONAL)

NOTE: A CRANIAL INSERTER (233-140) IS AVAILABLE FOR ORDER IN SITUATIONS WHERE ANATOMY MAY NOT PERMIT THE USE OF THE STRAIGHT INSERTER.

1 Assemble the Inserter by attaching the Impact Cap or desired handle to the proximal end.

2 To unlock the Inserter, push the slide feature forward and rotate the thumbwheel counterclockwise. The slide feature will automatically reengage the thumbwheel once fully unlocked.

3 Using the selected Spacer, engage the Inserter prongs with the slots located within the lateral screw holes of the Spacer.

NOTE: TWO LASER MARKS ON THE SPACER INDICATE THE DIRECTION THAT THE LATERAL SCREWS WILL EXIT THE SPACER. CONSIDER ORIENTATION WHEN ATTACHING TO THE INSERTER.

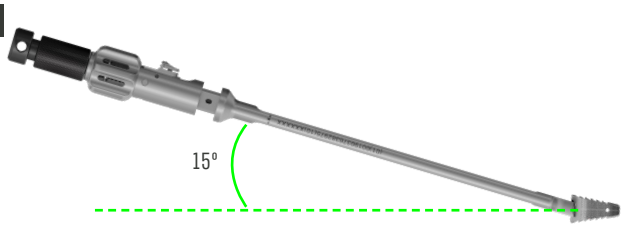
4 To lock the Spacer to the Inserter, confirm that the prongs are engaged with the Spacer and rotate the thumbwheel clockwise until the connection is rigid.

NOTE: CONFIRM THAT THE RATCHETING TEETH OF THE SLIDE FEATURE ARE ENGAGED WITH THE THUMBWHEEL AND THERE IS NO GAP BETWEEN THEM WHILE LOADING THE SPACER. THE SPACER SHOULD FIT SNUGLY AGAINST THE INSERTER.

5 Insert the Spacer at the indicated level.

NOTE: ATTACH THE OFFSET HANDLE FOR IMPROVED LEVERAGE.

1



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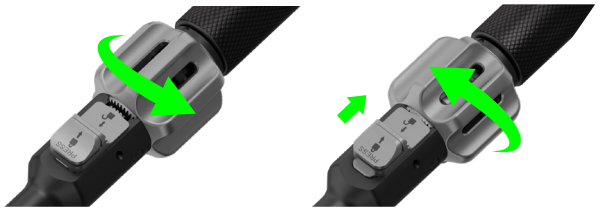
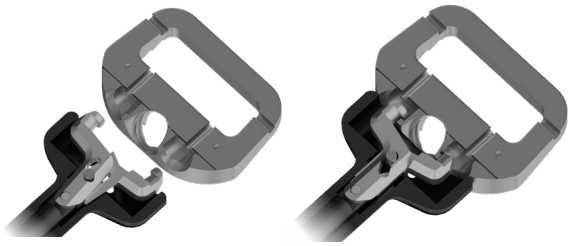


UNLOCKING INSERTER LOCKING INSERTER

5



UNLOCKED LOCKED

GRAFT BOLT HOLE PREPARATION

NOTE: PROPER TRAJECTORY AND IMPLANTATION OF THE GRAFT BOLT IS FACILITATED BY HOLE PREPARATION USING THE TREPHINE PUNCH.

CAUTION: CARE SHOULD BE TAKEN IN PERFORMING SCREW HOLE PREPARATION TO FACILITATE A PROPER GRAFT BOLT INSERTION TRAJECTORY AND IMPLANTATION. CONFIRM UNDER FLUOROSCOPY THAT THE GRAFT BOLT INSERTION ANGLE IS AS CLOSE AS POSSIBLE TO A 40° TRAJECTORY. A SHALLOW OR INCORRECT GRAFT BOLT TRAJECTORY MAY RESULT IN ENCROACHMENT OF THE SPACER AND LEAD TO GRAFT BOLT BREAKAGE.

TIP: MEDIAL HOLE PREPARATION INSTRUMENTS ARE DENOTED BY A BLACK HANDLE INLAY.

1 A Trephine Punch is provided with different tip options for Graft Bolt hole preparation.

TIP: THE PUNCH TIP IS DESIGNED FOR NORMAL BONE AND THE SAW TIP IS DESIGNED FOR SCLEROTIC BONE. THESE TIPS ARE DISPOSABLE.

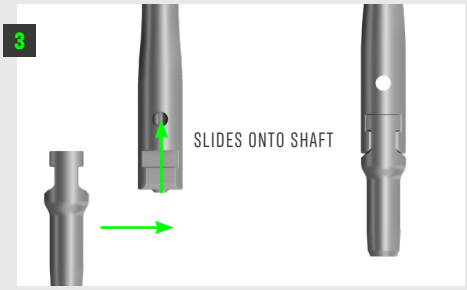
2 First, disassemble the Trephine Punch by pressing down on the gold button on the Sleeve and removing the inner Shaft.

3 Attach the desired Tip to the Trephine Shaft by pulling up on the innermost knob and sliding the Tip into place.

4 Assemble the Trephine Punch by inserting the Shaft into the cannula of the Sleeve.

TIP: THE TREPHINE IS FULLY ASSEMBLED WHEN THE SHAFT CANNOT BE PULLED OUT FROM THE SLEEVE.

3



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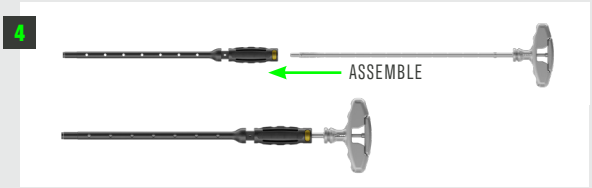
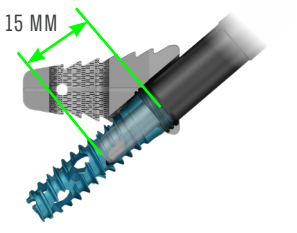


5 Center the Trephine Punch into the medial hole of the Spacer and verify that the thin distal ring is fully seated in the cage. Once properly seated, carefully advance it to create a pilot hole through the cortical bone.

TIP: A COATED RING ON THE THIN DISTAL END OF THE TREPHINE PUNCH SLEEVE WILL NO LONGER BE VISIBLE ONCE PROPERLY SEATED IN THE SPACER.

NOTE: BOTH THE PUNCH AND SAW TIPS MEASURE 15 MM RELATIVE TO THE HEAD OF THE BOLT WHEN FULLY ADVANCED.

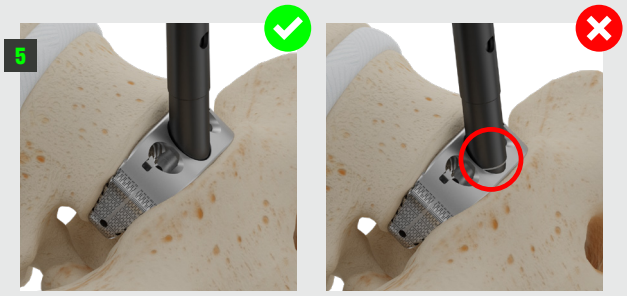


6 Leave the Trephine Punch advanced into bone, lift the innermost knob and rotate 90° within the T-handle of the Trephine Shaft, then release the knob but do not advance it.

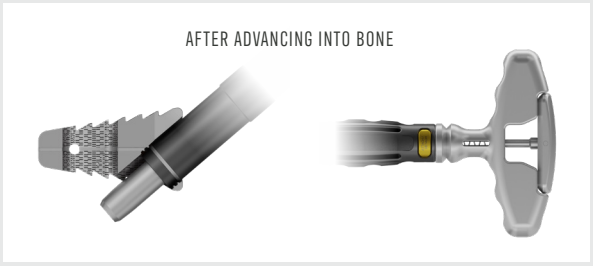
NOTE: THIS WILL ALLOW THE PLUNGER TO CONTACT BONE WITHOUT COMPRESSING IT.

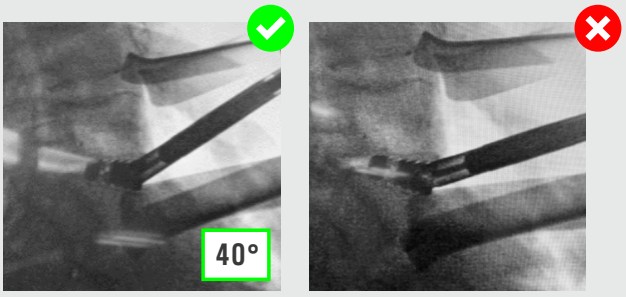
7 Simultaneously hold the inner knob in place with a thumb while pulling up on the Trephine T-handle until the tip is removed from bone.

TIP: IF BONE IS REMOVED BY THE PUNCH OR SAW TIP, PACK IT INTO THE GRAFT BOLT.

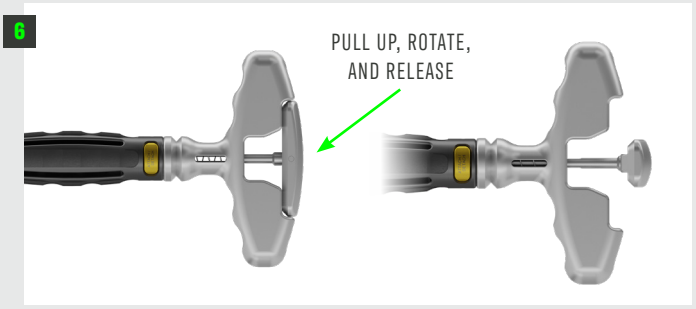


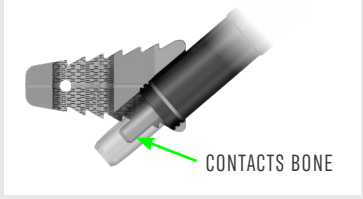
DISTAL TIP EXPOSED = NOT FULLY SEATED





TOO SHALLOW OF AN ANGLE





1 Following hole preparation, attach the Graft Bolt to the Straight Driver. If the access does not permit use of the Straight Driver, use the desired Angled Driver option.

NOTE: USE OF A T40 DRIVER IS REQUIRED FOR THE 9.0 MM CANNULATED GRAFT BOLT. A GREEN BAND ON THE PROXIMAL END OF THE DRIVER DENOTES A T40 HEX.

TIP: A DETACHABLE DRIVER SLEEVE IS PROVIDED FOR THE STRAIGHT AND BALL-END DRIVERS.

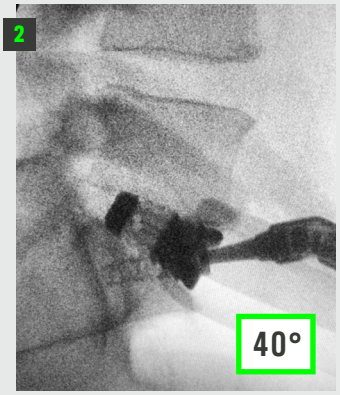
2 Align the Graft Bolt in the center hole of the Spacer and begin advancing into bone. **If at any time a steep torque increase is experienced prior to the Graft Bolt fully seating, stop and reassess the trajectory under fluoroscopy.**

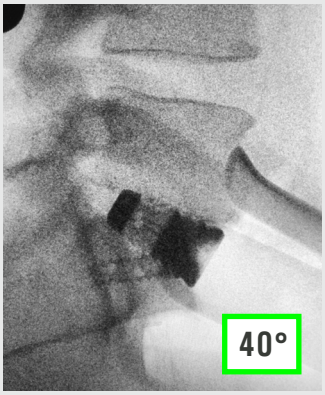
CAUTION: CARE SHOULD BE TAKEN IN PERFORMING SCREW HOLE PREPARATION TO FACILITATE A PROPER GRAFT BOLT INSERTION TRAJECTORY AND IMPLANTATION. CONFIRM UNDER FLUOROSCOPY THAT THE GRAFT BOLT INSERTION ANGLE IS AS CLOSE AS POSSIBLE TO A 40° TRAJECTORY. A SHALLOW OR INCORRECT GRAFT BOLT TRAJECTORY MAY RESULT IN ENCROACHMENT OF THE SPACER AND LEAD TO GRAFT BOLT BREAKAGE.

3 Locking threads on the Graft Bolt head mate with locking threads in the Spacer. The bolt is locked when it will no longer advance.

NOTE: THE MATING THREADS ALLOW FOR A 1/8TH TURN OF ADDITIONAL LAG BEFORE LOCKING.

2





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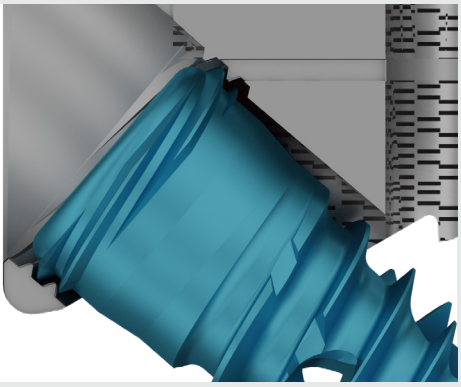


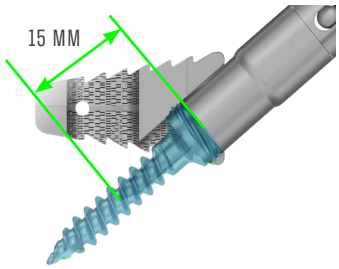
A traditional Center Screw option is provided if electing not to use the Graft Bolt.

CAUTION: LATERAL AWLS MUST NOT BE USED FOR CENTER SCREW HOLE PREPARATION, AS OVER-INSERTION INTO BONE MAY OCCUR.

TIP: A COATED RING ON THE DISTAL END OF BOTH THE TREPHINE PUNCH AND MEDIAL ANGLED AWL WILL NO LONGER BE VISIBLE ONCE PROPERLY SEATED IN THE SPACER.

TIP: MEDIAL HOLE PREPARATION INSTRUMENTS UTILIZE A BLACK HANDLE INLAY.

NOTE: AWLS MEASURE 15 MM RELATIVE TO THE HEAD OF THE SCREW WHEN FULLY ADVANCED.



STRAIGHT HOLE PREPARATION

1. Disassemble the Trephine Punch, attach the Awl Tip to the Trephine Shaft, and reassemble as described on page 9.

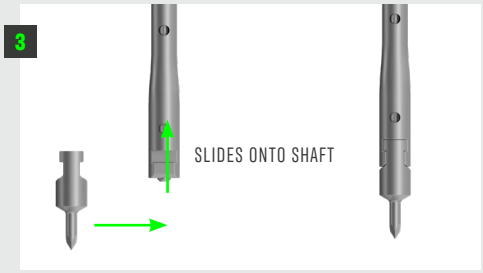
2. Center the Trephine Punch into the medial hole of the Spacer and carefully advance it to create a pilot hole through the cortical bone.

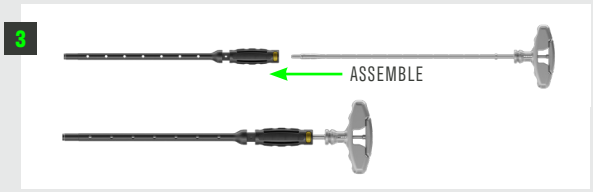
ANGLED HOLE PREPARATION

1. Confirm that the thumbwheel is fully rotated counterclockwise and that the proximal red band is not visible. This will confirm that the Awl is in a deployable position.

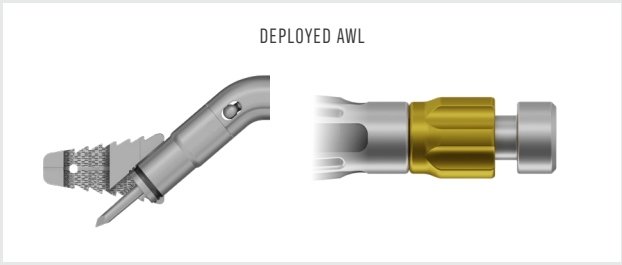
NOTE: THE RED BAND ON THE PROXIMAL END OF THE MEDIAL ANGLED AWL WILL INDICATE THAT THE AWL IS IN ITS RETRACTED STATE. THE AWL CANNOT BE ADVANCED WHEN THE RED BAND IS VISIBLE.

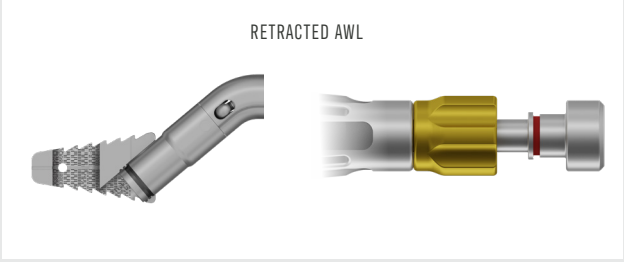
2. Center the Medial Angled Awl into the medial hole of the Spacer and carefully advance it to create a pilot hole.





DISTAL TIP EXPOSED = NOT FULLY SEATED





1 Attach the Center Screw to the Straight Driver. If the access does not permit use of the Straight Driver, use the desired Angled Driver option.

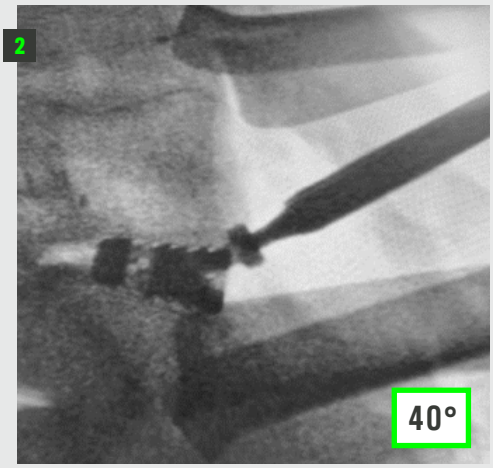
2 Align the Center Screw with the created pilot hole and begin inserting.

> **NOTE:** ALL SCREWS ARE DESIGNED TO INSERT AT A 40° TRAJECTORY. CONFIRM UNDER FLUOROSCOPY THAT SCREW INSERTION IS AT THE PROPER ANGLE.

3 Locking threads on the Center Screw head mate with locking threads in the Spacer. The screw is locked when it will no longer advance.

> **NOTE:** THE MATING THREADS ALLOW FOR A 1/8TH TURN OF ADDITIONAL LAG BEFORE LOCKING.

2



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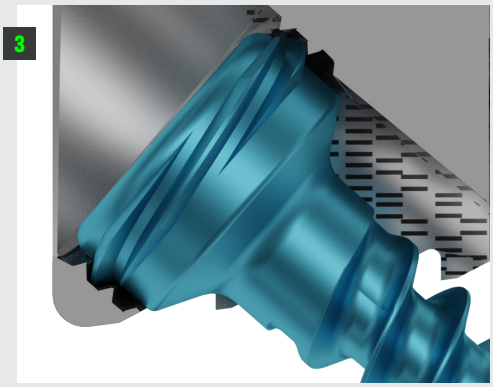
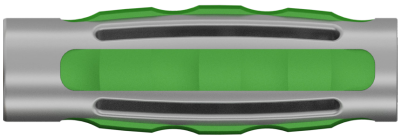


TIP: LATERAL HOLE PREPARATION INSTRUMENTS UTILIZE A GREEN HANDLE INLAY.



1 Using the Straight or Angled Awl, confirm that the thumbwheel is fully rotated counterclockwise and that the proximal red band is not visible. This will confirm that the Awl is in a deployable position.

TIP: THE RED BAND ON THE PROXIMAL END OF THE AWLS WILL INDICATE THAT THE AWL IS IN ITS RETRACTED STATE. THE AWL CANNOT BE DEPLOYED WHEN THE RED BAND IS VISIBLE.

2 Align the indent on the distal end of the Awl with the detent tabs on the lateral screw holes of the Spacer. The laser-marked line on the distal end of the Awls should align and contact the laser marks on the face of the Spacer.

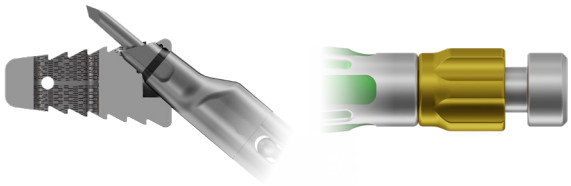
3 Once properly seated, carefully advance the Awl to create a pilot hole.

4 To remove, rotate the thumbwheel clockwise until the Awl is dislodged from the bone or connect the Slap Hammer to the proximal end and back it out.

2

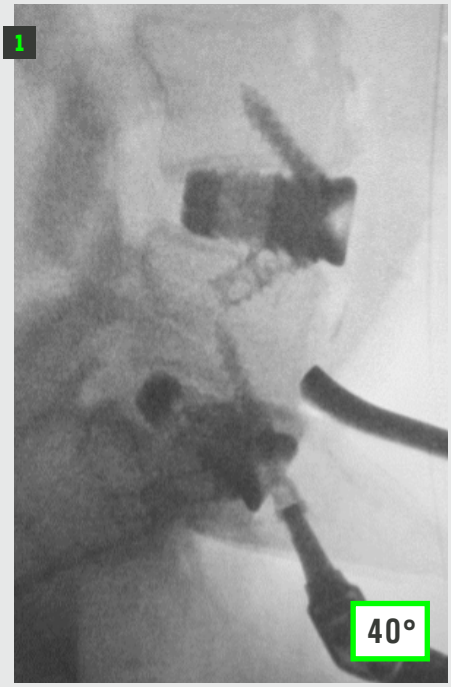
3

DEPLOYED AWL

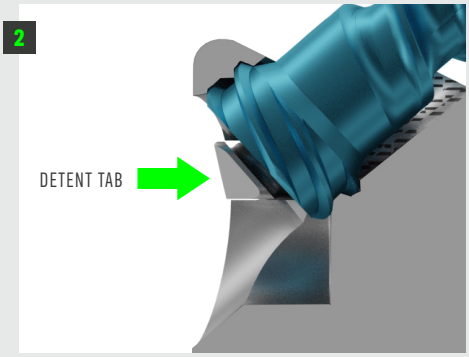


RETRACTED AWL

1 Connect the Lateral Screw to the Straight Driver and advance the screw into the prepared screw hole. If access doesn't permit the use of the Straight Driver, use the Angled Driver.



2 Locking threads on the screw head mate with locking threads on the Spacer. The screw is locked when it will no longer advance and the screw head is beneath the detent tab.



1 The IdentiTi ALIF Standalone Interbody System implants of ≤20° may be used as a standalone system. The IdentiTi ALIF Standalone Interbody System implants of >20° must be used with supplemental spinal fixation systems for use in the lumbar spine in addition to the integrated screws.

CAUTION: WHEN IMPLANTED AT TWO CONTIGUOUS LEVELS, THE IDENTITI ALIF STANDALONE INTERBODY SYSTEM MUST BE IMPLANTED IN THE SAME ORIENTATION TO PREVENT SCREW IMPINGEMENT.

NOTE: WHEN USED IN THE US, SUPPLEMENTAL FIXATION SYSTEMS MUST BE CLEARED BY THE FDA PER THE INDICATIONS FOR USE.

1

SCREW REMOVAL

1 Using the Straight or Angled Removal Driver, thread the distal tip counterclockwise into the screw or bolt and continue to thread until the screw is removed from the Spacer.

> **NOTE:** ONCE A SCREW HAS BEEN REMOVED, IT CANNOT BE USED AGAIN.

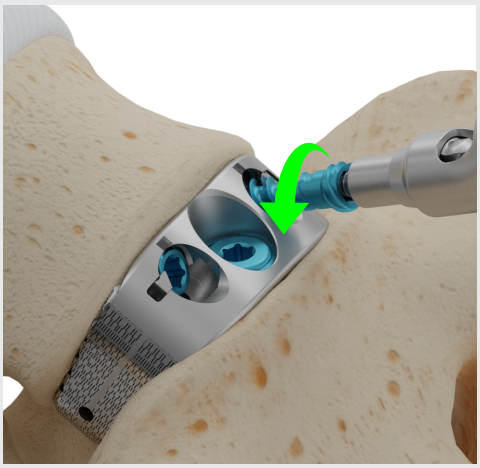
If removing the 9.0 mm Cannulated Graft Bolt, use the T40 Removal Driver.

2 To disengage the removed screw from the Removal Driver, insert the screw into the removal block built into Insert 2 of the IDASCRW tray and rotate clockwise to disengage.

SPACER REMOVAL

1 Once all the bolts and/or screws are removed, attach the Straight Inserter, Cranial Inserter, or Anterolateral Inserter to the Spacer and reverse impact to remove. The Slap Hammer can be used if necessary.

1



INSERTERS & TAMPS

Straight Inserter Part #: 233-100

Anterolateral Inserter Part #: 233-150

Cranial Inserter Part #: 233-140*

Straight Tamp Part #: 233-900

Offset Tamp Part #: 233-950

MEDIAL HOLE PREPARATION

Trephine Punch Sleeve Part #: 233-200-10

Trephine Punch Shaft Part #: 233-200-20

Medial Angled Awl Part #: 233-560-400

Awl Tip Part #: 233-200-35-15

Punch Tip Part #: 233-200-31-15

Saw Tip Part #: 233-200-32-15

LATERAL HOLE PREPARATION

Straight Awl Part #: 233-500

40° Angled Awl Part #: 233-550-400

60° Angled Awl Part #: 233-550-600

**Instrument must be ordered independently*

DRIVERS

T25 Straight Driver Part #: 233-700

T40 Straight Driver Part #: 233-725

Ball-End Driver Part #: 233-705

Detachable Driver Sleeve Part #: 233-075

Variable Angled Driver Part #: 233-760

40° Angled Driver (Long Tip) Part #: 233-750-400

40° Angled Driver (Short Tip) Part #: 233-751-400

60° Angled Driver Part #: 233-752-600

T40 Angled Driver Part #: 233-775-400*

AUXILIARY

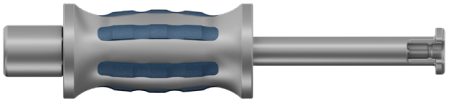
Trial Handle Part #: 233-000

Offset Handle Part #: 233-025

Ratcheting Axial Handle Part #: 16117

Impact Cap Part #: 233-001

Slap Hammer Part #: 27421-03



REMOVAL

T25 Straight Removal Driver Part #: 233-800

T40 Straight Removal Driver Part #: 233-825

Cranial Inserter Part #: 233-140

Angled Removal Driver Part #: 233-850-400

Straight Inserter Part #: 233-100

Anterolateral Inserter Part #: 233-150

**Instrument must be ordered independently*

IdentiTi™ ALIF Standalone Interbody System
INSTRUCTIONS FOR USE

GENERAL INFORMATION:
The IdentiTi ALIF Standalone Interbody System is an integrated intervertebral body fusion device for use in anterior lumbar interbody fusion (ALIF) procedures. The IdentiTi ALIF Standalone Interbody System consists of interbody spacers and bone screws in multiple configurations to accommodate individual patient anatomy. The IdentiTi ALIF Standalone Interbody System interbody spacers are manufactured from a combination of commercially pure porous titanium (CP Ti Grade 2) per ASTM F67 and titanium alloy (Ti-6Al-4V ELI) per ASTM F136. The IdentiTi ALIF Standalone Interbody System interbody spacers are provided in multiple footprints with varying lengths, widths, heights, and angles of lordosis to accommodate individual patient anatomy. The interbody spacers accept three bone screws that are made of titanium alloy (Ti-6Al-4V ELI) per ASTM F136 in varying lengths and diameters.

INDICATIONS FOR USE:
The IdentiTi ALIF Standalone Interbody System is indicated for spinal fusion procedures from L2 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. These patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved levels.

Additionally, the IdentiTi ALIF Standalone Interbody System can be used as an adjunct to fusion in patients diagnosed with multilevel degenerative scoliosis and sagittal deformity. However, when used in these patients at multiple levels, and for patients with degenerative spondylolisthesis (>Grade 1) and spinal stenosis at one or two adjacent levels, the IdentiTi ALIF Standalone Interbody System must be used with supplemental spinal fixation systems cleared by the FDA for use in the lumbar spine. The IdentiTi ALIF Standalone 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 allogenic bone graft comprised of cortical, cancellous, and/or corticocancellous bone, and/or demineralized allograft bone with bone marrow aspirate.

The IdentiTi ALIF Standalone Interbody System implants of ≤20° are a standalone system. The IdentiTi ALIF Standalone Interbody System implants of >20° must be used with supplemental spinal fixation systems cleared by the FDA for use in the lumbar spine.

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 and single-use instruments 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. Bone screws are provided non-sterile and must be sterilized prior to surgery. All instruments are provided non-sterile and must be cleaned and sterilized prior to surgery. See CLEANING and STERILIZATION sections in this IFU.
5. All 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. All instruments in the IdentiTi ALIF Standalone Interbody System are reusable surgical devices except for the Trephine Punch Tips, which are single use only. 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.
7. The system is used to augment the development of a spinal fusion by providing temporary stabilization. If fusion is delayed or does not occur, material fatigue may cause breakage of the implant. Damage to the implant during surgery (i.e., scratches, notches) and loads from weight bearing and activity will affect the implant's longevity.
8. Over-distraction of the disc space can lead to facet over-distraction and spinous process contact.
9. Potential risks identified with the use of these fusion devices, which may require additional surgery, include device component failure, loss of fixation, pseudoarthrosis (i.e., non-union), fracture of the vertebra, neurological injury, and/or vascular or visceral injury.
10. 10. 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.
11. 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).
12. 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.
13. Placement and positional adjustment of implants must only be done 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.
14. The physician/surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc., which may impact the performance of this system.
15. Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without previous surgery.
16. The IdentiTi ALIF Standalone Interbody System is a standalone system intended to be used with the bone screws provided and requires no additional supplementary fixation. In the case that fewer than the maximum number of screws accommodated by the device are used, the system should be used with additional FDA-cleared supplemental fixation for use in the lumbosacral spine.
17. All components should be final tightened per the specifications in the Surgical Technique. Implants should not be tightened past the locking point, as damage to the implant may occur.
18. When implanted at two contiguous levels, the IdentiTi ALIF Standalone Interbody System must be implanted in the same orientation to prevent screw impingement.
19. Lateral Awls must not be used for Center Screw Hole preparation, as over-insertion into bone may occur.
20. Care should be taken in performing screw hole preparation to facilitate a proper Graft Bolt insertion trajectory and implantation. Confirm under fluoroscopy that the Graft Bolt insertion angle is as close as possible to a 40° trajectory. A shallow or incorrect Graft Bolt trajectory may result in encroachment of the spacer and lead to Graft Bolt breakage.

MRI SAFETY INFORMATION:
The IdentiTi ALIF Standalone 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 IdentiTi ALIF Standalone 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.
5. IdentiTi ALIF Standalone interbody implant anterior heights provided on product labels are theoretical calculations from other geometry (e.g., posterior height, width, lordosis). Anterior heights should be considered reference only. Use trials to assess implant sizing prior to implantation.

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-130

℞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

IdentiTi™ ALIF Standalone Interbody System
INSTRUCTIONS FOR USE (International)

GENERAL INFORMATION:
The IdentiTi ALIF Standalone Interbody System is an integrated intervertebral body fusion device for use in anterior lumbar interbody fusion (ALIF) procedures. The IdentiTi ALIF Standalone Interbody System consists of interbody spacers and bone screws in multiple configurations to accommodate individual patient anatomy. The IdentiTi ALIF Standalone Interbody System interbody spacers are manufactured from a combination of commercially pure porous titanium (CP Ti Grade 2) per ASTM F67 and titanium alloy (Ti-6Al-4V ELI) per ASTM F136. The IdentiTi ALIF Standalone Interbody System interbody spacers are provided in multiple footprints with varying lengths, widths, heights, and angles of lordosis to accommodate individual patient anatomy. The interbody spacers accept three bone screws that are made of titanium alloy (Ti-6Al-4V ELI) per ASTM F136 in varying lengths and diameters.

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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.
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8. Over-distraction of the disc space can lead to facet over-distraction and spinous process contact.
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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.
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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-130-01

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

AUSTRALIA SPONSOR:
ALPHATEC AUSTRALIA, PTY LTD
101 Cremorne St.
Cremorne VIC 3121, Australia

CUSTOMER SERVICE
Toll Free: 800.922.1356
Local: 760.431.9286
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