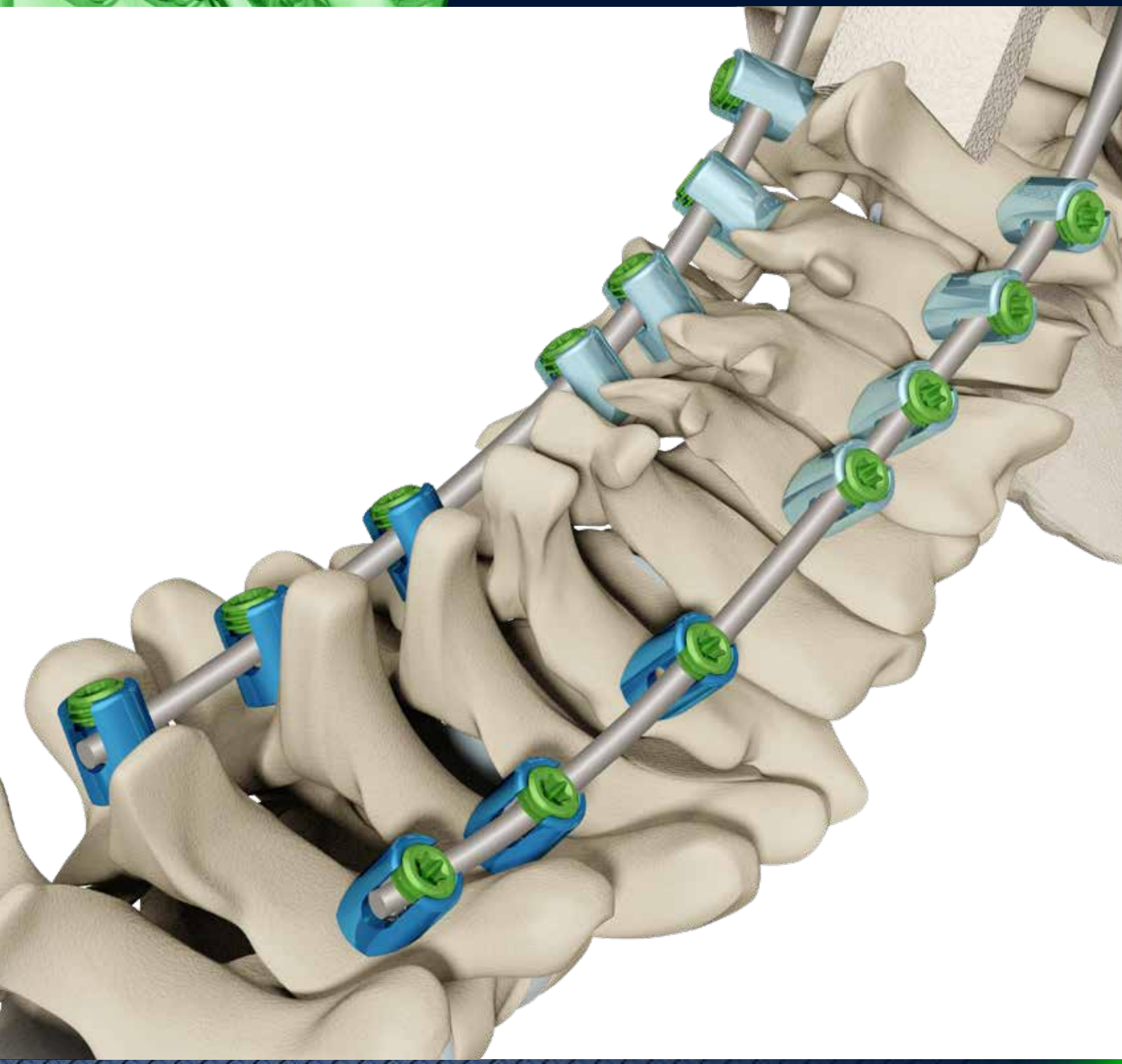
Solanas®

Posterior Cervico-Thoracic Fixation System

POSTERIOR APPROACH | Surgical Technique Guide



PREFACE

SOLANAS® Posterior Cervico-Thoracic Fixation System is designed to improve the stability of the cervical, cervico-thoracic and upper thoracic spine from C1-T3.

This low profile, titanium alloy (Ti6Al-4V ELI (UNS R5640i), ASTM F136) and colbalt chrome (Co-28 Cr-6Mo ASTM F1537)* system is both simple and versatile in its application facilitating:

- Anatomic screw placement
- Secure posterior rod fixation
- Integrated functioning of screws, rods, hooks, and connectors

The components in the SOLANAS® Posterior Cervico-Thoracic Fixation System can be linked to components in the ZODIAC® Polyaxial Spinal Fixation System, or the Arsenal® Spinal Fixation System, and the Invictus™ Spinal Fixation System offered by Alphatec Spine using the axial rod connectors, parallel rod connectors, or transitional rods.

The SOLANAS® Posterior Cervico-Thoracic Fixation System can be used with Alphatec's Adjustable Bridge System and the Avalon® Occipital Fixation System.

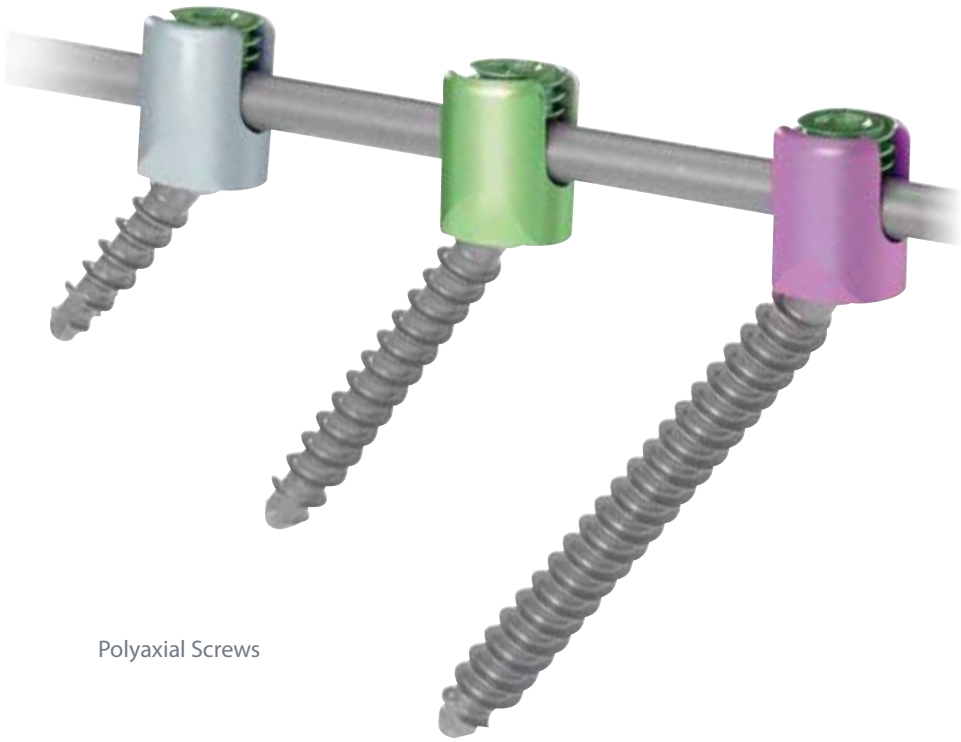
CONTENTS

*Co-28 Cr-6Mo, Available in U.S. only

POLYAXIAL SCREWS

Top loading polyaxial screws are available with diameters of 3.5 mm, 4.0 mm, and 4.35 mm. The System also features 3.5 mm diameter smooth shank screws.

A polyaxial screw allows up to 80˚ of variability in the sagittal plane and up to 56˚ of variability in the axial plane.



Polyaxial Screws

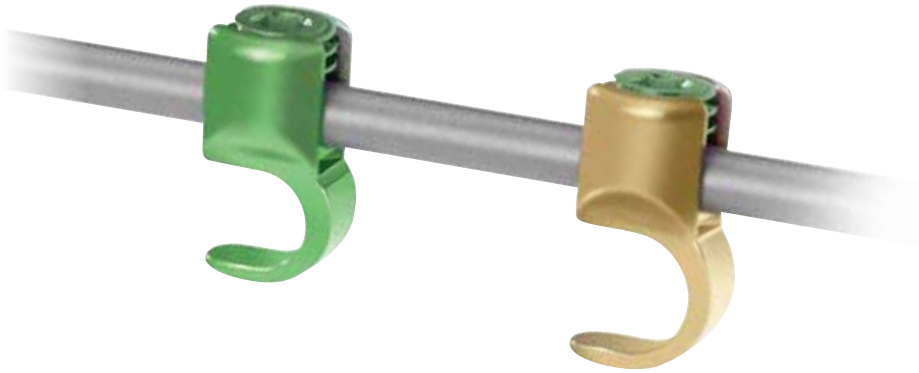
SET SCREWS

The precision-machined size and pitch of the set screw threads are designed to assure quick insertion while minimizing the potential of cross threading.

Set Screw

LAMINAR HOOKS

Top loading laminar hooks are designed to provide stabilization in the cervical spine with throat depths of 5 mm and 6 mm.



Hooks

RODS AND CONNECTORS

The rods are available in surgical grade titanium alloy (Ti-6Al-4V ELI) and cobalt chrome (Co-28Cr-6Mo). Rods are manufactured in lengths of 120 mm & 240 mm with a diameter of 3.3 mm.

Open and closed Lateral Connectors may be used as extensions from the rod.

Parallel and Axial Rod-to-Rod Connectors offer additional system variability by adjoining the 3.3 mm SOLANAS rod with the 5.5 mm rod of the ZODIAC System.

Ti 6Al-4V Rod Lengths:

- 3.3 mm x 120 mm
- 3.3 mm x 240 mm
- 3.3-5.5 mm x 500 mm

CoCr Rod Lengths:

- 3.3 mm x 120 mm
- 3.3 mm x 240 mm

Lateral Connector

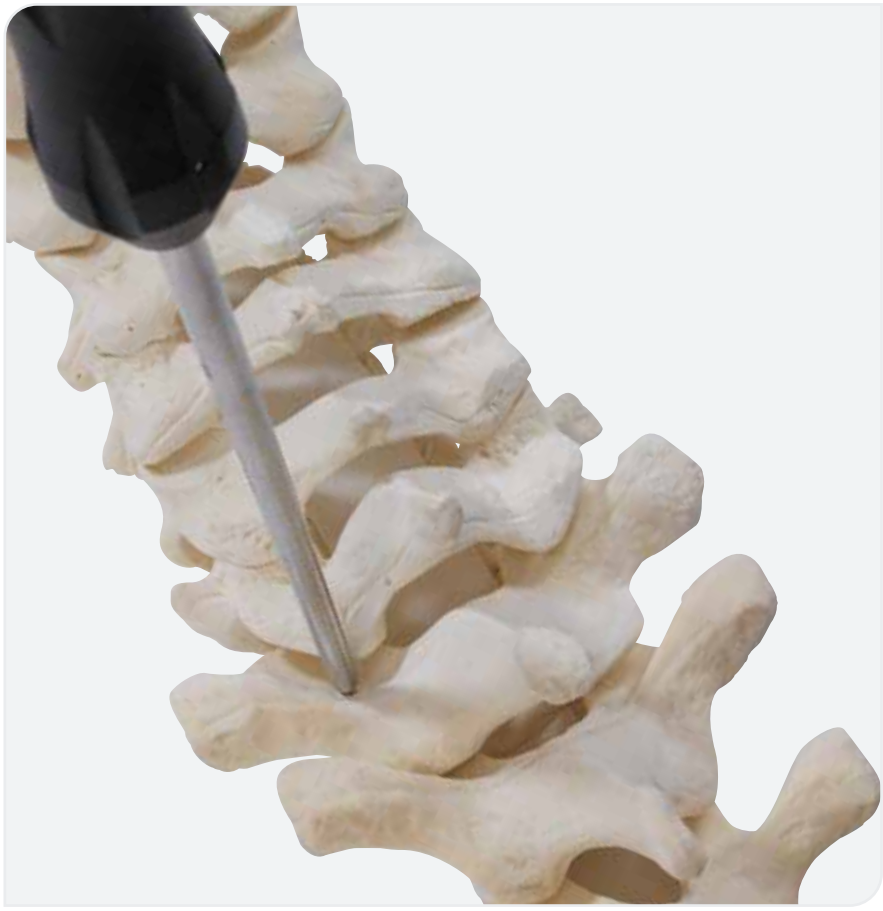
Axial Connector

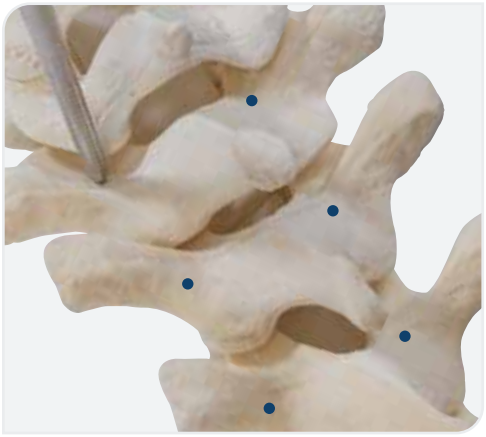
Parallel Connector

Place patient in the prone position avoiding pressure points. An image intensifier or radiograph should be utilized to verify level(s) of fusion. A midline incision is made and exposure should include the lateral masses, facet joints, and transverse processes of the cervico-thoracic spine.

CREATE PILOT HOLE

Identify the entry point and penetrate the cortex with the Thoracic Screw Bone Awl. A small Pedicle Probe may be used to penetrate the cortical wall.





TIP: Minimize need for rod contouring and to facilitate rod insertion, align the screw hole entry points as close to linear as possible with regard to patient anatomy.

DRILL PILOT HOLE

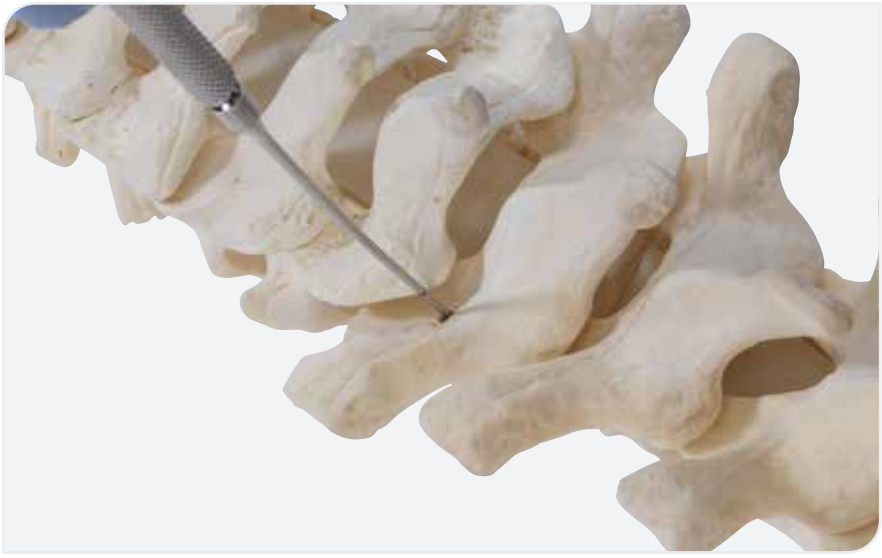
Attach either a fixed length drill (color coded 8 mm-18 mm in 2 mm increments) or adjustable drill (20 mm-50 mm), as shown, with the Universal Thoracic Handle and slide through the Drill Guide.

The adjustable stop can be set to a pre-determined depth. Depress the drill stop button to slide it along the drill shaft with drill length indicated by the largest number visible below the stop. Advance the drill to the desired depth and trajectory.

Fixed Drills Available

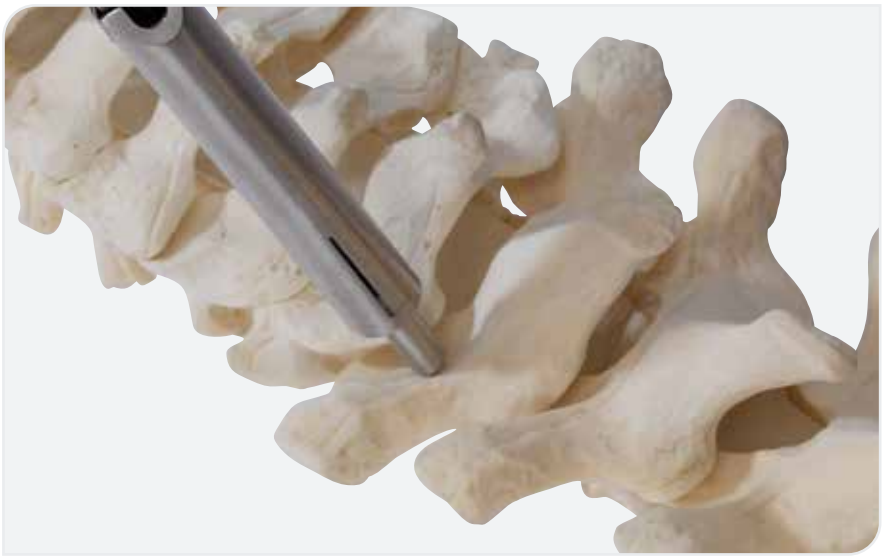
CONFIRM AND MEASURE PILOT HOLE

Insert the Ball Tip Probe to confirm cortical bone continuity. Depth Gauge may be used to measure depth.

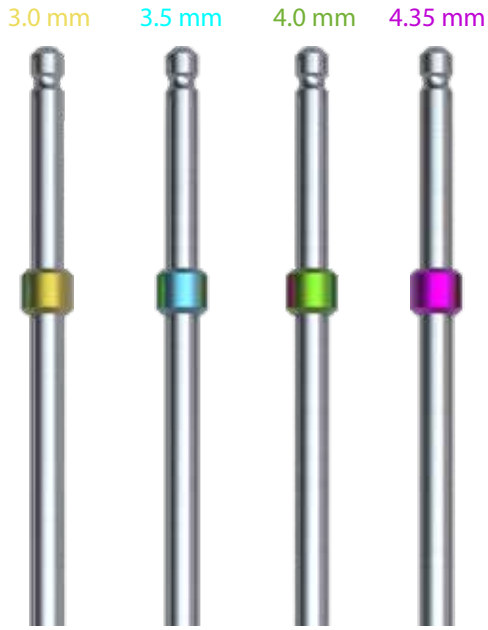


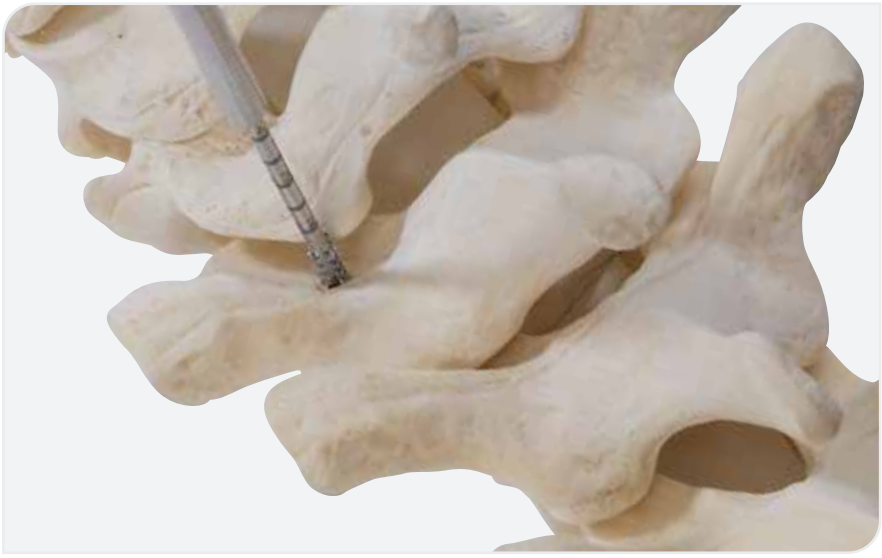
TAP DRILL HOLE (Optional)

Connect the Tap (color coded by diameters of 3.0, 3.5, 4.0, or 4.35 mm) with the Universal Thoracic Handle and advance into the drill hole to the desired depth. Etching on the Tap shaft indicates depth of insertion.



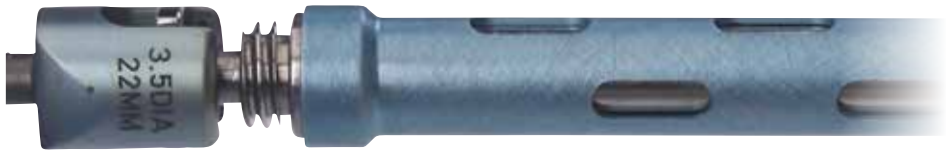
NOTE: Polyaxial Screws are self-tapping. In procedures with dense cortical bone a Tap may be used to create a threaded pathway.



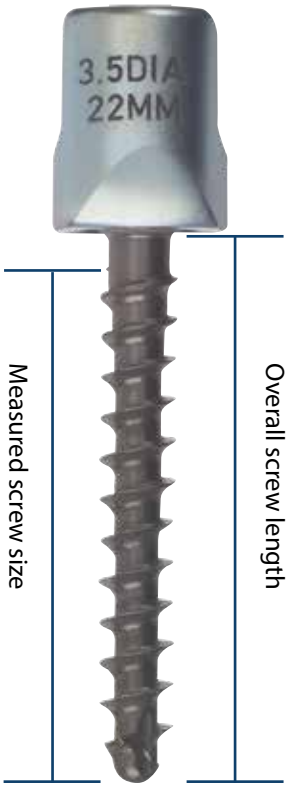


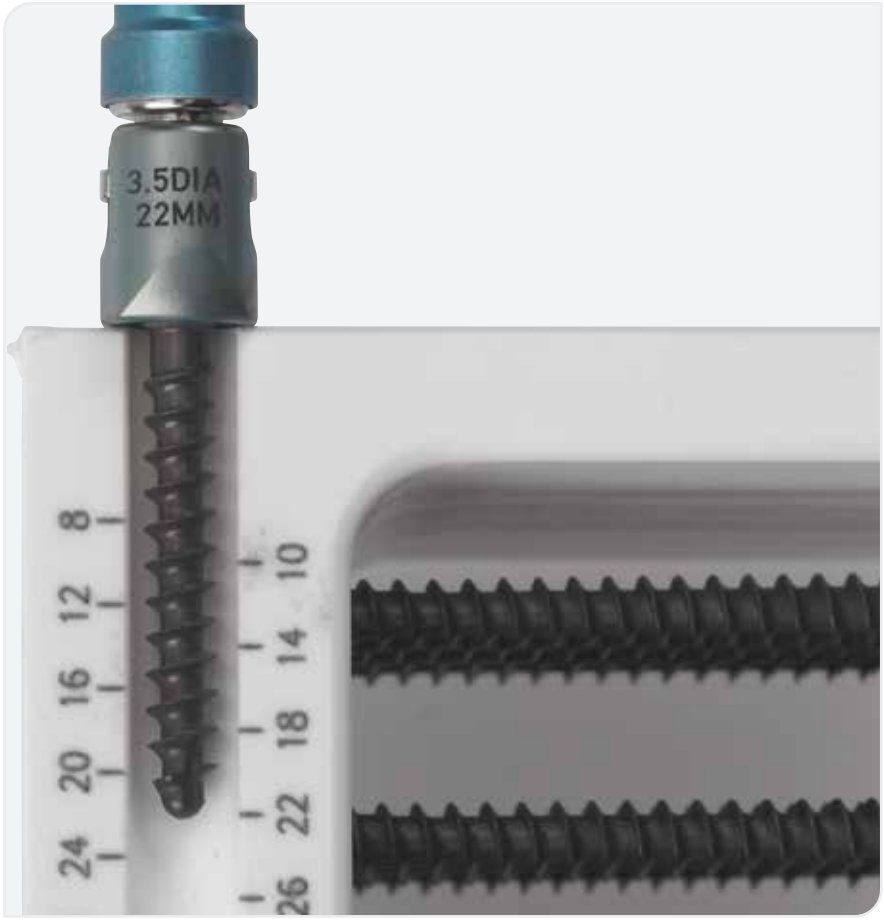
LOAD SCREW

Place Driver over the screw and insert the hex tip into the recessed opening of screw shaft. Push the Knurled Sleeve down and rotate clockwise to engage the Driver's threads with screw.



• *CAUTION! With exception of Smooth Shank Screws, screw length is measured from the tip of the screw to the proximal thread. Therefore, be aware that there is an additional 1.3 mm length from the undersurface of the screw body to the most proximal thread. For example, when verifying a 22 mm screw in the gauge on the screw caddy, the overall length is actually 23.3 mm from distal tip to undersurface of body. The clinician must be aware of this difference to avoid over advancing the screw tip.*

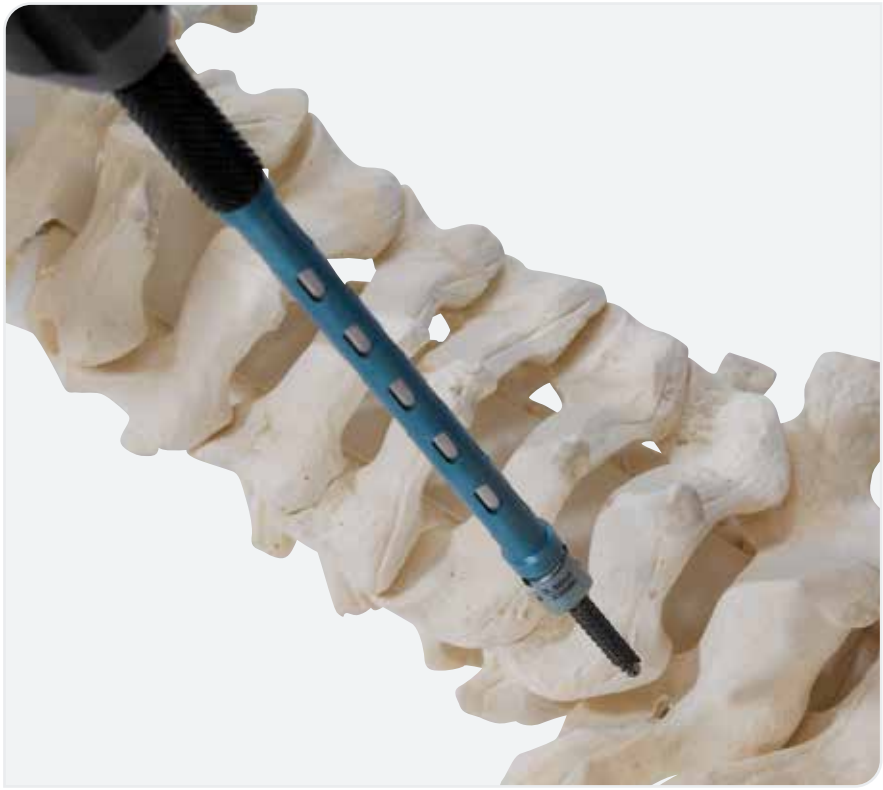




INSERT SCREWS

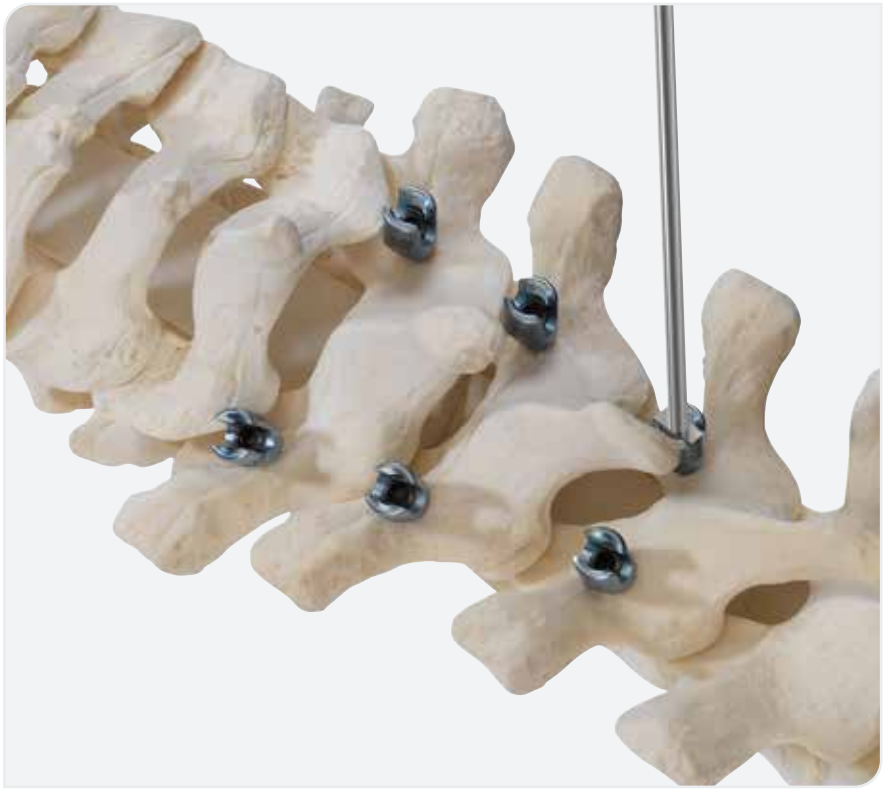
Advance the screw into the prepared hole. Disengage the Driver by rotating the Knurled Sleeve counterclockwise until released. Verify screw placement with intra-operative imaging.

NOTE: It is recommended to leave the screw body slightly above bony surface. This will facilitate screw variability and ease of reducer/persuader instrument positioning.



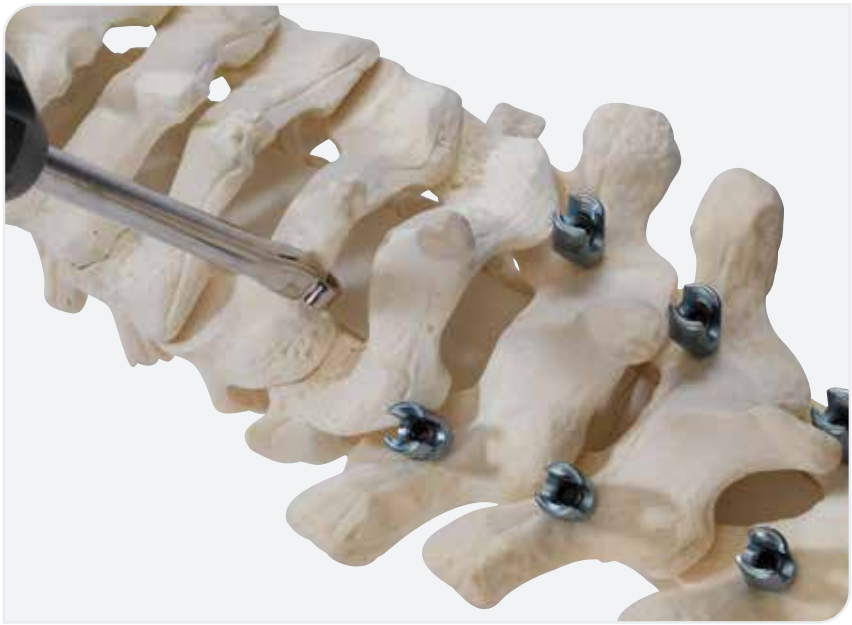
ADJUST SCREW BODIES

Orient screw heads for rod placement using the Screw Head Positioner as needed.



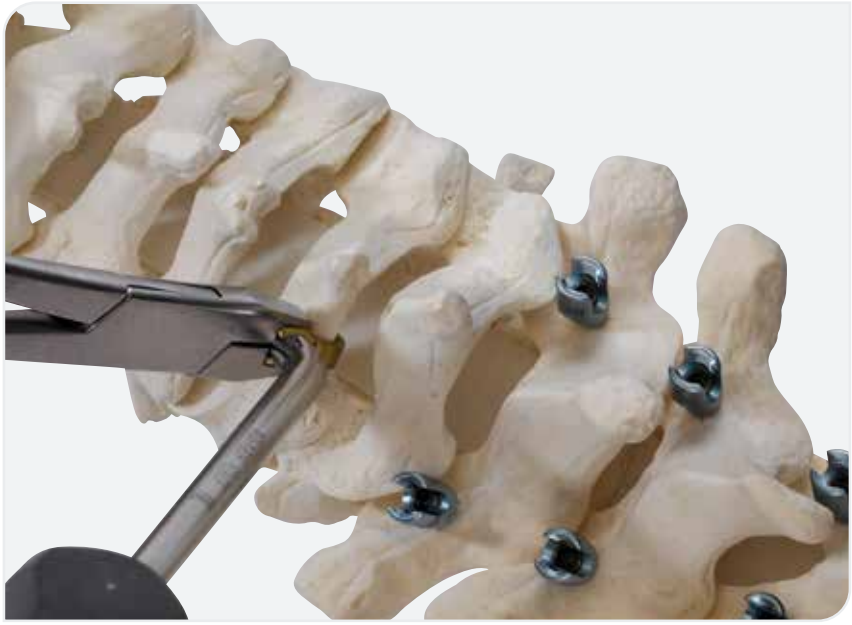
PLACE HOOKS

Dissect the ligamentum flavum with the Cervical Hook Trial.



Insert the Hooks with the Cervical Hook Holder and, if needed, Cervical Hook Impactor.

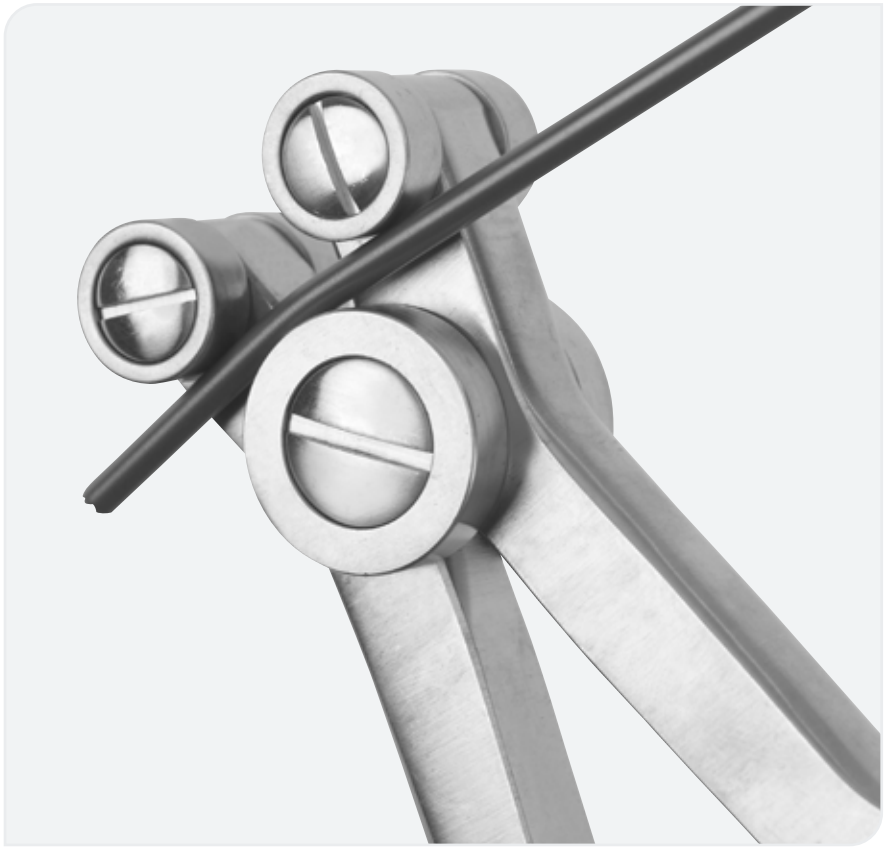
NOTE: The Cervical Hook Holder controls the implant while the Cervical Hook Impactor may be used to advance it into final position.



PREPARE ROD

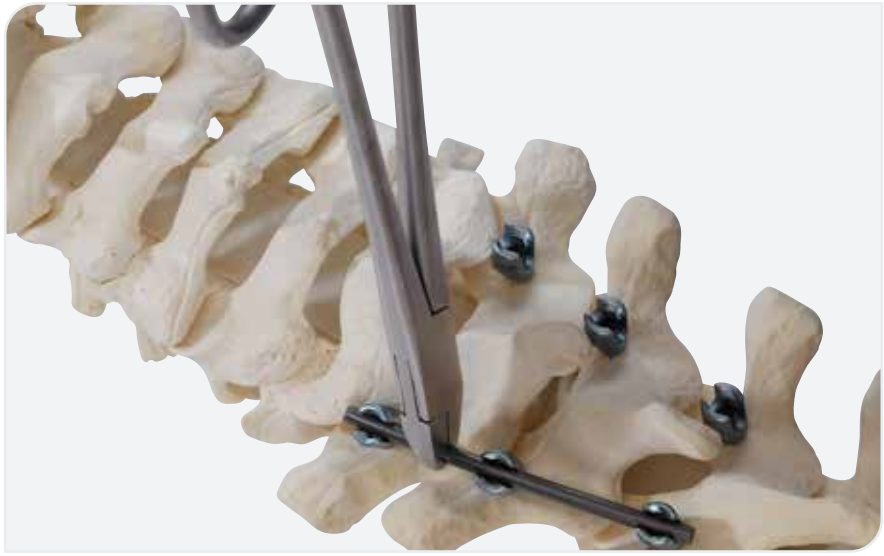
Use the Rod Template to determine the desired rod length and curvature. Cut the rod to the appropriate length with the Rod Cutter.

Contour the rod to the desired lordotic curve with the Rod Bender.



INTRODUCE RODS

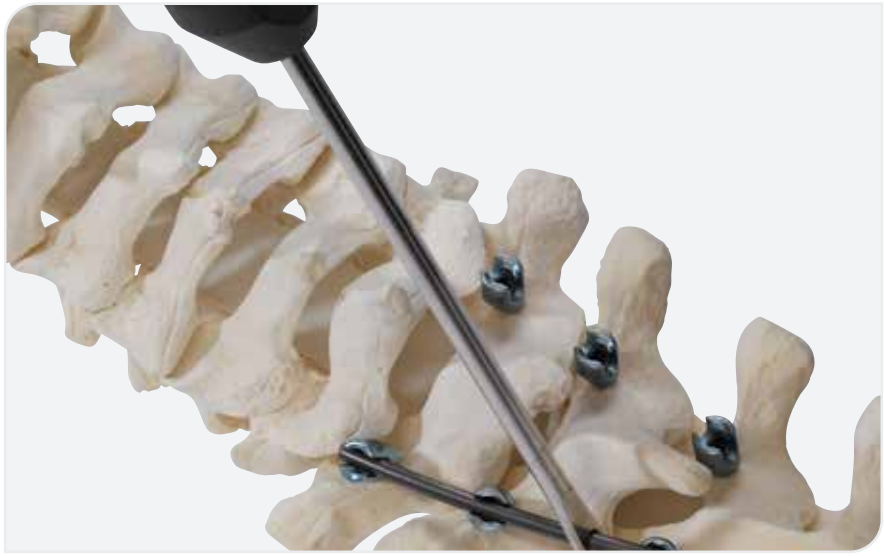
Grasp the rod using the Rod Holder and insert it into the Cervical Hooks or Screw Bodies.



ROD REDUCTION

Option 1: Pusher

Use the Rod Pusher when necessary to introduce the rod into the desired position.



Option 2: Persuader

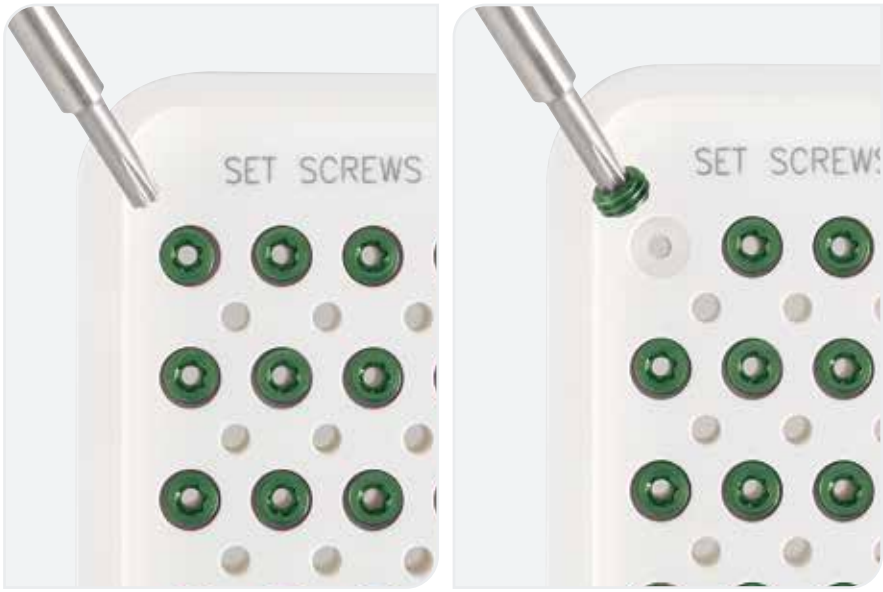
Grip the screw head at the base of the screw head taper. Advance the actuation lever until both laser marks align. At this position, the rod persuader's inner shaft will have fully seated the rod into the screw head.

TIP: Advancing the actuation lever past the laser mark alignment will force the persuader off the screw head.

NOTE: The surgeon may grip the screw head further up, but the actuation lever will have to be squeezed harder and the release will be more difficult.

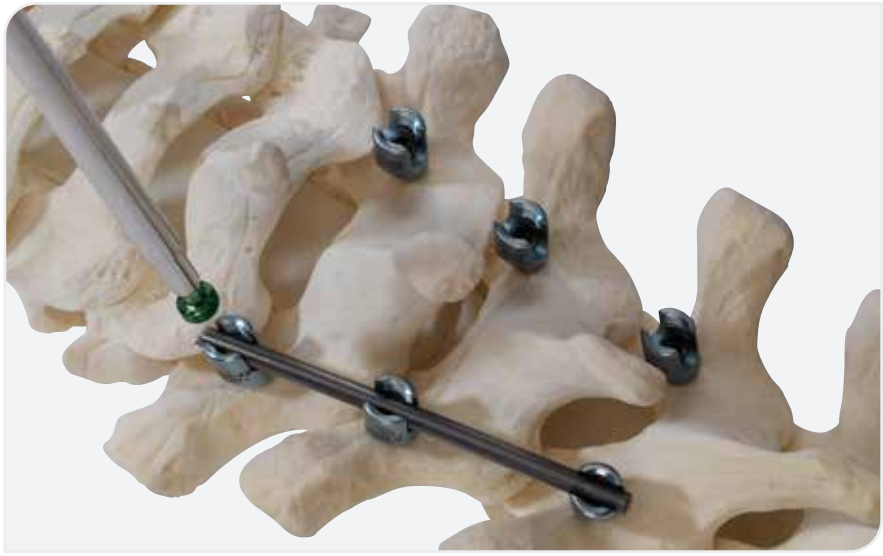
LOAD SET SCREWS

Retrieve the set screws from the caddy with the "Stab and Grab" Hexalobe Set Screw Inserter.

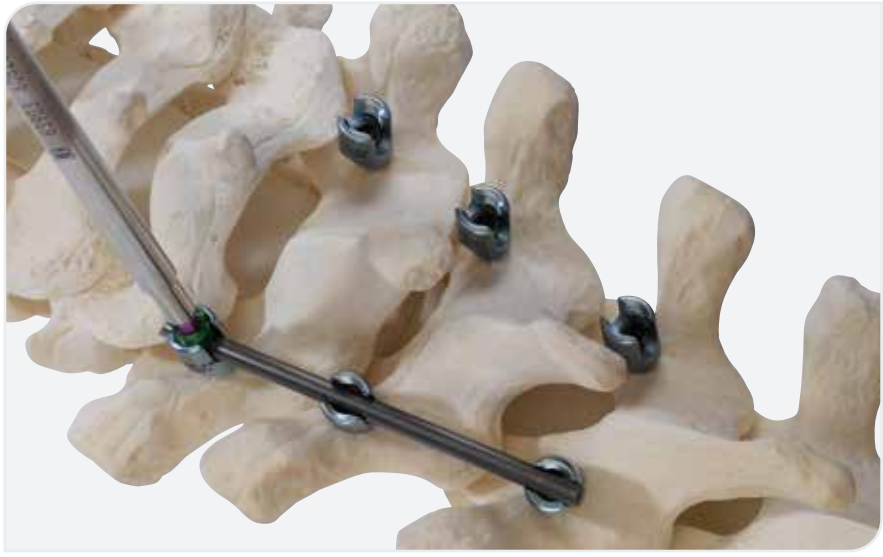


INSERT SET SCREWS

Place the set screw into the Hook or Screw Body.



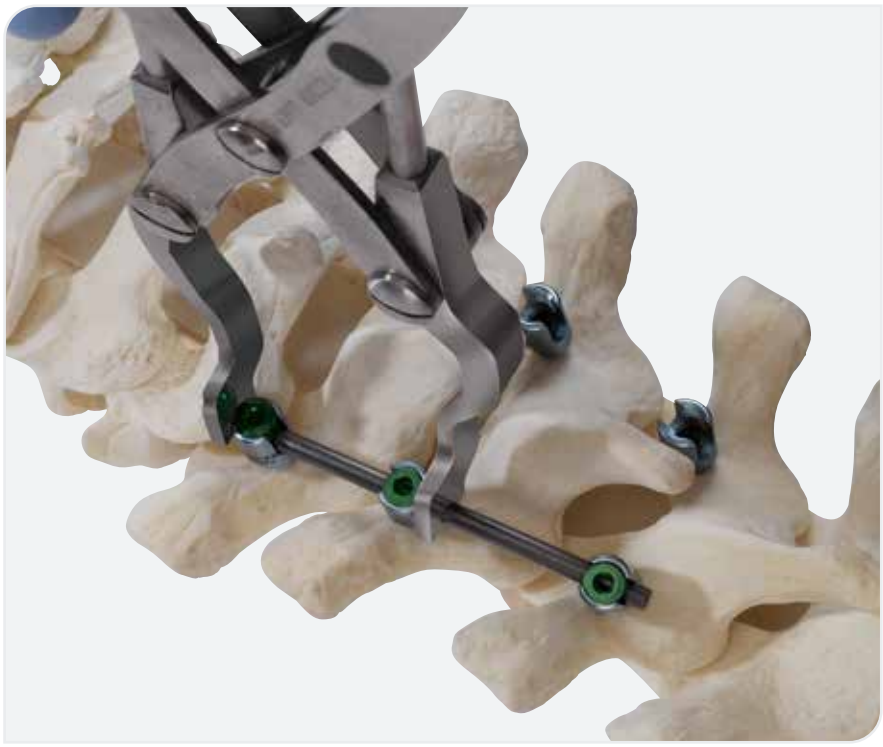
Rotate clockwise until provisionally tightened.

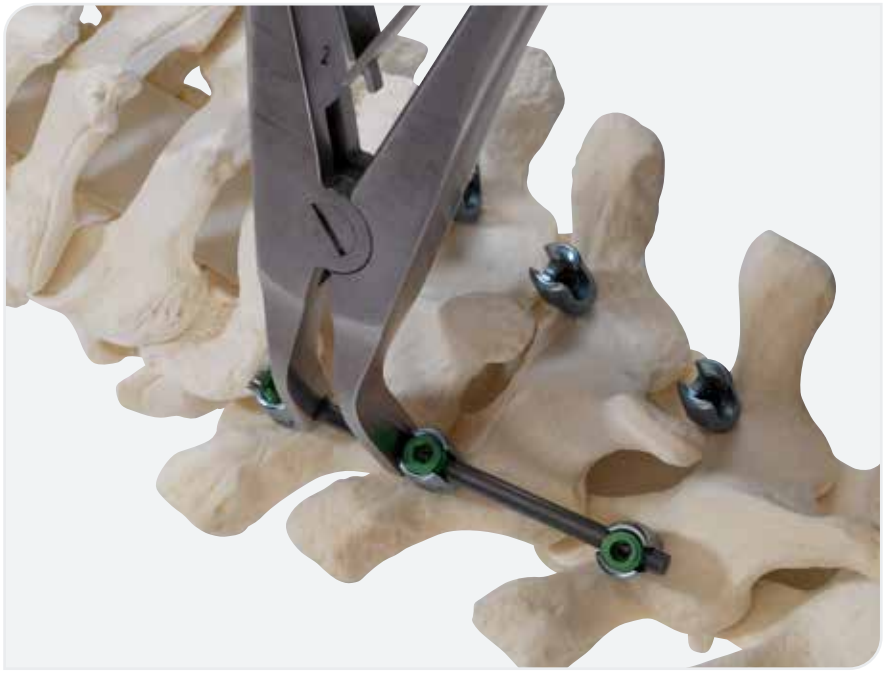


COMPRESS/DISTRACT

Loosen a set screw adjacent to a provisionally tightened screw on one side of the motion segment allowing the rod to slide freely.

Lordosis may be increased using the Compressor and kyphosis may be decreased with the Distractor. Place Compressor onto rod above and below the screw/hook bodies or Distractor onto rod between the screw/hook bodies and squeeze instrument's handle until desired lordosis or kyphosis is achieved. Provisionally tighten set screws.





PERFORM FINAL TIGHTENING

Confirm final positioning of the construct radiographically and tighten the set screws by assembling the Hexalobe Set Screw Torque Shaft (color coded with a green band) with the 25 in-lb Torque Limiting Handle (2.82 Nm). Slide the shaft through the cannula of the Solanas Counter Torque. Insert the tip of the shaft into the set screw and then advance the Counter Torque over screw/hook body. Rotate the Counter Torque until the "U" shaped openings capture rod. Perform the final tightening by rotating the Torque Limiting Handle clockwise while providing stabilization of the rod/screw with the Counter Torque. Tightening is achieved when the Torque Limiting Handle audibly clicks.

NOTE: To minimize potential stripping of the hex fitting of the set screw, ensure the torque wrench shaft is fully seated in the set screw.

It is important to use the supplied torque limiting instrument in accordance with the surgical technique to ensure sufficient torque is applied to the set screw and associated connector. Failure to tighten the set screw to the recommended torque could compromise the mechanical stability of the connector.

IMPLANT REVISION AND REMOVAL

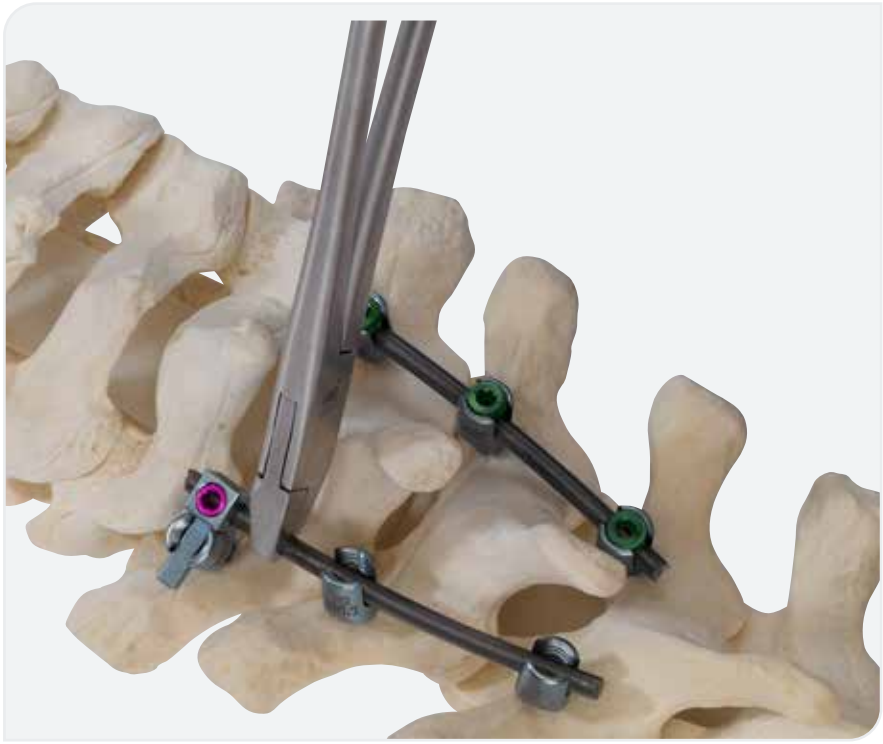
Posterior Fixation Implants may be explanted or revised. The original instrumentation set contains all imperative instruments to perform these procedures. Remove all necessary Set Screws using the Set Screw Remover. The Rod Inserter may then be used to adjust or completely remove the previously implanted rods. Remove Pedicle Screws using the Screw Remover.

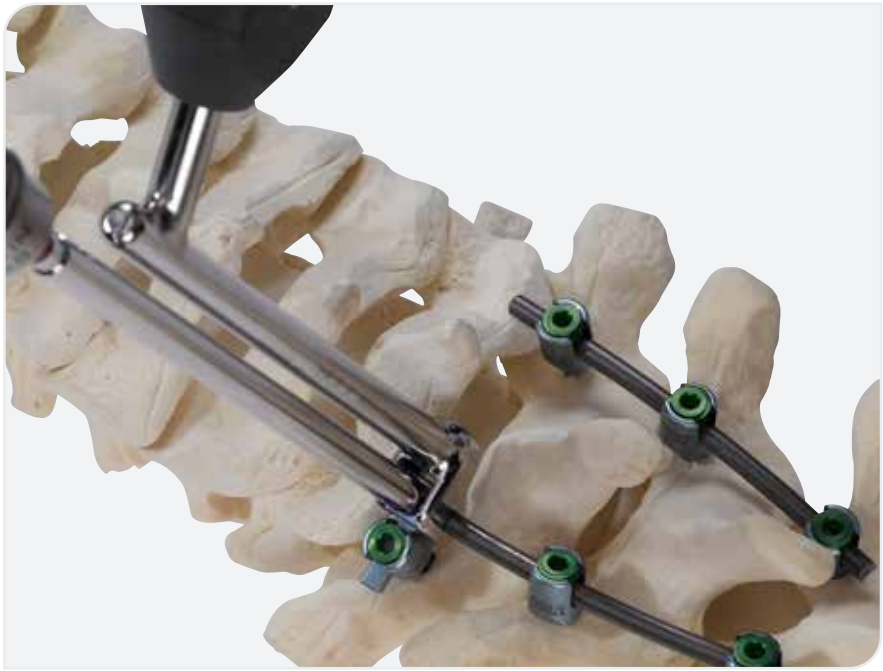
TIP: The green color of the set screw corresponds to the colored ring on the Set Screw Torque Shaft. All green set screws in the SOLANAS System have a recommended final tightening torque of 25 in-lb (2.82 Nm).

LATERAL CONNECTORS

Select either the open or closed Lateral Connector and ensure the set screw is loose to accommodate the rod. Attach either an open or closed connector to the rod and insert the connection post into the screw/hook body. Provisionally tighten the set screw.

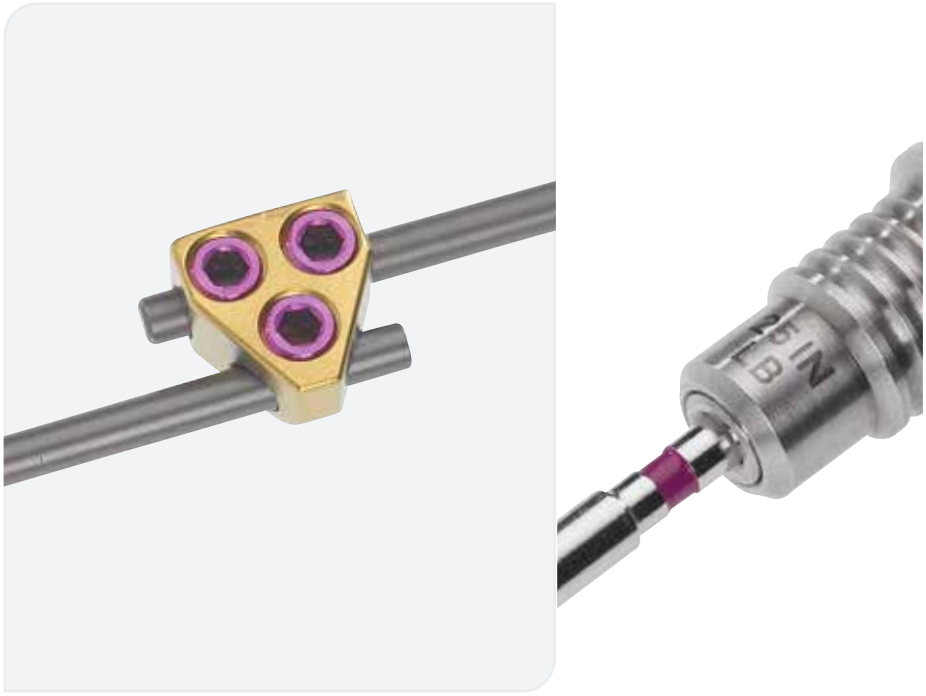
When all implants are in the optimal position, perform final tightening using the Hexagon Set Screw Torque Shaft (color coded with a magenta band), 25 in-lb Torque Limiting Handle (2.82 Nm) and the Lateral Connector Counter Torque. Connect the shaft with the Torque Limiting Handle and slide through the Counter Torque. Insert the tip of Torque Shaft into the set screw and then advance the Counter Torque to capture the connector. Perform final tightening by rotating the Torque Limiting Handle clockwise while providing stabilization with the Counter Torque. Tightening is achieved when the Torque Limiting Handle audibly clicks.





PARALLEL ROD–TO–ROD CONNECTORS

Join two rods together when not axially aligned with the Parallel Rod-to-Rod Connector. Be sure the rods are cut and contoured such that they have a slight overlap. Place the connector on the rods and provisionally tighten the set screws. After the system is fully assembled, perform final tightening using the 25 in-lb Axial Torque Limiting Handle (2.82 Nm) connected with the Set Screw Torque Shaft (colored coded with a magenta band). Rotate the handle clockwise until the Torque Limiting Driver audibly clicks.



AXIAL ROD–TO–ROD CONNECTORS

Connect two, axially aligned rods with the appropriate Axial Rod-to Rod Connector. Cut and contour the rods as required. Place the connector on the rods and provisionally tighten the set screws. After the components are in their aligned position perform the final tightening using the 40 in-lb Torque Limiting T-Handle (4.52 Nm) connected with the Domino Hex Driver (color coded with a blue band). Rotate the T-Handle clockwise until the Domino Hex Driver audibly clicks.

TIP: The blue color of the set screw corresponds to the colored ring on the Domino Hex Driver. All blue set screws in the SOLANAS System have a recommended final tightening torque of 40 in-lb (4.52 Nm).

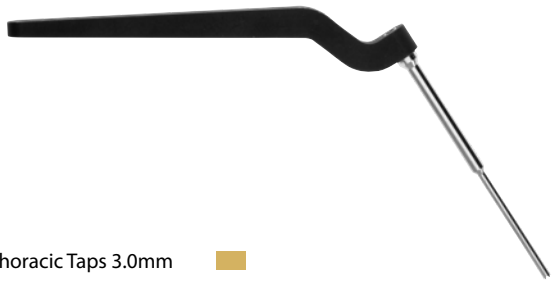
INSTRUMENTS

Small Depth Gauge

Thoracic Polyaxial Screwdriver

Hexalobe Set Screw Inserter

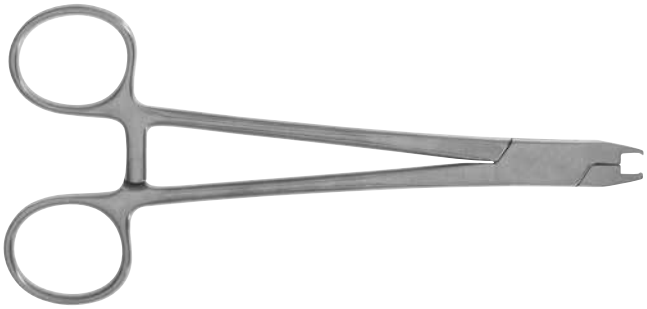
Thoracic Drill Guide



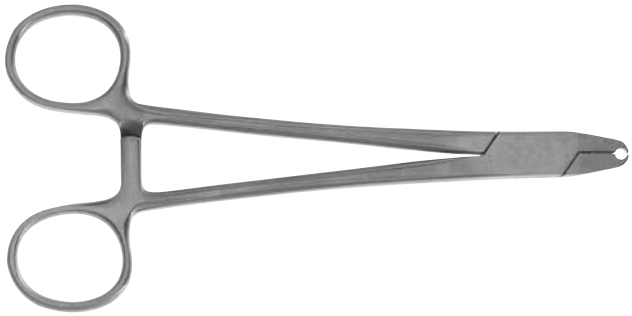
Thoracic Taps 3.0mm
Thoracic Taps 3.5mm
Thoracic Taps 4.0mm
Thoracic Taps 4.35mm

Cervical Hook Trial

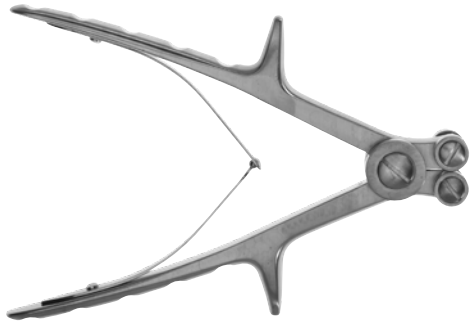
Cervical Hook Holder



3.3mm Rod Holder



3.3mm Rod Bender

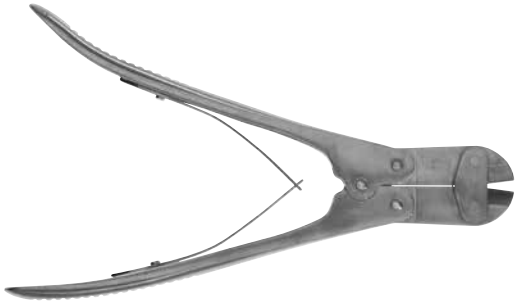


Thoracic Screw Head Positioner

Thoracic Screw Bone Awl

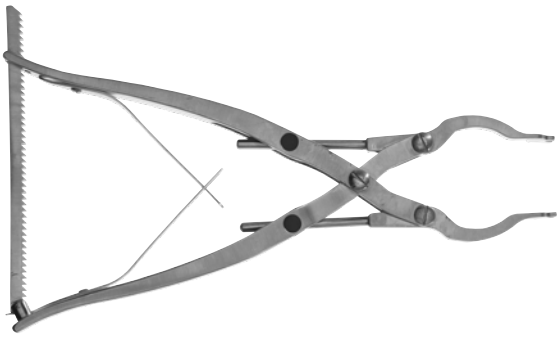
INSTRUMENTS

Rod Cutter



Rod Persuader

Compressor

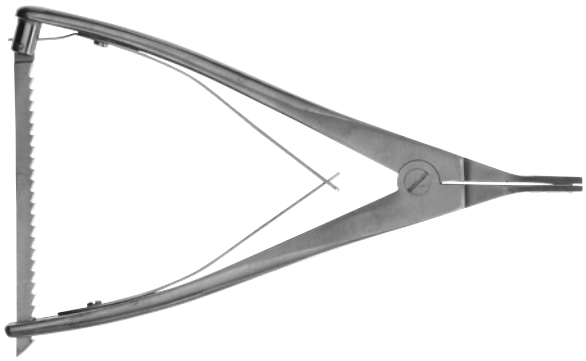


150mm Rod Template 3.0mm

Ball Tip Probe

Pedicle Probe

Cervical Distractor



Offset Connector Counter Torque

Fixed Length Drills 8mm
Fixed Length Drills 10mm
Fixed Length Drills 12mm
Fixed Length Drills 14mm
Fixed Length Drills 16mm
Fixed Length Drills 18mm

In Situ Bender - left

In Situ Bender - right

INSTRUMENTS

Universal Thoracic Handle (Silicone)

Rod Pusher

Cervical Hook Impactor

Quick Connect T-Handle

25 in-lb Torque Limiting Handle (2.82 Nm)

Ø3.5mm Adjustable Drill (20mm-50mm)
Adjustable Drill Stop

40 in-lb Torque Limiting T-Handle (4.52 Nm)

Hexagon Set Screw Torque Shaft
(Lateral & Parallel Rod-to-Rod Connectors)

Hexalobe Set Screw Torque Shaft
(Polyaxial Screws & Hooks)

Domino Hex Driver
(Axial Rod-to-Rod Connector)

SOLANAS Counter-Torque

Sterilization Case, Instruments

Sterilization Case, Implants

Hexagon Set Screw Removal Tool

ADJUSTABLE BRIDGES

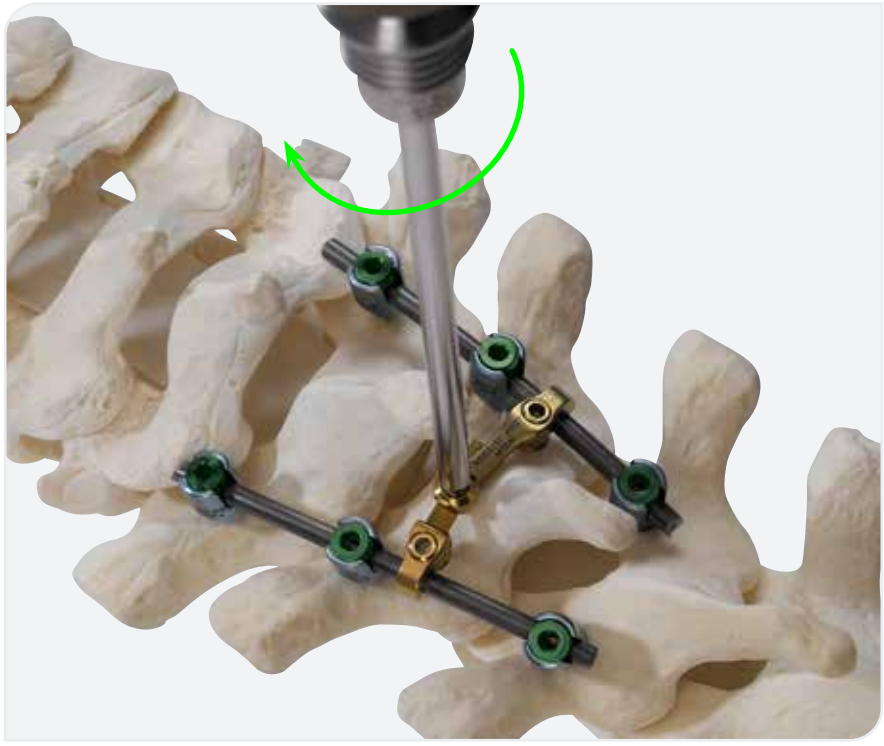
Alphatec's Adjustable Bridges are an optional system that can be used to supplement the Solanas system.

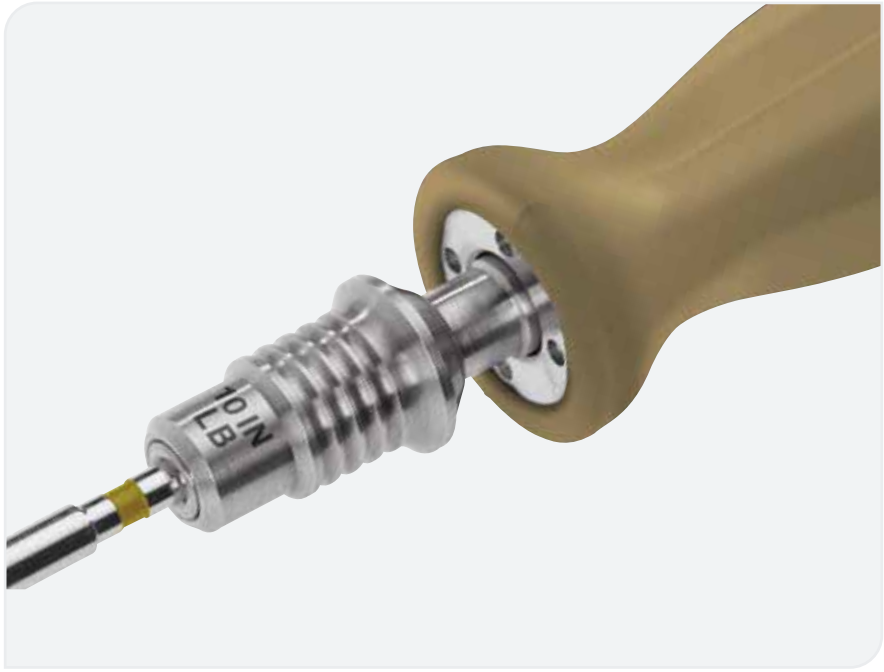
Connect the two rods with the appropriate size bridge (small, medium, large) to ensure torsional stability. Assemble the Adjustable Bridge Driver (color coded with a gold band) with the gold 10 in-lb Axial Torque Limiting Handle (1.13 Nm). Each bridge has two lateral clamping screws and one center midline set screw that initially should be loose to pivot about its midpoint. Verify that the clamping screws are in the open (down) position. Each clamping screw attaches to a rod. Before final tightening, check that the bridge fit is correct and clamp connection secure. Insert the shaft tip into one clamping screw and rotate the Torque Limiting Handle clockwise until the Adjustable Bridge Driver audibly clicks. Repeat on the opposite clamp screw and finish the final tightening by applying torque to the center set screw.

Adjustable bridges in lengths of 26mm, 37mm & 60mm connect rods to increase construct stability.

Adjustable Bridges

TIP: The gold color of the set screws corresponds to the color of the Axial Torque Limiting Handle and the colored ring on the Adjustable Bridge Driver. All gold set screws in the SOLANAS System have a recommended final tightening torque of 10 in-lb (1.13 Nm).





Adjustable Bridge Driver

10 in-lb Torque Limiting Handle (1.13 Nm)

INSTRUCTIONS FOR USE

SOLANAS® POSTERIOR OCT FIXATION SYSTEM

GENERAL INFORMATION:
The Solanas OCT Spinal Fixation System is a spinal fixation system intended to improve stability of the occipital, cervical, and thoracic areas of the spine (Occiput-T3).
The Solanas OCT Spinal Fixation System is comprised of two sub-systems: a cervical thoracic system (Solanas) and an occipital cervical thoracic system (Solanas Avalon®) which share many of the same implants and instruments.
The implants are manufactured from titanium alloy (Ti-6Al-4V ELI) per ASTM F136, and cobalt chromium (Co-28Cr-6Mo) alloy 1 (annealed and cold worked) and alloy 2 (warm worked) per ASTM F1537. The Solanas OCT Spinal Fixation System consists of a variety of shapes and sizes of screws, rods, hooks, bridges, connectors and general surgical instruments that provide temporary internal fixation and stabilization during bone graft healing and/or fusion mass development.
The implants are provided non-sterile to be steam sterilized by the end user. The Class I general instruments are made of stainless steel and other materials, and are provided non-sterile to be cleaned and sterilized by the end user.

INDICATIONS FOR USE:
The Solanas OCT Spinal Fixation System is intended to provide immobilization and stabilization of spinal segments as an adjunct into fusion for the following acute and chronic instabilities of the craniocervical junction, the cervical spine (C1 to C7) and the thoracic spine from T1-T3: traumatic spinal fractures and/or traumatic dislocations; instability or deformity; failed previous fusions (e.g.,pseudoarthorsis); tumors involving the cervical spine; and degenerative disease, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies, and degenerative disease of the facets with instability. The Solanas OCT Spinal Fixation System is also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advance stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion.
In order to achieve additional levels of fixation, the Solanas OCT Spinal Fixation System may be connected to the components in the Zodiac® Polyaxial Spinal Fixation System, the Arsenal® Spinal Fixation System, or the Invictus™ Spinal Fixation System offered by Alphatec Spine using the Rod to Rod Connectors or Transitional Rods.

CONTRAINDICATIONS:
The Solanas OCT Spinal Fixation System is contraindicated for:
1. Use in the thoracic-lumbo-sacral spine below T3.
2. Patients with osteopenia, bone absorption, bone and/or joint disease, deficient soft tissue at the wound site or probable metal and/or coating intolerance.
3. Patients with infection, inflammation, fever, tumors, elevated white blood count, obesity, pregnancy, mental illness and other medical conditions, which would prohibit beneficial surgical outcome.
4. Spinal surgery cases that do not require bone grafting and/or spinal fusion.
5. Use with bone cement.
6. Patients resistant to following post-operative restrictions on movement especially in athletic and occupational activities.
7. Use with stainless steel components.
8. Reuse, or multiple use.
9. Patients resistant to following post-operative instruction.
10. Patients with allergy to Titanium or Cobalt Chrome.

WARNINGS/CAUTIONS:
1. The implants and instruments of the system are provided non-sterile and must be cleaned and sterilized prior to use. Refer to the CLEANING and STERILIZATION sections.
2. The safety and effectiveness of pedicle screw spinal systems have been established only for spinal conditions with significant mechanical instability or deformity requiring fusion with instrumentation. These conditions are significant mechanical instability or deformity of the thoracic, lumbar, and sacral spine secondary to severe spondylolisthesis (grades 3 and 4) of the L5-S1 vertebra, degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis). The safety and effectiveness of these devices for any other conditions are unknown.
3. The system implants are 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 these devices. Without solid bone fusion, these devices cannot be expected to support the spine indefinitely and may fail due to bone-metal interface, rod failure or bone failure.
4. The 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.
5. The benefit of spinal fusions utilizing any pedicle screw fixation system has not been adequately established in patients with stable spines.
6. The product 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.
7. The instruments in the Solanas System are reusable surgical devices except for the Single-Use Rod Template used with the Solanas System, which are single use only. Single use instruments are disposable devices, designed for single use and should not be re-used or re-processed. Reprocessing of Single Use Instruments may lead to instrument damage and possible improper function.
8. The final operative procedure with the system must include tightening of the set screws in order to maintain construct integrity. Each locking mechanism must be rechecked for tightness before closing the soft tissues as noted in the Intraoperative Management section.
9. The safety and effectiveness of pedicle screw spinal systems have been established only for spinal conditions with significant mechanical instability or deformity requiring fusion with instrumentation. These conditions are significant mechanical instability or deformity of the thoracic, lumbar, and sacral spine secondary to severe spondylolisthesis (grades 3 and 4) of the L5-S1 vertebra, degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis). The safety and effectiveness of these devices for any other conditions are unknown.
10. Based on the fatigue test results, the physician/surgeon should consider the levels of implantation, patient weight, patient activity level and patient conditions, which may impact the performance of the system when using this device. Use of these systems is significantly affected by the surgeon's proper patient selection, preoperative planning, proper surgical technique, proper selection and placement of implants.
11. Risks identified with the use of these devices, which may require additional surgery, include device component failure, loss of fixation/stabilization, non-union, vertebral fracture, neurological injury, vascular or visceral injury.
12. 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.
13. The benefit of spinal fusions utilizing any pedicle screw fixation system has not been adequately established in patients with stable spines. Without solid bone fusion, these devices cannot be expected to support the spine indefinitely and may fail due to bone-metal interface, rod failure or bone failure.
14. It is critical that Set Screws are final tightened as recommended in the Surgical Technique Guides, using the appropriate instrument(s), e.g., Torque Handle. Failure to tighten the Set Screws using the recommended instrument(s) could compromise the mechanical stability of the construct.
15. Without solid bone fusion, this device cannot be expected to support the spine indefinitely and may fail due to bone-metal interface, rod failure or bone failure.
16. Do not comingle titanium and stainless steel components within the same construct.
17. The implants and instruments of Alphatec Spine product lines should not be used with any other company's spinal systems.
18. The Avalon occipital plate should only be connected to components of Solanas OCT Fixation System.

PRECAUTIONS:
1. The implantation of pedicle screw spinal systems should be performed only by experienced spinal surgeons with specific training in the use of this pedicle screw spinal system because this is a technically demanding procedure presenting a risk of serious injury to the patient.
2. Device components should be received and accepted only in packages that have not been damaged. Damaged implants and damaged or worn instruments should not be used. Components must be carefully handled and stored in a manner that prevents scratches, damage, and corrosion.
3. The physician/surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc. which may have an impact on the performance of the system.
4. Preoperative planning prior to implantation of posterior cervical screw systems should include review of cross-sectional imaging studies (e.g., CT and/or MRI) to evaluate the patient's cervical anatomy including the transverse foramen, neurologic structures, and the course of the vertebral arteries. If any findings would compromise the placement of these screws, other surgical methods should be considered. In addition, use of intraoperative imaging should be considered to guide and/or verify device placement, as necessary.
5. Use of posterior cervical pedicle screw fixation at the C3 through C6 spinal levels requires careful consideration and planning beyond that required for lateral mass screws placed at these spinal levels, given the proximity of the vertebral arteries and neurologic structures in relation to the cervical pedicles at these levels.

MRI SAFETY INFORMATION:
The Solanas 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 the Solanas System in the MR environment is unknown. Scanning a patient who has this 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 must be discussed with the patient preoperatively.

1. Initial or delayed loosening, disassembly, bending, dislocation and/or breakage of device components
2. Physiological reaction to implant devices due to foreign body intolerance including inflammation, local tissue reaction, and possible tumor formation
3. 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
4. Loss of desired spinal curvature, spinal correction and/or a gain or loss in height
5. Infection and/or hemorrhaging
6. Bone graft, vertebral body fracture, and/or discontinued growth of fused bone at, above and/or below the surgery level
7. Non-union and/or pseudarthrosis
8. Neurological disorder, pain and/or abnormal sensations
9. Inability to perform routine activities
10. Revision surgery
11. Death

PREOPERATIVE MANAGEMENT:

1. Only patients meeting the criteria listed in the indications for 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 construct strategy, pre-assembly of component parts (if required), and verification of required inventory for the case.

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, especially upon insertion of spinal hooks.
2. Rods should be contoured in only one direction, one time. Avoid notching, scratching or reverse bending of the devices because these alterations will produce defects in the surface finish and internal stresses which may become the focal point for eventual breakage of the implant.
3. If it is mandatory to cut the rods to a more specific length, rod cutting should be done at a distance from the operative range, and such that a non-sharp edge remains on the rod.
4. A new bone tap should be used each time to ensure a sharp cutting edge and the absence of clogging bone debris. Use of the improper length or diameter of bone tap or bone screw may allow loosening of implants, nerve damage, and undesirable fusion.
5. The final operative procedure with the Solanas System must include tightening of all setscrews to the torque values indicated by the surgical technique with the instruments provided. Each locking mechanism must be rechecked for tightness before closing the soft tissues.
6. Final Set Screw Tightening: All Set Screws must be tightened using the appropriate instrument (e.g., Torque Handle) as indicated in the Surgical Technique Guide.
7. 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, including instruction and warning and compliance by the patient, of the following is essential:

1. Patient should be informed and compliant with the purpose and limitations of the implant devices.
2. 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 possible consequences of any type of early or excessive weight bearing, vibratory motion, fall, jolts or other movements preventing proper healing and/or fusion development.
3. In the case of delayed, mal-, 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.
4. Postoperative patients should be instructed to not use tobacco or nicotine products, consume alcohol, and non-steroidal anti-inflammatory drugs (NSAIDs) such as ibuprofen or aspirin. Complete postoperative management as determined by the surgeon following implant surgery to maintain the desired result.
5. The 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.

℞Only

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

Excerpt from INS-103

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

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