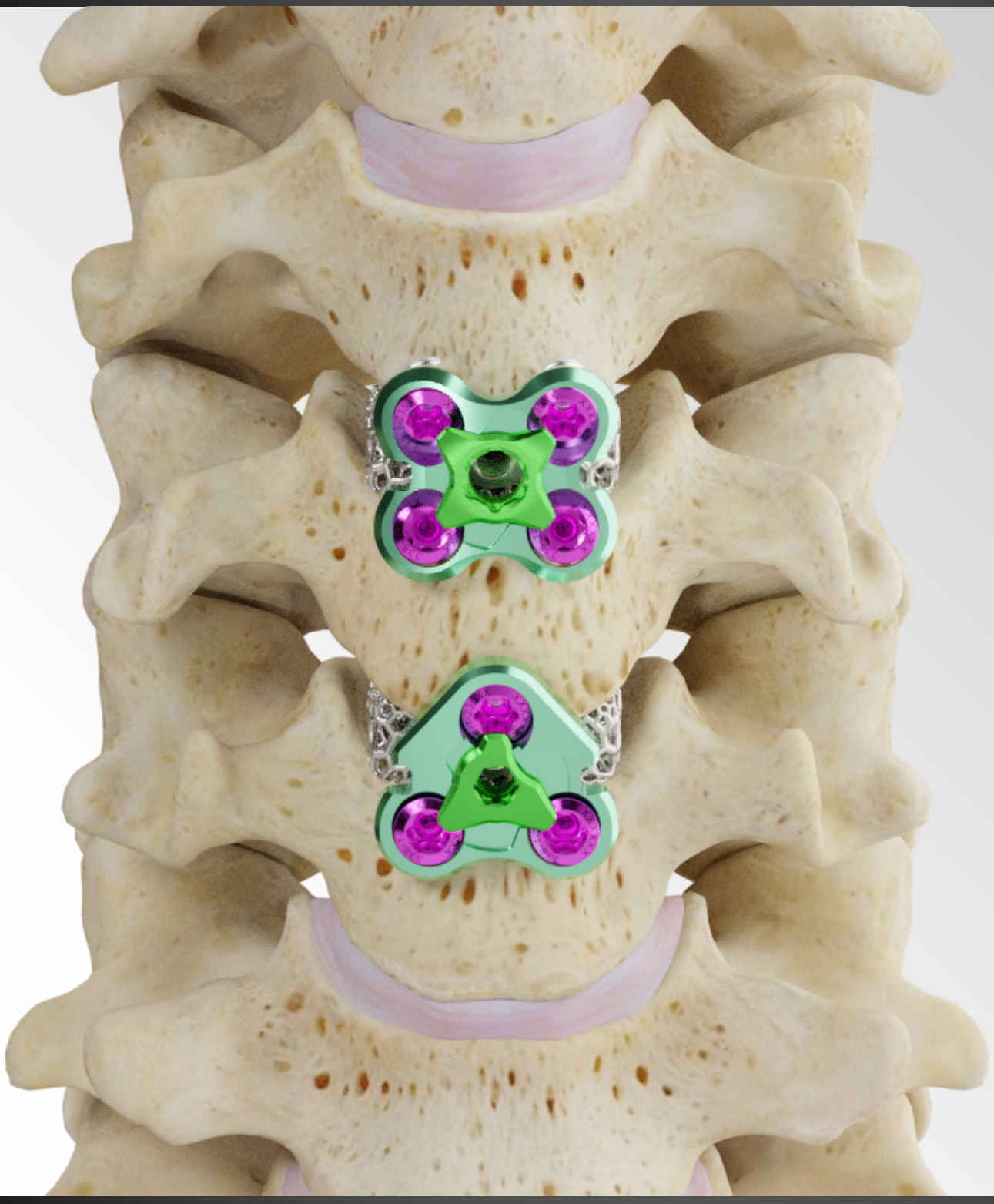
SPS™

SEGMENTAL PLATING SYSTEM

atec™ INFORMED BY EOS



SPS™
SEGMENTAL PLATING SYSTEM

CONTENTS

PATIENT POSITIONING

1 Place the patient in a supine position with the neck in slight extension. The surgeon chooses either a right-or left-sided approach to the cervical vertebral column. After the approach has been decided, the head may be rotated to allow for adequate exposure of the cervical spine.

EXPOSURE

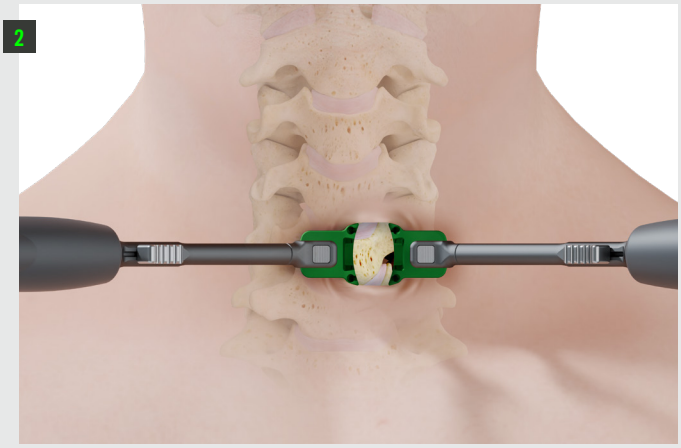
2 The initial incision should be made to create an avascular dissection plane between the trachea and esophagus. Retractors can be utilized to provide initial exposure of the anterior side of the vertebral column and the adjacent muscles.

> **TIP:** THE PLATE TEMPLATE CAN BE UTILIZED TO HELP DETERMINE APPROPRIATE SPACING OF THE CASPAR PINS.

DISCECTOMY

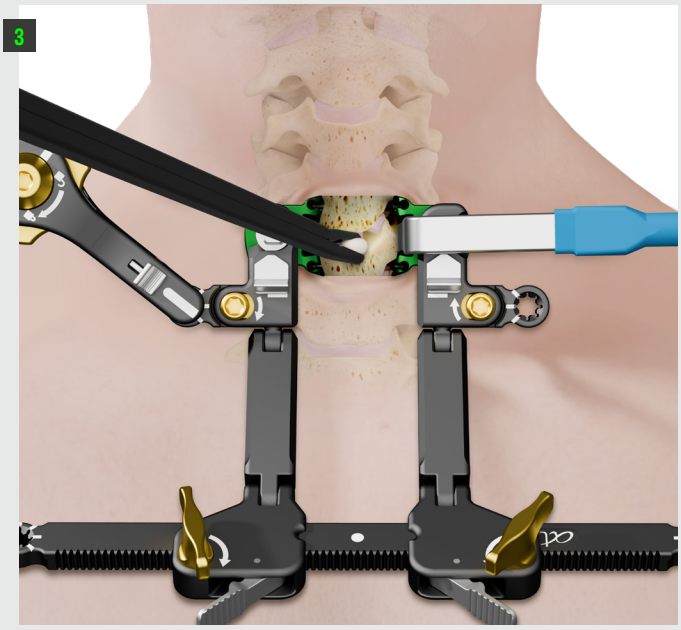
3 Using commercially available pituitary rongeurs, curettes, and Kerrison rongeurs, perform the discectomy at the indicated level(s). Remove disc material and cartilage to expose the posterior longitudinal ligament. Confirm the anterior surface of the disc space has been appropriately prepared by removing any large osteophytes.

2



SPS PLATE TEMPLATE, 3-HOLE
PART #: 439-0017

3

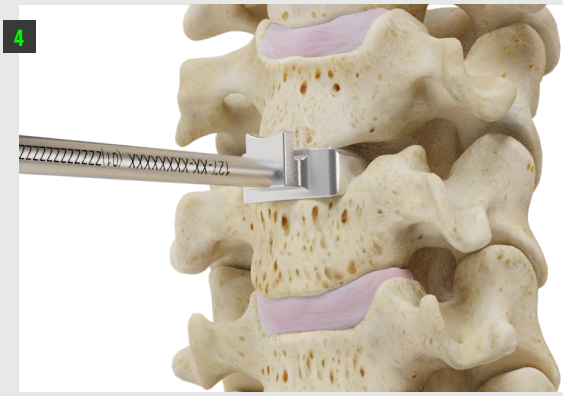


INTERBODY TRIALING

4 In the newly prepared disc space, insert a Cervical Trial to confirm the correct disc height and interbody spacer footprint. The Trial should properly restore the disc space height and lordosis, creating a snug fit by way of gentle impaction. Use A/P and/or lateral fluoroscopy to confirm position.

NOTE: THE TRIALS ARE DESIGNED TO MATCH THE CORRESPONDING IMPLANTS LINE TO LINE. THE HEIGHT AND FOOTPRINT IS LABELED ON THE FACE OF THE TRIAL, WHILE THE LORDOSIS IS LOCATED ON THE LATERAL SIDE. THE COLORED BANDS INDICATE THE TRIAL'S FOOTPRINT WHILE THE UNDERLINED NUMBER ON THE IMPACTION SURFACE REFERENCES THE HEIGHT.

4



TRIAL COLOR-CODING KEY

IMPLANT SELECTION

5 Select the preferred SPS Two-, Three-, or Four-Hole Anterior Cervical Plate (ACP). If utilizing an ATEC titanium or PEEK spacer, the sizing charts below may be referenced for recommended minimum plate sizing. Recommended plate sizing is based off the anterior height of the interbody spacer. The plate may be oversized if desired. To accommodate use with small plates, IdentiTi II and SPS Interbody Spacers feature scallops on their inferior and superior proximal edges.

IDENTITI II OR IDENTITI/TRANSCEND SPS INTERBODY SPACER	
SPS Plate Size	**Anterior Height**
14	5 mm, 6 mm & 7mm
15	8 mm
16	9 mm
17	10 mm

IDENTITI/TRANSCEND INTERBODY SPACER	
SPS Plate Size	**Anterior Height**
14	5 mm
15	6 mm
16	7 mm
17	8 mm
18*	9 mm
19*	10 mm

**Longer plate lengths available upon request.*

NOTE: THE SPS 3-HOLE PLATE IS 0.5 MM LONGER THAN CORRESPONDING 4-HOLE AND 2-HOLE PLATES.

NOTE: THERE IS A STANDARD 1.5 MM OFFSET BETWEEN THE PLATE AND THE INTERBODY SPACER WHEN UTILIZING AN ATEC CERVICAL INTERBODY IMPLANT.

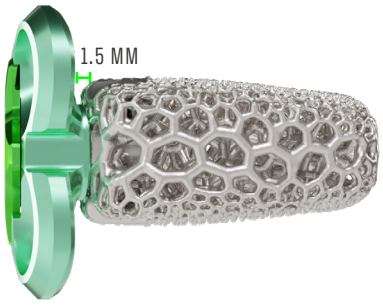
NOTE: THE SPS LOADING BLOCK CAN ALSO BE UTILIZED FOR PACKING GRAFT INTO THE INTERBODY SPACER'S APERTURE PRIOR TO INSERTION.

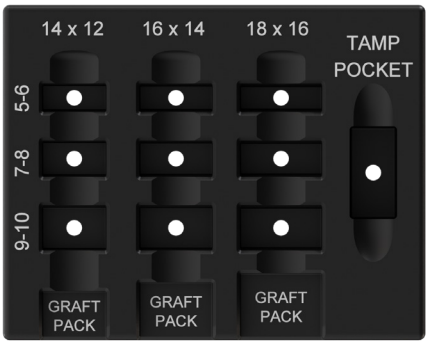
5

SPS 2-HOLE ACP
PART #: 338-02XX

SPS 3-HOLE ACP
PART #: 338-03XX

SPS 4-HOLE ACP
PART #: 338-04XX





SPS LOADING BLOCK
PART #: 439-0009

SPACER/PLATE ASSEMBLY

6 Once the final plate and interbody spacer have been selected, use the Loading Block to stabilize the interbody spacer. Place the plate over the anterior face of the interbody spacer and confirm the alignment posts are engaged into the holes of the interbody spacer. Thread the SPS Inserter through the front of the plate and into the interbody spacer to maintain alignment during insertion.

> **NOTE:** WHEN UTILIZING A 3-HOLE PLATE WITH THE SPS INTERBODY SPACER, IT IS IMPORTANT TO CONFIRM PROPER ALIGNMENT OF THE PLATE TO THE INTERBODY SPACER. CONFIRM THE MIDDLE SCALLOP IS ON THE SUPERIOR SIDE OF THE IMPLANT.

IMPLANT INSERTION

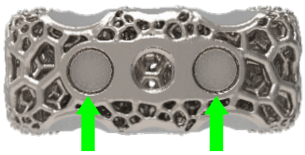
7 Fully tighten the implant construct to the Inserter by turning the knob on the proximal end of the Inserter clockwise, then insert the implant into the disc space.

> **TIP:** IF THE INTERBODY SPACER IS IMPLANTED SEPARATELY OR IF USED WITHOUT AN INTERBODY SPACER, THE PLATE FORCEPS CAN BE USED TO INSERT AND POSITION THE PLATE INDEPENDENTLY. CONFIRM THAT THE PLATE IS SITTING FLUSH WITH VERTEBRAL BODIES AND THAT THE PLATE'S ALIGNMENT POSTS ARE FULLY CONTAINED WITHIN THE DISC SPACE, PRIOR TO SCREW INSERTION.

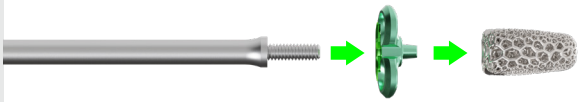
CASPAR PIN REMOVAL (OPTIONAL)

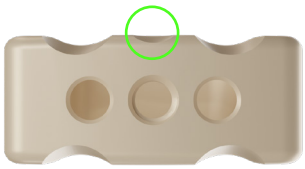
8 After confirming the implants are properly positioned remove the Caspar pins for screw preparation and seating.

6



INTERBODY SPACER HOLES
FOR SPS PLATE ALIGNMENT





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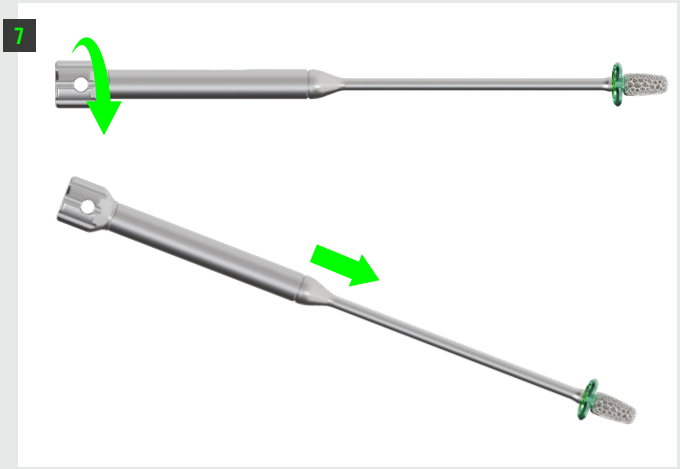

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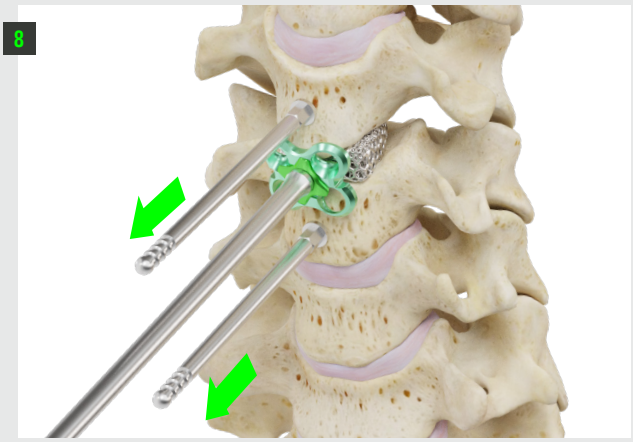


INSERTER REMOVAL (OPTIONAL)

9 The SPS Inserter may be left attached or removed prior to screw preparation and insertion.

SCREW PREPARATION

10 Once the implant has been fully seated within the operative disc space, the SPS Drill or Awl may be used to create a pilot hole for subsequent screw insertion.

SPS SCREW PREPARATION OPTIONS		
Instrument		Hole Depth
SPS Drill	SPS Fixed Angle Drill Guide	12 mm*
	SPS Variable Angle Drill Guide	
	SPS Fixed Angle Drill Guide, Double Barrel**	
	SPS Variable Angle Drill Guide, Double Barrel**	
SPS Straight Awl	Variable Angle	12 mm

**Drill bits must be ordered separately. Longer drill lengths available upon request.*
*** Double Barrel Drill Guides available upon request.*

COUNTERSINKING (OPTIONAL)

11 If recessing the interbody spacer deeper into the disc space, it is recommended to leave the Inserter attached until at least one screw has been implanted. Then remove the Inserter to utilize the SPS Countersinking Tamp or SPS Universal Tamp.

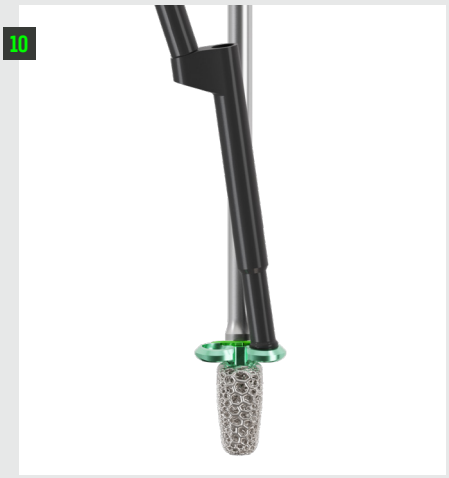
NOTE: IF USING THE SPS COUNTERSINKING TAMP, INSERT THE TAMP THROUGH THE MIDDLE CANNULA OF THE SPS PLATE AND LIGHTLY IMPACT TO RECESS THE SPACER. THE SPS COUNTERSINKING TAMP CANNOT BE USED WITH THE 3-HOLE PLATE.

NOTE: IF USING THE SPS UNIVERSAL TAMP, INSERT THE TAMP THROUGH THE LATERAL EDGES OF THE SPS PLATE AND LIGHTLY IMPACT TO RECESS THE SPACER. THE SPS UNIVERSAL TAMP CAN BE USED WITH ALL PLATE CONFIGURATIONS.

NOTE: THE SPS TAMPS ARE AVAILABLE IN 1 MM AND 2 MM OPTIONS. THE MEASUREMENT IS DEPICTED BY THE NUMBER OF STRIPES ON THE PROXIMAL PORTION OF THE HANDLE.

9

10



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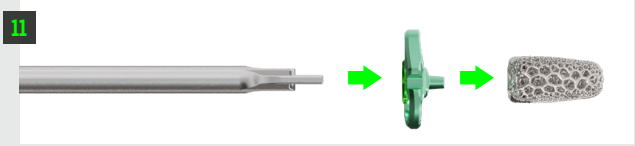


SCREW FIXATION

12 After creating pilot holes via the SPS Straight Awl or SPS Drill, insert the desired fixed or variable screws using the Universal or Locking Screwdriver. More information about screw types and ranges of angulation are provided in the table below.

NOTE: SCREWS ARE AVAILABLE IN BOTH SELF-DRILLING AND SELF-TAPPING OPTIONS.

SCREW ANGULATION	
Variable Angle Screws	14 - 30° C/C
	-2 - 14° M/L
Fixed Angle Screws	22° C/C
	6° M/L

TIP: WHEN USING A 3-HOLE PLATE, THE SPS INSERTER MUST BE REMOVED TO SEAT THE MIDLINE SCREW.

SPS LOCKING DRIVER (OPTIONAL)

13 To lock the SPS Locking Screwdriver to the screw, engage the Screwdriver Threaded Rod with the threaded screw cannula and turn the proximal knob clockwise until completely fastened. To unlock the screw, rotate the knob counter-clockwise.

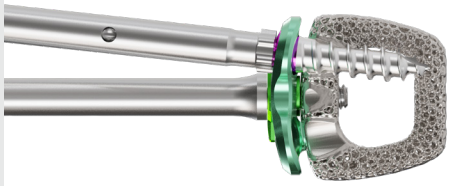
CAUTION: TO PREVENT PREMATURE FAILURE OR BREAKAGE, THE LOCKING DRIVER MUST BE USED WITH THE DRAW ROD. CONFIRM THAT THE DRAW ROD IS FULLY TIGHTENED TO THE LOCKING DRIVER PRIOR TO USE.

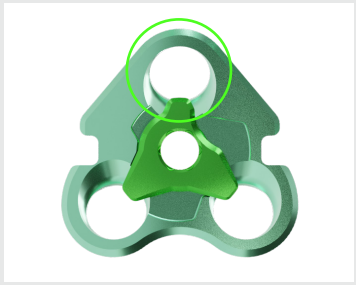
FINAL TIGHTENING

14 Fully seat the screws into the plate. Utilize the Universal or Locking Screwdriver to turn the locking mechanism. The surgeon will perceive tactile feedback confirming the blocker is fully locked.

CAUTION: TO PREVENT POSSIBLE SCREW BACK OUT, VISUALLY CONFIRM THAT THE LOCKING MECHANISM IS FULLY SEATED OVER THE SCREW HEAD.

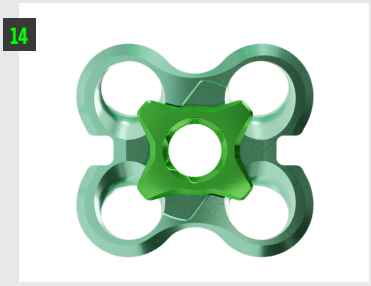
12





13

14



MULTI-LEVEL CONSTRUCT

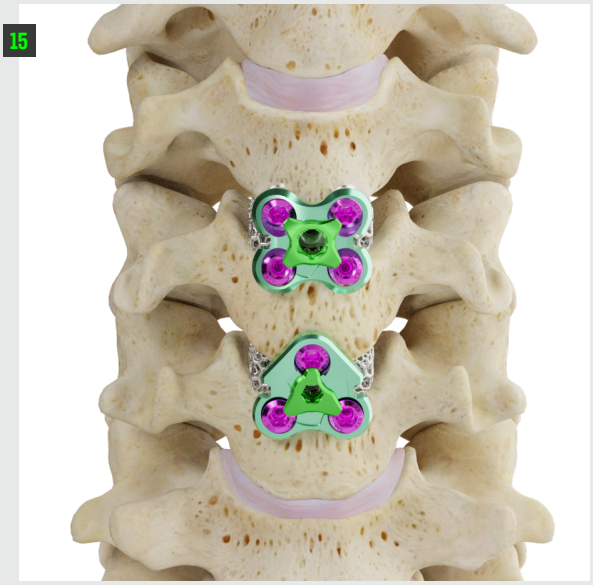
15 If more than one level is being fused, repeat the above steps at each level.

> **NOTE:** WHEN MOVING TO THE NEXT LEVEL, THE PLATE TEMPLATE CAN BE UTILIZED TO SPACE THE NEXT CASPAR PINS FAR ENOUGH APART TO ACCOMMODATE THE PLATE.

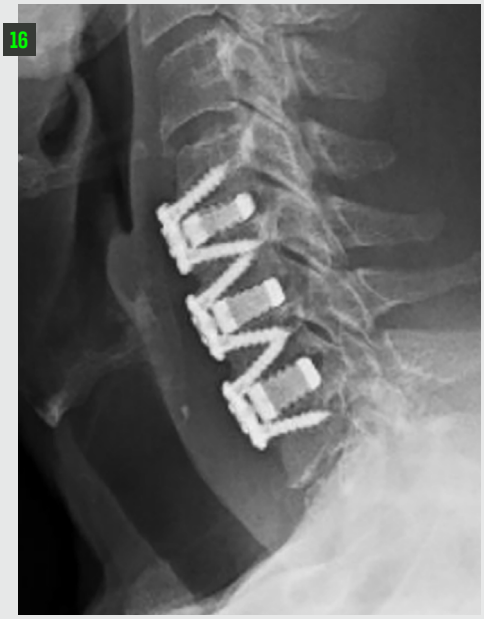
VERIFICATION

16 Utilize fluoroscopy to verify that both the A/P and lateral positioning of the implant is satisfactory.

15



16



IMPLANT REMOVAL

18 To remove the SPS implant assembly, insert the Universal Driver into the locking mechanism. Then turn counterclockwise to unlock the plate. Using the same Driver, remove the screws from the vertebral body. Engage the Inserter through the plate and interbody spacer and turn the proximal knob clockwise until the Inserter is fastened to the interbody spacer.

When the implant is fully engaged with the Inserter, carefully sway the assembly medial/laterally and remove the plate/interbody spacer assembly.

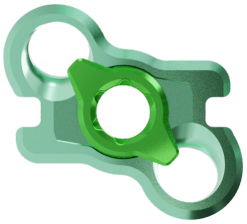
TIP: TO ACHIEVE SECURE ATTACHMENT OF THE SCREWS FOR REMOVAL, USE THE LOCKING DRIVER.

CAUTION: TO PREVENT PREMATURE FAILURE OR BREAKAGE, THE LOCKING DRIVER MUST BE USED WITH THE DRAW ROD. CONFIRM THAT THE DRAW ROD IS FULLY TIGHTENED TO THE LOCKING DRIVER PRIOR TO USE.

18

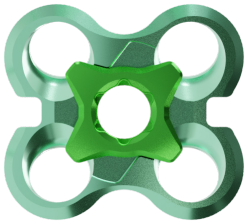
PLATE OPTIONS

SPS 2-Hole ACP
Part #: 338-02XX



SPS 3-Hole ACP
Part #: 338-03XX

SPS 4-Hole ACP
Part #: 338-04XX



INSTRUMENTATION

Cervical SA Angled Driver, Tapered, Short
Part #: 135-2415

SPS Inserter
Part #: 439-0001

SPS Locking Screwdriver
Part #: 439-0002

SPS Universal Screwdriver
Part #: 439-0003

SPS Straight Awl, 12 mm
Part #: 439-0004

SPS Plate Holder
Part #: 439-0008

2-Hole Plate Template
Part #: 439-0017

3-Hole Plate Template
Part #: 439-0018

4-Hole Plate Template
Part #: 439-0019

SPS Universal Tamp, 1 mm
Part #: 439-0031

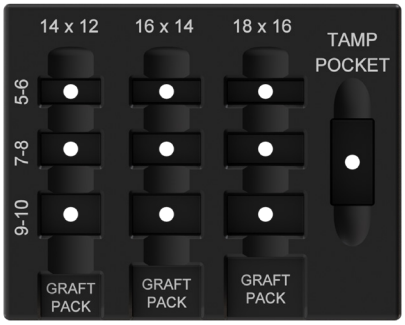
SPS Universal Tamp, 2 mm
Part #: 439-0032

SPS Drill, 12 mm*
Part #: 439-2012-S

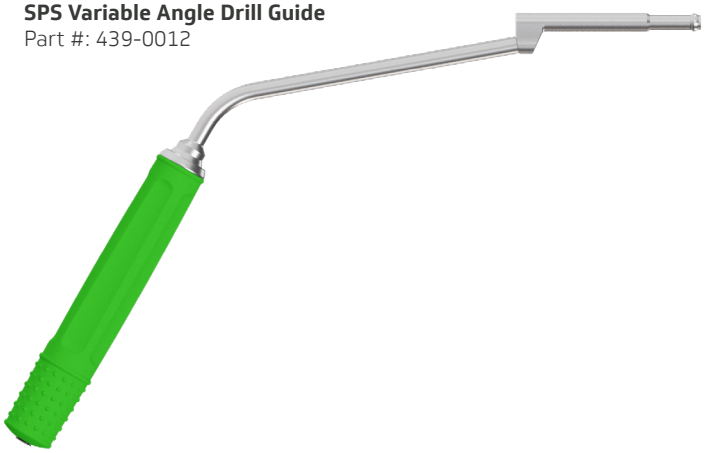
**Drill bit must be ordered separately.*

SPS Fixed Angle Drill Guide
Part #: 439-0011

SPS Loading Block
Part #: 439-0009



SPS Variable Angle Drill Guide
Part #: 439-0012



AO Quick Connect Handle
Part #: 86002-0121-004

TRIALS, RASPS AND TAMPS

Cervical Trial, 14 x 12 mm, 7°
Part #: 127-10-XX141207

Cervical Trial, 16 x 14 mm, 7°
Part #: 127-10-XX161407

Cervical Trial, 16 x 14 mm, 10°
Part #: 127-10-XX161410

Cervical Trial, 18 x 16 mm, 7°
Part #: 127-10-XX181607

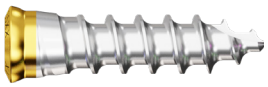
Cervical Trial, 18 x 16 mm, 10°
Part #: 127-10-XX181610

Cervical Rasp, Single Sided
Part #: 127-200

Cervical Tamp
Part #: 127-300

SCREW OPTIONS

Fixed Angle
3.5 Self-Drilling
Part #: 338-1-435XX



Fixed Angle
3.5 Self-Tapping
Part #: 338-1-335XX

Fixed Angle
4.0 Self-Tapping
Part #: 338-1-340XX

Variable Angle
3.5 Self-Drilling
Part #: 338-1-235XX

Variable Angle
3.5 Self-Tapping
Part #: 338-1-135XX

Variable Angle
4.0 Self-Tapping
Part #: 338-1-140XX

SPS™
SEGMENTAL PLATING SYSTEM

SET ID: CSPSCS

- SKIF-338-10

PLATES AND CORE INSTRUMENTS	
Part Number	Description
338-0214	SPS 2-Hole ACP, 14
338-0215	SPS 2-Hole ACP, 15
338-0216	SPS 2-Hole ACP, 16
338-0217	SPS 2-Hole ACP, 17
338-0314	SPS 3-Hole ACP, 14
338-0315	SPS 3-Hole ACP, 15
338-0316	SPS 3-Hole ACP, 16
338-0317	SPS 3-Hole ACP, 17
338-0414	SPS 4-Hole ACP, 14
338-0415	SPS 4-Hole ACP, 15
338-0416	SPS 4-Hole ACP, 16
338-0417	SPS 4-Hole ACP, 17
439-0001	SPS Inserter
439-0002	SPS Locking Screwdriver
439-0003	SPS Universal Screwdriver
439-0004	SPS Straight Awl, 12 mm
439-0008	SPS Plate Holder
439-0009	SPS Loading Block
439-0011	SPS Fixed Angle Drill Guide
439-0012	SPS Variable Angle Drill Guide
439-0017	SPS 3-Hole Plate Template
439-0018	SPS 4-Hole Plate Template
439-0019	SPS 2-Hole Plate Template
439-0031	SPS Universal Tamp, 1 mm
439-0032	SPS Universal Tamp, 2 mm
127-200	Cervical Rasp, Single Sided
127-300	Cervical Tamp
135-2415	Cervical SA Angled Screw Driver, Tapered, Short
86002-0121-004	AO Quick Connect Axial Handle, Fixed with Jeweler's knob

SCREWS	
Part Number	Description
338-1-13512	SPS VA Self-Tap Screw, 3.5 x 12 mm
338-1-13514	SPS VA Self-Tap Screw, 3.5 x 14 mm
338-1-13516	SPS VA Self-Tap Screw, 3.5 x 16 mm
338-1-13518	SPS VA Self-Tap Screw, 3.5 x 18 mm
338-1-13520	SPS VA Self-Tap Screw, 3.5 x 20 mm
338-1-23512	SPS VA Self-Drill Screw, 3.5 x 12 mm
338-1-23514	SPS VA Self-Drill Screw, 3.5 x 14 mm
338-1-23516	SPS VA Self-Drill Screw, 3.5 x 16 mm
338-1-23518	SPS VA Self-Drill Screw, 3.5 x 18 mm
338-1-23520	SPS VA Self-Drill Screw, 3.5 x 20 mm
338-1-33512	SPS FA Self-Tap Screw, 3.5 x 12 mm
338-1-33514	SPS FA Self-Tap Screw, 3.5 x 14 mm
338-1-33516	SPS FA Self-Tap Screw, 3.5 x 16 mm
338-1-33518	SPS FA Self-Tap Screw, 3.5 x 18 mm
338-1-33520	SPS FA Self-Tap Screw, 3.5 x 20 mm
338-1-43512	SPS FA Self-Drill Screw, 3.5 x 12 mm
338-1-43514	SPS FA Self-Drill Screw, 3.5 x 14 mm
338-1-43516	SPS FA Self-Drill Screw, 3.5 x 16 mm
338-1-43518	SPS FA Self-Drill Screw, 3.5 x 18 mm
338-1-43520	SPS FA Self-Drill Screw, 3.5 x 20 mm
338-1-14012	SPS VA Self-Tap Screw, 4.0 x 12 mm
338-1-14014	SPS VA Self-Tap Screw, 4.0 x 14 mm
338-1-14016	SPS VA Self-Tap Screw, 4.0 x 16 mm
338-1-14018	SPS VA Self-Tap Screw, 4.0 x 18 mm
338-1-14020	SPS VA Self-Tap Screw, 4.0 x 20 mm
338-1-34012	SPS FA Self-Tap Screw, 4.0 x 12 mm
338-1-34014	SPS FA Self-Tap Screw, 4.0 x 14 mm
338-1-34016	SPS FA Self-Tap Screw, 4.0 x 16 mm
338-1-34018	SPS FA Self-Tap Screw, 4.0 x 18 mm
338-1-34020	SPS FA Self-Tap Screw, 4.0 x 20 mm

SET ID: CSPSCS

- SKIF-338-10

CERVICAL TRIALS	
Part Number	Description
127-10-05141207	Cervical Trial, 5 x 14 x 12 mm, 7°
127-10-06141207	Cervical Trial, 6 x 14 x 12 mm, 7°
127-10-07141207	Cervical Trial, 7 x 14 x 12 mm, 7°
127-10-08141207	Cervical Trial, 8 x 14 x 12 mm, 7°
127-10-09141207	Cervical Trial, 9 x 14 x 12 mm, 7°
127-10-10141207	Cervical Trial, 10 x 14x 12 mm, 7°
127-10-05161407	Cervical Trial, 5 x 16 x 14 mm, 7°
127-10-06161407	Cervical Trial, 6 x 16 x 14 mm, 7°
127-10-07161407	Cervical Trial, 7 x 16 x 14 mm, 7°
127-10-08161407	Cervical Trial, 8 x 16 x 14 mm, 7°
127-10-09161407	Cervical Trial, 9 x 16 x 14 mm, 7°
127-10-10161407	Cervical Trial, 10 x16 x 14 mm, 7°
127-10-06161410	Cervical Trial, 6 x 16 x 14 mm, 10°
127-10-07161410	Cervical Trial, 7 x 16 x 14 mm, 10°
127-10-08161410	Cervical Trial, 8 x 16 x 14 mm, 10°
127-10-09161410	Cervical Trial, 9 x 16 x 14 mm, 10°
127-10-10161410	Cervical Trial, 10 x 16 x 14 mm, 10°
127-10-05181607	Cervical Trial, 5 x 18 x 16 mm, 7°
127-10-06181607	Cervical Trial, 6 x 18 x 16 mm, 7°
127-10-07181607	Cervical Trial, 7 x 18 x 16 mm, 7°
127-10-08181607	Cervical Trial, 8 x 18 x 16 mm, 7°
127-10-09181607	Cervical Trial, 9 x 18 x 16 mm, 7°
127-10-10181607	Cervical Trial, 10 x18 x 16 mm, 7°
127-10-06181610	Cervical Trial, 6 x 18 x 16 mm, 10°
127-10-07181610	Cervical Trial, 7 x 18 x 16 mm, 10°
127-10-08181610	Cervical Trial, 8 x 18 x 16 mm, 10°
127-10-09181610	Cervical Trial, 9 x 18 x 16 mm, 10°
127-10-10181610	Cervical Trial, 10 x 18 x 16 mm, 10°

SET ID: ID2CIMP

- SKIF-826-01

IDENTITI II CERVICAL TI SPACERS	
Part Number	Description
826-05141207-S	IdentiTi II Cervical Ti Spacer, 5 x 14 x 12 mm, 7°
826-06141207-S	IdentiTi II Cervical Ti Spacer, 6 x 14 x 12 mm, 7°
826-07141207-S	IdentiTi II Cervical Ti Spacer, 7 x 14 x 12 mm, 7°
826-08141207-S	IdentiTi II Cervical Ti Spacer, 8 x 14 x 12 mm, 7°
826-09141207-S	IdentiTi II Cervical Ti Spacer, 9 x 14 x 12 mm, 7°
826-10141207-S	IdentiTi II Cervical Ti Spacer, 10 x 14 x 12 mm, 7°
826-05161407-S	IdentiTi II Cervical Ti Spacer, 5 x 16 x 14 mm, 7°
826-06161407-S	IdentiTi II Cervical Ti Spacer, 6 x 16 x 14 mm, 7°
826-07161407-S	IdentiTi II Cervical Ti Spacer, 7 x 16 x 14 mm, 7°
826-08161407-S	IdentiTi II Cervical Ti Spacer, 8 x 16 x 14 mm, 7°
826-09161407-S	IdentiTi II Cervical Ti Spacer, 9 x 16 x 14 mm, 7°
826-10161407-S	IdentiTi II Cervical Ti Spacer, 10 x 16 x 14 mm, 7°
826-06161410-S	IdentiTi II Cervical Ti Spacer, 6 x 16 x 14 mm, 10°
826-07161410-S	IdentiTi II Cervical Ti Spacer, 7 x 16 x 14 mm, 10°
826-08161410-S	IdentiTi II Cervical Ti Spacer, 8 x 16 x 14 mm, 10°
826-09161410-S	IdentiTi II Cervical Ti Spacer, 9 x 16 x 14 mm, 10°
826-10161410-S	IdentiTi II Cervical Ti Spacer, 10 x 16 x 14 mm, 10°
826-05181607-S	IdentiTi II Cervical Ti Spacer, 5 x 18 x 16 mm, 7°
826-06181607-S	IdentiTi II Cervical Ti Spacer, 6 x 18 x 16 mm, 7°
826-07181607-S	IdentiTi II Cervical Ti Spacer, 7 x 18 x 16 mm, 7°
826-08181607-S	IdentiTi II Cervical Ti Spacer, 8 x 18 x 16 mm, 7°
826-09181607-S	IdentiTi II Cervical Ti Spacer, 9 x 18 x 16 mm, 7°
826-10181607-S	IdentiTi II Cervical Ti Spacer, 10 x 18 x 16 mm, 7°
826-06181610-S	IdentiTi II Cervical Ti Spacer, 6 x 18 x 16 mm, 10°
826-07181610-S	IdentiTi II Cervical Ti Spacer, 7 x 18 x 16 mm, 10°
826-08181610-S	IdentiTi II Cervical Ti Spacer, 8 x 18 x 16 mm, 10°
826-09181610-S	IdentiTi II Cervical Ti Spacer, 9 x 18 x 16 mm, 10°
826-10181610-S	IdentiTi II Cervical Ti Spacer, 10 x 18 x 16 mm, 10°

SET ID: TRCNASPS

- SKIF-310-PRO-01

CERVICAL SPACERS	
Part Number	Description
310-PRO-05141207-S	Transcend NanoTec SPS PEEK Spacer, 5 x 14 x 12 mm, 7°
310-PRO-06141207-S	Transcend NanoTec SPS PEEK Spacer, 6 x 14 x 12 mm, 7°
310-PRO-07141207-S	Transcend NanoTec SPS PEEK Spacer, 7 x 14 x 12 mm, 7°
310-PRO-08141207-S	Transcend NanoTec SPS PEEK Spacer, 8 x 14 x 12 mm, 7°
310-PRO-09141207-S	Transcend NanoTec SPS PEEK Spacer, 9 x 14 x 12 mm, 7°
310-PRO-10141207-S	Transcend NanoTec SPS PEEK Spacer, 10 x 14 x 12 mm, 7°
310-PRO-05161407-S	Transcend NanoTec SPS PEEK Spacer, 5 x 16 x 14 mm, 7°
310-PRO-06161407-S	Transcend NanoTec SPS PEEK Spacer, 6 x 16 x 14 mm, 7°
310-PRO-07161407-S	Transcend NanoTec SPS PEEK Spacer, 7 x 16 x 14 mm, 7°
310-PRO-08161407-S	Transcend NanoTec SPS PEEK Spacer, 8 x 16 x 14 mm, 7°
310-PRO-09161407-S	Transcend NanoTec SPS PEEK Spacer, 9 x 16 x 14 mm, 7°
310-PRO-10161407-S	Transcend NanoTec SPS PEEK Spacer, 10 x 16 x 14 mm, 7°
310-PRO-06161410-S	Transcend NanoTec SPS PEEK Spacer, 6 x 16 x 14 mm, 10°
310-PRO-07161410-S	Transcend NanoTec SPS PEEK Spacer, 7 x 16 x 14 mm, 10°
310-PRO-08161410-S	Transcend NanoTec SPS PEEK Spacer, 8 x 16 x 14 mm, 10°
310-PRO-09161410-S	Transcend NanoTec SPS PEEK Spacer, 9 x 16 x 14 mm, 10°
310-PRO-10161410-S	Transcend NanoTec SPS PEEK Spacer, 10 x 16 x 14 mm, 10°
310-PRO-05181607-S	Transcend NanoTec SPS PEEK Spacer, 5 x 18 x 16 mm, 7°
310-PRO-06181607-S	Transcend NanoTec SPS PEEK Spacer, 6 x 18 x 16 mm, 7°
310-PRO-07181607-S	Transcend NanoTec SPS PEEK Spacer, 7 x 18 x 16 mm, 7°
310-PRO-08181607-S	Transcend NanoTec SPS PEEK Spacer, 8 x 18 x 16 mm, 7°
310-PRO-09181607-S	Transcend NanoTec SPS PEEK Spacer, 9 x 18 x 16 mm, 7°
310-PRO-10181607-S	Transcend NanoTec SPS PEEK Spacer, 10 x 18 x 16 mm, 7°
310-PRO-06181610-S	Transcend NanoTec SPS PEEK Spacer, 6 x 18 x 16 mm, 10°
310-PRO-07181610-S	Transcend NanoTec SPS PEEK Spacer, 7 x 18 x 16 mm, 10°
310-PRO-08181610-S	Transcend NanoTec SPS PEEK Spacer, 8 x 18 x 16 mm, 10°
310-PRO-09181610-S	Transcend NanoTec SPS PEEK Spacer, 9 x 18 x 16 mm, 10°
310-PRO-10181610-S	Transcend NanoTec SPS PEEK Spacer, 10 x 18 x 16 mm, 10°

SEGMENTAL PLATING SYSTEM (SPS)
INSTRUCTIONS FOR USE

GENERAL INFORMATION:
The Segmental Plating System (SPS) is intended for anterior fixation to the cervical spine. The Segmental Plating System consists of a variety of sizes of plates and screws that are manufactured from titanium alloy conforming to ASTM F136. The instruments in this system are intended for use in surgical procedures.

INDICATIONS FOR USE:
The Segmental Plating System (SPS) is intended for anterior screw fixation to the cervical spine (C2-T1) for the following indications: degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), trauma (including fractures), tumors, deformity (kyphosis, lordosis, or scoliosis), pseudarthrosis, failed previous fusions, spondylolisthesis, and spinal stenosis.

CONTRAINDICATIONS:
The Segmental Plating System (SPS) is contraindicated for:
1. Patients with osteopenia, osteoporosis, bone absorption or rapid joint disease.
2. Patients with infection in or adjacent to the spine or spinal structures, fever, leukocytosis.
3. Patients with probable intolerances to titanium, titanium alloy or its components (such as aluminum, titanium, or vanadium).
4. Patients with deficient soft tissue at the wound site or inadequate bone stock or quality.
5. Patients with morbid obesity or gross distorted anatomy due to congenital abnormalities.
6. Pregnant patients or patients with mental illness or other medical conditions which would prohibit beneficial surgical outcome.
7. Patients resistant to following post-operative restrictions on movement.
8. Reuse or multiple uses..

WARNINGS/CAUTIONS/PRECAUTIONS:
1. The Segmental Plating System (SPS) is an implant device used only to provide internal fixation during the bone fusion process with the assistance of a bone graft. A successful result may not be achieved in every instance of use with this device.
2. Without solid bone fusion, this device cannot be expected to support the cervical spine indefinitely and may fail due to bone-metal interface, metal, or bone failure.
3. Based on the fatigue testing results, the physician/surgeon should consider the levels of implantation, patient weight, patient activity level, compliance of the patient, and other patient conditions which may have an impact on the performance and results of this system. No spinal implant can withstand body loads for an indefinite period of time without the support of bone. In the event that successful fusion is not achieved; bending, breakage, loosening, migration and/or disassembly of the device will occur.
4. ***This product is a single use device.*** Under no circumstances should it be reused. While the device may appear to be undamaged, it may have small defects or internal stress patterns, as a result of the prior implantation or removal that could lead to fatigue failure. Additionally, please note that the removed implant has not been designed or validated so as to allow for decontamination of microorganisms. Reuse of this product could lead to cross-infection and/or material degradation as a result of the decontamination process. The company accepts no responsibility for implants which have been reused.
5. Potential risks identified with the use of this device, which may require additional surgery, include device component fracture, loss of fixation, non-union, fracture of the vertebrae, and necrosis of bone, neurological injury and vascular or visceral injury.
6. Patients who smoke should be advised of the consequences and of the fact that an increased incidence of non-union has been reported with patients who smoke.
7. Spinal surgery is not recommended for patients with alcohol abuse, morbid obesity, poor bone and muscle quality and/or nerve paralysis.
8. The implants and instruments are provided non-sterile and must be cleaned and sterilized before use. Device components should be sterilized using one of the noted validated sterilization cycle parameters.
9. This device is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.
10. Excessive convergent and divergent hole patterns may prohibit proper seating of bone screws.
11. To prevent premature failure of Locking Driver, do not use the Locking Driver without the Threaded Rod.

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

POSSIBLE ADVERSE EFFECTS:
The following complications and adverse reactions have been shown to occur with the use of similar spinal instrumentation. These effects and any other known by the surgeon should be discussed with the patient preoperatively.
1. Loss of desired spinal curvature, spinal correction and/or a gain or loss in height.
2. Initial or delayed loosening, disassembly, bending, dislocation and/or breakage of device components.
3. Bone graft fracture, vertebral body fracture or discontinued growth of fused bone at, above and/or below the surgery level.
4. Non-union or pseudoarthrosis.
5. In the case of insufficient soft tissue at and around the wound site to cover devices, skin impingement and possible protrusion through the skin may occur.
6. Physiological reaction to implant devices due to foreign body intolerance including inflammation, local tissue reaction, and possible tumor formation.
7. Neurological disorder including paralysis, appearance of radiculopathy and/or abnormal pain development.
8. Displacement of a screw due to incorrect positioning or implant size.
9. Hemorrhaging.
10. Infection.
11. Revision surgery.
12. Death.

PREOPERATIVE MANAGEMENT:
1. The surgeon should only consider utilizing the Segmental Plating System (SPS) with those patients who satisfy the noted indications.
2. The surgeon should avoid utilizing this device with those patients who have contraindicated conditions and/or predispositions.
3. The surgeon should have a complete understanding of the surgical technique, design rationale, indications, and contraindications.
4. The surgeon should have a complete understanding of the function and limitations of the implants and instruments
5. Careful preoperative planning should include construct strategy and verification of required inventory for the case.
6. Device components should be received and accepted only in packages that have not been damaged or tampered with. Components must be carefully handled and stored in a manner that prevents scratches, damage, and corrosion.
7. The condition of all implants & instruments should be checked prior to use. Damaged and/or worn implants and instruments should not be used.
8. The implants and instruments that are provided non-sterile and must be cleaned and sterilized before use.
9. Do not use SPS Plating System with components of other systems.

INTRAOPERATIVE MANAGEMENT:
1. To prevent possible nerve damage and associated disorders, extreme caution should be taken to avoid the spinal cord and nerve roots at all times.
2. Segmental Plating System (SPS) plates are contoured to closely match the anatomical configuration of the spine. SPS plates should not be additionally contoured.
3. Proper sizing and positioning of bone graft is essential to obtain successful spinal fusion. The bone graft must extend from the upper to the lower vertebrae to be fused.
4. Bone screws should not be removed more than once to prevent damage to the screw retention mechanism. If necessary, screw removal should only be conducted with instrumentation provided.
5. Single use instruments should be discarded after use.
6. To prevent possible screw back out, visually confirm that the blocking mechanism is fully seated over the screw head.
7. The SPS Countersinking Tamp cannot be used with the 3-hole plate. The SPS Universal Tamp can be used with all plate configurations..

POSTOPERATIVE MANAGEMENT:
Postoperative management by the surgeon, including instruction and warning and compliance by the patient, of the following is essential:
1. The patient should have a complete understanding of and compliance with the purpose and limitations of the implant devices. The surgeon should instruct the patient on how to compensate for any loss in range of spinal motion due to bone fusion.
2. Additional or revision surgery may be necessary to correct an adverse effect.
3. The surgeon should instruct the patient regarding amount and time frame after surgery of any weight bearing activity. The increased risk of bending, dislocation, and /or breakage of the implant devices, as well as an undesired surgical result are consequences of any type of early or excessive weight bearing, vibration motion, fall, jolts or other movements preventing proper healing and/or fusion development.
4. In the case of delayed union or non-union of bone, the patient must continue to be immobilized in order to prevent bending, dislocation, or breakage of the implant devices. Immobilization should continue until a complete bone fusion mass has developed and been confirmed.
5. Postoperative patients should be instructed not to smoke, consume alcohol, or consume non-steroidals and aspirin, as determined by surgeon.
6. Implant devices should be revised or removed immediately, if appropriate, upon a case of a non-union, pseudoarthrosis or if the devices have been bent, dislocated, or broken.
7. Retrieved implants should be properly disposed of and are not to be reused under any circumstance.

Excerpt from INS-168

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

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

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1950 Camino Vida Roble
Carlsbad, CA 92008 USA
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Ph: (800) 922-1356
atecspine.com

TRANSCEND® NANOTEC™ INTERBODY SYSTEM
INSTRUCTIONS FOR USE

GENERAL INFORMATION:
The Transcend NanoTec 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 Transcend NanoTec interbody spacers are manufactured from PEEK (polyetheretherketone) Optima LT1 per ASTM F2026, tantalum per ASTM F560, and titanium alloy per ASTM F136 with a nano-scale hydroxyapatite surface treatment. The Transcend NanoTec cervical platform includes Transcend NanoTec Cervical and Transcend NanoTec SPS system. The Transcend NanoTec thoracolumbar platform includes Transcend NanoTec PS, Transcend NanoTec PO, and Transcend NanoTec LIF system.

Use Transcend NanoTec Cervical interbody spacers with supplemental fixation systems from Alphatec Spine such as: Trestle Luxe® Cervical Plate System or Invictus® OCT Spinal Fixation System, Insignia™ Anterior Cervical Plate System, or Segmental Plating System (SPS).

Use Transcend NanoTec 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:
Transcend NanoTec Cervical Platform
The Transcend PEEK Cervical Interbody System with advanced NanoTec surface treatment is an anterior cervical interbody fusion system intended for use 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 Transcend NanoTec PEEK Cervical 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 bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion.

Transcend NanoTec Thoracolumbar Platform
The Transcend PEEK Interbody System with advanced NanoTec surface treatment is indicated for spinal fusion procedures from T1 to S1 in skeletally mature patients for the treatment of 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 Transcend NanoTec Interbody System can be used as an adjunct to fusion in patients diagnosed with multilevel degenerative scoliosis and sagittal deformity.

The Transcend NanoTec 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, or a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion. When used with or without integrated fixation, the system is intended to be used with supplemental fixation systems that are cleared by FDA for use in the thoracic and lumbar spine.

AMP™ Anti-Migration Plate may be used with Transcend NanoTec LIF interbody spacers to provide integrated fixation. Transcend NanoTec LIF spacers with >20° lordosis must be used with AMP Anti-Migration Plate in addition to supplemental fixation.

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

WARNINGS/CAUTIONS/PRECAUTIONS:
1. Interbody implants 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 Transcend NanoTec 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.

MRI SAFETY INFORMATION:
The Transcend NanoTec 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 Transcend NanoTec 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 and LIF 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-141

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

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

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

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 (unalloyed titanium) per ASTM F67. The IdentiTi Porous Ti cervical platform includes the following sub-systems: IdentiTi Cervical (IdentiTi-C) and IdentiTi SPS. 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 such as: Trestle Luxe® Cervical Plate System, Invictus® OCT Spinal Fixation System, Insignia™ Anterior Cervical Plate System, or Segmental Plating System (SPS).

Use IdentiTi thoracolumbar interbody spacers with supplemental fixation systems 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 bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion.

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, or a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion. When used with or without integrated fixation, the system is intended to be used with 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.

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 devices to sale by or on the order of a physician.**

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

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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 (unalloyed titanium) per ASTM F67. The IdentiTi Porous Ti cervical platform includes the following sub-systems: IdentiTi Cervical (IdentiTi-C) and IdentiTi SPS. 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 such as: Trestle Luxe® Cervical Plate System, Invictus® OCT Spinal Fixation System, Insignia™ Anterior Cervical Plate System, or Segmental Plating System (SPS).

Use IdentiTi thoracolumbar interbody spacers with supplemental fixation systems 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 II Cervical Platform
The IdentiTi™ II Cervical 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 II Cervical 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 bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion.

IdentiTi II Thoracolumbar Platform
The IdentiTi II 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 II System can be used as an adjunct to fusion in patients diagnosed with multilevel degenerative scoliosis and sagittal deformity.

The IdentiTi II 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, or a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion. When used with or without integrated fixation, the system is. intended to be used with supplemental fixation systems that are cleared by FDA for use in the thoracic and lumbar spine.

AMP™ II Anti-Migration Plate may be used with IdentiTi II LIF interbody spacers to provide integrated fixation. IdentiTi II LIF spacers with >20° lordosis must be used with AMP II Anti-Migration Plate in addition to supplemental fixation.

CONTRAINDICATIONS:
The IdentiTi II 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:
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14. To avoid injury to the spinal cord, do not use a slap hammer to remove the IdentiTi II PC implant/inserter assembly when it is in the locked and articulated position. Confirm the inserter is in the unlocked position prior to removing from the disc space.
15. Use of an AMP II plate sized smaller than the posterior height of the IdentiTi II LIF interbody implant may result in improper seating of the plate.

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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.
4. Infection and/or hemorrhaging.
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7. Subsidence of the device into the vertebral body.
8. Revision surgery.
9. Death.

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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-176

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SYMBOLS:
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