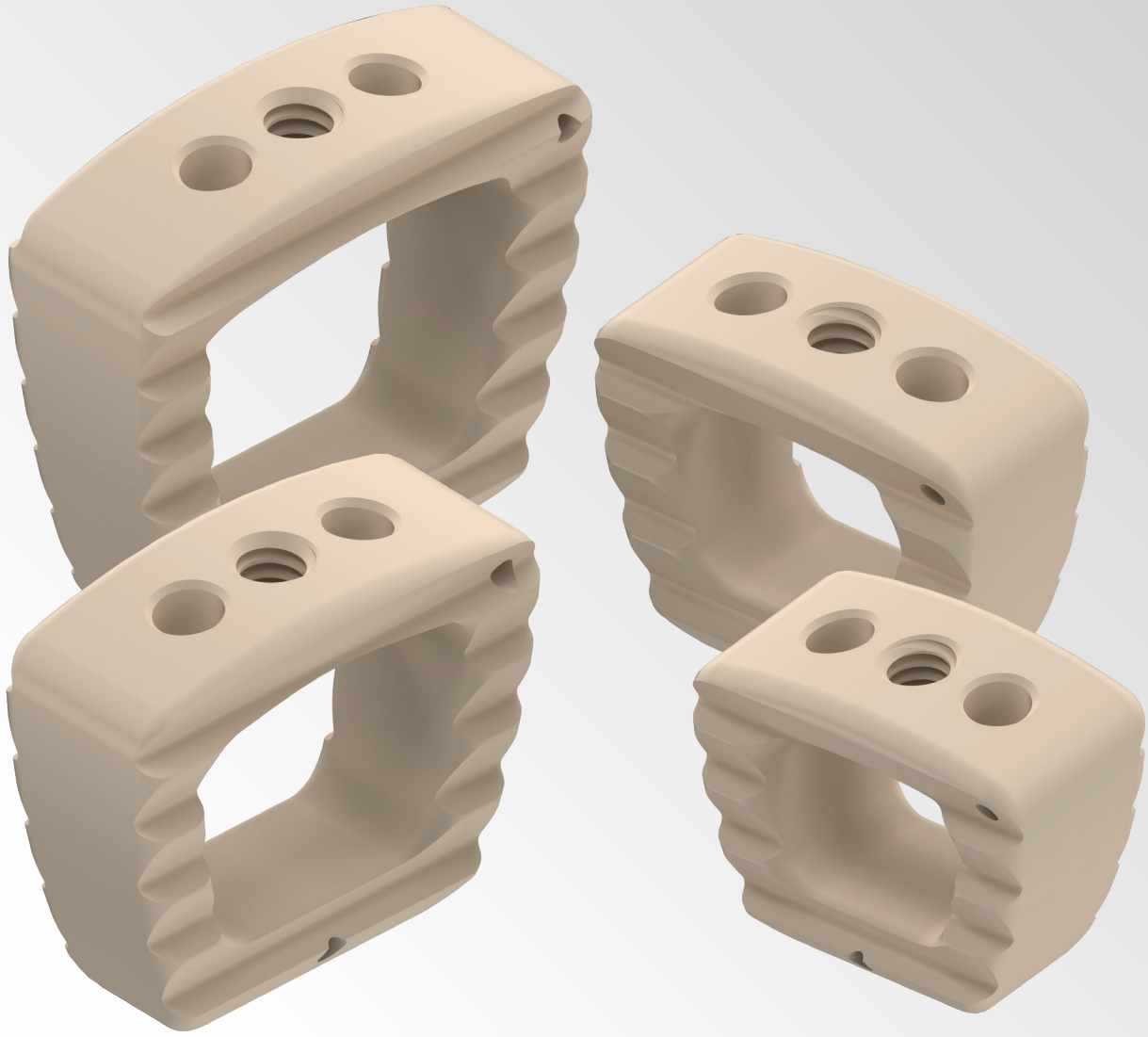
Transcend®

WITH ADVANCED **NANOTEC**® TREATMENT

atec™ INFORMED BY EOS



ACDF | Surgical Technique Guide

Transcend

WITH ADVANCED **NANOTEC**® TREATMENT

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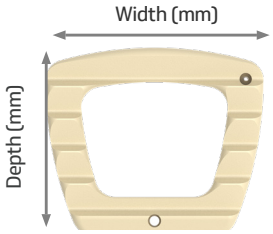
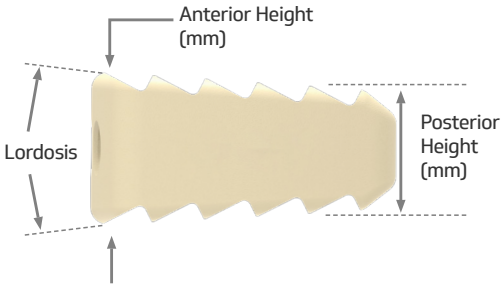
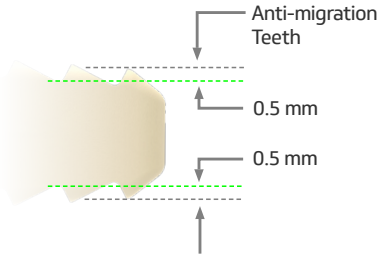
SYSTEM OVERVIEW

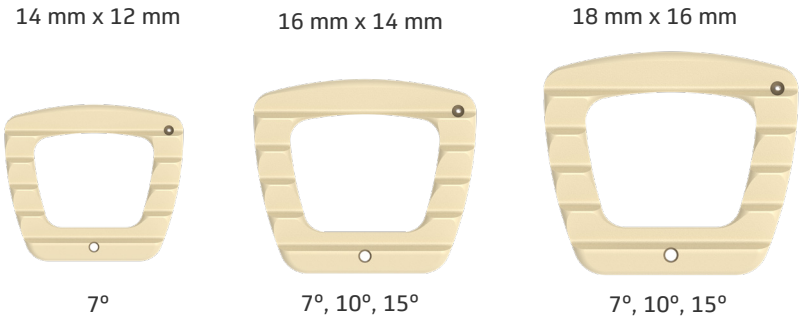
Transcend-C NanoTec Interbody Spacers are made of polyetheretherketone (PEEK) with tantalum alloy markers, and includes a nano-scale hydroxyapatite surface treatment. The interbody spacers are available in a wide variety of height and footprint options.



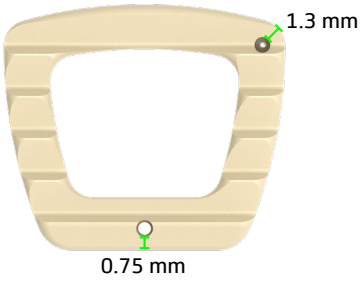


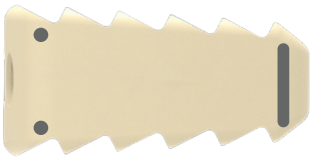


INTERBODY SPACER SIZES



RADIOGRAPHIC MARKERS

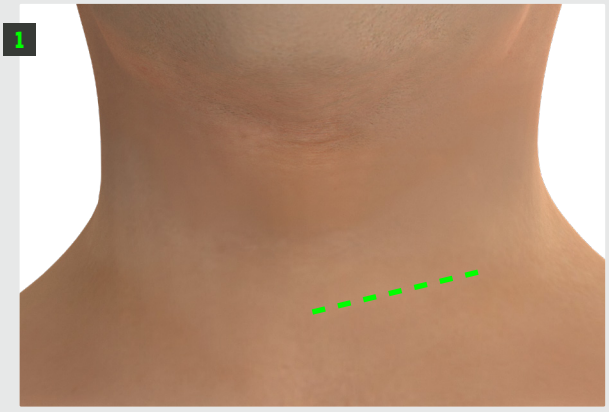




Lateral markers only visible under radiographic imaging

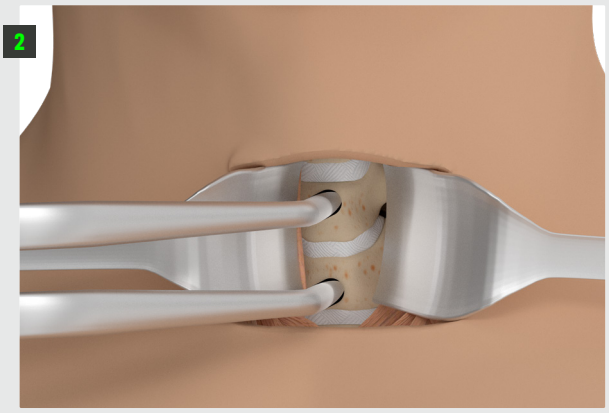
PATIENT POSITIONING

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.



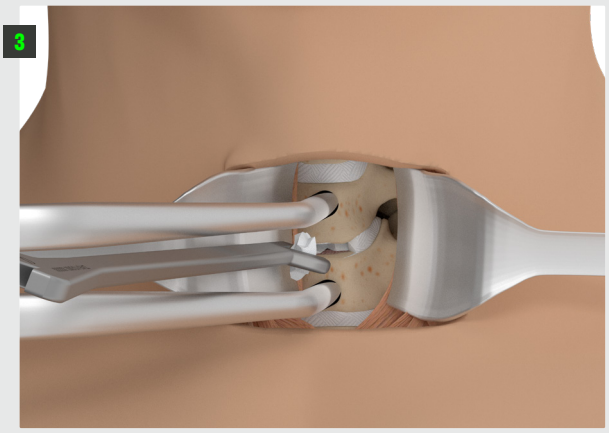
EXPOSURE

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.



DISCECTOMY

3 Using pituitary rongeurs, curettes, and Kerrison rongeurs, perform the discectomy at the indicated level. Disc material and cartilage will be removed to expose the posterior longitudinal ligament.



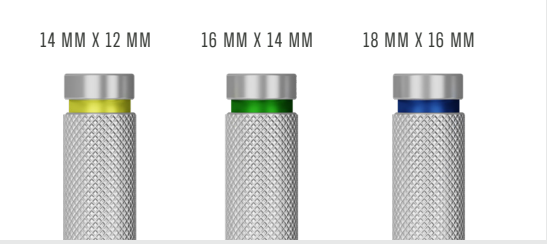
1 In the newly prepared disc space, insert a Trial to confirm the correct disc height and Interbody Spacer footprint. The Trials are color-coded to help identify the desired Interbody Spacer footprint and lordosis. The appropriate Interbody Spacer size is determined by selecting the Trial that provides the most satisfactory fit in the disc space. A/P and/or lateral fluoroscopy may be used to confirm position.

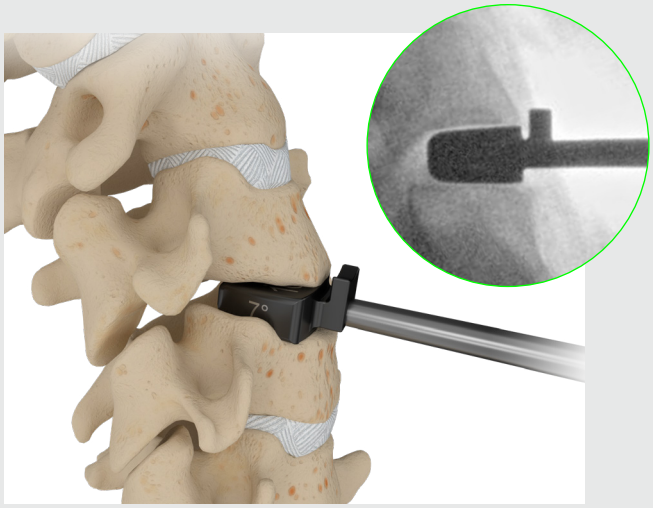
NOTE: THE TRIALS AND THE INTERBODY SPACERS ARE MEASURED LINE-TO-LINE FROM THEIR ANTERIOR HEIGHT. THIS INCLUDES THE HEIGHT OF THE TEETH. THE ANTERIOR HEIGHT AND FOOTPRINT OF THE INTERBODY SPACER IS INDICATED ON THE FACE OF THE TRIAL AND ON THE INTERBODY SPACER CARTON LABEL.

NOTE: RASPING TRIALS ARE ALSO AVAILABLE UPON REQUEST (SET ID: IDCINSRT). IF PREFERRED, A SINGLE-SIDED RASP IS PROVIDED IN THE SET TO PERFORM THE DESIRED DECORTICATION AND PREPARATION OF THE ENDPLATES, PRIOR TO INTERBODY SPACER INSERTION.

NOTE: SOME TRIALS (RASPING AND SMOOTH) HAVE A DEPTH STOP LOCATED 1.5 MM FROM THE PROXIMAL END OF THE INSTRUMENT TIP AND ARE DESIGNED TO PREVENT OVER-INSERTION INTO THE DISC SPACE.

1





INSERTER ATTACHMENT

1 Upon disc height confirmation through trialing, select the corresponding Interbody Spacer.

> **NOTE:** THE INTERBODY SPACER'S WIDTH, DEPTH, HEIGHT, AND LORDOSIS ARE MARKED ON THE CARTON LABEL.

Attach the selected implant to the Inserter by aligning the holes on the anterior face of the Interbody Spacer with the distal tip of the Inserter, then turning the dial on the Inserter clockwise to thread the Inserter to the Interbody Spacer.

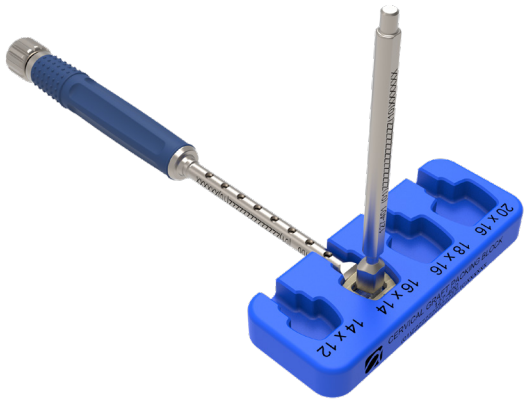
GRAFT PACKING

2 Using the Graft Packing Block and Tamp, pack the selected Interbody Spacer with bone graft material prior to insertion.

> **NOTE:** THE BACK OF THE GRAFT PACKING TAMP CAN BE USED TO HELP DISENGAGE THE INSERTER IF ADDITIONAL FORCE IS REQUIRED.

1

2



INSERTER ATTACHMENT

1 Using the assembled Interbody Spacer/Inserter, insert the Interbody Spacer into the disc space. The Interbody Spacer Inserter may be used to reposition the implant as needed.

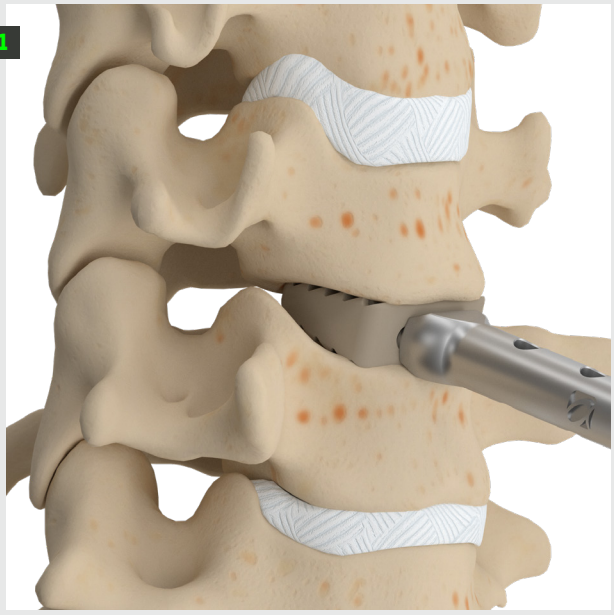
NOTE: THE INSERTER DOES NOT HAVE A DEPTH STOP.

NOTE: CONFIRM THAT THE INSERTER IS COMPLETELY UNTHREADED FROM THE INTERBODY SPACER BEFORE ATTEMPTING TO REMOVE IT FROM THE SURGICAL SITE.

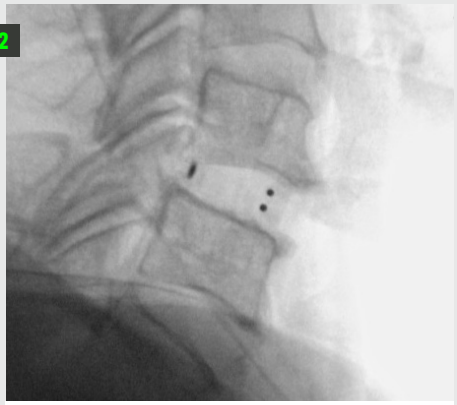
VERIFY POSITIONING

2 Confirm Interbody Spacer position with A/P and lateral fluoroscopy.

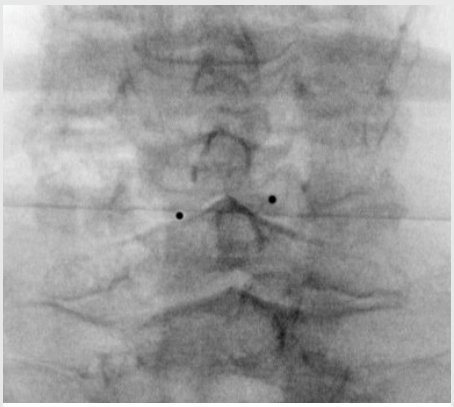
1



2



LATERAL VIEW



A/P VIEW

SUPPLEMENTAL FIXATION

1 The Transcend NanoTec Cervical Interbody System must be used with supplemental fixation cleared by the FDA for use in the cervical spine. Implant the supplemental fixation according to the recommended surgical technique for the fixation system.

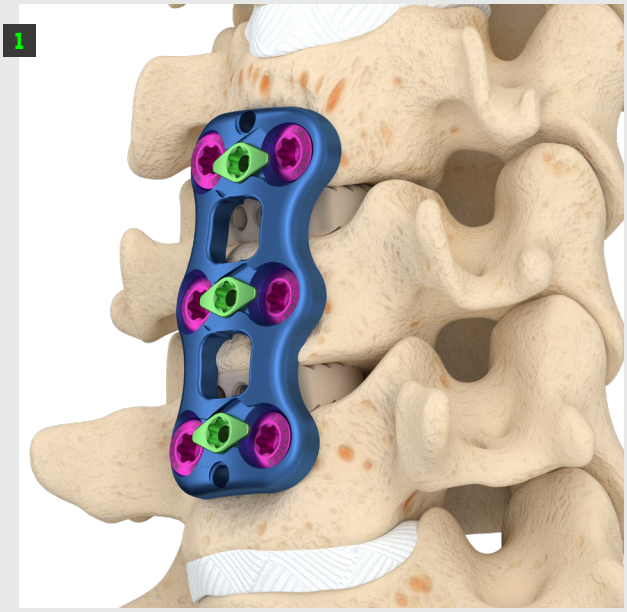
CLOSURE

2 Close the wound using standard surgical techniques.

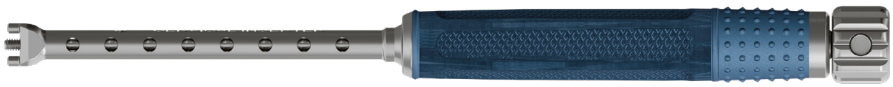
INTERBODY SPACER REMOVAL

3 If Interbody Spacer removal is necessary, access to the implantation site can be achieved in a similar fashion to the original access. Remove supplemental fixation according to the recommended surgical technique for the fixation system. Once the Interbody Spacer device is exposed, reattach the Cervical Interbody Inserter and gently remove.

1



Cervical Inserter Part #: 127-100



Cervical Trial Part #: 127-10-XXXXXXXX

Cervical Trial, Rasp, Double-Sided Part #: 127-20-XXXXXXXX

Cervical Rasp, Single-Sided Part #: 127-200

Cervical Tamp Part #: 127-300

Cervical Graft Packing Tamp Part #: 127-401

Cervical Graft Packing Block Part #: 127-400

PART NUMBER	DESCRIPTION	QTY
Cervical Instruments | **Set ID:** IDCINS		
127-100	Cervical Inserter, Standard	2
127-300	Cervical Tamp	1
127-400	Cervical Graft Packing Block	1
127-401	Cervical Graft Packing Tamp	1
127-200	Cervical Rasp, Single-Sided	1
127-10-05141207	Cervical Trial, 5 x 14 x 12 mm, 7°	1
127-10-06141207	Cervical Trial, 6 x 14 x 12 mm, 7°	1
127-10-07141207	Cervical Trial, 7 x 14 x 12 mm, 7°	1
127-10-08141207	Cervical Trial, 8 x 14 x 12 mm, 7°	1
127-10-09141207	Cervical Trial, 9 x 14 x 12 mm, 7°	1
127-10-10141207	Cervical Trial, 10 x 14 x 12 mm, 7°	1
127-10-05161407	Cervical Trial, 5 x 16 x 14 mm, 7°	1
127-10-06161407	Cervical Trial, 6 x 16 x 14 mm, 7°	1
127-10-07161407	Cervical Trial, 7 x 16 x 14 mm, 7°	1
127-10-08161407	Cervical Trial, 8 x 16 x 14 mm, 7°	1
127-10-09161407	Cervical Trial, 9 x 16 x 14 mm, 7°	1
127-10-10161407	Cervical Trial, 10 x 16 x 14 mm, 7°	1
127-10-06161410	Cervical Trial, 6 x 16 x 14 mm, 10°	1
127-10-07161410	Cervical Trial, 7 x 16 x 14 mm, 10°	1
127-10-08161410	Cervical Trial, 8 x 16 x 14 mm, 10°	1
127-10-09161410	Cervical Trial, 9 x 16 x 14 mm, 10°	1
127-10-10161410	Cervical Trial, 10 x 16 x 14 mm, 10°	1
127-10-05181607	Cervical Trial, 5 x 18 x 16 mm, 7°	1
127-10-06181607	Cervical Trial, 6 x 18 x 16 mm, 7°	1
127-10-07181607	Cervical Trial, 7 x 18 x 16 mm, 7°	1
127-10-08181607	Cervical Trial, 8 x 18 x 16 mm, 7°	1
127-10-09181607	Cervical Trial, 9 x 18 x 16 mm, 7°	1
127-10-10181607	Cervical Trial, 10 x 18 x 16 mm, 7°	1
127-10-06181610	Cervical Trial, 6 x 18 x 16 mm, 10°	1
127-10-07181610	Cervical Trial, 7 x 18 x 16 mm, 10°	1
127-10-08181610	Cervical Trial, 8 x 18 x 16 mm, 10°	1
127-10-09181610	Cervical Trial, 9 x 18 x 16 mm, 10°	1
127-10-10181610	Cervical Trial, 10 x 18 x 16 mm, 10°	1

PART NUMBER	DESCRIPTION	QTY
Cervical Instruments | **Set ID:** IDC15INS		
127-100	Cervical Inserter, Standard	2
127-300	Cervical Tamp	1
127-400	Cervical Graft Packing Block	1
127-401	Cervical Graft Packing Tamp	1
127-200	Cervical Rasp, Single-Sided	1
127-10-07161415	Cervical Trial, 7 x 16 x 14 mm, 15°	1
127-10-08161415	Cervical Trial, 8 x 16 x 14 mm, 15°	1
127-10-09161415	Cervical Trial, 9 x 16 x 14 mm, 15°	1
127-10-10161415	Cervical Trial, 10 x 16 x 14 mm, 15°	1
127-10-11161415	Cervical Trial, 11 x 16 x 14 mm, 15°	1
127-10-12161415	Cervical Trial, 12 x 16 x 14 mm, 15°	1
127-10-08181615	Cervical Trial, 8 x 18 x 16 mm, 15°	1
127-10-09181615	Cervical Trial, 9 x 18 x 16 mm, 15°	1
127-10-10181615	Cervical Trial, 10 x 18 x 16 mm, 15°	1
127-10-11181615	Cervical Trial, 11 x 18 x 16 mm, 15°	1
127-10-12181615	Cervical Trial, 12 x 18 x 16 mm, 15°	1

PART NUMBER	DESCRIPTION	QTY
Implants | **Set ID:** TRCNA		
110-PRO-05141207-S	Transcend NanoTec Cervical PEEK Spacer, 5 x 14 x 12 mm, 7°	2
110-PRO-06141207-S	Transcend NanoTec Cervical PEEK Spacer, 6 x 14 x 12 mm, 7°	3
110-PRO-07141207-S	Transcend NanoTec Cervical PEEK Spacer, 7 x 14 x 12 mm, 7°	3
110-PRO-08141207-S	Transcend NanoTec Cervical PEEK Spacer, 8 x 14 x 12 mm, 7°	3
110-PRO-09141207-S	Transcend NanoTec Cervical PEEK Spacer, 9 x 14 x 12 mm, 7°	2
110-PRO-10141207-S	Transcend NanoTec Cervical PEEK Spacer, 10 x 14 x 12 mm, 7°	1
110-PRO-05161407-S	Transcend NanoTec Cervical PEEK Spacer, 5 x 16 x 14 mm, 7°	2
110-PRO-06161407-S	Transcend NanoTec Cervical PEEK Spacer, 6 x 16 x 14 mm, 7°	3
110-PRO-07161407-S	Transcend NanoTec Cervical PEEK Spacer, 7 x 16 x 14 mm, 7°	3
110-PRO-08161407-S	Transcend NanoTec Cervical PEEK Spacer, 8 x 16 x 14 mm, 7°	3
110-PRO-09161407-S	Transcend NanoTec Cervical PEEK Spacer, 9 x 16 x 14 mm, 7°	2
110-PRO-10161407-S	Transcend NanoTec Cervical PEEK Spacer, 10 x 16 x 14 mm, 7°	1
110-PRO-06161410-S	Transcend NanoTec Cervical PEEK Spacer, 6 x 16 x 14 mm, 10°	2
110-PRO-07161410-S	Transcend NanoTec Cervical PEEK Spacer, 7 x 16 x 14 mm, 10°	2
110-PRO-08161410-S	Transcend NanoTec Cervical PEEK Spacer, 8 x 16 x 14 mm, 10°	2
110-PRO-09161410-S	Transcend NanoTec Cervical PEEK Spacer, 9 x 16 x 14 mm, 10°	2
110-PRO-10161410-S	Transcend NanoTec Cervical PEEK Spacer, 10 x 16 x 14 mm, 10°	1
110-PRO-05181607-S	Transcend NanoTec Cervical PEEK Spacer, 5 x 18 x 16 mm, 7°	2
110-PRO-06181607-S	Transcend NanoTec Cervical PEEK Spacer, 6 x 18 x 16 mm, 7°	3
110-PRO-07181607-S	Transcend NanoTec Cervical PEEK Spacer, 7 x 18 x 16 mm, 7°	3
110-PRO-08181607-S	Transcend NanoTec Cervical PEEK Spacer, 8 x 18 x 16 mm, 7°	2
110-PRO-09181607-S	Transcend NanoTec Cervical PEEK Spacer, 9 x 18 x 16 mm, 7°	2
110-PRO-10181607-S	Transcend NanoTec Cervical PEEK Spacer, 10 x 18 x 16 mm, 7°	1
110-PRO-06181610-S	Transcend NanoTec Cervical PEEK Spacer, 6 x 18 x 16 mm, 10°	2
110-PRO-07181610-S	Transcend NanoTec Cervical PEEK Spacer, 7 x 18 x 16 mm, 10°	2
110-PRO-08181610-S	Transcend NanoTec Cervical PEEK Spacer, 8 x 18 x 16 mm, 10°	2
110-PRO-09181610-S	Transcend NanoTec Cervical PEEK Spacer, 9 x 18 x 16 mm, 10°	2
110-PRO-10181610-S	Transcend NanoTec Cervical PEEK Spacer, 10 x 18 x 16 mm, 10°	1

PART NUMBER	DESCRIPTION	QTY
Implants | **Set ID:** TRCN15IM		
110-PRO-07161415-S	Transcend NanoTec Cervical PEEK Spacer, 7 x 16 x 14 mm, 15°	3
110-PRO-08161415-S	Transcend NanoTec Cervical PEEK Spacer, 8 x 16 x 14 mm, 15°	3
110-PRO-09161415-S	Transcend NanoTec Cervical PEEK Spacer, 9 x 16 x 14 mm, 15°	3
110-PRO-10161415-S	Transcend NanoTec Cervical PEEK Spacer, 10 x 16 x 14 mm, 15°	1
110-PRO-11161415-S	Transcend NanoTec Cervical PEEK Spacer, 11 x 16 x 14 mm, 15°	1
110-PRO-08181615-S	Transcend NanoTec Cervical PEEK Spacer, 8 x 18 x 16 mm, 15°	3
110-PRO-09181615-S	Transcend NanoTec Cervical PEEK Spacer, 9 x 18 x 16 mm, 15°	2
110-PRO-10181615-S	Transcend NanoTec Cervical PEEK Spacer, 10 x 18 x 16 mm, 15°	1
110-PRO-11181615-S	Transcend NanoTec Cervical PEEK Spacer, 11 x 18 x 16 mm, 15°	1

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 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.

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 combination thereof.

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 and supplemental fixation systems that are cleared by FDA for use in the thoracic and lumbar spine.

AMP™ Anti-Migration Plate may be used with 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. 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.
14. The Center Screw - Back Table (116-5-01, green) must be assembled to the AMP and interbody prior to insertion and must not be assembled in situ.

MRI SAFETY INFORMATION:
The 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

Transcend® NanoTec™ Interbody System
INSTRUCTIONS FOR USE (AUSTRALIA)

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 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.

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 combination thereof.

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 and supplemental fixation systems 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.

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. 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.
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Excerpt from INS-141-01

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Alphatec Australia, Pty. Ltd.
101 Cremorne St.
Cremorne, VIC 3121
Australia

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

1950 Camino Vida Roble, Carlsbad, CA 92008

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