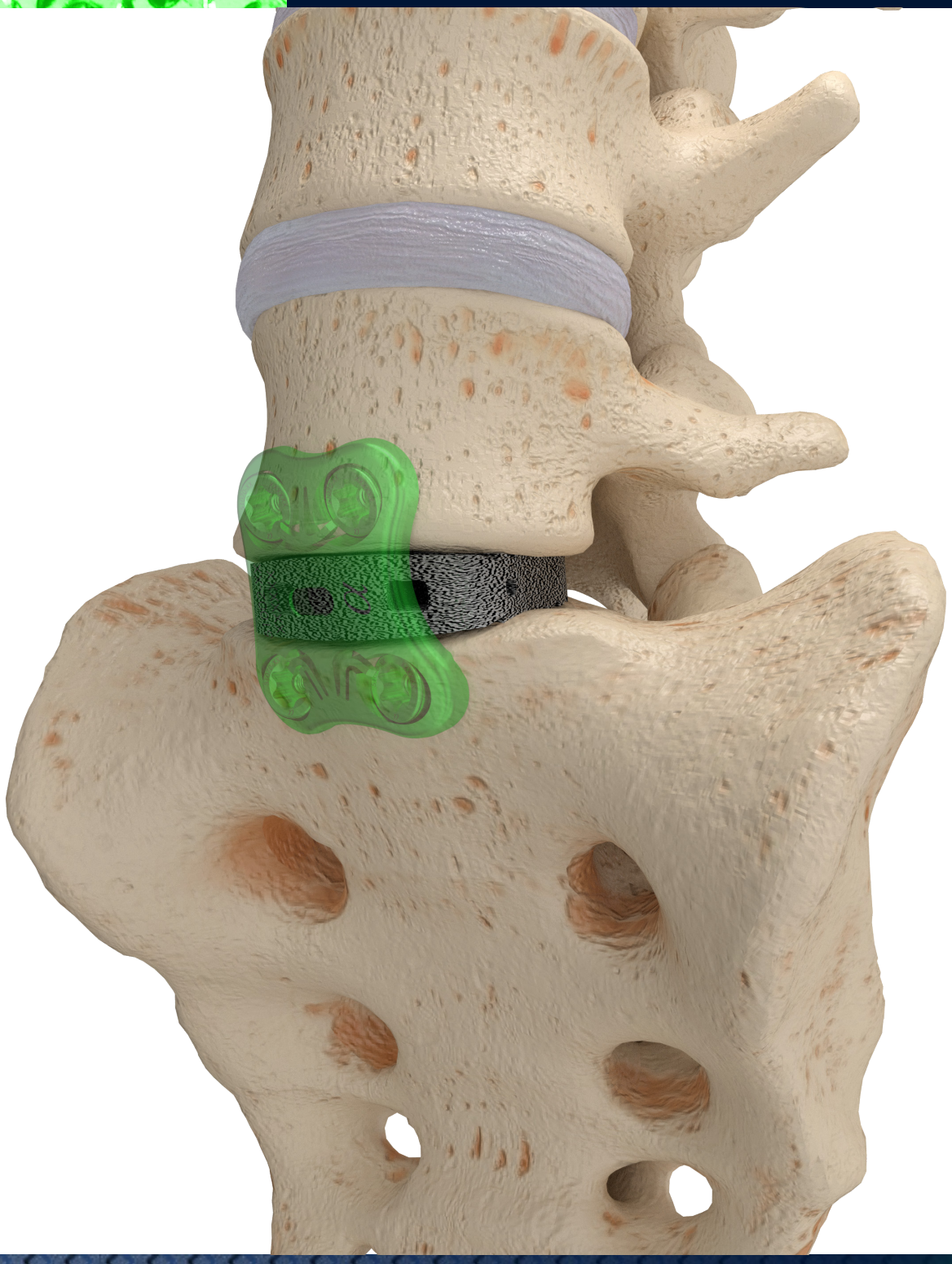
IdentiTi™ ALIF

Porous Titanium Spacer System

ANTERIOR APPROACH | Surgical Technique Guide



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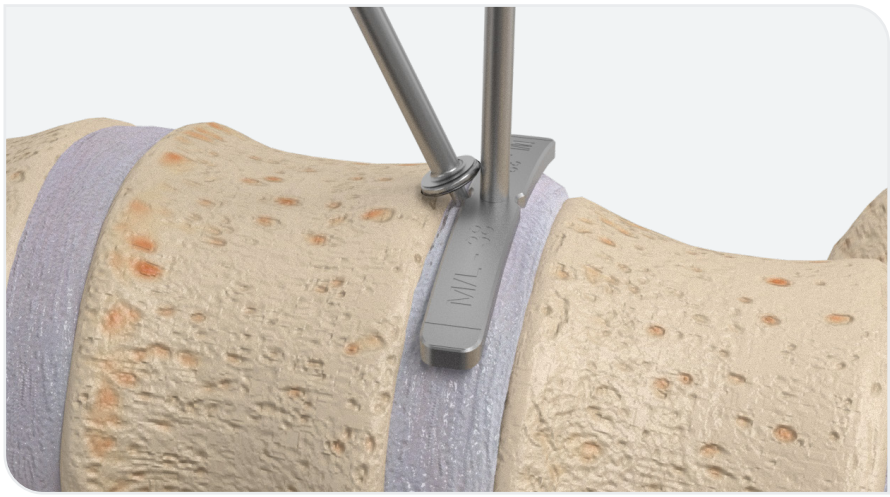
DETERMINATION OF APPROACH

Surgical approach is dependent upon the indicated level for treatment. Universal instrumentation accommodates an anterior or anterolateral (45° offset) approach.

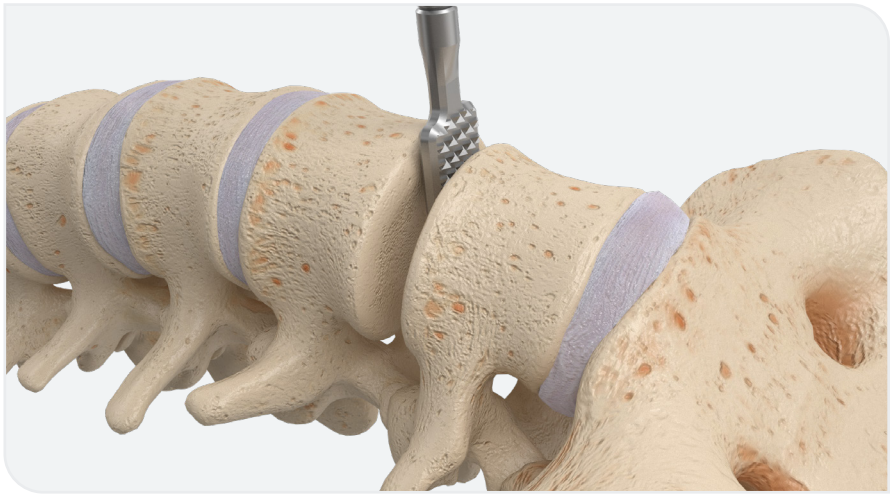


DISC SPACE PREPARATION

The Disc Needle and Template Tools are provided to locate the level, assess midline alignment, and give reference to the various implant widths offered in relation to the intervertebral disc at the selected level.

Once anatomic reference points are identified, remove disc material using available Pituitary Ronguers, Currettes, and other select instruments.

If desired, a Rasp is provided to assist in the removal of the superficial layers of the cartilaginous endplates and to further prepare the site.



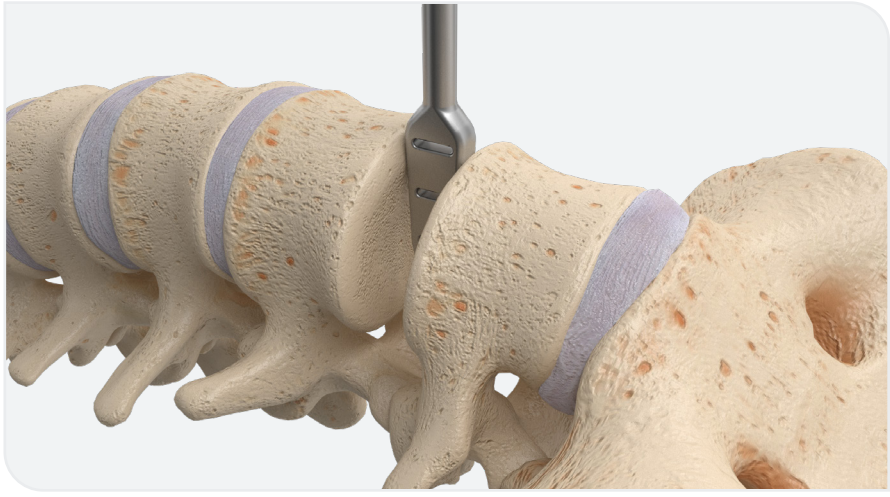
DISTRACTION

Impacting and/or Rotating Distractors may be used to further prepare the site by providing more room and visualization of the space.

Both the Impacting and Rotating Distractors are modular and are provided in various heights. Impacting Distractors have 10° of lordosis and Rotating Distractors have 5°.

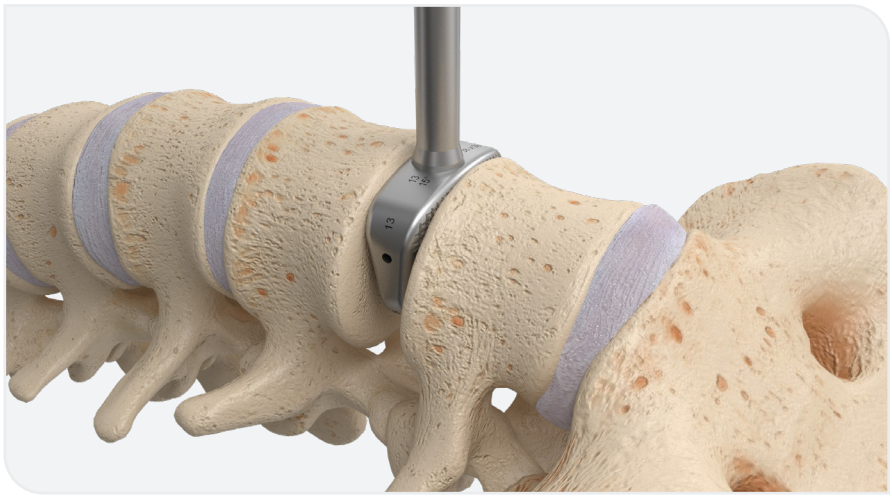
Both Distractor types assemble to the Inserter by aligning the proximal end of the distractor with the distal end of the Inserter and pressing into place. To detach, pull the gold trigger on the Inserter.

To use the Rotating Distractors, gently insert the flat side into the disc space and rotate 90°. To use the Impacting Distractors, insert the tapered tip into the disc space and impact. Distraction will occur as you sequentially insert by increasing heights.



TRIALING

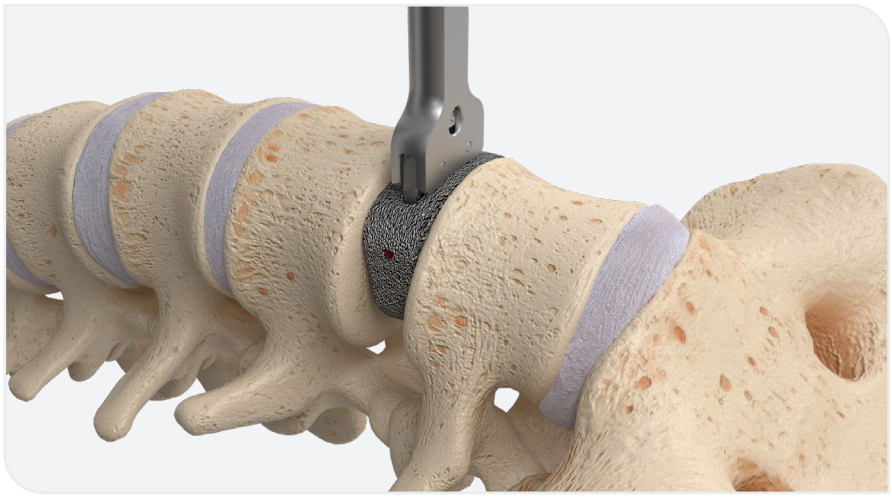
The Trial Handle provided may then be used to engage the Modular Implant Trials to determine proper implant sizing.



NOTE: The Trial Handle may be attached to the Trial centrally or anterolaterally, depending on the selected approach.

IMPLANT INSERTION

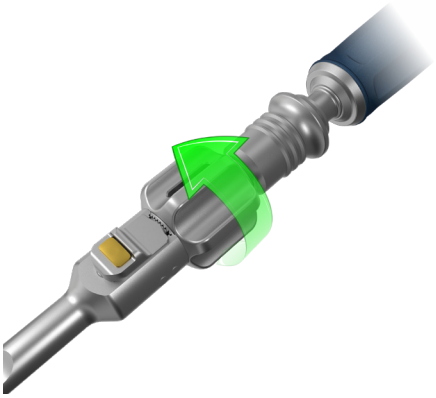
With the appropriately sized implant selected, load the Straight Inserter by turning the thumbwheel clockwise and engaging the prongs with the slots located on the anterior face of the implant. Align the implant at the selected level and insert into the prepared disc space.



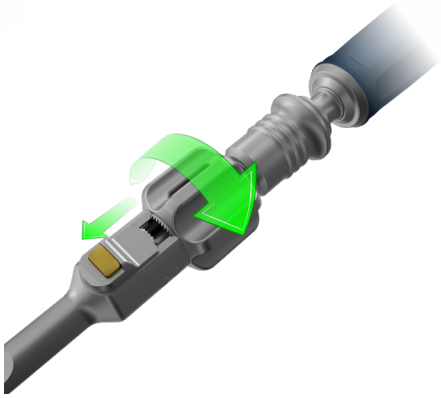
Once placed, press the slide feature forward until it clicks in place and rotate the thumbwheel counter-clockwise to disengage. When the Inserter prongs are opened fully, the slide feature will automatically snap back to engage the ratcheting teeth and the Inserter may be removed.

NOTE: Confirm that the ratcheting teeth are engaged and there is no gap present while loading the implant.

Do not hold the slide forward while loading the implant. When properly engaged, the ratcheting teeth between the slide and thumbwheel will make an audible clicking sound when the thumbwheel is turned clockwise.



Loading Implant



Unloading Implant

IMPLANT INSERTION WITH ANTEROLATERAL INSERTER (OPTIONAL)

An anterolateral insertion device is available as an optional instrument that may be used to place the implant in the disc space via an anterolateral approach, by utilizing one of the two prong slots located on the anterior face of the implant.

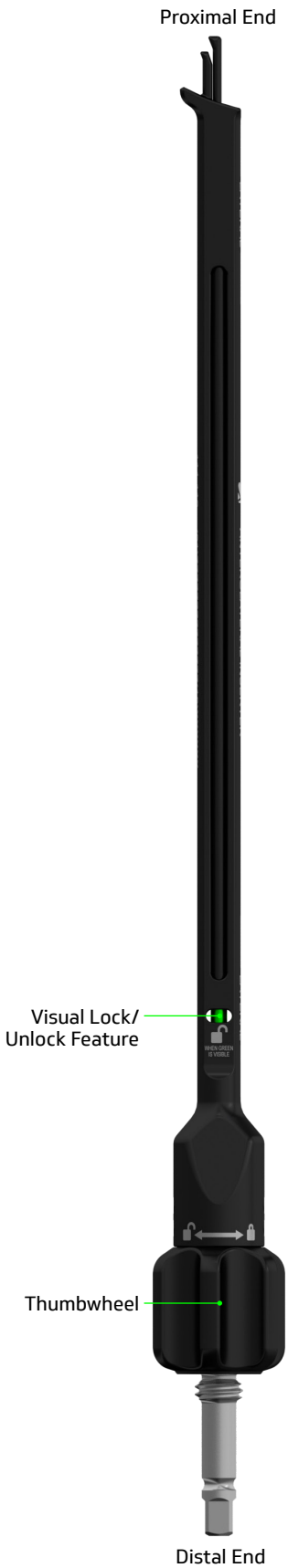
Loading the Implant:

- Rotate the thumbwheel counter-clockwise to ensure the green epoxy band is showing, indicating the “unlocked” position.
- Feed the distal end of the instrument into one of the implant prong slots so that the instrument sits nearly flush with the anterior face of the implant. Confirm that the Inserter is oriented correctly with the side marked “LATERAL” matching the lateral face of the implant.
- Once the instrument is seated properly in the prong slot of the implant, rotate the thumbwheel clockwise until the green epoxy band is no longer visible and the implant feels secure on the Inserter.

Inserter Unlocked State

Unlocked

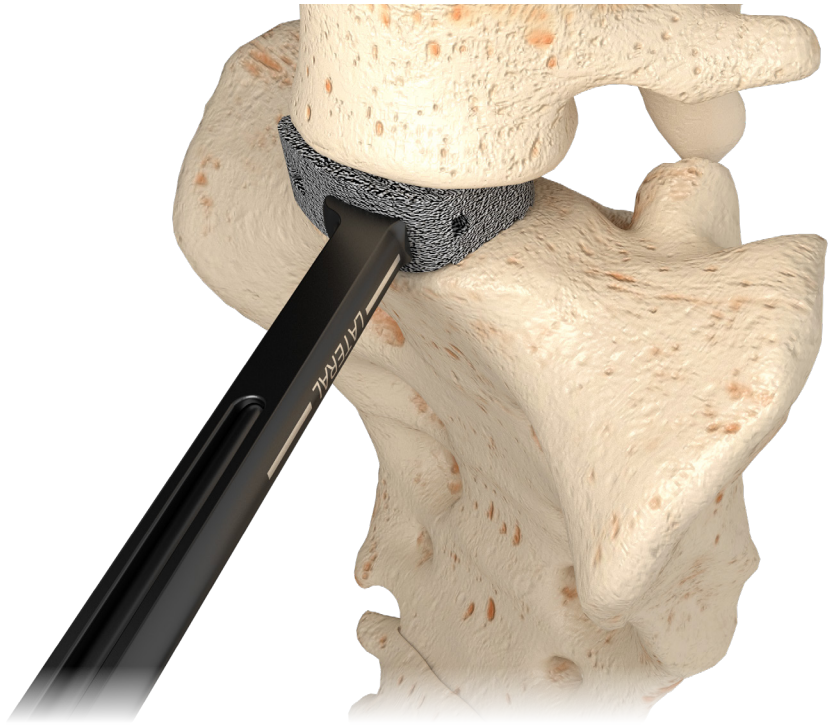
Locked



IMPLANT INSERTION WITH ANTEROLATERAL INSERTER (OPTIONAL)

To Insert the Implant:

- Insert the implant at an angle in accordance with the access available to the disc space.
- Impaction may be used to facilitate implant placement.
- Once the Implant is in the desired location within the disc space, rotate the thumbwheel counter-clockwise until the green epoxy band is showing, indicating the inserter is “unlocked” from the implant.
- Gently remove the inserter from the implant prong slot, maintaining the interfacing angulation of the instrument to the implant.
- Confirm implant position with A/P and lateral fluoroscopy.

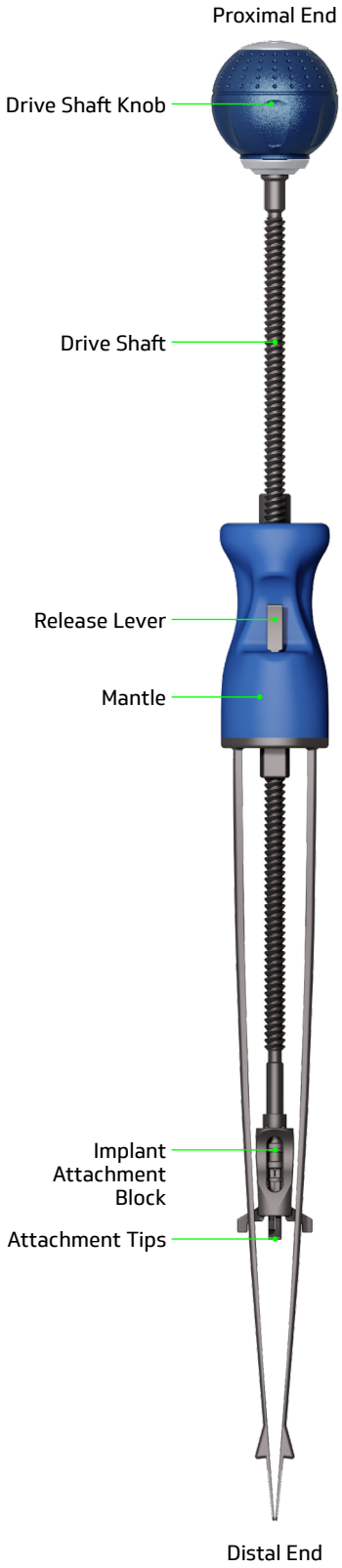


TIP: The Anterolateral Inserter (Part # 114-110) may be used to reposition the implant within the disc space if desired.

IMPLANT INSERTION WITH INSERTER/DISTRACTOR (OPTIONAL)

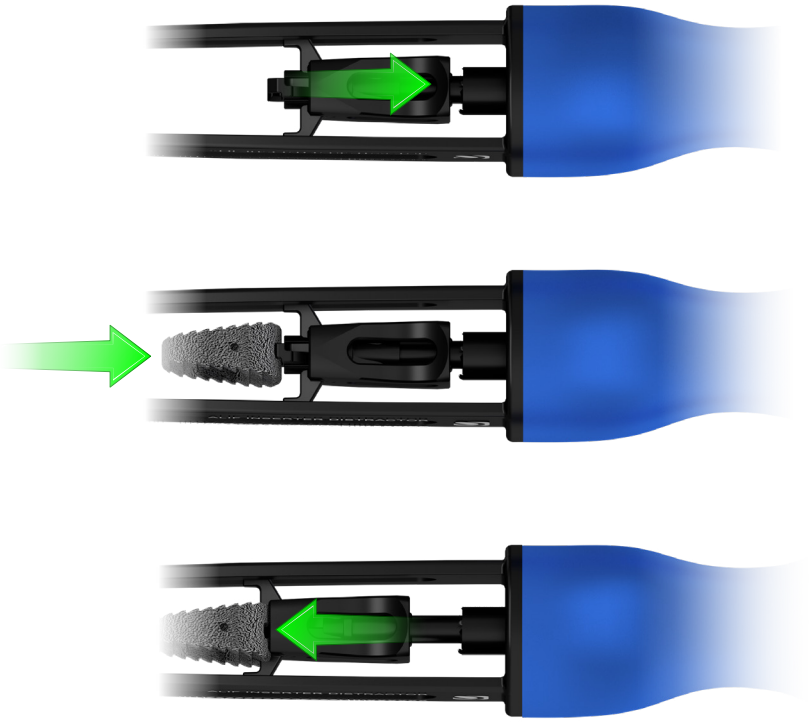
An Inserter/Distractor instrument is available as an optional instrument that may be used to simultaneously distract the vertebral space while inserting the implant. This instrument is not included in the IdentiTi ALIF Instrument Set.

Ordering Information: Part Number 114-200



Loading the Implant:

- Retract the Drive Shaft fully by depressing the Release Lever and drawing back the Drive Shaft Knob towards the Proximal End of the instrument.
- Pull back the spring loaded Implant Attachment Block so the Attachment Tips protrude out of the block.
- Engage the Attachment Tips with the Implant Prong Slots. Release the Implant Attachment Block to lock the Implant in place.



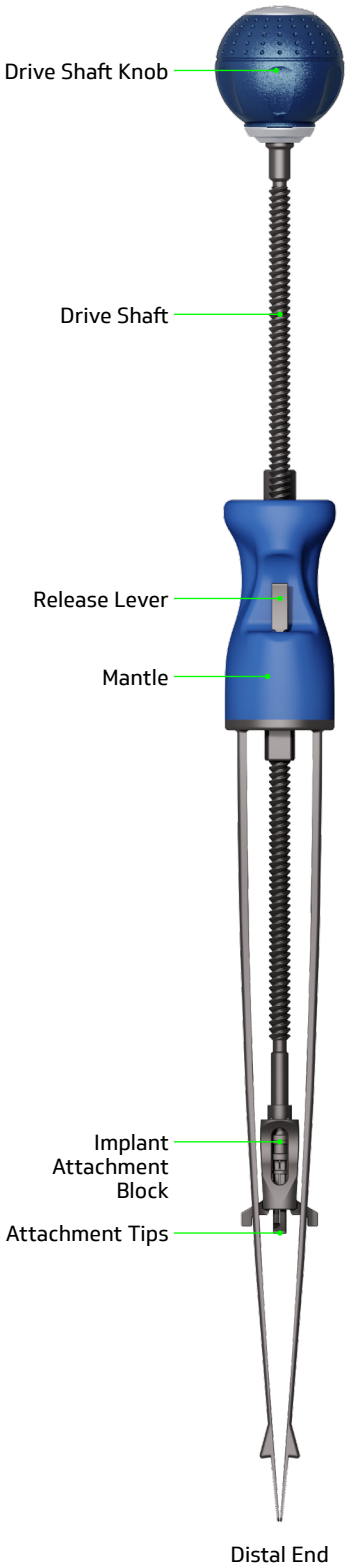
IMPLANT INSERTION WITH INSERTER/DISTRACTOR (OPTIONAL)

To Insert the Implant:

- Advance the Drive Shaft forward by impacting or rotating the Drive Shaft Knob.
- As the implant is advanced, ensure the distal end of the instrument is contacting the endplates, and the stops are against the vertebral body.

NOTE: Fine posterior adjustments can be made by turning the Drive Shaft Knob clockwise. A 360° turn will progress the Drive Shaft 10 mm.

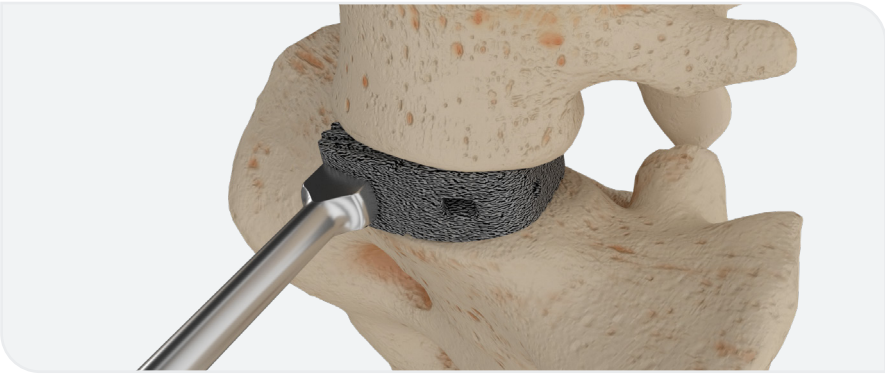
- Once the implant is in the desired location within the disc space, continue rotating the Drive Shaft until the Inserter is ejected from the disc space.
- The implant will automatically be released from the Inserter/Distractor once the Drive Shaft has been advanced completely. The implant will not detach from the Inserter/Distractor until the Drive Shaft Knob is contacting the top of the Mantle.
- Confirm implant position with A/P and lateral fluoroscopy.

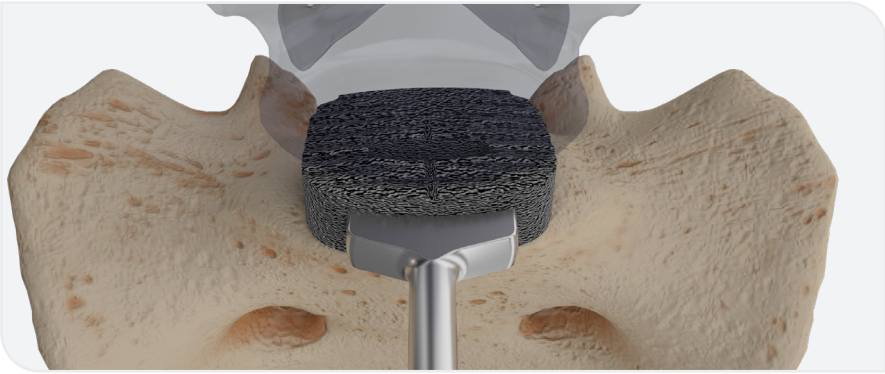


IMPLANT POSITION VERIFICATION

Confirm implant position with A/P and lateral fluoroscopy. If needed, use the Implant Tamps provided to manipulate the implant into final position. The implant Inserter may also be used to reposition the implant.

NOTE: For select sizes, the lateral window may be used to assess alignment with lateral fluoroscopy. See below for the lateral window designs of both the LW and SW implants.





IMPLANT SIZES

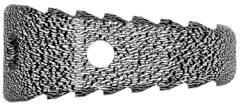
Implants are offered in various footprints with a large or small axial graft window, and lordotic angles ranging from 10 to 30°.

Large Window (LW)

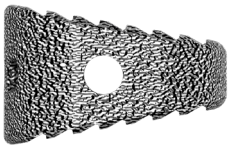
34 x 24 mm
10, 15, 20 & 30°

38 x 28 mm
10, 15, 20 & 30°

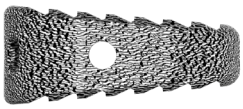
42 x 30 mm
10, 15 & 20°



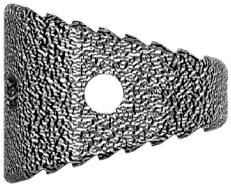
10° Lordotic Angle



20° Lordotic Angle



15° Lordotic Angle



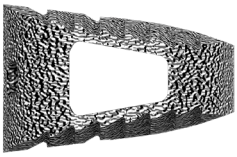
30° Lordotic Angle

Small Window (SW)

34 x 24 mm
10, 15, 20 & 30°

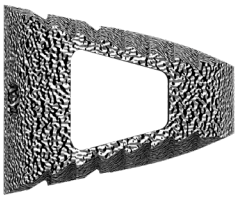
38 x 28 mm
10, 15, 20 & 30°

10° Lordotic Angle



20° Lordotic Angle

15° Lordotic Angle



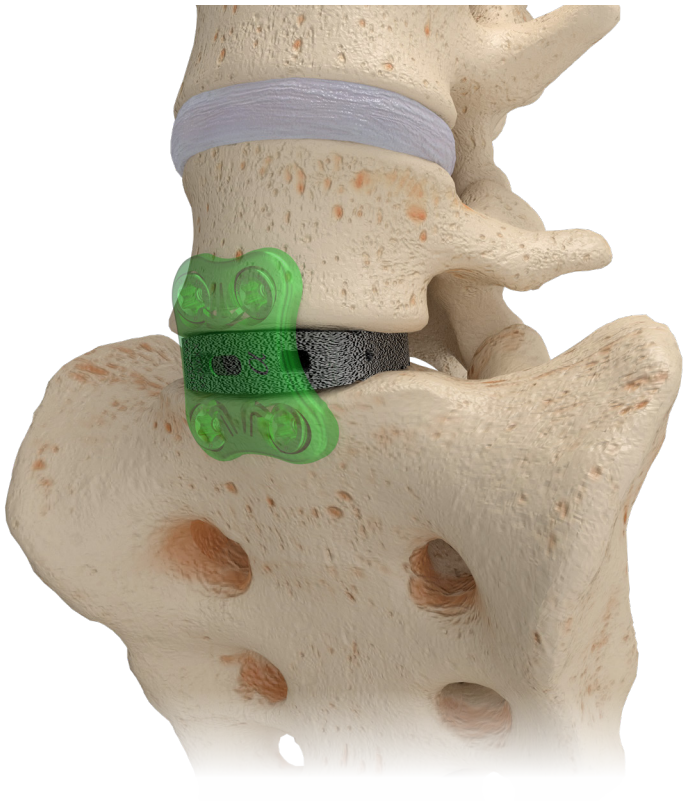
30° Lordotic Angle

SUPPLEMENTAL FIXATION

- The Aspida™ Anterior Lumbar Plating System may be used for supplemental fixation [see LIT-84153 Aspida STG], as the IdentiTi ALIF Porous Ti Interbody System must be used with supplemental fixation for use in the thoracolumbar spine.

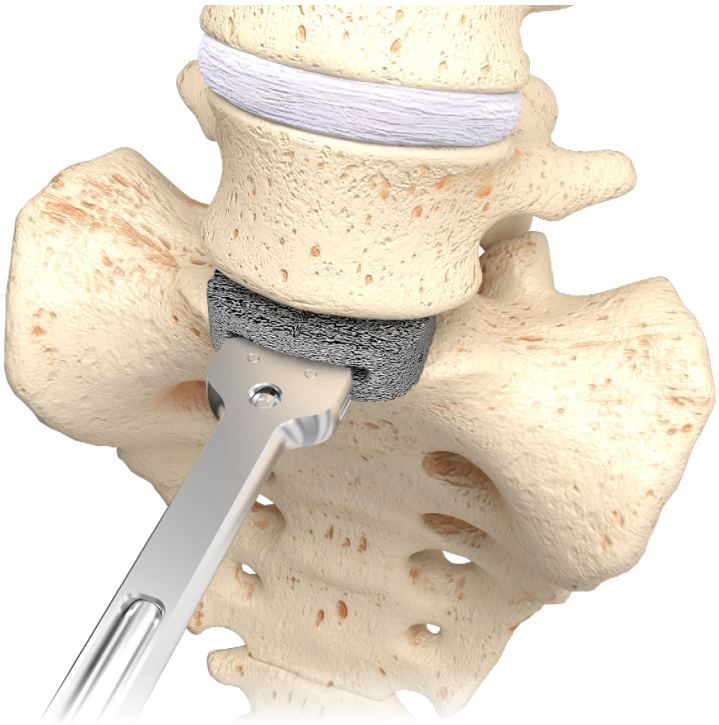
NOTE: When used in the US, supplemental fixation systems must be cleared by the FDA per the indications for use.

- IdentiTi ALIF interbody spacers with >20° lordosis must be used with an anterior plate as the form of supplemental fixation.
- Posterior supplemental fixation options available include the Kodiak™ Arsenal® (open) and the Illico® (MIS) Systems for pedicle screw fixation.



IMPLANT REMOVAL

- Using the Implant Inserter, engage the prongs with the slots located on the implant and gently remove.
- CAUTION: To avoid possible neurological injury and/or vascular or visceral injury, extreme caution should be taken at all times. Fluoroscopy should be employed where vision is obstructed.
- The Removal Tool provided in the set accommodates an alternative removal technique. To use, thread the distal tip of the Removal Tool into the central feature, or one of the prong slots, located on the anterior face of the implant. Once engaged, gently remove the implant form the disc space. If additional removal force is required, the Slap Hammer provided can be attached to the proximal end of the Removal Tool.



IdentiTi™ Porous Ti Interbody System
INSTRUCTIONS FOR USE

GENERAL INFORMATION:
The IdentiTi Porous Ti Interbody System is an intervertebral body fusion device with implants of various lengths, widths, heights, and degrees of lordosis to accommodate individual patient anatomy. The IdentiTi interbody spacers are manufactured from commercially pure titanium Grade 2 per ASTM F67. The IdentiTi Porous Ti cervical platform includes sub-system IdentiTi Cervical (IdentiTi-C). The IdentiTi Porous Ti thoracolumbar platform includes the following sub-systems: IdentiTi PS, IdentiTi PC, IdentiTi PO, IdentiTi ALIF, and IdentiTi LIF.

Use IdentiTi cervical interbody spacers with supplemental fixation systems from Alphatec Spine such as: Trestle Luxe® Cervical Plate System or Invictus® OCT Spinal Fixation System. Use IdentiTi thoracolumbar 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:
IdentiTi Cervical Platform
The IdentiTi Cervical Porous Ti Interbody System is an anterior cervical interbody fusion system intended for spinal fusion procedures in skeletally mature patients with cervical disc degeneration and/or cervical spinal instability, as confirmed by imaging studies (radiographs, CT, MRI), that results in radiculopathy, myelopathy, and/or pain at multiple contiguous levels from C2-T1. The IdentiTi Cervical Porous Ti Interbody System is intended for use with supplemental fixation systems. The system is designed for use with autograft, allograft comprised of cortical, cancellous, and/or corticocancellous bone graft, demineralized allograft with bone marrow aspirate, or a combination thereof.

IdentiTi Thoracolumbar Platform
The IdentiTi Porous Ti Interbody System is indicated for spinal fusion procedures from T1 to S1 in skeletally mature patients for the treatment of symptomatic degenerative disc disease (DDD), degenerative spondylolisthesis, spinal stenosis, and/or thoracic disc herniation (with 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 IdentiTi Porous Ti System can be used as an adjunct to fusion in patients diagnosed with multilevel degenerative scoliosis and sagittal deformity.

The IdentiTi Porous Ti Interbody System is intended for use on patients who have had at least six months of nonoperative 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 and supplemental fixation systems that are cleared by FDA for use in the thoracic and lumbar spine.

AMP™ Anti-Migration Plate may be used with IdentiTi LIF interbody spacers to provide integrated fixation. IdentiTi LIF spacers with >20° lordosis must be used with AMP Anti-Migration Plate in addition to supplemental fixation. IdentiTi ALIF interbody spacers with >20° lordosis must be used with an anterior plate as the form of supplemental fixation.

CONTRAINDICATIONS:
The IdentiTi Porous Ti 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 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. All instruments except the single-use 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. Resection of the anterior longitudinal ligament (ALL) may facilitate insertion of the IdentiTi LIF implant for greater sagittal correction, when used with AMP Anti-Migration Plate and supplemental fixation per the indications, 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.
14. The Center Screw - Back Table (116-5-01, green) must be assembled to the AMP and interbody prior to insertion and must not be assembled in situ.

MRI SAFETY INFORMATION:
The IdentiTi Porous Ti 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 Porous Ti 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. Cervical, LIF, and ALIF interbody implant anterior heights provided on product labels are theoretical calculations from other geometry (e.g., posterior height, width, lordosis). PS and PO interbody implant anterior heights provided on product labels reflect the maximum apex height. 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-100

℞ 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**

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IdentiTi™ Porous Ti Interbody System
INSTRUCTIONS FOR USE (AUSTRALIA)

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INDICATIONS FOR USE:
IdentiTi Cervical Platform
The IdentiTi Cervical Porous Ti Interbody System is an anterior cervical interbody fusion system intended for spinal fusion procedures in skeletally mature patients with cervical disc degeneration and/or cervical spinal instability, as confirmed by imaging studies (radiographs, CT, MRI), that results in radiculopathy, myelopathy, and/or pain at multiple contiguous levels from C2-T1. The IdentiTi Cervical Porous Ti Interbody System is intended for use with supplemental fixation systems. The system is designed for use with autograft, allograft comprised of cortical, cancellous, and/or corticocancellous bone graft, demineralized allograft with bone marrow aspirate, or a combination thereof.

IdentiTi Thoracolumbar Platform
The IdentiTi Porous Ti Interbody System is indicated for spinal fusion procedures from T1 to S1 in skeletally mature patients for the treatment of symptomatic degenerative disc disease (DDD), degenerative spondylolisthesis, spinal stenosis, and/or thoracic disc herniation (with 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 IdentiTi Porous Ti System can be used as an adjunct to fusion in patients diagnosed with multilevel degenerative scoliosis and sagittal deformity.

The IdentiTi Porous Ti 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 and supplemental fixation systems for use in the thoracic and lumbar spine.
AMP™ Anti-Migration Plate may be used with IdentiTi LIF interbody spacers to provide integrated fixation. IdentiTi LIF spacers with >20° lordosis must be used with AMP Anti-Migration Plate in addition to supplemental fixation. IdentiTi ALIF interbody spacers with >20° lordosis must be used with an anterior plate as the form of 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 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. All instruments except the single-use 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. Resection of the anterior longitudinal ligament (ALL) may facilitate insertion of the IdentiTi LIF implant for greater sagittal correction, when used with AMP Anti-Migration Plate and supplemental fixation per the indications, 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.
14. The Center Screw - Back Table (116-5-01, green) must be assembled to the AMP and interbody prior to insertion and must not be assembled in situ.

MRI SAFETY INFORMATION:
The IdentiTi Porous Ti 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 Porous Ti 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. Cervical, LIF, and ALIF interbody implant anterior heights provided on product labels are theoretical calculations from other geometry (e.g., posterior height, width, lordosis). PS and PO interbody implant anterior heights provided on product labels reflect the maximum apex height. 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-100-01

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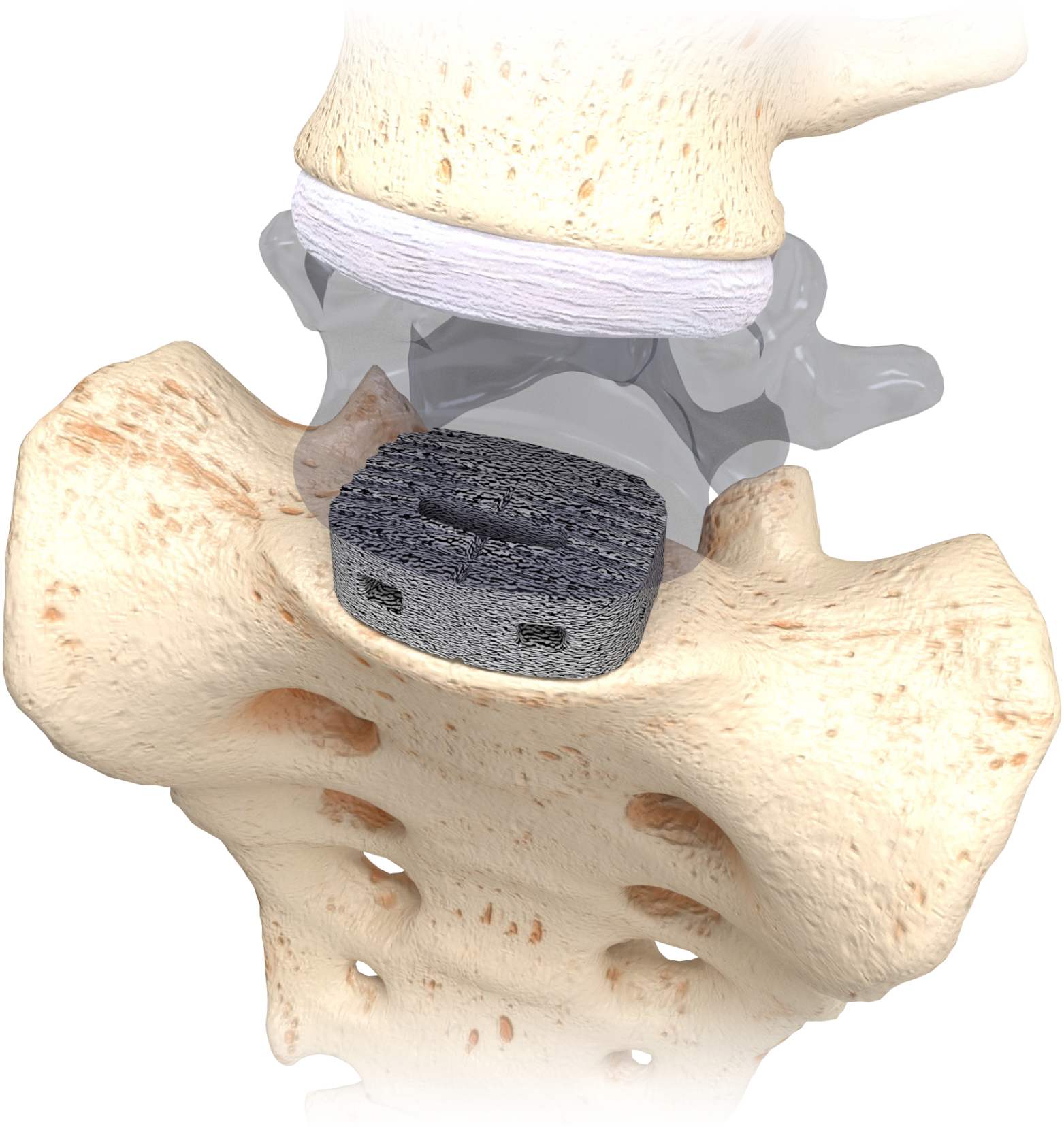
IdentiTi™ ALIF – Surgical Technique Guide



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