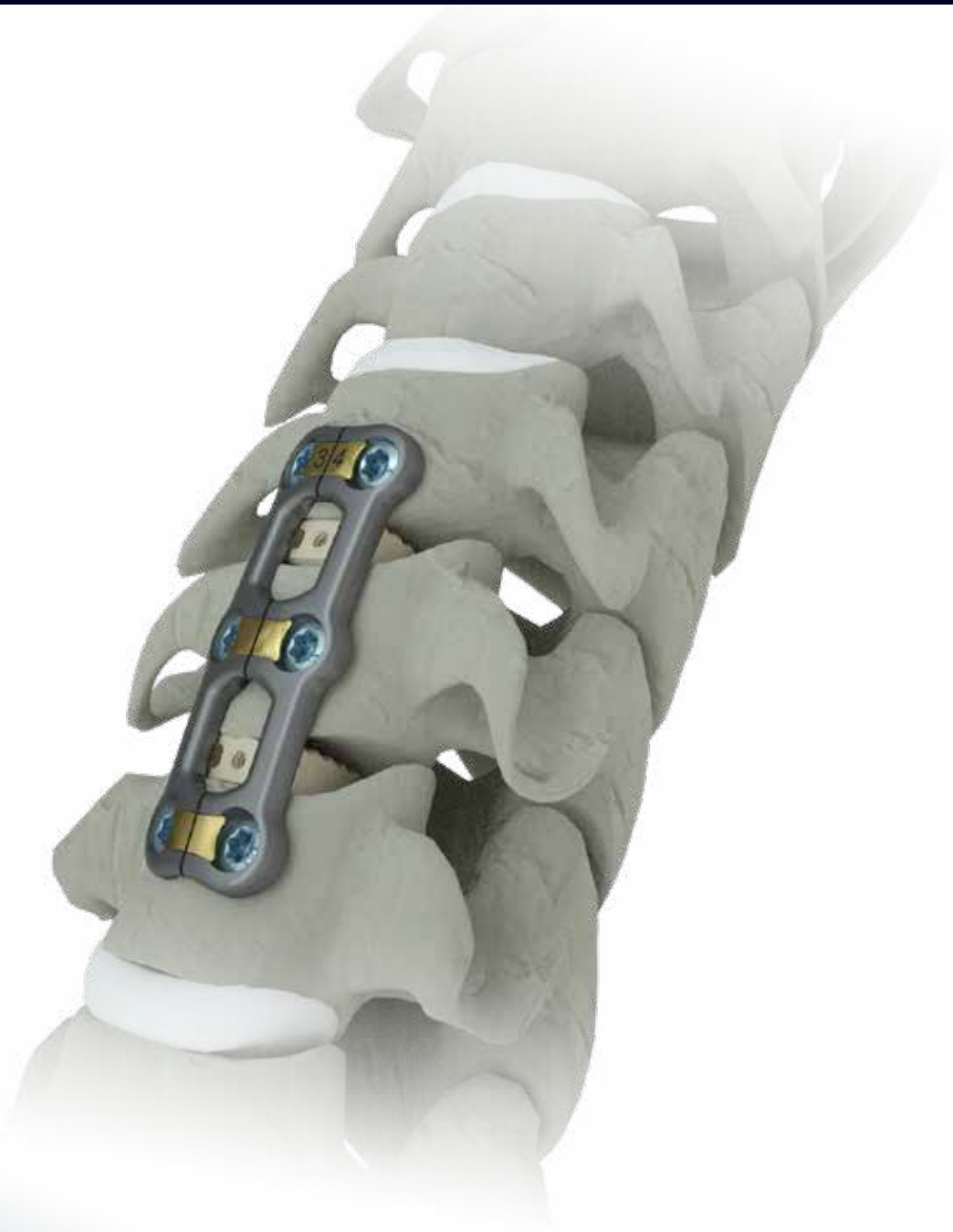
Trestle Luxe®

Anterior Cervical Plating System



Alphatec Spine®

CERVICAL | Surgical Technique Guide

SYSTEM FEATURES

Low-profile plate construct
Screws and blocking plates fit flush within the plate maintaining a low profile design and minimizing soft tissue irritation

Proprietary zero-step locking mechanism
Facilitates implantation and minimizes operative time

Large graft window
Provides optimal graft visualization

ELEVATING A PROVEN DESIGN

The Trestle Luxe Anterior Cervical Plating System is a unique, easy to use system with a zero-step locking mechanism, and one of the market's lowest-profile plates. Based upon a proven design, the Trestle Luxe system offers an elevated implant design with market-leading features and state-of-the-art instruments.

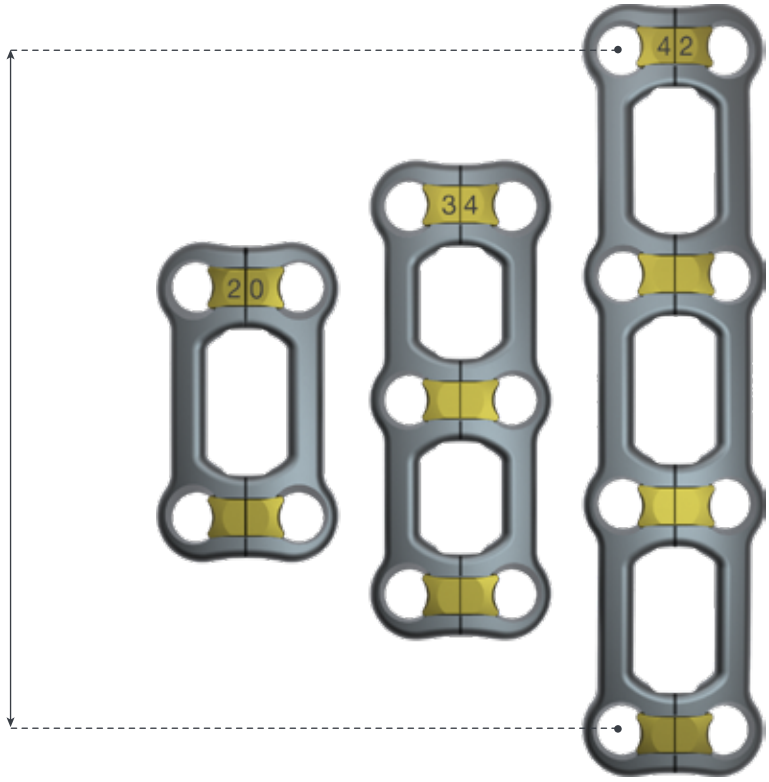
CONTENTS

SELECT PLATE

Select the appropriately sized plate. Plate sizes are shown on the superior blocking slide. Refer to page 16 implants for plate and screw sizes.

42MM

Plate length measured center hole to center hole.



POSITION PLATE

Use the plate holder to position the plate into the operative site for placement and sizing verification.

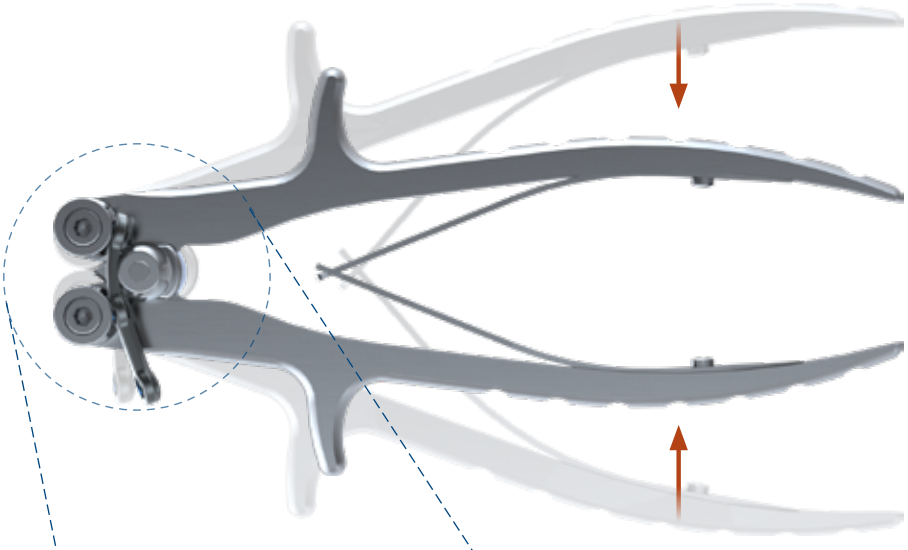
NOTE: Plate holder may be placed at any level.

CONTOUR PLATE (OPTIONAL)

The Trestle Luxe plate is precountoured with 6° of lordosis. Should additional contouring be required, the plate can be contoured to the desired degree of lordosis or kyphosis utilizing the Plate Bender.

Insert the Trestle Luxe 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 outer edge working inward helps ensure an even contour of the plate.



NOTE: When contouring the plate, care should be taken not to scratch, notch or dent the surface of the plate or the Blocking Slide, as the implant strength may be compromised.

Plates 28mm or shorter should not be contoured.

Plate holder may be placed at any level.

In longer plate lengths, care should be taken to not bend the blocking slide. Incremenatally place bends as opposed to one big bend to prevent plate kicking

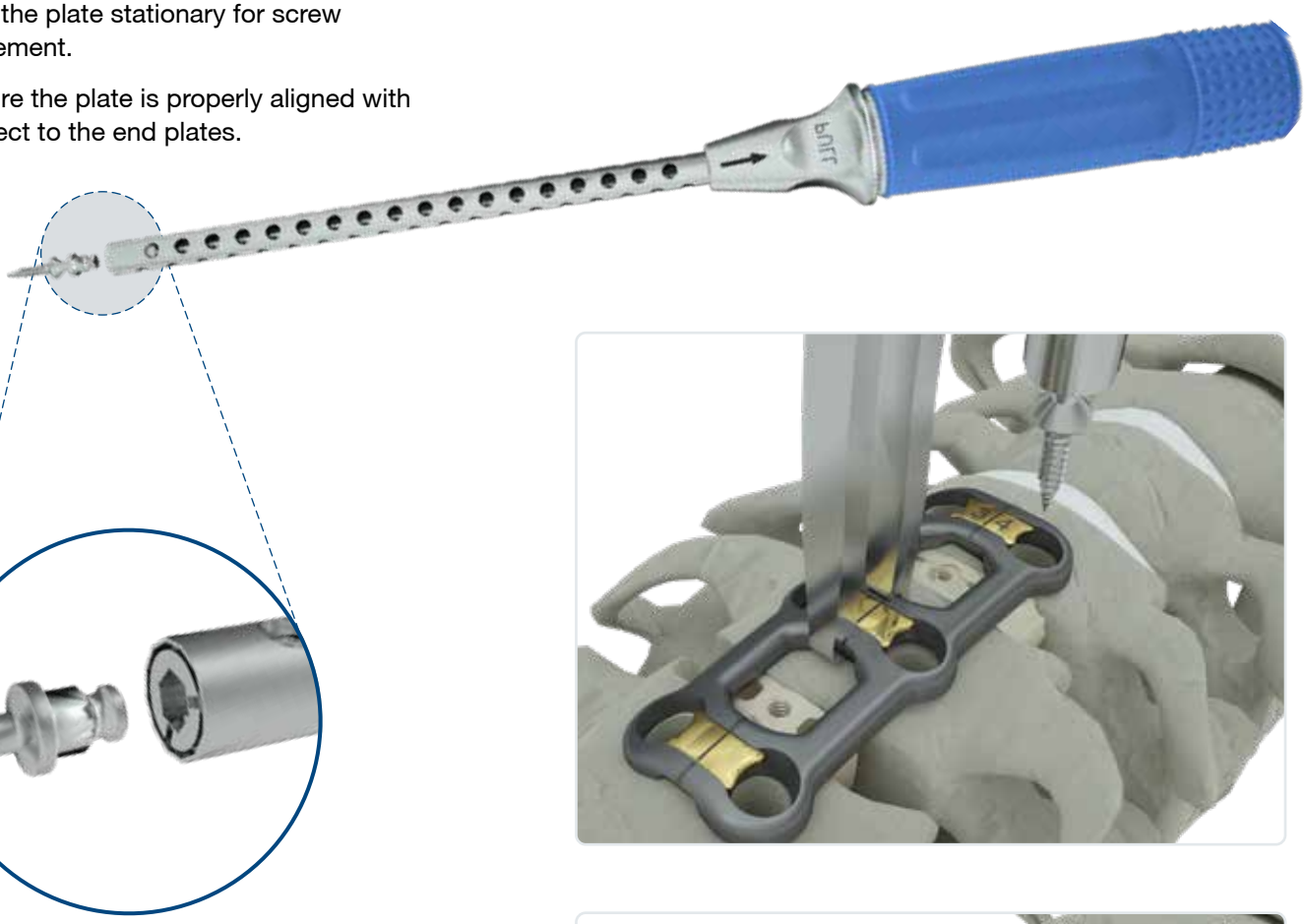
• **CAUTION:** *Do not place the anvil portion of the Plate Bender over the Blocking Slide as damage can occur and affect its function.*

Option 1: Self-Drilling Screws

TEMPORARY FIXATION OF PLATE

Use the Temporary Fixation Pins to hold the plate stationary for screw placement.

Ensure the plate is properly aligned with respect to the end plates.



Load the Temporary Fixation Pins onto the Temporary Fixation Pin Inserter by pulling on the collar of the Temporary Fixation Pin Inserter.

Advance the Temporary Fixation Pin until it is fully seated in the plate.

NOTE: The screw cannot be placed next to the temporary fixation pin.

CREATE SCREW HOLE

When using self-drilling screws, insert the Self Constrained Awl into the screw hole and push down on the Awl handle to break the cortex. Remove the Self Constrained Awl by pulling straight up on the instrument.

NOTE: The surgeon must take great care to properly position bone screw holes when using the Self Constrained Awl. Excessively converging hole patterns and hole patterns angled beyond 9° may prohibit proper seating of the bone screws.

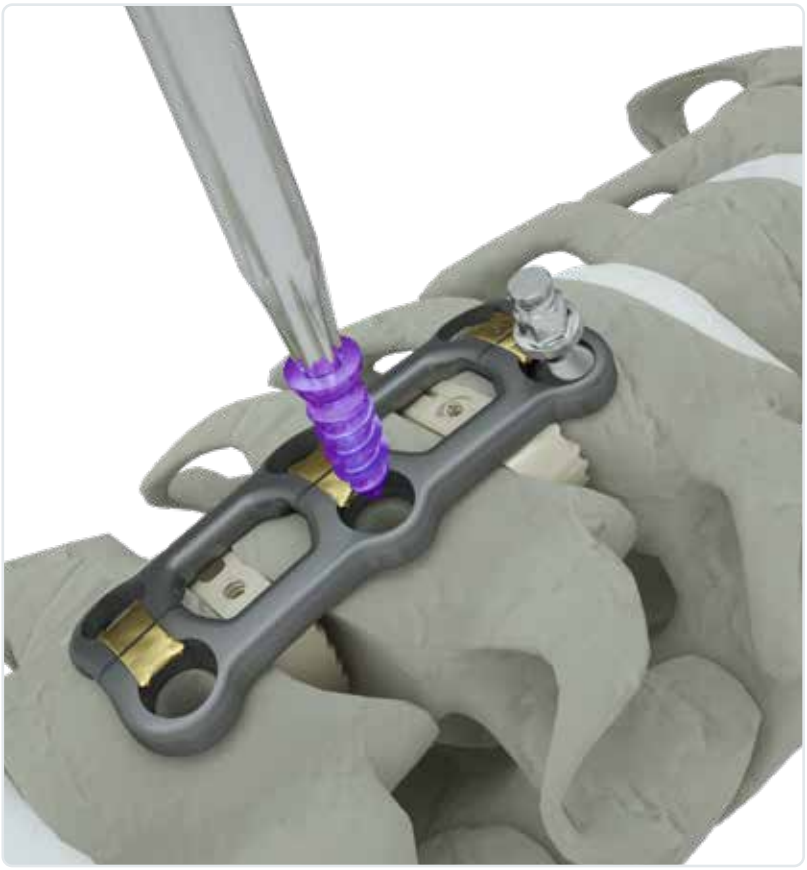
Self Constrained Awl is variable angle up to 9°. For fixed screw placement, use the Fixed Drill Guide with the Fixed Awl and attach the Axial Handle.

SCREW INSERTION

Load the appropriate length self-drilling screw onto the screwdriver. Advance the screw until the head of the screw is fully seated into the plate and the laser marks on the blocking slide and plate are aligned.

NOTE: Do not use Screwdriver to remove screw from plate. Use the Removal Tool.

NOTE: It is not recommended to place a screw lateral to the Temporary Fixation Pin.



Option 2: Drill Guide Insertion Technique

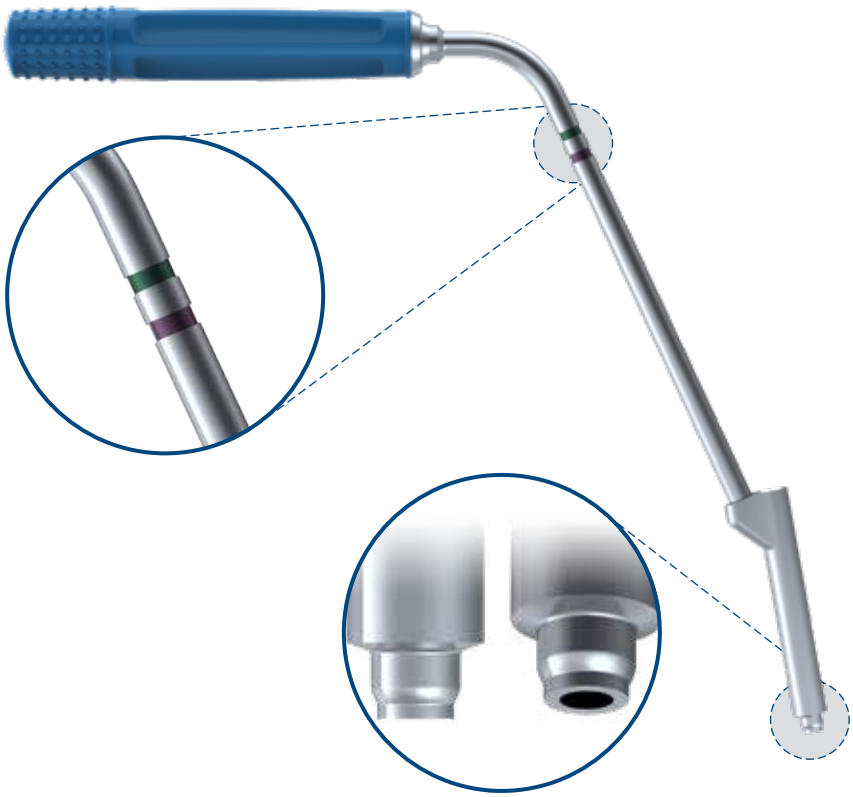
SELECT DRILL GUIDE

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: Only the Awls and Drills can be used with the Drill Guides.



INSERT DRILL GUIDE

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

NOTE: The Blocking Slide on the plate will translate out of the way as the Drill Guide is placed in the hole. The Blocking Slide will have slight press against the Drill Guide.

Option 2: Drill Guide Insertion Technique

CREATE SCREW HOLE

Using the Axial Handle, connect it to the Awl. Place the Awl through the Drill Guide and lightly tap through the cortical surface of the vertebral body to create a pilot hole.

NOTE: The surgeon must take great care to properly position bone screw holes when using the Variable Angle Drill Guide. Excessively converging hole patterns may prohibit proper seating of the bone screws. Hole patterns angled beyond 9° may prohibit proper seating of the bone screws.

DRILL HOLE

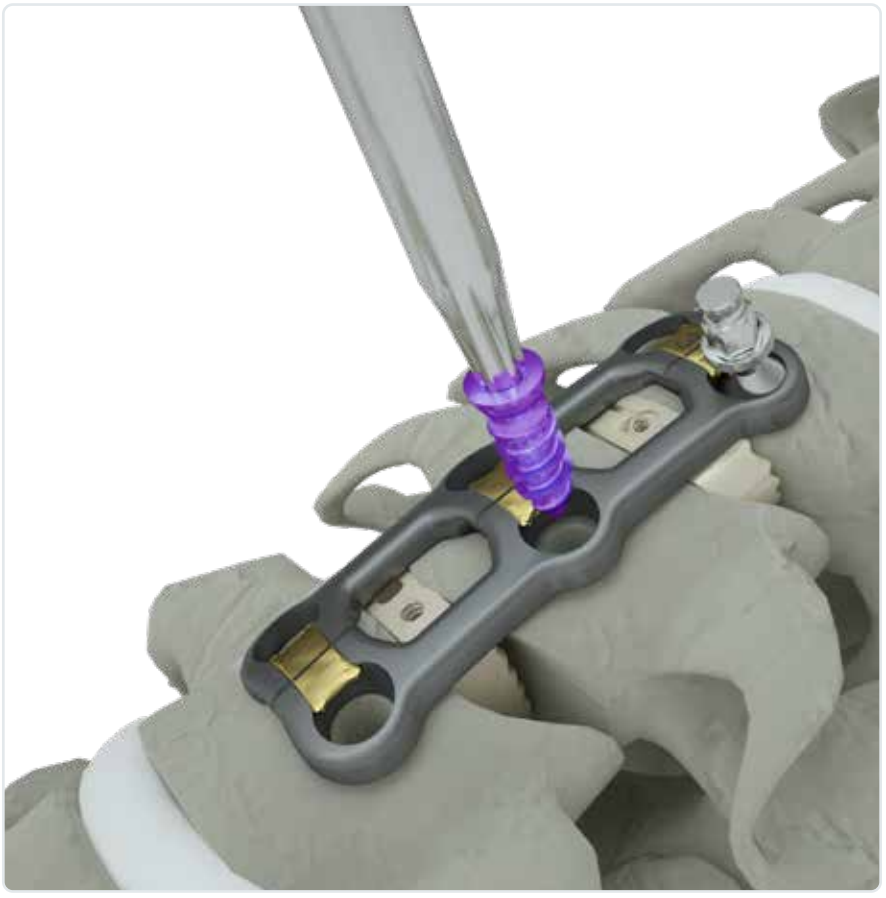
Select the appropriate length Drill Bit with stop and attach it to the Quick Connect Handle. Insert the Drill Bit into the Drill Guide and rotate the Handle in a clockwise direction to create the pilot hole for the screw. The depth stop will limit the drilling depth by contacting the Drill Guide.

REMOVE DRILL GUIDE

Once the hole has been created, remove the Drill Guide by pulling up to disengage it from the plate.

SCREW INSERTION

Connect the Screw Driver to the Quick Connect Handle. Load the appropriate length self-tapping screw onto the screwdriver. Advance the screw until the head of the screw is fully seated into the plate and the blocking slide is positioned over the head of the screw.



Option 3: Drill Guide Insertion Technique

SELECT DTS GUIDE

Select the Single or Double Barrel DTS (Drill, Tap, Screw) Guide

GUIDE POSITIONING

Position the DTS Guide over the blocking slide so that the barrel(s) align with the screw holes of the plate.

SET BARREL ANGLE

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

NOTE: Do not angulate the handle as the instrument can detach from the plate and affect the angulation and screw insertion.

CREATE SCREW HOLE

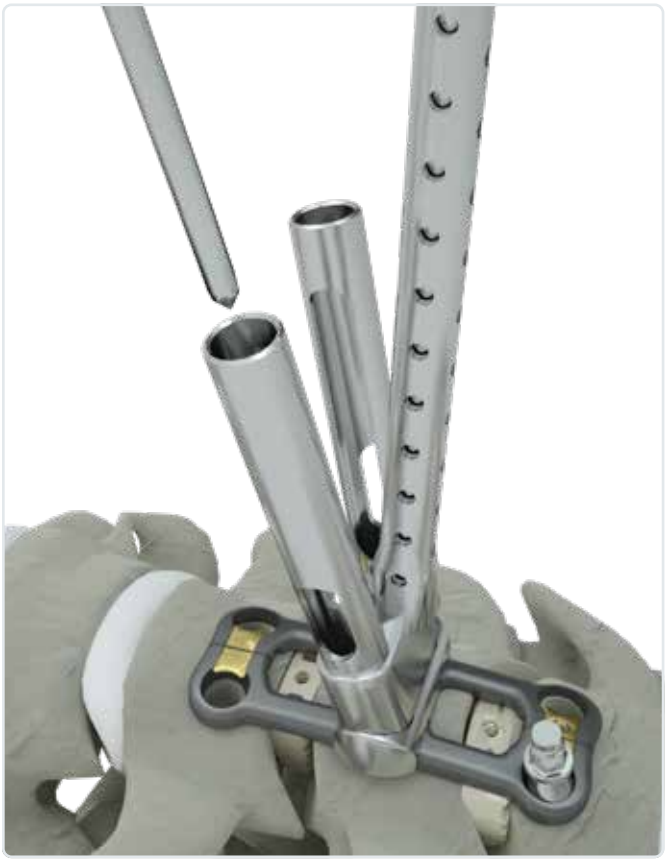
Place the Awl through the DTS Guide and lightly tap through the cortical surface of the vertebral body to create a pilot hole.

SET GUIDE ANGLE

To adjust the screw angle, loosen the gold knob and move the tube(s) to the desierd position.

NOTE: The DTS Guide does not lock to the plate, it only locks the angle.

Double Barrel DTS Guide



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.

NOTE: The surgeon must take great care to properly position bone screw holes when using the DTS Guide. Excessively converging hole patterns may prohibit proper seating of the bone screws. Hole patterns angled beyond 9° may prohibit proper seating of the bone screws.

TAP FOR SCREW

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

SCREW INSERTION

Connect Screwdriver to Quick Connect Handle. Load the appropriate length self-drilling or self-tapping screw onto the Screwdriver. Advance the screw until it is fully seated into the plate and the blocking slide is positioned over the head of the screw. Confirm the laser marks on the slide and plate are aligned.

NOTE: When the laser mark line on the shaft of the screw driver is fully inside the barrel of the DTS, the screw is approaching its fixed position in the plate.

VERIFY ALIGNMENT

Ensure that the screws are fully seated and underneath the blocking slide with the vertical line on the blocking slide in direct alignment with the vertical lines on the plate.

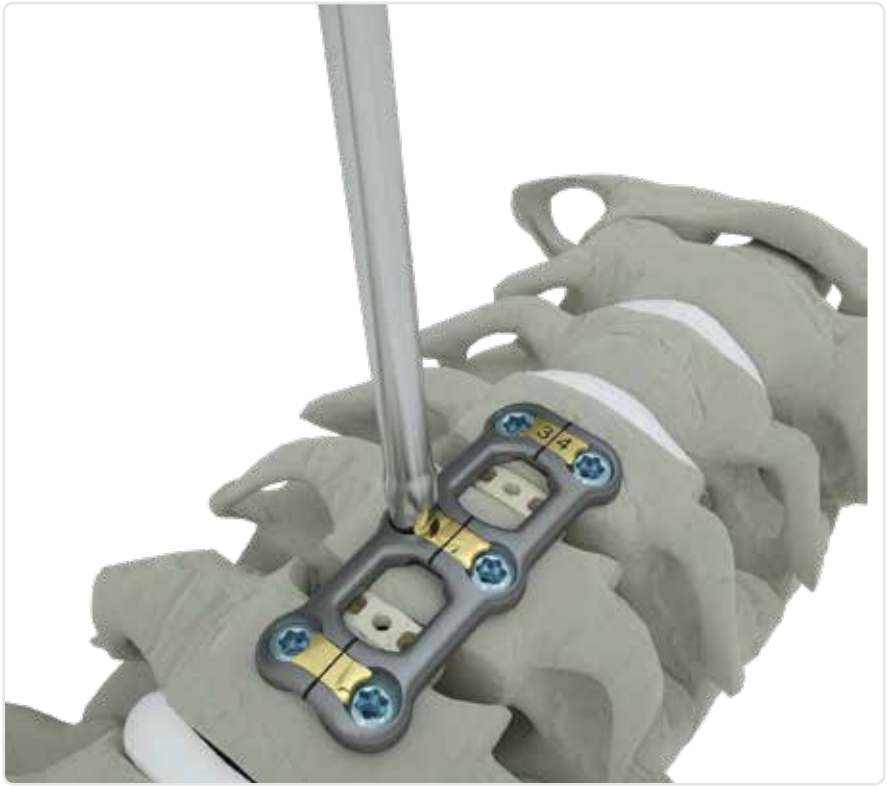
Aligned

Not Aligned

REPOSITION BLOCKING SLIDE

To re-position the blocking slide, place the Slider Alignment Tool in a vertical orientation over the screw head.

Manually rotate the alignment tool until the vertical line on the blocking slide is in direct alignment with the vertical lines on the plate.

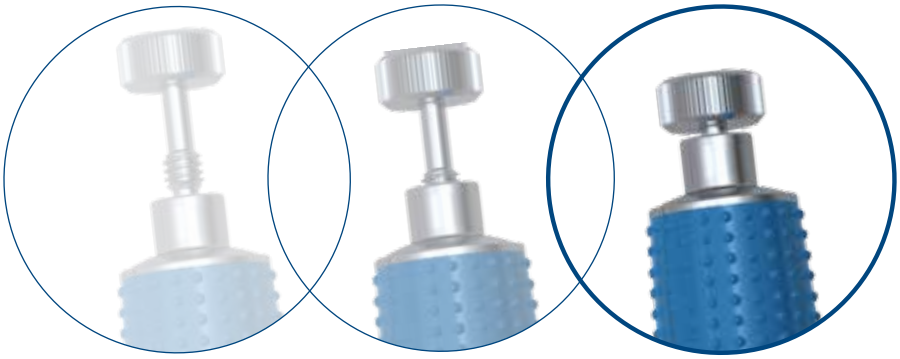


INSPECT PLATE POSITION

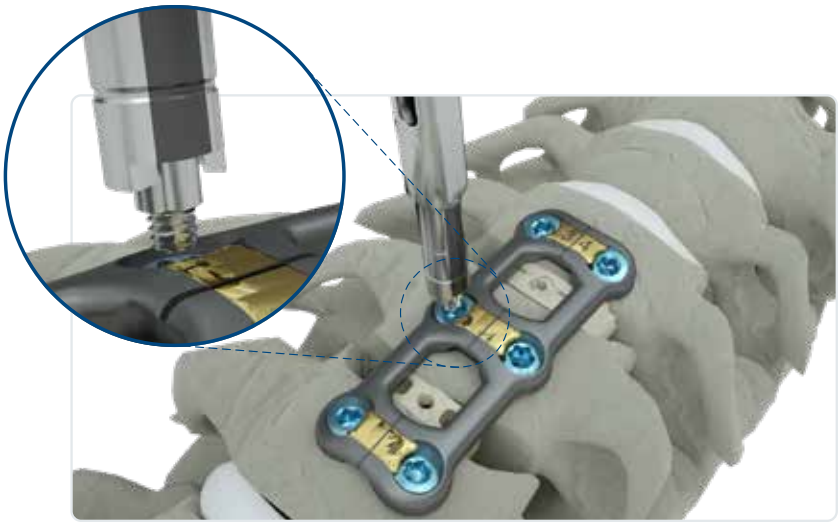
Check the final position of the plate and screws both visually and radiographically.

SCREW REMOVAL

Pre-assemble Screw Removal Tool and inner shaft prior to placement. Insert the tip of the Removal Tool into the head of the desired screw.

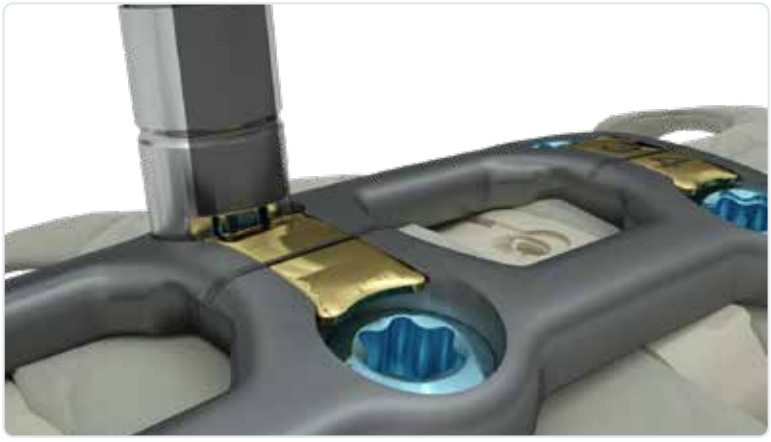


NOTE: The tip of the screw removal tool is designed to unlock the self locking mechanism. The opening on the distal tip, the laser mark on the shaft, and the gold collar on the removal tool must be facing the blocking slide mechanism as illustrated.

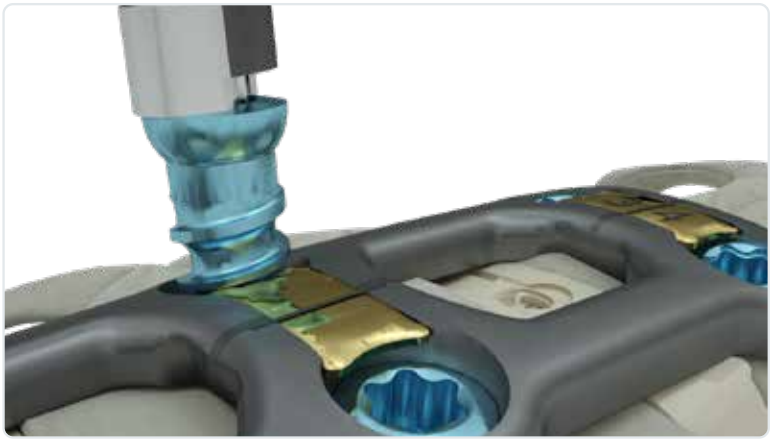


Ensure the tip is fully seated within the screw head. Thread the inner shaft into the screw's internal threads capturing the screw.

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



Removal Tool



Trestle Luxe Plate Dimensions

Available in sizes 10mm - 100mm

Plates		Length*										
Level	I	10	12	14	16	18	20	22	24	26		
	II	24	26	28	30	32	34	37	40	43	46	
	III	39	42	45	48	51	54	57	60	63	66	69
	IV	60	64	68	72	76	80	84				
	V	85	90	95	100							

Included in set Optional

***Note:** Plate length is measured from most superior hole center to most inferior hole center (add 8mm for edge to edge)

Trestle Luxe Screw Dimensions

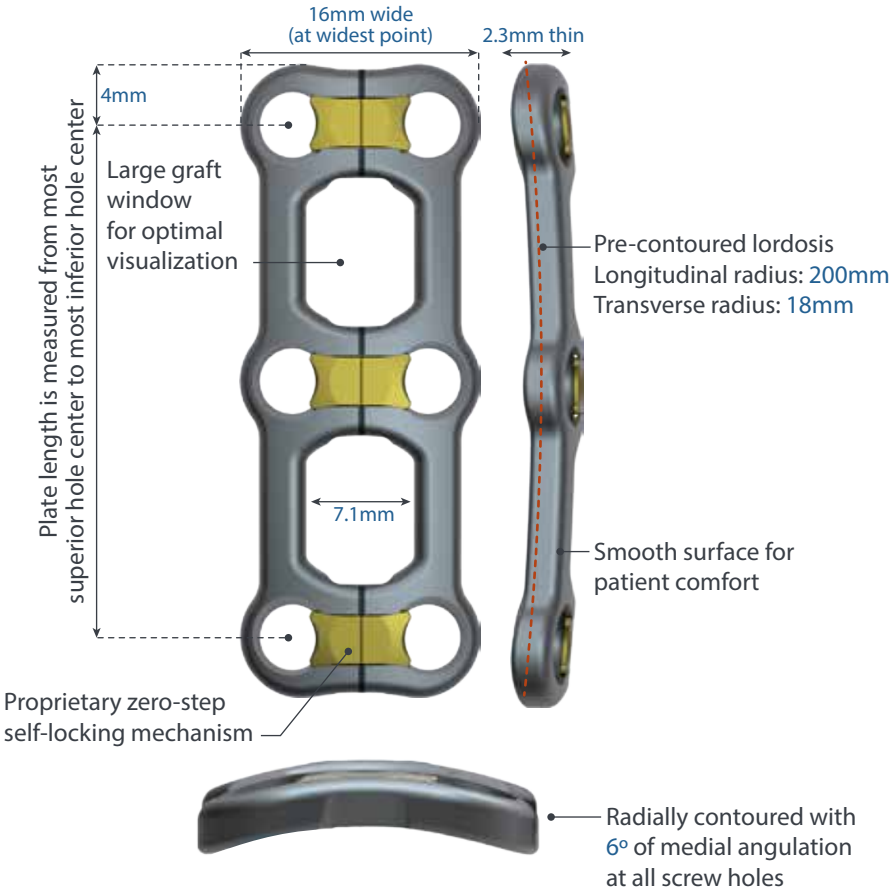
Fixed and variable angle

Screws		Length*											
Diameter	Self-Tapping												
	4.0	10	11	12	13	14	15	16	17	18	20	22	
	4.5	10	11	12	13	14	15	16	17	18	20	22	24
	Self-Drilling												
	4.0	10	11	12	13	14	15	16	17	18	20		

Included in set Optional

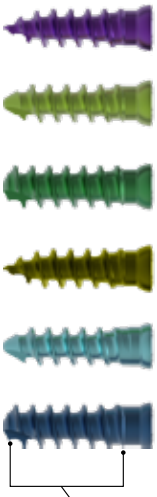
***Note:** Amount of purchase below plate

PLATE SPECIFICATIONS



Radially contoured with 6º of medial angulation at all screw holes

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

· Measurement starts from bottom of screw head to distal tip

Zero-profile (blocking slide covers screw heads)

Precision hexalobe drive feature

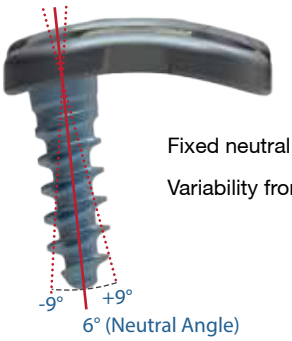
Thread pitch: 1.75mm

Ti-6Al-4V ELI

Inner threads in the screw head for screw removal tool attachment

ANGULATION

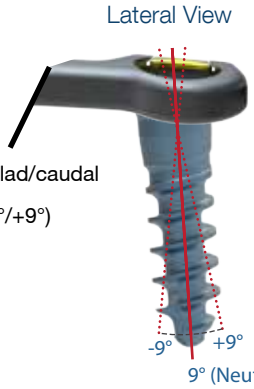
Axial View



Fixed neutral position 6° medial/lateral

Variability from neutral: 18° (-9°/+9°)

Lateral View



Fixed neutral position 9° cephalad/caudal

Variability from neutral: 18° (-9°/+9°)

Hexalobe Screwdriver

Awl for Drill Guide and DTS

Drill for Drill Guide and DTS

Tap for Drill Guide and DTS

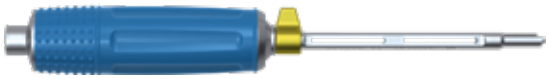
Slider Alignment Tool

Self Constrained Awl

Temporary Fixation Pin

Plate Holder

Removal Tool



Inner Shaft, Removal Tool

Plate Bender

Single Barrel DTS Guide

Double Barrel DTS Guide

Variable Angle Drill Guide

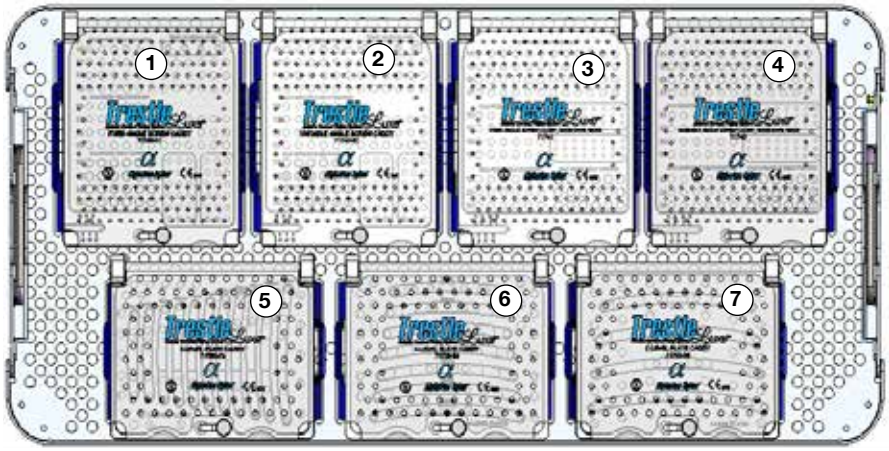
Fixed Angle Drill Guide

Quick-Connect Handle

Temporary Fixation Pin Inserter

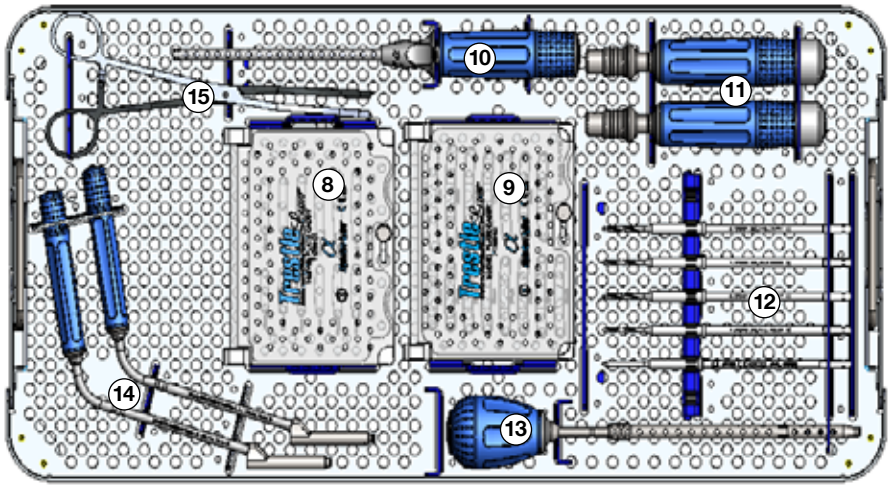
TRAY 1

1. **Fixed Angle Hexalobe Screw Caddy**
   Screw lengths 10mm - 16mm, 2mm increments
   4 fixation pins
2. **Variable Angle Hexalobe Screw Caddy**
   Screw lengths 10mm - 16mm, 2mm increments
   4 fixation pins
3. **3 level plate caddy**
   Sizes 39mm - 69mm
4. **4 level plate caddy**
   Sizes 60mm – 84mm
5. **5 level plate caddy**
   Sizes 85mm – 100mm
6. **Additional Sizes Fixed Angle Screw Caddy**
7. **Additional Sizes Variable Angle Screw Caddy**



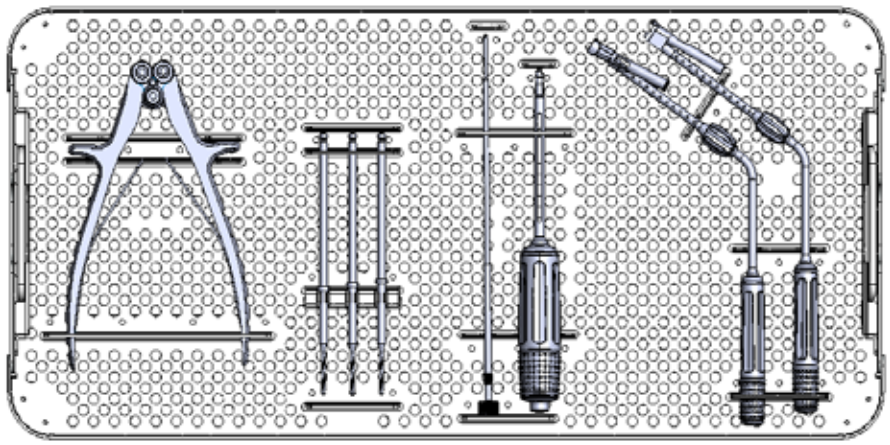
TRAY 2

8. **1 level plate caddy:**
   Sizes 10mm – 26mm
9. **2 level plate caddy:**
   Sizes 24mm – 46mm
10. **Temporary Fixation Pin Inserter**
11. **Axial Spin Cap Handle**
12. **Awl, For Drill Guide**
    Hexalobe Screwdriver
    Fixed 2.3mm Drill Bit, 10mm
    Fixed 2.3mm Drill Bit, 12mm
    Fixed 2.3mm Drill Bit, 14mm
    Fixed 2.3mm Drill Bit, 16mm
    4.0mm Tap, 10mm
    Slide Alignment Tool
13. **Self Constrained Awl**
14. **Variable Angle Drill Guide**
    Fixed Angle Drill Guide
15. **Plate Holder**



TRAY 3

16. **Hexalobe Screw Removal Tool**
17. **Inner Shaft, Hexalobe Screw Removal Tool**
18. **Single Barrel DTS**
19. **Double Barrel DTS**
20. **Parallel Screwdriver and Optional Instruments**
21. **Plate Bender**



TRESTLE LUXE® AND LUXE II ANTERIOR CERVICAL PLATING SYSTEM

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.**

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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.

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.
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Excerpt from INS-116-01

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