Trestle Luxe® II

ANTERIOR CERVICAL PLATING SYSTEM

SURGICAL TECHNIQUE GUIDE

atec™
Spine Approach Technologies

Anterior Cervical Plate System

Trestle Luxe® II

ANTERIOR CERVICAL PLATING SYSTEM

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TRESTLE LUXE II PLATE DIMENSIONS

› Plate offering in 18 mm - 110 mm options

PLATE LENGTHS*

LEVEL													
I	18	20	22	24	26	28	30	32	34				
II	32	34	36	38	40	42	44	46	48	50	52	54	
III	50	52	54	56	58	60	62	64	66	68			
IV	66	68	70	74	78	82	86	90					
V	90	95	100	105	110								

Included in Set Available upon Request

**Plate length is measured from end to end*

TRESTLE LUXE II SCREW DIMENSIONS

› Screw offering in Fixed and Variable angles

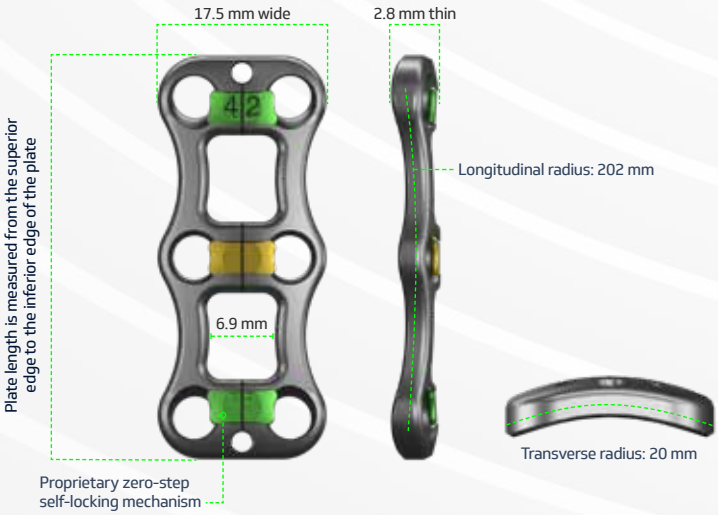
SCREW LENGTHS*

DIAMETER									
SELF-TAPPING									
4.0	10	11	12	13	14	15	16	17	18
4.5	10	11	12	13	14	15	16	17	18
SELF-DRILLING									
4.0	10	11	12	13	14	15	16		

Included in Set Available upon Request

**Amount of purchase into bone*

PLATE SPECIFICATIONS



SCREW SPECIFICATIONS

› **Variable**
4.0 self-drilling, purple

› **Variable**
4.0 self-tapping, light green

› **Variable**
4.5 self-tapping, green

› **Fixed**
4.0 self-drilling, gold

› **Fixed**
4.0 self-tapping, light blue

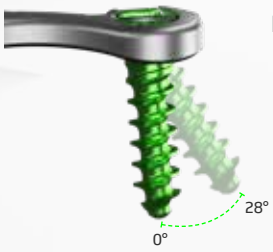
› **Fixed**
4.5 self-tapping, blue

ANGULATION

Axial View

› Fixed neutral position
6° medial/lateral

› Variability from neutral:
18° (-3° - 15°)



Lateral View

› Fixed neutral position
15° cephalad/caudad

› Variability from neutral:
28° (0° - 28°)

NOTE: THE TRESTLE LUXE II COMPONENTS ARE NOT COMPATIBLE WITH THE ORIGINAL TRESTLE LUXE COMPONENTS.

1 **PATIENT POSITIONING**

Place the patient in supine position with the head in slight extension. Surgeon must choose the preferred approach: either right- or left-sided to the cervical vertebral column. After approach is decided, the head may be rotated to allow for adequate exposure of the upper cervical spine.

2 **ACCESS**

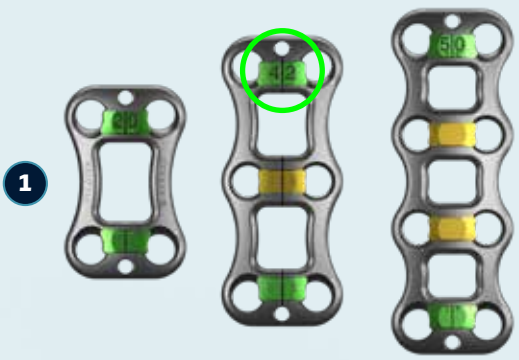
The initial incision should be used to create an avascular dissection plane between the trachea and esophagus. Retractors are typically utilized to provide initial exposure of the anterior vertebral column and the adjacent muscles.

3 **DISCECTOMY**

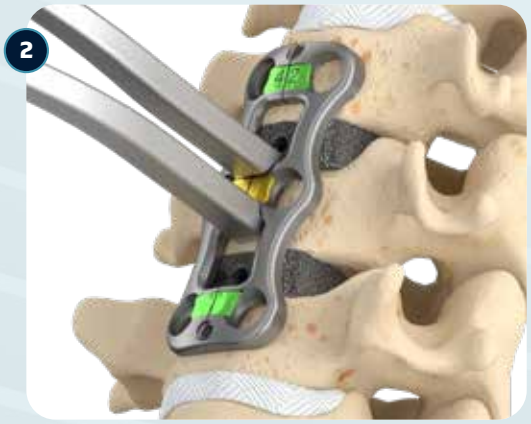
Using commercially available pituitary rongeurs, curettes, and Kerrison rongeurs, perform the discectomy at the indicated level. Disc material and cartilage will be removed to expose the posterior longitudinal ligament by the removal of the posterior disc and any osteophytes that may occur.

1. Select the appropriately sized plate determined by preoperative planning. Refer to page 2 for plate and screw sizes and specifications.

NOTE: PLATE SIZES ARE SHOWN ON THE SUPERIOR BLOCKING SLIDE.



2. **PLATE POSITION**
Use the Plate Holder to position the plate into the operative site for placement and sizing verification.



3. **PLATE CONTOUR (OPTIONAL)**
Should a patient's anatomy require additional contouring, the plate can be contoured to the desired degree of lordosis or kyphosis by the Plate Bender.

4. Insert the Trestle Luxe II plate into the Plate Bender as shown. Squeeze the handles of the Plate Bender together to contour the plate. Contouring along the graft window, starting from the outer edge working inward helps to evenly contour the plate.

CAUTION: DO NOT PLACE THE ANVIL PORTION OF THE PLATE BENDER OVER THE BLOCKING SLIDE AS DAMAGE CAN OCCUR AND AFFECT ITS FUNCTION.

NOTE: PLATES 28 MM OR SHORTER SHOULD NOT BE CONTOURED.

MIDLINE TEMPORARY PREFIXATION PIN

1. Confirm that the plate is properly aligned with the endplates. Attach the Midline Prefixation Pin to the Inserter by pulling on the collar.

2. Thread the Midline Prefixation Pin until it is fully seated on the superior and inferior midline aspects of the plate.

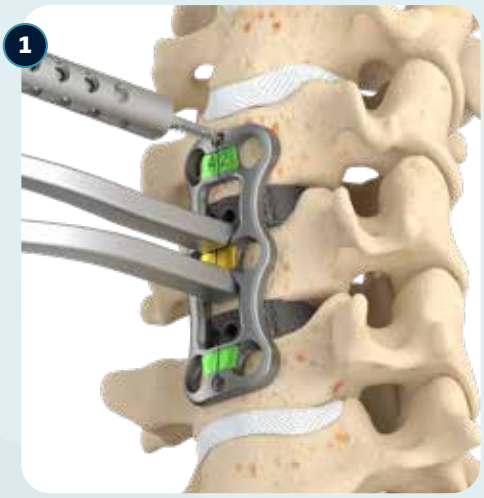
INTRADISCAL DRILL GUIDE (OPTIONAL)

3. The Intradiscal Drill Guide places bone screw pilot holes parallel to the endplate surface at a 15° or 28° trajectory.

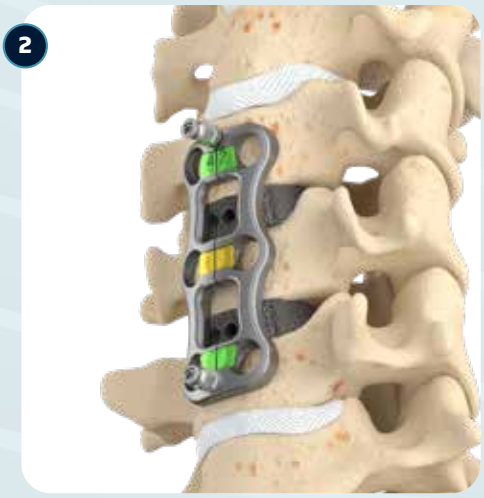
4. Match the patient's disc space with the corresponding Intradiscal Drill Guide. Select which degree of screw angulation is needed and insert guide into the disc space. Then drill cranial or caudal bone screw holes.

NOTE: THE INTRADISCAL PORTION IS ONLY USED TO SECURE THE GUIDE INTO THE DISC SPACE WHILE DRILLING AND IS NOT USED TO DETERMINE THE INTERBODY IMPLANT SIZE.

1



2



3

1 **SELECT DRILL GUIDE**

Select the corresponding color-coded Drill Guide based on the type of screw selected (fixed or variable angle).

Fixed Drill Guides

Variable Drill Guides

NOTE: THE AWLS AND DRILLS CAN ONLY BE USED WITH THE DRILL GUIDES.

2 **INSERT DRILL GUIDE**

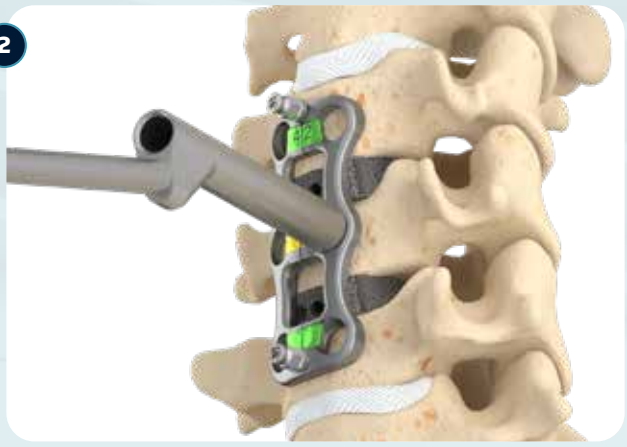
Insert the Drill Guide by placing into the desired screw hole of the plate.

3 **CREATE SCREW HOLE**

Attach the Quick Connect Handle to the Awl by pulling the collar back. Place the Awl through the Drill Guide and lightly tap through the cortical surface of the vertebral body to create a pilot hole.

1

2



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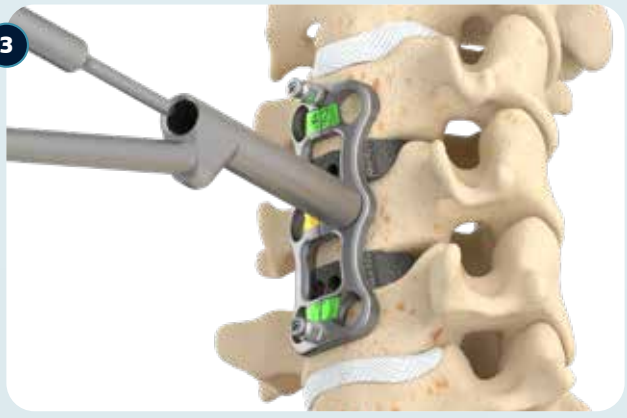
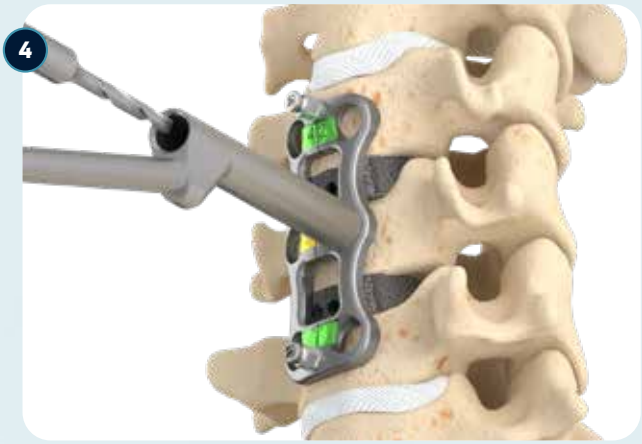


4 **SELECT DRILL BIT**

Select the appropriate length Drill Bit with stop and attach it to the Quick Connect Handle. Insert the Drill Bit into the Drill Guide and rotate the handle in a clockwise direction to create the pilot hole for the screw. The depth stop will limit the drilling depth by contacting the Drill Guide.

5 **SCREW INSERTION**

After removal of the Drill Guide, connect the Screwdriver to the Quick Connect Handle. Attach the appropriate Self-Tapping Screw onto the screwdriver and advance until the head of the screw is fully seated into the plate. The Blocking Slide will be positioned over the head of the screw for verification that it is fully seated.



1 **GUIDE POSITIONING**

Position the DTS Guide over the Blocking Slide so that the barrels align with the screw holes of the plate.

NOTE: THE DTS GUIDE DOES NOT LOCK TO THE PLATE.

2 **SET BARREL ANGLE**

To adjust the screw angle, use the knob on the shaft to adjust and set the barrel angle.

3 **CREATE SCREW HOLE**

Place the Awl through the DTS Guide and lightly tap through the cortical surface of the vertebral body to create a pilot hole.

CAUTION: EXCESSIVE CONVERGENT AND DIVERGENT HOLE PATTERNS MAY PROHIBIT PROPER SEATING OF BONE SCREWS.

4 **DRILL HOLE**

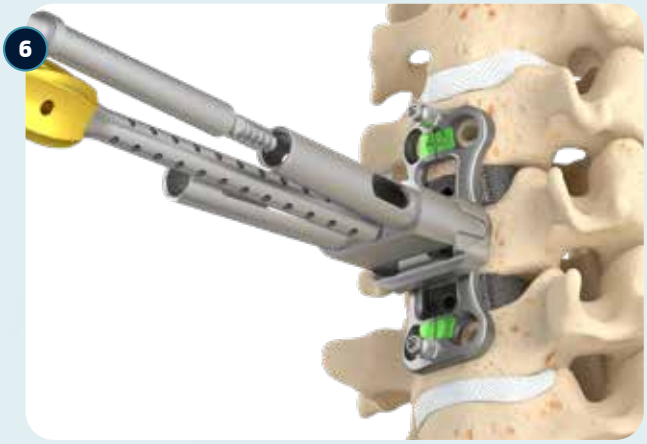
Select the appropriate length Drill Bit and attach it to the Quick Connect Handle. Insert the Drill Bit into the DTS Guide and rotate the handle in a clockwise direction to create the pilot hole for the screw. The depth stop will limit the drilling depth by contacting the DTS Guide.

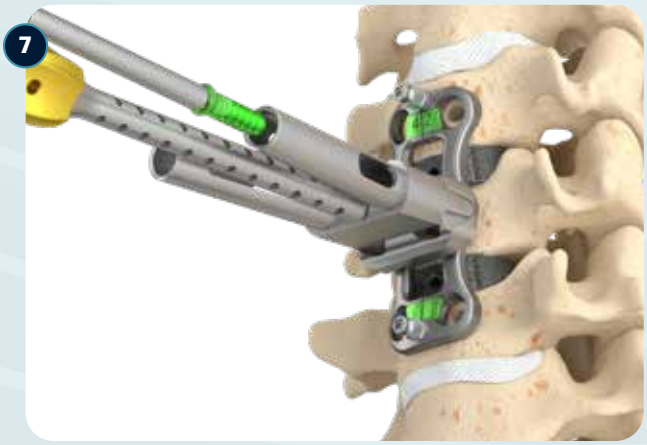
6 **TAP FOR SCREW**

If tapping the hole is preferred, connect the Tap to the Quick Connect Handle. Insert the Tap into the DTS Guide and advance the Tap to the preferred depth.

7 **SCREW INSERTION**

Connect preferred Screwdriver to the Quick Connect Handle. Load the appropriate length Self-Drilling or Self-Tapping Screw to the driver. Advance the screw until it is fully seated into the plate and the Blocking Slide is positioned over the head of the screw.





1 **VERIFY ALIGNMENT**
Once the screws are fully seated and underneath the Blocking Slide, verify that the vertical line on the Blocking Slide is in direct alignment with the vertical lines on the plate.

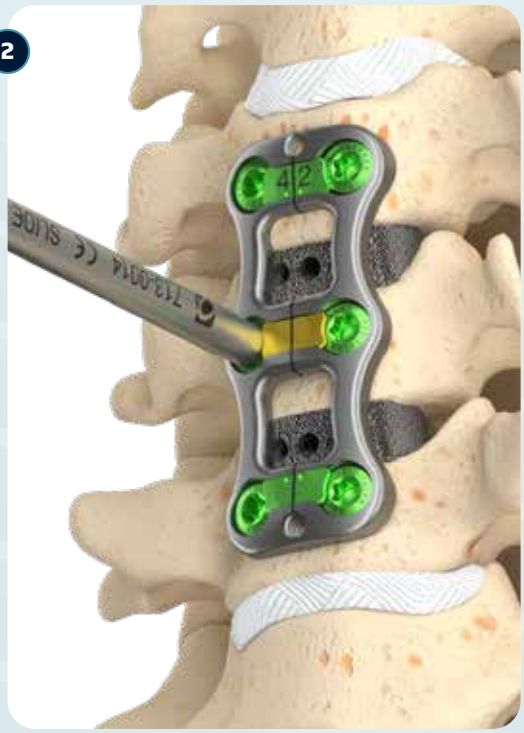
2 **CORRECTING BLOCKING SLIDE**
To reposition, place the Slide Alignment Tool in a vertical orientation over the screw head. Rotate the alignment tool until the vertical line on the Blocking Slide is directly aligned with the vertical lines on the plate.

3 **PLATE VERIFICATION**
Check the final position of the plate and screws both visually and radiographically.

ALIGNED **NOT ALIGNED**

1

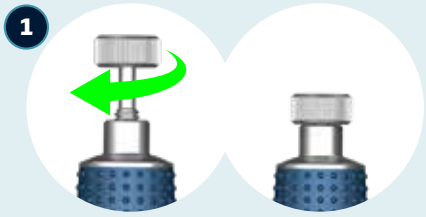
2

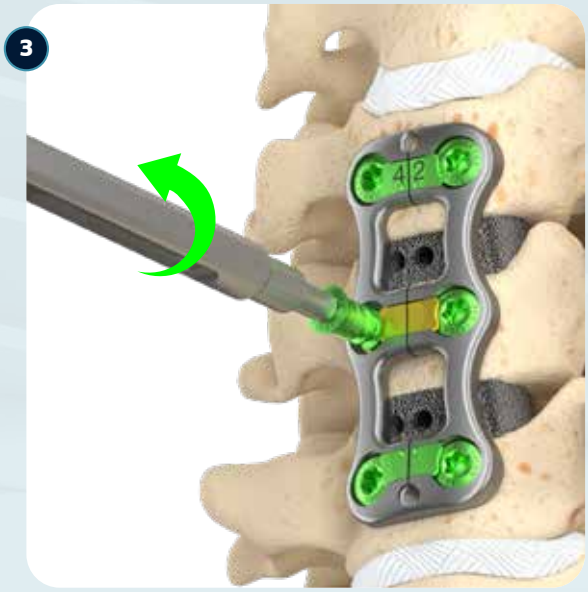


1. Pre-assemble Screw Removal Tool and Inner Shaft prior to placement. Verify that the Gold Collar is facing the Blocking Slide while inserting the tip of the Removal Tool into the head of the desired screw.

2. Confirm that the tip is fully seated within the screw head. Thread the Inner Shaft into the screw's internal threads capturing the screw.

3. Rotate the Removal Tool counter-clockwise to disengage the Blocking Slide to allow for screw extraction. Continue turning until the screw is removed from the plate.





TRAY 1 (UPPER TRAY INSERT)

1. 1 -3 Level Plate Caddy
   Sizes 18 mm – 68 mm
2. Self-Tapping Screw Caddy
   Sizes 10 mm – 18 mm
3. Self-Drilling Screw Caddy
   Sizes 10 mm – 18 mm
4. Plate Holder
5. Plate Bender

TRAY 1 (LOWER TRAY INSERT)

1. Self Constrained Awl
2. Temporary Fixation Pin Inserter
3. Hexalobe Screw Removal Tool
4. Inner Shaft, Hexalobe Screw Removal Tool
5. Quick Connect Handle, Spin Top
6. Double Barrel DTS Guide
7. Fixed Angle Drill Guide
8. Variable Angle Drill Guide
9. Awl, For Drill Guide
10. Fixed 2.3 mm Drill Bit, 10 mm
    Fixed 2.3 mm Drill Bit, 12 mm
    Fixed 2.3 mm Drill Bit, 14 mm
    Fixed 2.3 mm Drill Bit, 16 mm
11. Slide Alignment Tool
12. Parallel Screwdriver
13. Twisted Hexalobe Screwdriver
14. Self Retaining Screwdriver

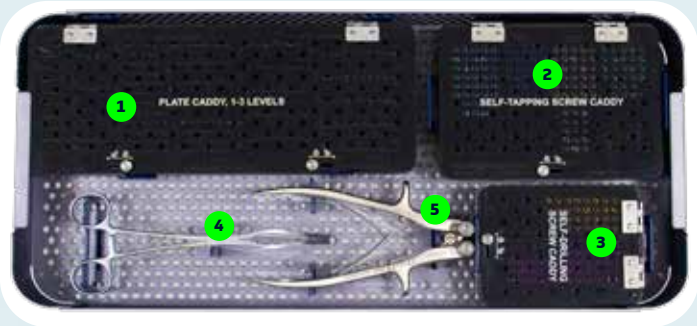
TRAY 2

1. 4 -5 Level Plate Caddy
   Sizes 66 mm – 110 mm

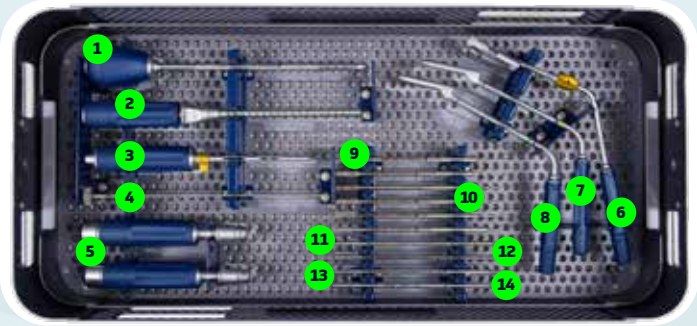
TRAY 3

1. Intradiscal Drill Guides
   Sizes 5 mm - 9 mm

TRAY 1 (UPPER TRAY INSERT)

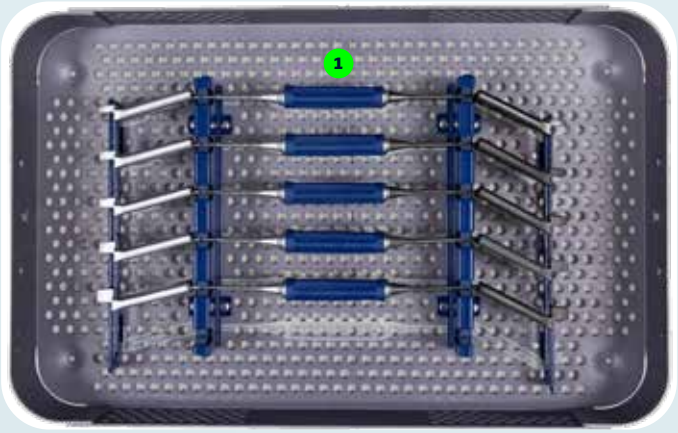


TRAY 1 (LOWER TRAY INSERT)



TRAY 2

TRAY 3



Twisted Hexalobe Screwdriver
713-0011

Parallel Screwdriver
713-0012

Self Retaining Screwdriver
71734

Awl, Drill Guide
713-0008

Drill Bit for Drill Guide and DTS
713-2010, 2012, 2014, 2016

Tap for Drill Guide and DTS
713-0005

Self Constrained Awl
713-0010

Midline Temporary Prefixation Pin
713-0013

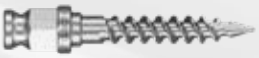
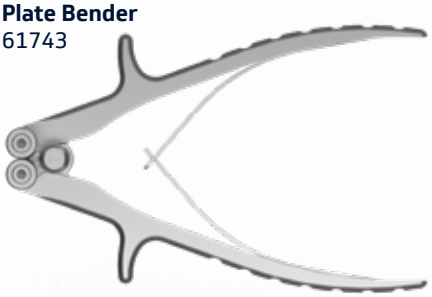


Plate Holder
713-0004

Hexalobe Screw Removal Tool
713-0018

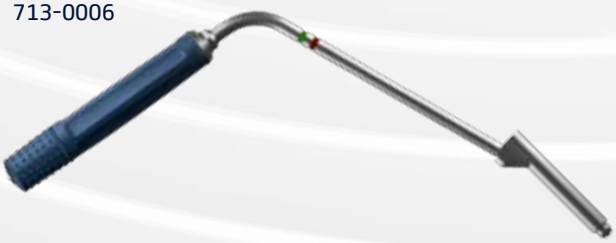
Inner Shaft, Hexalobe Screw Removal Tool
713-0019

Plate Bender
61743



Double Barrel DTS
713-0003

Variable Angle Drill Guide
713-0006



Fixed Angle Drill Guide
713-0007

Intradiscal Drill Guide
713-1005, 1006, 1007, 1008, 1009

Quick-Connect Handle
86001-0120

Temporary Fixation Pin Inserter
71732

Part Number	Product Description
PLATE OFFERINGS	
711-0118	Trestle Luxe II, ACP, 1-Level, 18 mm
711-0120	Trestle Luxe II, ACP, 1-Level, 20 mm
711-0122	Trestle Luxe II, ACP, 1-Level, 22 mm
711-0124	Trestle Luxe II, ACP, 1-Level, 24 mm
711-0126	Trestle Luxe II, ACP, 1-Level, 26 mm
711-0128	Trestle Luxe II, ACP, 1-Level, 28 mm
711-0130	Trestle Luxe II, ACP, 1-Level, 30 mm
711-0132	Trestle Luxe II, ACP, 1-Level, 32 mm
711-0134	Trestle Luxe II, ACP, 1-Level, 34 mm
711-0232	Trestle Luxe II, ACP, 2-Level, 32 mm
711-0234	Trestle Luxe II, ACP, 2-Level, 34 mm
711-0236	Trestle Luxe II, ACP, 2-Level, 36 mm
711-0238	Trestle Luxe II, ACP, 2-Level, 38 mm
711-0240	Trestle Luxe II, ACP, 2-Level, 40 mm
711-0242	Trestle Luxe II, ACP, 2-Level, 42 mm
711-0244	Trestle Luxe II, ACP, 2-Level, 44 mm
711-0246	Trestle Luxe II, ACP, 2-Level, 46 mm
711-0248	Trestle Luxe II, ACP, 2-Level, 48 mm
711-0250	Trestle Luxe II, ACP, 2-Level, 50 mm
711-0252	Trestle Luxe II, ACP, 2-Level, 52 mm
711-0254	Trestle Luxe II, ACP, 2-Level, 54 mm
711-0350	Trestle Luxe II, ACP, 3-Level, 50 mm
711-0352	Trestle Luxe II, ACP, 3-Level, 52 mm
711-0354	Trestle Luxe II, ACP, 3-Level, 54 mm
711-0356	Trestle Luxe II, ACP, 3-Level, 56 mm
711-0358	Trestle Luxe II, ACP, 3-Level, 58 mm
711-0360	Trestle Luxe II, ACP, 3-Level, 60 mm
711-0362	Trestle Luxe II, ACP, 3-Level, 62 mm
711-0364	Trestle Luxe II, ACP, 3-Level, 64 mm
711-0366	Trestle Luxe II, ACP, 3-Level, 66 mm
711-0368	Trestle Luxe II, ACP, 3-Level, 68 mm
711-0466	Trestle Luxe II, ACP, 4-Level, 66 mm
711-0468	Trestle Luxe II, ACP, 4-Level, 68 mm
711-0470	Trestle Luxe II, ACP, 4-Level, 70 mm
711-0474	Trestle Luxe II, ACP, 4-Level, 74 mm
711-0478	Trestle Luxe II, ACP, 4-Level, 78 mm
711-0482	Trestle Luxe II, ACP, 4-Level, 82 mm
711-0486	Trestle Luxe II, ACP, 4-Level, 86 mm
711-0490	Trestle Luxe II, ACP, 4-Level, 90 mm
711-0590	Trestle Luxe II, ACP, 5-Level, 90 mm
711-0595	Trestle Luxe II, ACP, 5-Level, 95 mm
711-05100	Trestle Luxe II, ACP, 5-Level, 100 mm
711-05105	Trestle Luxe II, ACP, 5-Level, 105 mm
711-05110	Trestle Luxe II, ACP, 5-Level, 110 mm

DRILL GUIDES	
713-1005	Intradiscal Drill Guide 5 mm
713-1006	Intradiscal Drill Guide 6 mm
713-1007	Intradiscal Drill Guide 7 mm
713-1008	Intradiscal Drill Guide 8 mm
713-1009	Intradiscal Drill Guide 9 mm

Part Number	Product Description
SCREW OFFERINGS	
722-14010	4.0 mm Variable Angle, Self-Tapping Screw, 10 mm
722-14012	4.0 mm Variable Angle, Self-Tapping Screw, 12 mm
722-14014	4.0 mm Variable Angle, Self-Tapping Screw, 14 mm
722-14016	4.0 mm Variable Angle, Self-Tapping Screw, 16 mm
722-14018	4.0 mm Variable Angle, Self-Tapping Screw, 18 mm
722-14510	4.5 mm Variable Angle, Self-Tapping Screw, 10 mm
722-14512	4.5 mm Variable Angle, Self-Tapping Screw, 12 mm
722-14514	4.5 mm Variable Angle, Self-Tapping Screw, 14 mm
722-14516	4.5 mm Variable Angle, Self-Tapping Screw, 16 mm
722-14518	4.5 mm Variable Angle, Self-Tapping Screw, 18 mm
722-24010	4.0 mm Variable Angle, Self-Drilling Screw, 10 mm
722-24012	4.0 mm Variable Angle, Self-Drilling Screw, 12 mm
722-24014	4.0 mm Variable Angle, Self-Drilling Screw, 14 mm
722-24016	4.0 mm Variable Angle, Self-Drilling Screw, 16 mm
722-34010	4.0 mm Fixed Angle, Self-Tapping Screw, 10 mm
722-34012	4.0 mm Fixed Angle, Self-Tapping Screw, 12 mm
722-34014	4.0 mm Fixed Angle, Self-Tapping Screw, 14 mm
722-34016	4.0 mm Fixed Angle, Self-Tapping Screw, 16 mm
722-34018	4.0 mm Fixed Angle, Self-Tapping Screw, 18 mm
722-34510	4.5 mm Fixed Angle, Self-Tapping Screw, 10 mm
722-34512	4.5 mm Fixed Angle, Self-Tapping Screw, 12 mm
722-34514	4.5 mm Fixed Angle, Self-Tapping Screw, 14 mm
722-34516	4.5 mm Fixed Angle, Self-Tapping Screw, 16 mm
722-34518	4.5 mm Fixed Angle, Self-Tapping Screw, 18 mm
722-44010	4.0 mm Fixed Angle, Self-Drilling Screw, 10 mm
722-44012	4.0 mm Fixed Angle, Self-Drilling Screw, 12 mm
722-44014	4.0 mm Fixed Angle, Self-Drilling Screw, 14 mm
722-44016	4.0 mm Fixed Angle, Self-Drilling Screw, 16 mm
713-0013	Midline Temporary Prefixation Pin

INSTRUMENT OFFERINGS	
713-0018	Hexalobe Screw Removal Tool
713-0019	Inner Shaft, Hexalobe Screw Removal Tool
71732	Temporary Fixation Pin Inserter
713-0003	Double Barrel DTS
713-0006	Variable Angle Drill Guide
713-0007	Fixed Angle Drill Guide
713-2010	Fixed 2.3 mm Drill Bit, 10 mm
713-2012	Fixed 2.3 mm Drill Bit, 12 mm
713-2014	Fixed 2.3 mm Drill Bit, 14 mm
713-2016	Fixed 2.3 mm Drill Bit, 16 mm
713-0005	4.0 mm Tap, 10 mm
713-0014	Slide Alignment Tool
713-0004	Plate Holder
713-0012	Parallel Screwdriver
713-0011	Twisted Hexalobe Driver
71734	Self-Retaining Screwdriver
713-0010	Self-Constrained Awl
86001-0120	Silicone Handle, Axial, Small, AO QC Modular, Spin Cap, Non-Cannulated
61743	Plate Bender
713-0008	Awl, Drill Guide

TRESTLE LUXE® AND LUXE II ANTERIOR CERVICAL PLATING SYSTEM
INSTRUCTIONS FOR USE

GENERAL INFORMATION:
The TRESTLE LUXE and LUXE II Anterior Cervical Plating System is a temporary device used to stabilize the cervical spine during bone fusion development. Device implants include a range of plate sizes and bone screws to provide the versatility required for the specific indications noted. Fixation is achieved by means of a rigid plate that is surgically attached to the spine with bone screws. Implant plates are manufactured from surgical grade titanium alloy (ASTM F136) and Nitinol (ASTM F2063) and the bone screws are manufactured from surgical grade titanium alloy (ASTM F136). All device components are intended for fixation/attachment to the anterior cervical spine only. It is intended that the implants be removed after successful fusion.

INDICATIONS FOR USE:
It is intended that this device, in any system configuration, be removed after the development of solid fusion mass of spinal segments in skeletally mature patients.
The Trestle Luxe and Luxe II Anterior Cervical Plating system is intended for use in anterior cervical decompression and fusion (ACDF) surgery (C2-C7). The system is indicated for use in the temporary stabilization of the anterior spine during the development of fusion in patients with the following conditions:

- degenerative disc disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies)
- spondylolisthesis
- trauma (i.e., fracture or dislocation)
- spinal stenosis
- pseudoarthrosis
- tumor
- and failed previous fusion.

CONTRAINDICATIONS:
The TRESTLE LUXE and LUXE II Anterior Cervical Plating System 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 probable intolerances to nitinol or its components (such as chromium, cobalt, copper, nickel, niobium, or titanium)
5. Patients with deficient soft tissue at the wound site or inadequate bone stock or quality.
6. Patients with morbid obesity or gross distorted anatomy due to congenital abnormalities.
7. Pregnant patients or patients with mental illness or other medical conditions which would prohibit beneficial surgical outcome.
8. Patients resistant to following post-operative restrictions on movement.
9. Use with components from other systems.
10. Use with bone cement.
11. Reuse or multiple uses.

WARNINGS/CAUTIONS:

1. The TRESTLE LUXE and LUXE II Anterior Cervical Plating System is an implant device used only to provide temporary 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.
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. Do not place the anvil portion of the plate bender over the blocking slide as damage can occur and affect its function.
11. Excessive convergent and divergent hole patterns may prohibit proper seating of bone screws.

MRI SAFETY INFORMATION:
The TRESTLE LUXE and LUXE II Anterior Cervical Plating System 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 TRESTLE LUXE and LUXE II Anterior Cervical Plating System 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 TRESTLE LUXE and LUXE II Anterior Cervical Plating System 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 TRESTLE LUXE II components are not compatible with the original TRESTLE LUXE components.
9. The implants and instruments are provided non-sterile and must be cleaned and sterilized before use.

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. TRESTLE LUXE and LUXE II anterior cervical plates are contoured to closely match the anatomical configuration of the spine. If the plate cannot be fitted and additional contouring is necessary, it is recommended that such contouring be minimal and be performed with the instrumentation provided. The plate must not be contoured in proximity of bone screw pockets or screw retention mechanism.
3. When contouring the plate, great care should be taken not to scratch, notch or dent the surface as such deformities may compromise the strength of the implant.
4. 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.
5. 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.
6. Drills are single use instruments and should be discarded after use.

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. The TRESTLE LUXE and LUXE II Anterior Cervical Plating System implants are designed and intended as temporary fixation devices. The devices should be removed after complete healing has occurred. Devices which are not removed after serving their intended purpose may bend, dislocate, or break and/or cause corrosion, localized tissue reaction, pain, infection, and/or bone loss due to stress shielding. Complete postoperative management to maintain the desired result should also follow implant removal surgery.
8. Retrieved implants should be properly disposed of and are not to be reused under any circumstance.

Excerpt from INS-116

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

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

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TRESTLE LUXE® AND LUXE II ANTERIOR CERVICAL PLATING SYSTEM
INSTRUCTIONS FOR USE (International)

GENERAL INFORMATION:
The TRESTLE LUXE and LUXE II Anterior Cervical Plating System is a temporary device used to stabilize the cervical spine during bone fusion development. Device implants include a range of plate sizes and bone screws to provide the versatility required for the specific indications noted. Fixation is achieved by means of a rigid plate that is surgically attached to the spine with bone screws. Implant plates are manufactured from surgical grade titanium alloy (ASTM F136) and Nitinol (ASTM F2063) and the bone screws are manufactured from surgical grade titanium alloy (ASTM F136). All device components are intended for fixation/attachment to the anterior cervical spine only. It is intended that the implants be removed after successful fusion.

INDICATIONS FOR USE:
It is intended that this device, in any system configuration, be removed after the development of solid fusion mass of spinal segments in skeletally mature patients.
The Trestle Luxe and Luxe II Anterior Cervical Plating system is intended for use in anterior cervical decompression and fusion (ACDF) surgery (C2-C7). The system is indicated for use in the temporary stabilization of the anterior spine during the development of fusion in patients with the following conditions:

- degenerative disc disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies)
- spondylolisthesis
- trauma (i.e., fracture or dislocation)
- spinal stenosis
- pseudoarthrosis
- tumor
- and failed previous fusion.

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Excerpt from INS-116-01

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