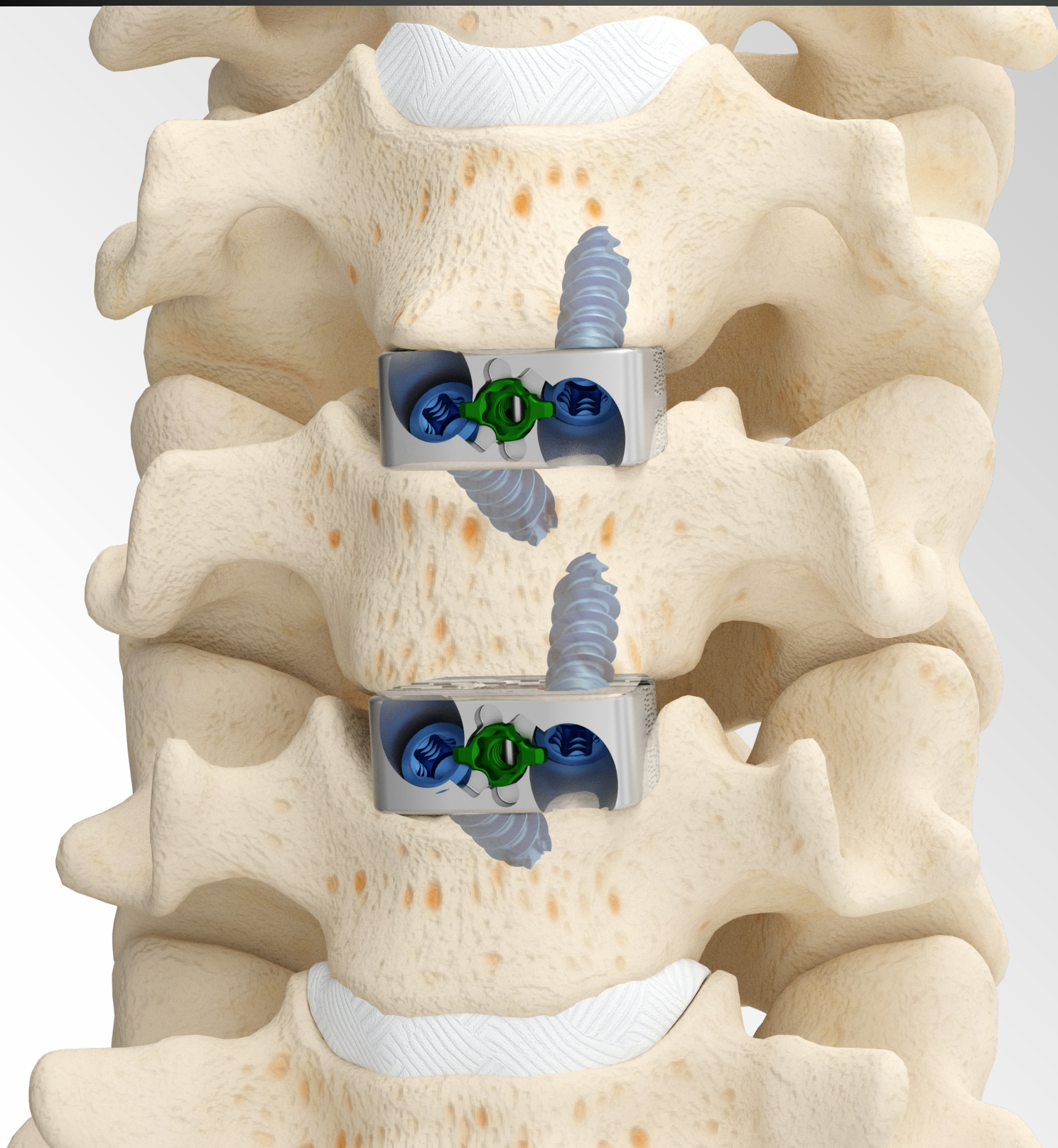


IdentiTi™ -C

Standalone Interbody System

atec[™]
INFORMED BY **EOS**



IdentiTi™ -C

Standalone Interbody System

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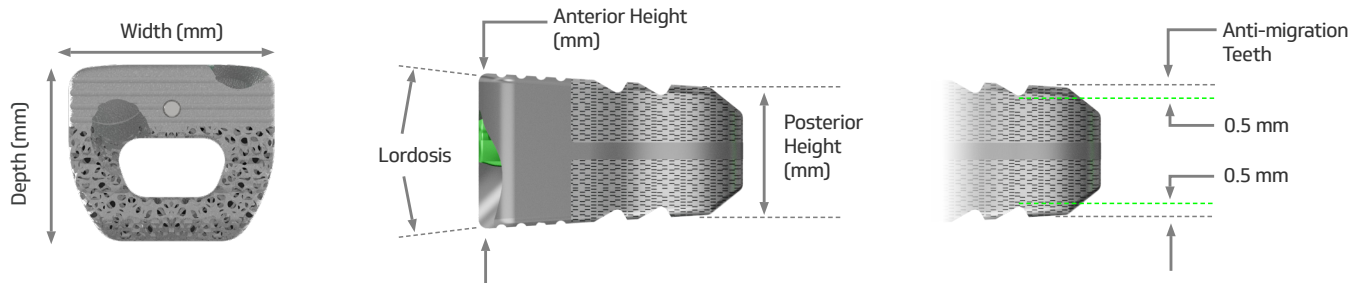
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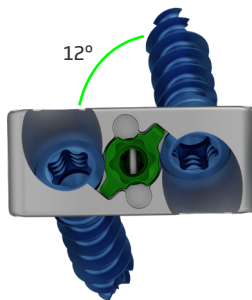
SYSTEM OVERVIEW

IdentiTi-C 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.

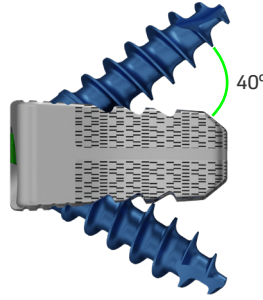


NOTE: IMPLANT HEIGHT IS BASED ON THE ANTERIOR MEASUREMENT

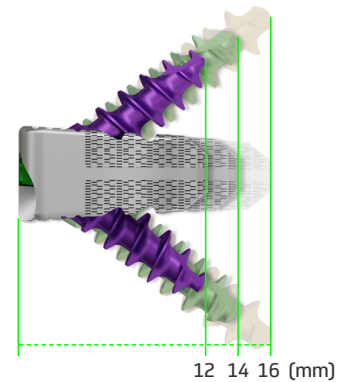
SCREW TRAJECTORIES



12° Medial



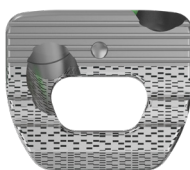
40° Cranial/Caudal



Screw Depth Reference Guide

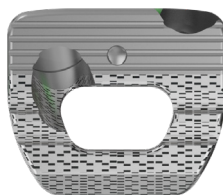
IMPLANT SIZES

14 mm x 12 mm



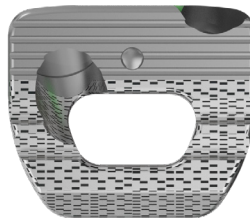
7°

16 mm x 14 mm



7°, 10°, 15°

18 mm x 16 mm



7°, 10°, 15°

NOTE: IMPLANT FOOTPRINT SIZES ARE REFERENCED IN WxD.

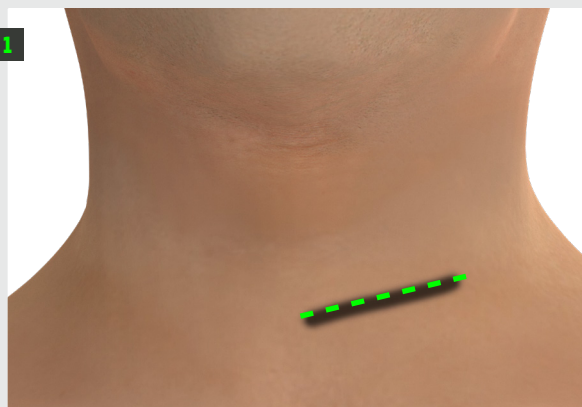
VOLUME IN CC'S

		IMPLANT FOOTPRINTS (MM)		
		14 X 12	16 X 14	18 X 16
HEIGHTS	5 mm	0.11	0.14	0.28
	6 mm	0.13	0.17	0.36
	7 mm	0.16	0.21	0.43
	8 mm	0.18	0.24	0.50
	9 mm	0.21	0.28	0.57
	10 mm	0.24	0.31	0.65

NOTE: THE VOLUMES OF THE GRAFT APERTURES SHOWN ARE CONSISTENT ACROSS ALL LORDOTIC SIZES.

PATIENT POSITIONING

- 1 Place the patient in a supine position with the head in slight extension. Choose the preferred approach: either right or left of the cervical vertebral column. After the approach is determined, rotate the head to allow for adequate exposure of the upper cervical spine.



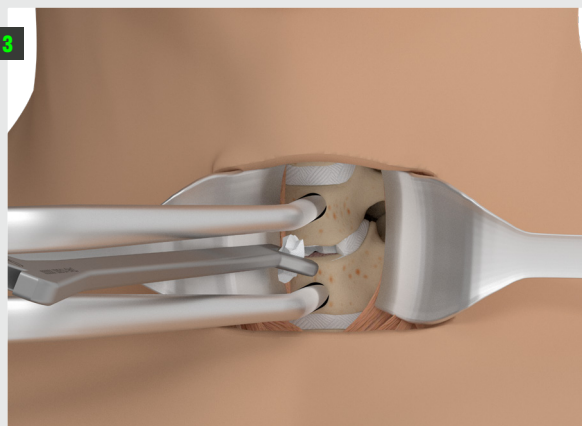
EXPOSURE

- 2 The initial incision should be used to create an avascular dissection plane between the trachea and esophagus. Retractors are typically utilized to provide initial exposure of the anterior vertebral column and the adjacent muscles. An 18-gauge needle may be inserted into the disc space using fluoroscopy to localize the desired level.



DISCECTOMY/DECOMPRESSION

- 3 Using commercially available pituitary rongeurs, curettes, and Kerrison rongeurs, perform the discectomy at the indicated level. Caspar pins may be placed appropriately in the adjacent vertebrae with a distractor to aid in disc preparation. Use of a microscope and fluoroscopy is recommended to confirm that the fibrocartilage of the annulus and disc as well as all osteophytes are carefully removed. A blunt hook can be used to confirm that any posterior osteophytes have been removed for a thorough decompression.



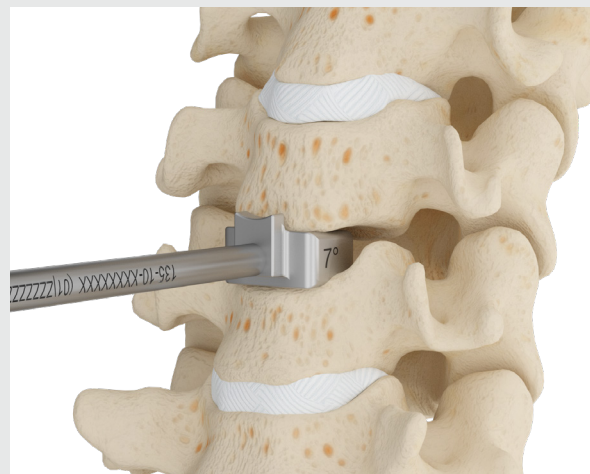
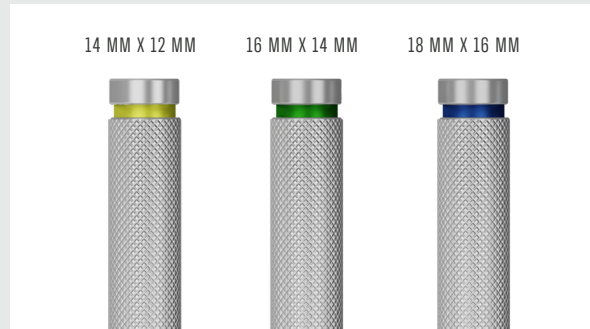
1 In the newly prepared disc space, begin trialing to identify the footprint, height, and lordosis of the disc space. The Trials are color-coded to help identify the desired Interbody Spacer footprint. Fluoroscopy can be utilized in the AP and lateral views to confirm final trial selection. The Trial should properly restore the disc space height and lordosis creating a snug fit via gentle impaction.

NOTE: THE TRIAL IS DESIGNED TO MATCH THE CORRESPONDING IMPLANT LINE-TO-LINE WHICH INCLUDES THE HEIGHT OF THE ANTI-MIGRATION TEETH. THE HEIGHT AND FOOTPRINT ARE DEPICTED ON THE ANTERIOR FACE OF THE TRIAL FOR REFERENCE, WHILE THE LORDOSIS IS LOCATED ON THE LATERAL PROFILE OF THE FACE. THE COLOR OF THE PROXIMAL IMPACTION SURFACE ALSO SERVES AS AN INDICATION OF THE TRIAL'S LORDOSIS WHILE THE UNDERLINED NUMBER REFERENCES THE HEIGHT.

TIP: THE COLOR-CODING OF THE TRIALS IS OUTLINED BELOW:

- 14 MM X 12 MM FOOTPRINT
- 16 MM X 14 MM FOOTPRINT
- 18 MM X 16 MM FOOTPRINT
- 7° LORDOSIS
- 10° LORDOSIS
- 15° LORDOSIS

NOTE: RASPING AND 15 DEGREE TRIALS ARE AVAILABLE UPON REQUEST (SET ID: CSRTLR AND CS15TRL RESPECTIVELY).

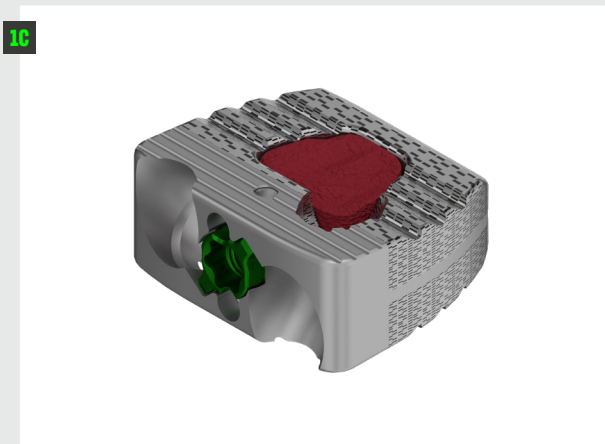
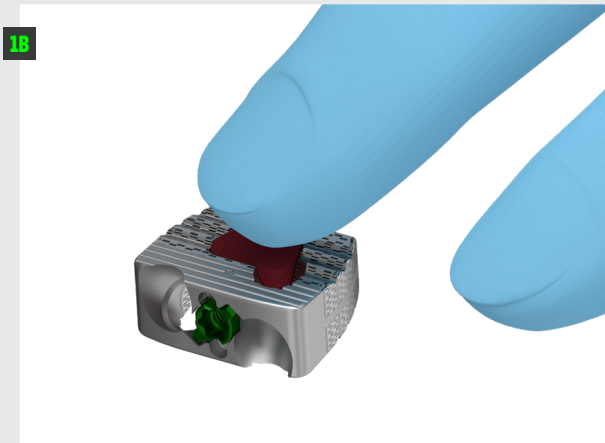
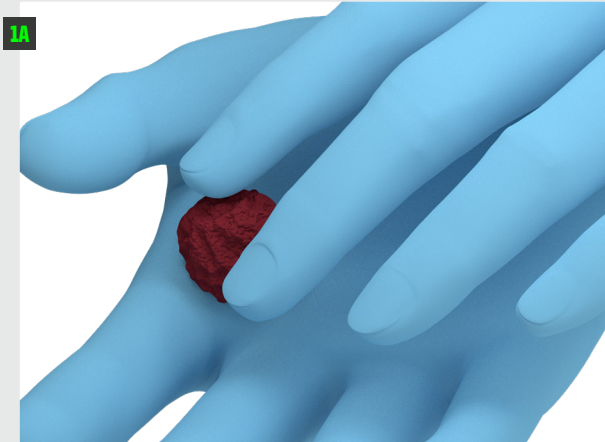


1 Once the final implant has been selected and verified, the central aperture must be packed with autograft and/or allograft composed of cancellous and/or cortico-cancellous bone graft. Prior to assembly and insertion with the Modular Inserter Handle, the preferred technique should be chosen from either the Freehand or Drill-Screw Guide options.

NOTE: THE IMPLANT'S HEIGHT, WIDTH, DEPTH, AND LORDOSIS ARE MARKED ON THE CARTON LABEL.

NOTE: THE VOLUMES OF THE GRAFT APERTURES SHOWN ARE DEPICTED IN CC'S AND CONSISTENT ACROSS ALL LORDOTIC SIZES.

IMPLANT FOOTPRINTS (MM)				
		14 X 12	16 X 14	18 X 16
HEIGHTS	5 mm	0.11	0.14	0.28
	6 mm	0.13	0.17	0.36
	7 mm	0.16	0.21	0.43
	8 mm	0.18	0.24	0.50
	9 mm	0.21	0.28	0.57
	10 mm	0.24	0.31	0.65



- 1** Select the appropriate Cervical Standalone Inserter Tip for attachment to the distal end of the Modular Inserter Handle.

NOTE: THE SMALL TIPS (CHROME) ARE USED FOR ALL IMPLANTS WITH A HEIGHT OF 5-7 MM AND THE MEDIUM TIPS (BLACK) ARE UTILIZED FOR ALL IMPLANTS WITH A HEIGHT OF 8-10 MM. THE SUB-FLUSH OPTION ALLOWS FOR THE CAGE TO BE RECESSED 1.5 MM DEEPER INTO THE DISC SPACE.

- 2** Attach the selected Inserter Tip to the Modular Inserter Handle by sliding the Inserter Tip over the long threaded post on the distal end of the Modular Inserter Handle until it is locked in place. The male divots on the outside of the Inserter Tip should engage into the female divots of the Modular Inserter Handle providing a tactile click when engaged properly.

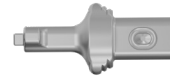
- 3** Once the appropriate Inserter Tip is attached to the distal end of the Modular Inserter Handle, thread the assembled Inserter into the hole located on the anterior surface of the implant. Tighten securely by rotating the silver knob on the proximal end of the Handle clockwise. Make sure that the divots on the face of the implant are aligned with the corresponding prongs on the distal tip of the Inserter before final tightening.

- 4** Gently impact the implant to the desired depth.

- 5** Once the implant is fully inserted into the disc space, the Modular Inserter Handle may be removed or left in place for the remainder of the procedure. Leaving the Modular Inserter Handle attached will allow for the inserter stop to prevent posterior migration of the cage while utilizing the Awl technique.

NOTE: THE CERVICAL STANDALONE TAMP IS AVAILABLE TO FURTHER RECESS THE IMPLANT IF THE MODULAR INSERTER HANDLE IS REMOVED.

1



SMALL INSERTER TIP, FLUSH
PART #: 135-125



SMALL INSERTER TIP, SUB-FLUSH
PART #: 135-135

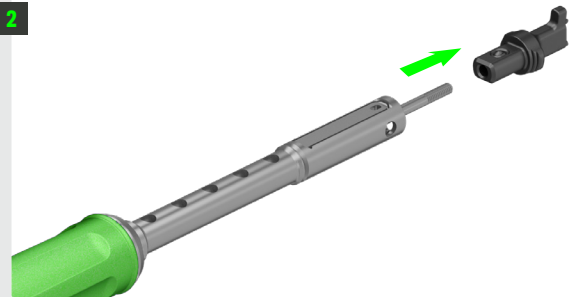


MEDIUM INSERTER TIP, FLUSH
PART #: 135-126

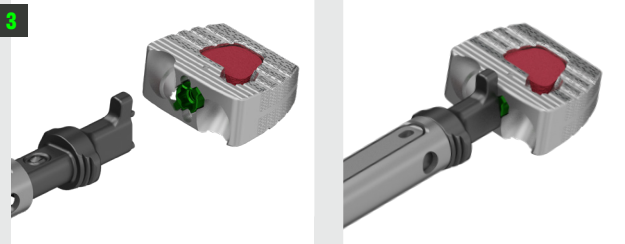


MEDIUM INSERTER TIP, SUB-FLUSH
PART #: 135-136

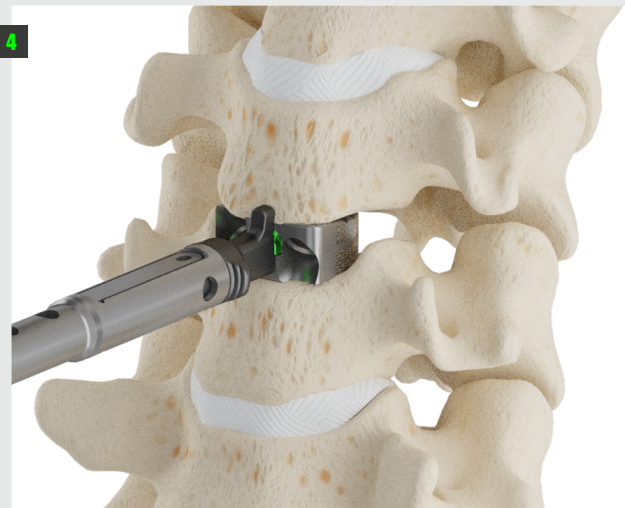
2



3



4



- 1** Select the preferred Awl to penetrate the cortical bone and create a path for screw insertion. The Straight Cervical Standalone Awl or Angled Awl, Beveled Tip, are the two options designed to be utilized with the freehand technique.

NOTE: THE AWLS IN THE SYSTEM HAVE AN AWL TIP LENGTH OF 12 MM. THIS LENGTH IS BASED ON ITS ANTERIOR TO POSTERIOR LENGTH IN BONE WHEN FULLY SEATED INTO THE SCREW POCKET OF THE INTERBODY SPACER.

NOTE: THE ANGLED AWL, BEVELED TIP AND STRAIGHT CERVICAL STANDALONE AWL CANNOT BE USED THROUGH THE DS GUIDES. THEY ARE DESIGNED TO BE USED FOR THE FREEHAND TECHNIQUE ONLY.

- 2** Fully seat the Awl into the screw pocket of the interbody spacer. Confirm that any toggle is minimized and that the trajectory of the Awl is consistent with the 40° cranial/caudal and 12° medial fixed screw angulation.

NOTE: IN SOME INSTANCES, THE REMOVAL OF ANTERIOR OSTEOPHYTES MAY BE NECESSARY TO ALLOW FOR PROPER SEATING OF THE AWL.

NOTE: THE SHAFT OF THE ANGLED AWL, SHOULD EXTEND STRAIGHT OUT OF INTERBODY SPACER WHEN PROPERLY ENGAGED. IF THE INSERTER HAS BEEN LEFT IN SITU, IT MAY BE USED AS A REFERENCE TO ASSES THE ALIGNMENT OF THE ANGLED AWL.

NOTE: AN INDICATOR IS ALSO AVAILABLE AT THE TIP OF THE ANGLED AWL TO ASSESS CORRECT ALIGNMENT. THE INDICATOR STRIPE SHOULD BE ORIENTED AT THE 12 O'CLOCK POSITION WHEN POSITIONED CORRECTLY.

1



ANGLED AWL, BEVELED TIP
PART #: 135-3210-120

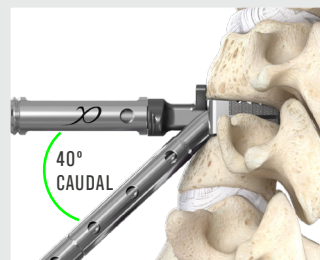
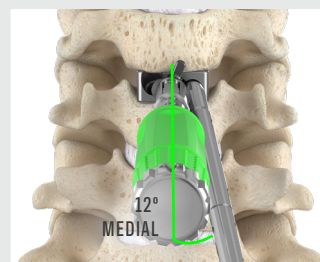
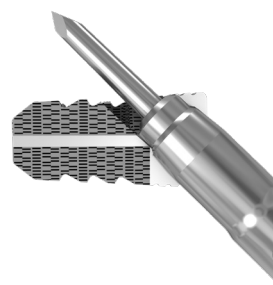


CERVICAL STANDALONE AWL
PART #: 135-3000-120

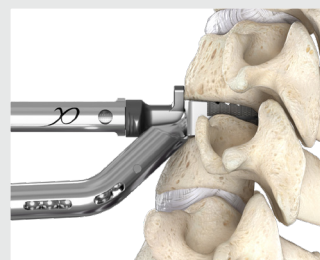
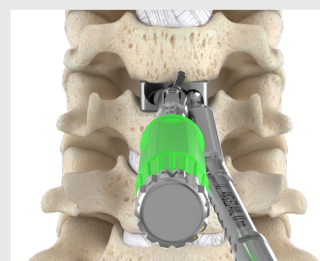
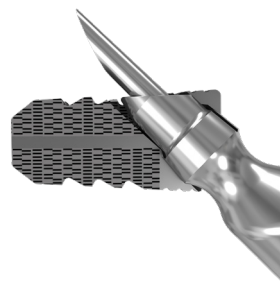


COUNTERTORQUE HANDLE
PART #: 135-7000

2A STRAIGHT AWL

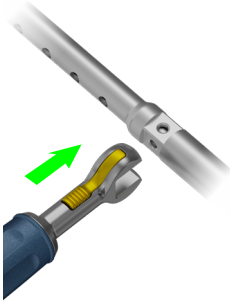


2B ANGLED AWL



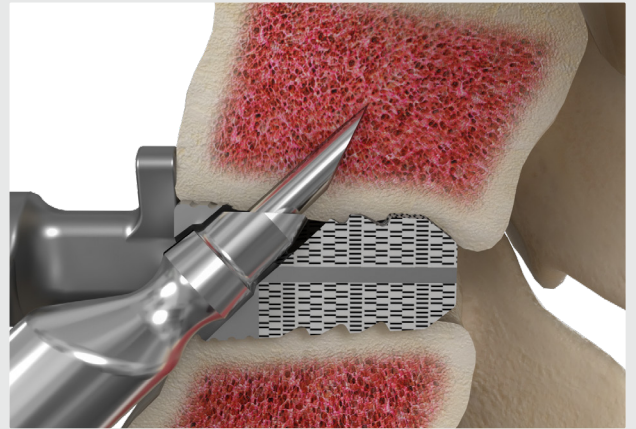
- 3** Select the preferred Awl to penetrate the cortical bone and create a path for screw insertion. The Straight Cervical Standalone Awl or Angled Awl, Beveled Tip, are the two options designed to be utilized with the freehand technique.

NOTE: THE COUNTERTORQUE HANDLE CAN BE USED WITH THE ANGLED BEVELED AWL TO AID WITH INSERTION.

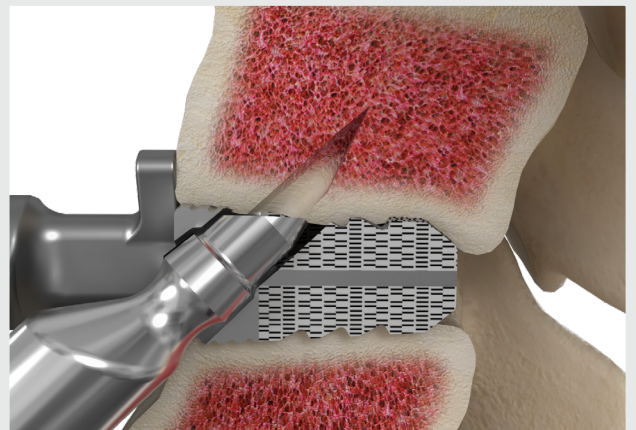


- 4** To remove the Angled Awl from the bone, turn the gold knob clockwise to remove the Awl tip from the bone. A red indicator stripe will be visible once the Awl tip has been fully removed from the bone.

3



4



- 1 If the surgeon prefers to prepare the screw pathway by drilling in the Freehand Technique, the Cervical SA Freehand Guide must be utilized with one of the drills available in the system.

- 2 Fully seat the Cervical SA Freehand Drill Guide into the screw pocket of the interbody spacer. The handle of the Drill Guide should extend laterally out of the exposure.

NOTE: THE MODULAR INSERTER HANDLE MAY BE REMOVED OR LEFT IN SITU WHILE DRILLING.

- 3 Drill by hand or power to the appropriate depth.

NOTE: THE ANGLED DRILLS SHOULD BE UTILIZED WHEN EXPOSURE IS LIMITED DUE TO SOFT TISSUE OR ANATOMY. THE COUNTERTORQUE HANDLE CAN BE UTILIZED FOR ADDITIONAL CONTROL WITH THE ANGLED DRILLS.

NOTE: THE DRILL LENGTHS ARE MEASURED BY THEIR ANTERIOR-TO-POSTERIOR DEPTH IN BONE AND MATCH LINE-TO-LINE WITH CORRESPONDING SCREW LENGTH.

NOTE: THE STRAIGHT DRILLS ARE AVAILABLE STERILE PACKED.

1



ANGLED DRILL

PART #: 135-4105-1XX



STRAIGHT DRILL

PART #: 135-4000-XXX-S



COUNTERTORQUE HANDLE

PART #: 135-7000



AO QUICK CONNECT AXIAL HANDLE

PART #: 86002-0121-004



CERVICAL SA FREEHAND GUIDE

PART #: 135-5000

2



3



- 1** Once the screw pathway has been prepared with an Awl or Drill, select the preferred Screwdriver for screw insertion.

NOTE: THE STRAIGHT TAPERED DRIVER OR THE SHORT TAPERED ANGLED DRIVER ARE THE DRIVER OPTIONS DESIGNED TO BE USED IN THE FREEHAND TECHNIQUE. CHOOSE THE APPROPRIATE OPTION BASED ON THE ANATOMY.

- 2** Select the preferred screw diameter and length for insertion through the interbody implant. Both 3.5 mm and 4.0 mm Rescue Screws are available in Self-Drilling and Self-Tapping options with a single-lead thread.

NOTE: THE SYSTEM IS DESIGNED FOR THE SCREW LENGTH TO MATCH THE INTERBODY IMPLANT DEPTH. FOR EXAMPLE, A 14 MM SCREW WILL END COLLINEAR WITH THE POSTERIOR EDGE OF AN INTERBODY IMPLANT WITH A 16 MM X 14 MM FOOTPRINT. THE SYSTEM OVERVIEW CAN BE REFERENCED FOR MORE DETAILS.

NOTE: 18 MM SCREWS ARE AVAILABLE THROUGH SPECIAL ORDER.

- 3** Insert both screws until they are fully recessed inside the screw holes of the interbody implant and rigid construct fixation has been achieved. It is important to verify that the screws are fully seated for subsequent deployment of the locking mechanism.

1

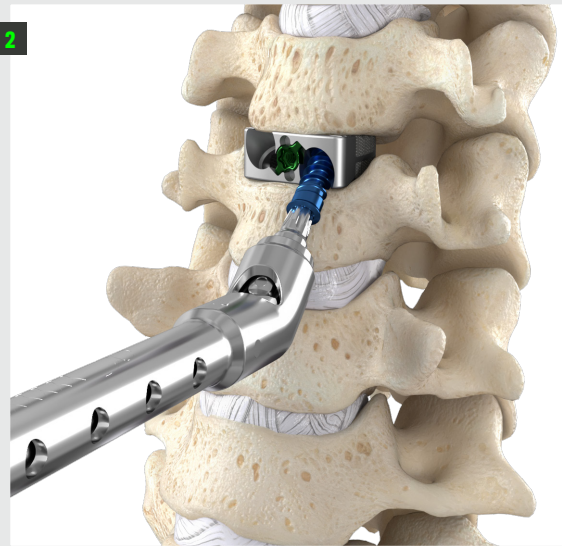


CERVICAL SA ANGLED DRIVER, TAPERED, SHORT
PART #: 135-2415



STRAIGHT SCREWDRIVER
PART #: 135-2000

2



3



- 1 Select the appropriate Drill-Screw (DS) Guide that matches the height and width of the selected implant.

NOTE: DS GUIDES ARE LOCATED IN THE MODULAR TIP CADDY AND ARE GROUPED BY THEIR WIDTH. THE SMALL (CHROME) GUIDES ARE DESIGNED TO BE USED WITH A FOOTPRINT WIDTH OF 14 MM OR 16 MM, AND THE LARGE (BLACK) GUIDES ARE DESIGNED TO BE USED FOR FOOTPRINTS WITH A WIDTH OF 18 MM OR 20 MM.

- 2 Attach the selected DS Guide to the Modular Inserter Handle.
- 3 Once the appropriate DS Guide is attached to the distal end of the Modular Inserter Handle, thread the assembled Inserter into the hole located on the anterior surface of the implant.
- 4 Insert the implant into the disc space leaving the Modular Inserter Handle attached.

NOTE: IF SPACE IS A LIMITING CONSTRAINT WHEN USING THE DS GUIDE, USE OF THE ANGLED INSTRUMENTATION IS RECOMMENDED.

1

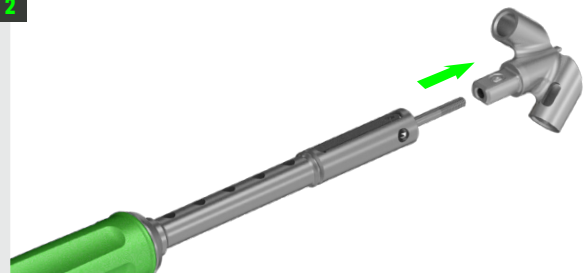


SMALL DRILL-SCREW GUIDE
PART #: 135-6000-XX

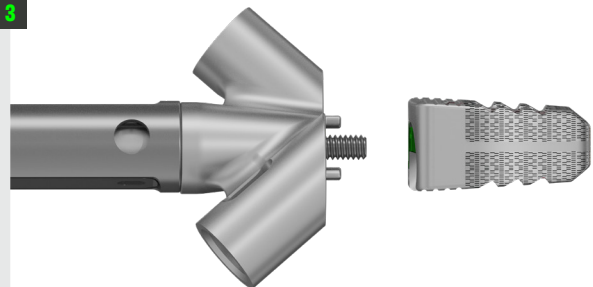


LARGE DRILL-SCREW GUIDE
PART #: 135-6100-XX

2



3



4



1 Select the preferred Awl to penetrate the cortical bone and create a path for screw insertion. The Straight Guided Awl or Angled Guided Awl are the two Awls designed to be used with the DS Guides.

2 Attach the selected Guided Awl to the Quick Connect Axial Handle.

3 Insert the Angled or Straight Guided Awl into the barrel of the DS Guide. There is an indicator on the distal end of the Guided Awl to help facilitate the proper orientation prior to impaction. The indicator should be facing up towards the user's field of view.

4 Impact the Awl into bone by tapping on the back of the Axial Quick Connect Handle. A black stripe should be visible inside the window of the DS Guide once the Guided Awl has been fully seated.

1

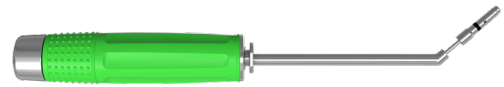


CERVICAL SA GUIDED AWL, 12 MM
PART #: 135-3100-120



CERVICAL SA GUIDED AWL, 12 MM
PART #: 135-3300-120

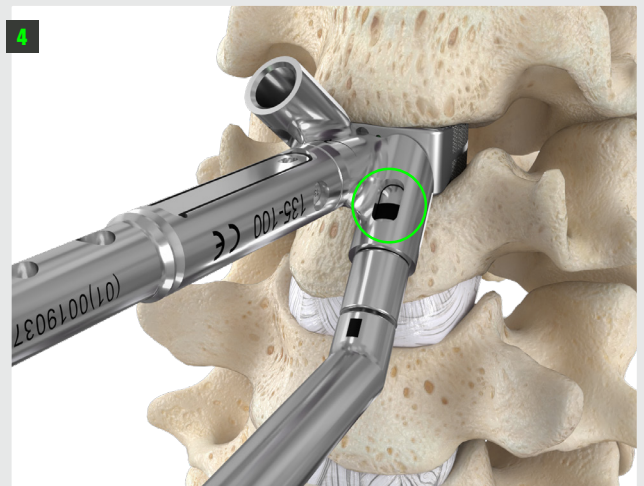
2



3



4



- 1** Select the preferred Drill to penetrate the cortical bone and create a path for screw insertion. The Straight or Angled Drills can be used through the DS Guide.

1



ANGLED DRILL
PART #: 135-4105-1XX



STRAIGHT DRILL
PART #: 135-4000-XXX-S



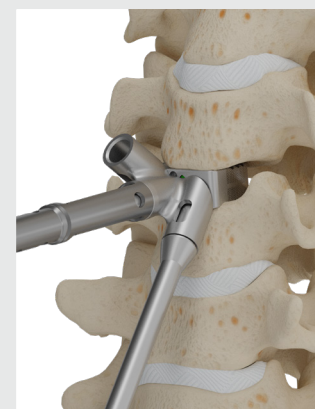
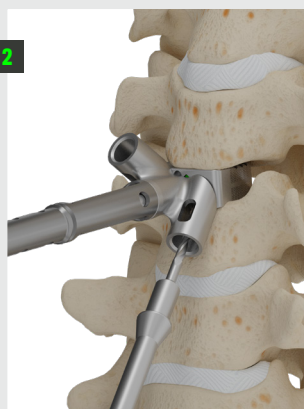
COUNTERTORQUE HANDLE
PART #: 135-7000



AO QUICK CONNECT AXIAL HANDLE
PART #: 86002-0121-004

- 2** Insert the Drill directly into the barrel of the DS Guide and drill by hand or power with the selected Drill until it is fully bottomed out in the DS Guide.

2



- 1** Once the screw pathway has been prepared with an Awl or Drill, select the preferred Screwdriver for screw insertion.

NOTE: THE STRAIGHT TAPERED DRIVER OR STANDARD ANGLED TAPERED DRIVER ARE THE DRIVER OPTIONS DESIGNED TO BE USED FOR THE DS GUIDE TECHNIQUE. THEY CAN BE IDENTIFIED AS COMPATIBLE WITH THE DS GUIDES BY THE LASER-MARKED-BAND LOCATED ON THE DISTAL END OF THE RESPECTIVE STRAIGHT OR ANGLED DRIVER.

- 2** Attach the preferred Driver to the Quick-Connect Axial Handle and fully insert the screw. The indicator band should not be visible outside of the DS Guide Barrell once the screw has been fully seated.

1



ANGLED SCREWDRIVER
PART #: 135-2205



STRAIGHT SCREWDRIVER
PART #: 135-2000

2



- 1** To securely lock the screws in place, use a Straight or Angled T10 Screwdriver to turn the Locking Mechanism on the front of the implant clockwise until it is in a horizontal position.

CAUTION: TURNING THE LOCKING MECHANISM SHOULD NOT REQUIRE MORE FORCE THAN WHAT IS EXERTED BY FINGER TIGHTENING. EXCESSIVE FORCE BEYOND THAT MAY INDICATE THAT THE SCREWS ARE NOT FULLY SEATED. VERIFY THAT THE SCREWS ARE FULLY SEATED AND DRIVE THEM IN FURTHER IF NECESSARY BEFORE ATTEMPTING TO REENGAGE THE LOCKING MECHANISM.

CAUTION: ATTEMPTING TO ROTATE THE LOCKING MECHANISM OVER SCREWS THAT ARE NOT FULLY SEATED WITHIN THE INTERBODY IMPLANT MAY RESULT IN DAMAGE TO THE LOCKING MECHANISM.

NOTE: IF THE LOCKING MECHANISM DOES NOT TURN OVER THE SCREWS ON THE FIRST ATTEMPT, FINAL TIGHTEN THE SCREW THAT WAS INSERTED FIRST, FOLLOWED BY THE SECOND SCREW AND THEN REATTEMPT FINAL LOCKING.



- 1** If implant removal is necessary, turn the locking mechanism to the unlocked position using one of the T10 Screwdrivers.
- 2** Remove the screws by turning the Removal Driver in a counterclockwise direction until the screws are backed out. Once the screws are removed, reattach the Inserter to the implant and gently remove the implant from the disc space.



IdentiTi™ Cervical Standalone Interbody System

INSTRUCTIONS FOR USE

GENERAL INFORMATION:

The IdentiTi Cervical Standalone Interbody System is an integrated intervertebral body fusion device for use in anterior cervical discectomy and fusion (ACDF) Procedures. The IdentiTi Cervical Standalone Interbody System consists of integrated interbody spacers and bone screws in multiple configurations to accommodate individual patient anatomy. The IdentiTi Cervical 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 Cervical 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 two bone screws that are made of titanium alloy (Ti-6Al-4V ELI) per ASTM F136 in varying lengths and diameters. The interbody spacers are provided individually packed and sterile. The bone screws are provided non-sterile to be cleaned and steam-sterilized by the end user.

The IdentiTi Cervical Standalone Interbody System provides reusable instruments to support varying surgical techniques, common with the ACDF approach, and are made of stainless steel and other materials. They are provided non-sterile to be cleaned and sterilized by the end user.

INDICATIONS FOR USE:

The IdentiTi Cervical Standalone Interbody System is a stand-alone anterior cervical interbody fusion system intended for use in skeletally mature patients for the treatment of cervical 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 Standalone Interbody System is intended to be used with autograft, allograft comprised of cortical, cancellous, and/or cortico-cancellous bone graft, demineralized allograft with bone marrow aspirate, or a combination thereof.

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 post-operative 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 spacer implants and single-use drills 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 devices.
 - 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 combine dissimilar materials (e.g., titanium and stainless steel) within the same construct.
4. Bone screw implants are provided non-sterile and must be sterilized prior to surgery. All instruments except for the single-use sterile drills are provided non-sterile and must be cleaned and sterilized prior to surgery. See CLEANING and STERILIZATION sections in this IFU. Sterile drills 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. 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. 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.
7. Over-distraction of the disc space can lead to facet over-distraction and spinous process contact.
8. 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.
9. 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.
10. Attempting to rotate the locking mechanism over screws that are not fully seated within the interbody implant may result in damage to the locking mechanism.
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 impact 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. The IdentiTi Cervical 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 cervical spine.

16. 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.

MRI SAFETY INFORMATION:

The IdentiTi Cervical 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 Cervical 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 pseudoarthrosis.
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 Cervical 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 vision 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-125



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™ Cervical Standalone Interbody System INSTRUCTIONS FOR USE (AUSTRALIA)

GENERAL INFORMATION:

The IdentiTi Cervical Standalone Interbody System is an integrated intervertebral body fusion device for use in anterior cervical discectomy and fusion (ACDF) Procedures. The IdentiTi Cervical Standalone Interbody System consists of integrated interbody spacers and bone screws in multiple configurations to accommodate individual patient anatomy. The IdentiTi Cervical 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 Cervical 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 two bone screws that are made of titanium alloy (Ti-6Al-4V ELI) per ASTM F136 in varying lengths and diameters. The interbody spacers are provided individually packed and sterile. The bone screws are provided non-sterile to be cleaned and steam-sterilized by the end user. The IdentiTi Cervical Standalone Interbody System provides reusable instruments to support varying surgical techniques, common with the ACDF approach, and are made of stainless steel and other materials. They are provided non-sterile to be cleaned and sterilized by the end user.

INDICATIONS FOR USE:

The IdentiTi Cervical Standalone Interbody System is a stand-alone anterior cervical interbody fusion system intended for use in skeletally mature patients for the treatment of cervical 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 Standalone Interbody System is intended to be used with autograft, allograft comprised of cortical, cancellous, and/or cortico-cancellous bone graft, demineralized allograft with bone marrow aspirate, or a combination thereof.

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.
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Excerpt from INS-125-01



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