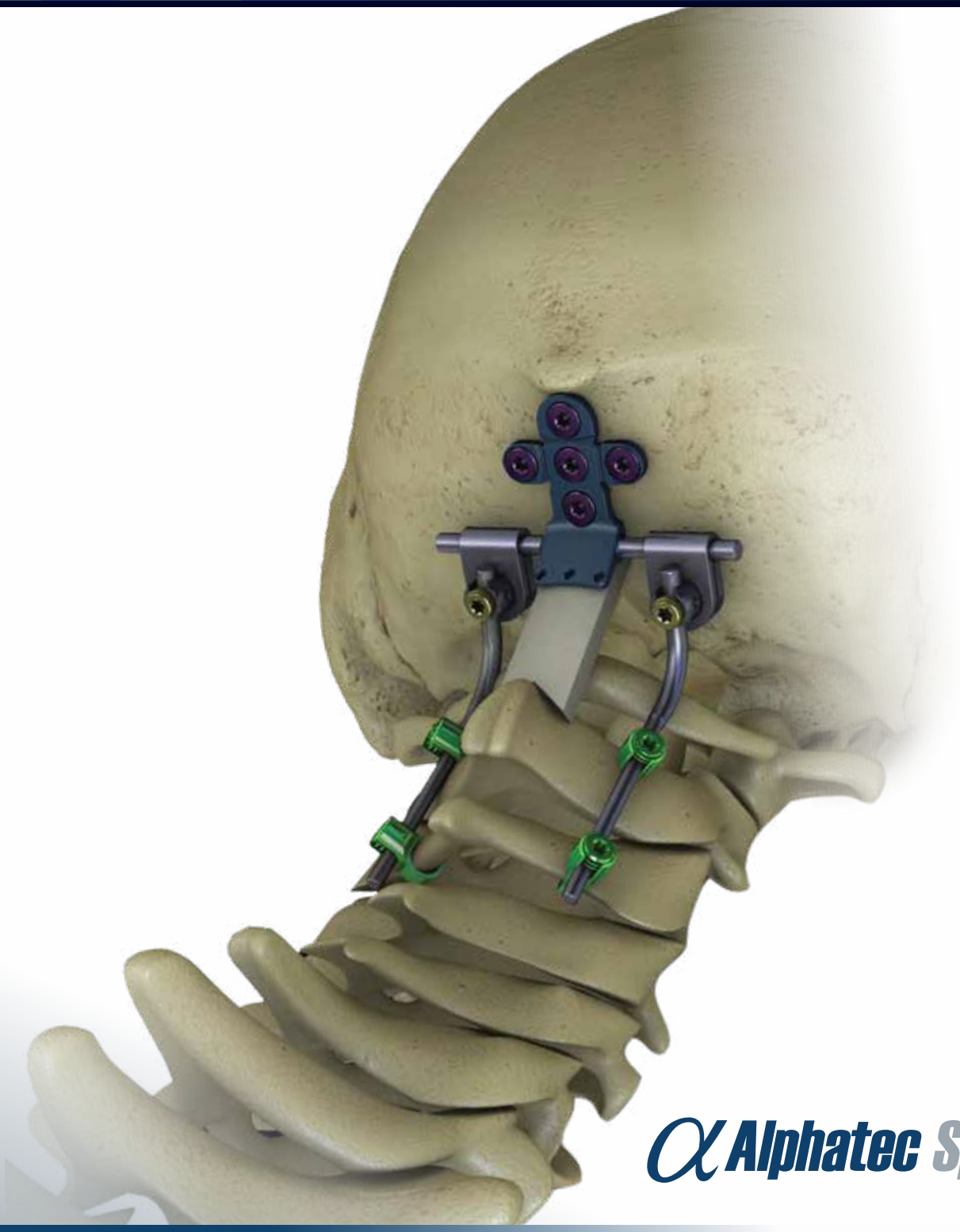
Avalon®

Occipital Fixation System



Alphatec Spine®

CERVICAL | Surgical Technique Guide

SYSTEM FEATURES

Unique buttress design simplifies bone graft placement

Three points of plate rotation and translation eases rod placement

Five points of screw fixation to the occiput maximizes bone purchase

Seamless integration with the Solanas® Posterior Cervico-Thoracic Fixation System.

IMPORTANT NOTE

As with any surgical procedure, a surgeon should be thoroughly trained before proceeding. Each surgeon must consider the particular needs of each patient and make the appropriate adjustments when necessary.

The Avalon™ Occiptal Fixation System must be used in conjunction with Alphatec Spine's SOLANAS Posterior Cervico-Thoracic Fixation System.

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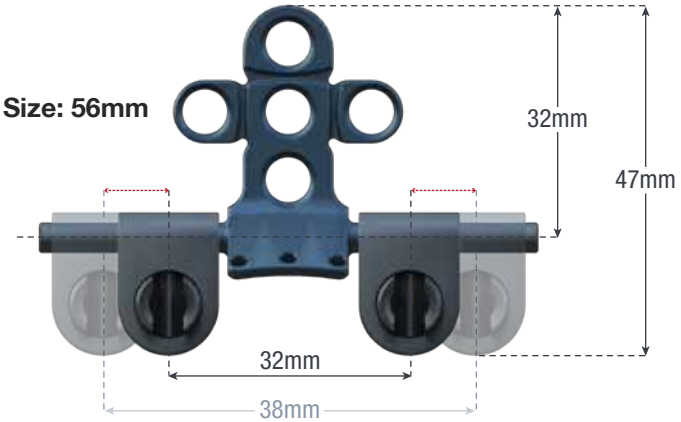
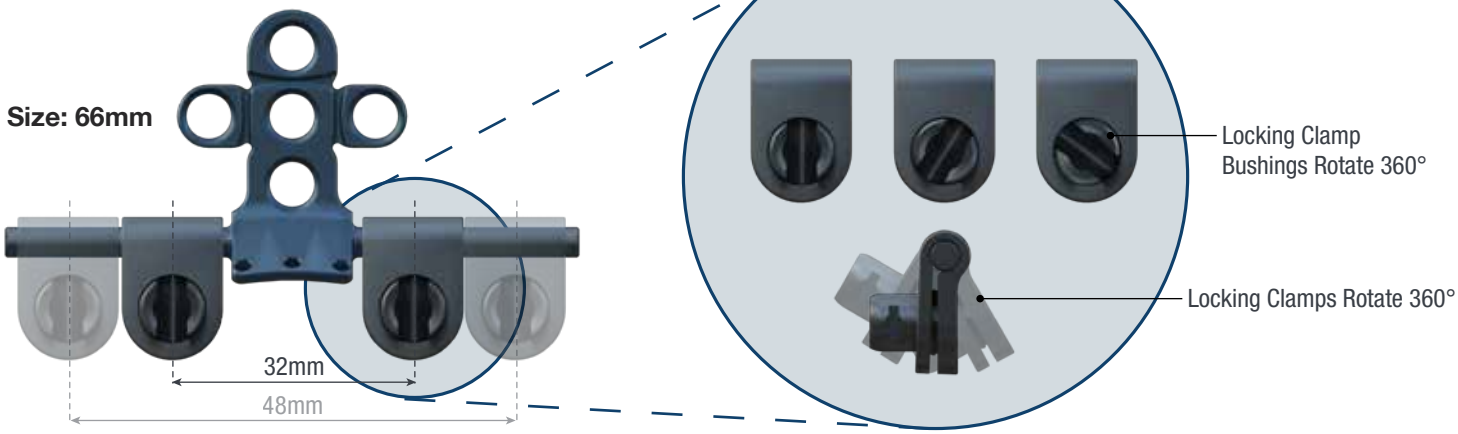
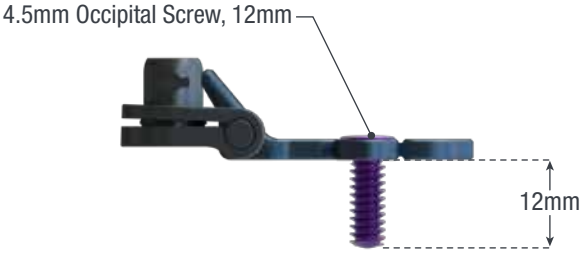
PLATE AND BONE SCREW SIZES







(sizes in millimeters) **6** **8** **10** 12 14 16

4.5mm

(sizes in millimeters) **6** **8** **10** 12 14 16

5.0mm

PREOPERATIVE PLANNING AND POSITIONING

The patient should be positioned prone in an appropriate manner per surgeon preference to avoid specific pressure points. Pre-operative sagittal and coronal CTs of the skull are strongly recommended to ascertain skull thickness in relation to plate placement.

Cervical Implant Placement

Select and insert the cervical laminar hooks at the desired levels of fixation (see Solanas Cervico-Thoracic System surgical technique). Rods are recommended to be placed at a later stage of the surgical technique.

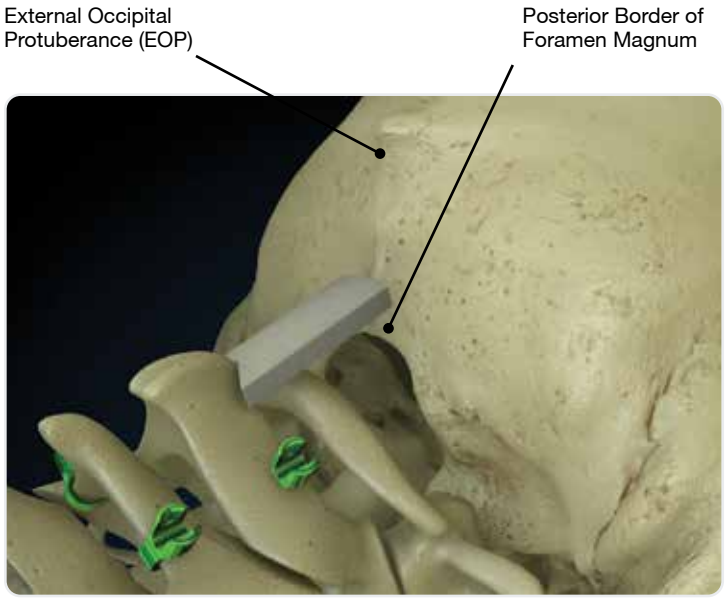
Bone Graft Placement

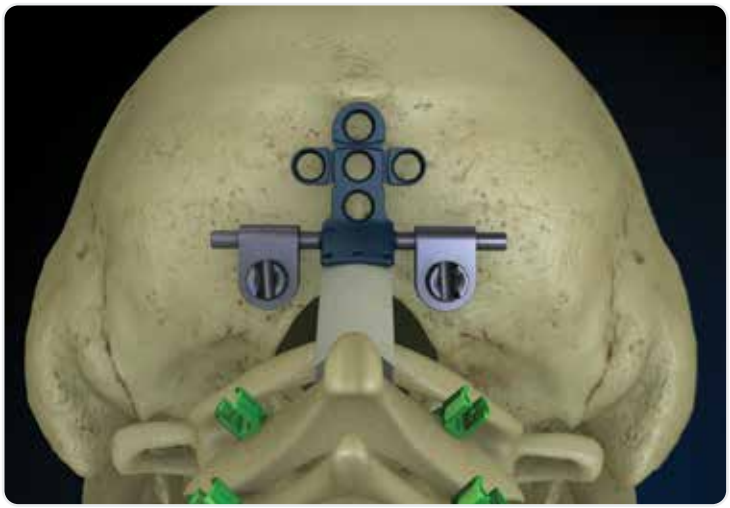
The bone graft can be either structural autogenous graft or freeze-dried allograft. The graft area should be measured from the occiput of the skull to the spinous process of C2. The bone graft should be cut and trimmed using a high-speed burr to ensure that it will lay flat against the occiput and precisely fit over the base of the spinous process of C2 and the C2 lamina. The bone graft must be in final placement before drilling into the skull and securing the occipital plate to the skull is initiated.

Occipital Plate Placement

In general, the thickest bone in the sub-occipital region is the occipital keel (internal occipital protuberance) in the midline. When positioning the Occipital Plate, it should be centered in the midline between the External Occipital Protuberance (EOP) and the posterior border of the Foramen Magnum. The goal is to maximize bone purchase (closer to EOP) while maintaining a low profile. The keel of the occipital plate must abut against the bone graft to hold it in place and to compress it against the lamina of C2.

NOTE: The Plate Rotating Body Adjustment Tool can be used to fine tune the positioning of the saddles.





OCCIPITAL PLATE CONTOURING

If necessary, the plate can be contoured using the Plate Benders for a more anatomic fit against the occiput. Repeated bending should be avoided as it may compromise the integrity of the implant. It may be necessary to contour a small portion of uneven occipital bone with a high-speed burr (not included) to allow the plate to lie flush.

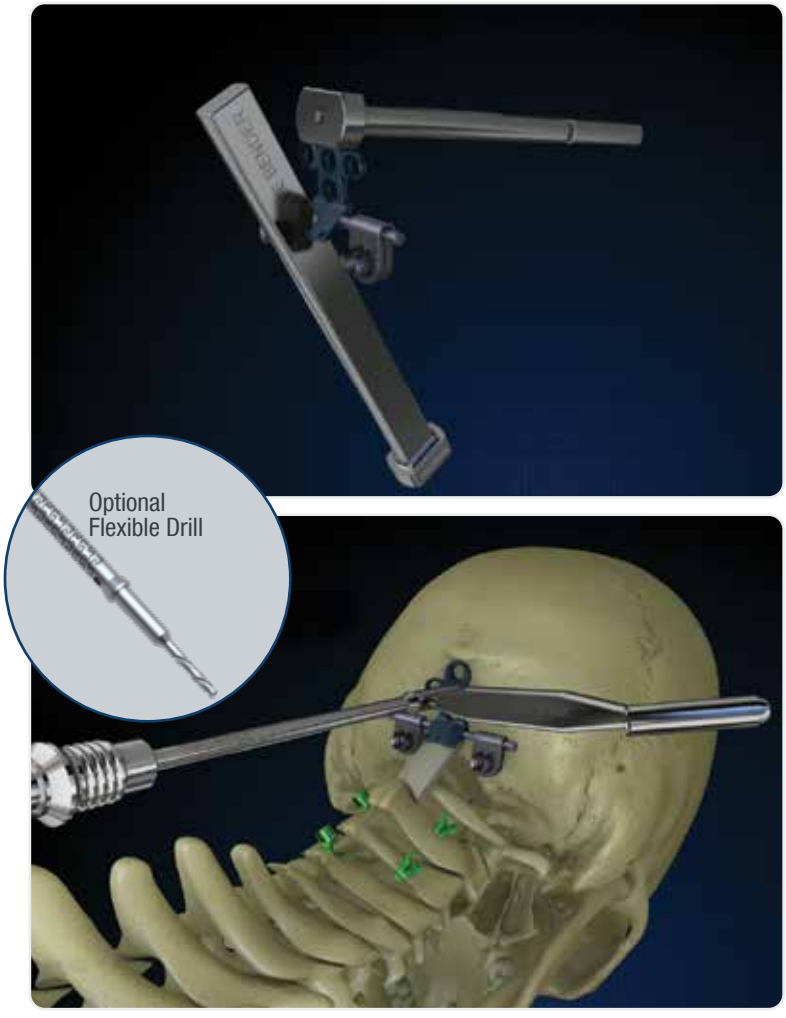
- **Caution:** The crossbar of the plate should not be bent.

DRILLING

Select the appropriate Drill-Tap (DT) Guide based on the desired drilling depth. The DT Guides are available with fixed drilling depths from 6mm to 16mm in 2mm increments. Using the DT Guide to align the drill hole in the Occipital Plate,insert the Straight or Flexible Drill Bit through the DT Guide and drill to the desired depth. It is recommended to start with the 6mm drill and then to sound the hole with a ball tip probe. Repeat process to achieve the optimal depth.

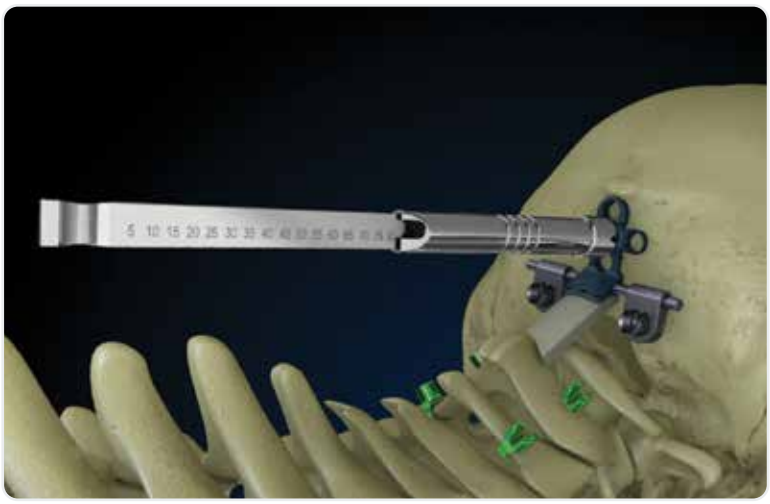
NOTE: It is recommended drilling be done through the plate.

NOTE: Both the Straight and Flexible Drill Bits must be used in conjunction with the DT Guide to achieve a fixed drilling depth. When the flexible drill bit is used, the DT Guide will help stabilize the flexible shaft and direct the drill bit in the proper position.



SCREW MEASUREMENT

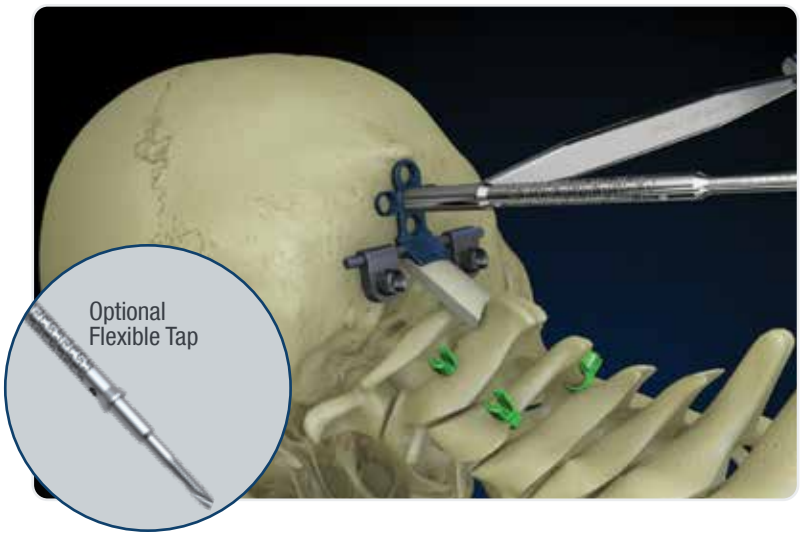
The Solanas Depth Gauge should be used to verify the hole depth as well as the occipital bone thickness.



Tapping

Once a satisfactory depth has been achieved, the appropriate Straight or Flexible Tap can be used to prepare the screw hole. Select the appropriate DT Guide based on the desired tapping depth. Insert the Straight or Flexible Tap through the DT Guide and tap to the desired depth. The occipital bone is very dense and each hole should be tapped to the desired screw length.

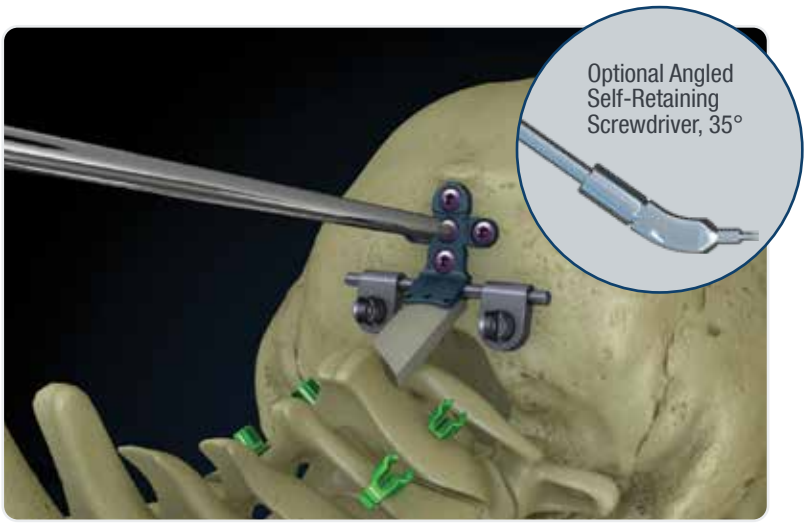
NOTE: Both the Straight and Flexible Taps must be used in conjunction with the DT Guide to achieve a fixed tapping depth. When the Flexible Tap is used, the DT Guide will prevent excessive motion of the flexible shaft and help direct the tap in the proper position.



Occipital Bone Screw Insertion

Choose the appropriate diameter and length screw for each screw location and verify the size before placement. Use the Self-Retaining Screwdriver to engage the bone screw, insert it into the occipital bone, and provisionally tighten. The Angled Self-Retaining Screwdriver may also be used for screw insertion.

The remaining screws can be placed using the same technique. Once all of the screws have been placed, use the Self-Retaining Screwdriver or the Angled Self-Retaining Screwdriver for final tightening.



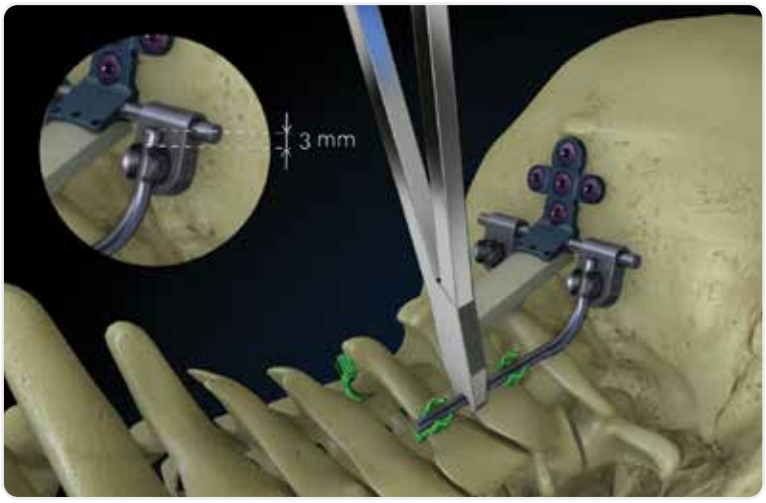
ROD CONTOURING

If necessary, use the Rod Bender to contour the Precontoured Transition Rod further to best fit the individual patient anatomy. Once the angle and position of the Transition Rod have been determined, cut both ends of the rod to the required length using the Rod Cutter.

Rod Placement

Use the Rod Holder to position the Occipital Precontoured Transition Rod. Determine the necessary adjustments required to align the rods with the laminar hooks and rod saddles on the Occipital Plate. A rod template is available in the Solanas System.

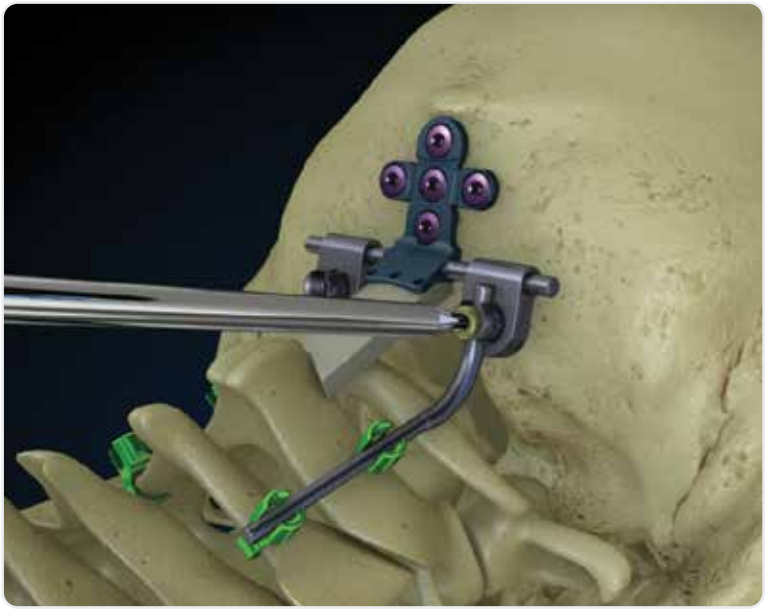
NOTE: Ensure the rod is long enough to clear the saddle of the locking clamp on the Occipital Plate by approximately 3mm.



Provisional Tightening of Construct

Once all of the Occipital Bone Screws have been final tightened and the rods have been adjusted to match the patient's anatomy, use the Self-Retaining Screwdriver to provisionally tighten the set screws in the saddles of the Occipital Plate to stabilize the rod. The Angled Self-Retaining Screwdriver may also be used to insert the set screw. Use the Solanas Set Screw Inserter to provisionally tighten the set screws in the laminar hooks.

NOTE: The Plate Rotating Body Adjustment Tool can be used to fine tune the positioning of the saddles.

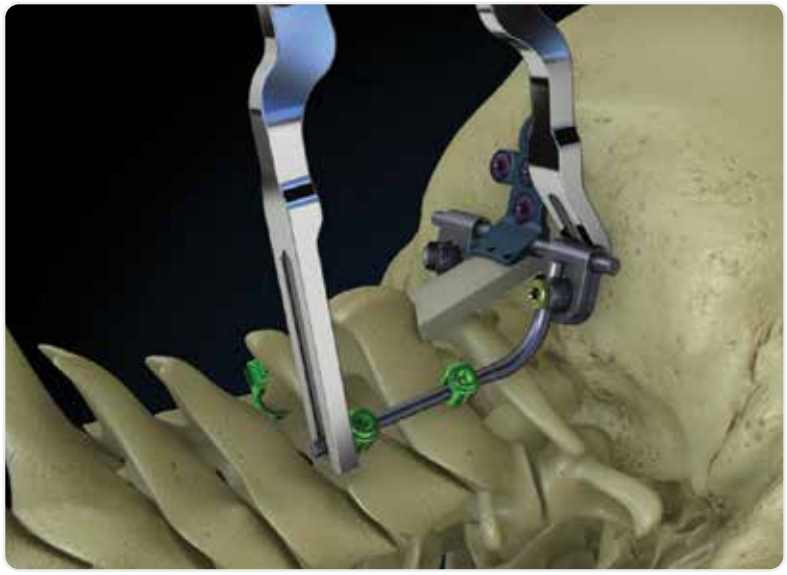


IN-SITU ROD BENDING

If the rod needs to be contoured further, left and right In-situ Rod Benders can be used.

Graft Compression

The Occipital Compressor should be used to compress the bone graft between the Occipital Plate/ Occiput and the C2 spinous process and lamina. Loosen the set screws on the cervical hooks to allow the rod to slide freely. Place the Occipital Compressor onto the rod above the Occipital Plate saddle and below the lowest hook and squeeze the handles until desired compression is achieved. Provisionally tighten the set screws.



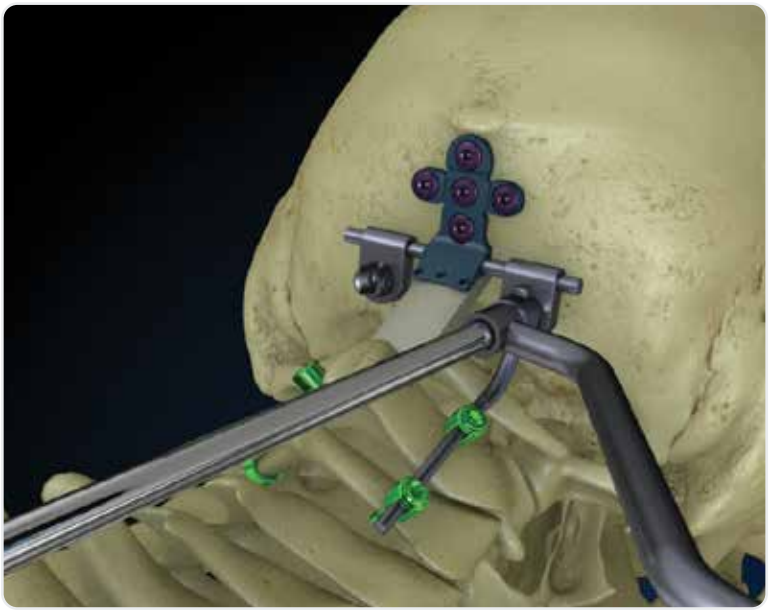
- **Caution:** The surgeon must exhibit care to avoid impacting the bone graft into the spinal canal.

Holes are provided as a design feature on the keel at the caudal end of the plate. These holes are provided to facilitate placing wires* from the plate to C2 as an additional fixation for the bone graft. Use of such wire is at the surgeon's discretion. The wiring technique chosen is at the discretion of the surgeon based on local anatomy, previous deformity/ trauma and desired construct formation.

*Titanium wires or cables are recommended to mitigate risks of Galvanic Reaction.

FINAL TIGHTENING OF CONSTRUCT

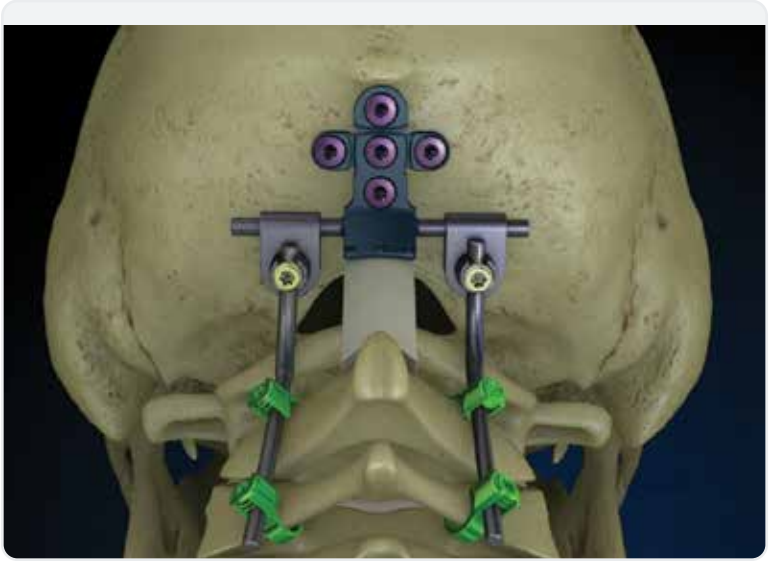
After all of the set screws have been placed and the rods are secured in the implants, use the Self-Retaining Screwdriver and the Torque-Limiting handle (25 in-lbs) in conjunction with the Counter Torque Device to final tighten the set screws in the saddles of the plate. The Angled Self-Retaining Screwdriver may also be used for final tightening of the set screws. Set screws in the laminar hooks should also be final tightened using the Solanas Set Screw Driver Shaft and the Solanas Torque-Limiting Handle (25 in-lbs) in conjunction with the Solanas Counter Torque Device.



- **Caution:** *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 the associated connector. Failure to tighten the set screw to the recommended torque could compromise the mechanical stability of the connector.*

Final Construct

Recheck all connections of the final construct prior to wound closure.

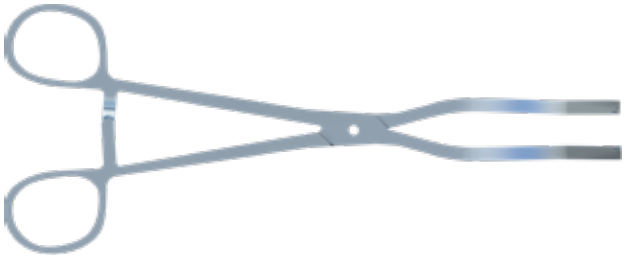


Revision and Removal

To remove any of the Avalon system implants described throughout the technique, engage the set screw with the Self-Retaining Screwdriver and turn counter-clockwise until the set screw is disengaged from the implant and the bone screw is disengaged from the bone. The implants can then be freely removed from the bone.

See Solanas surgical technique for revision and removal of cervical hooks.

Plate Holder



Rod-Bender, 3.3mm and 4.0mm

Rod Cutter, 3.3mm and 4.0mm

Plate Benders

Double Barrel Drill/Tap Guide, 6-16mm in 2mm increments

Straight Drill, 3.2mm

Flexible Drill, 3.2mm

Straight Tap, 4.5mm

Flexible Tap, 4.5mm

Self Retaining Screwdriver

Angled Self Retaining Screwdriver, 35°

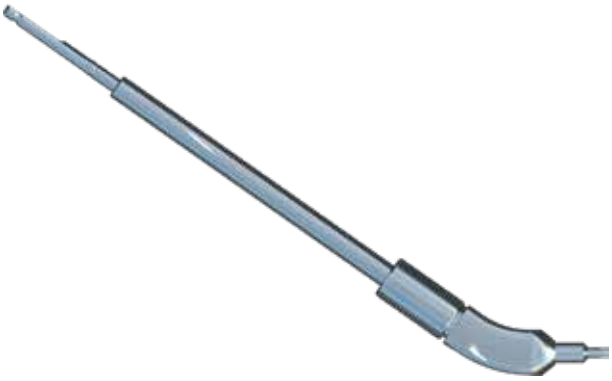
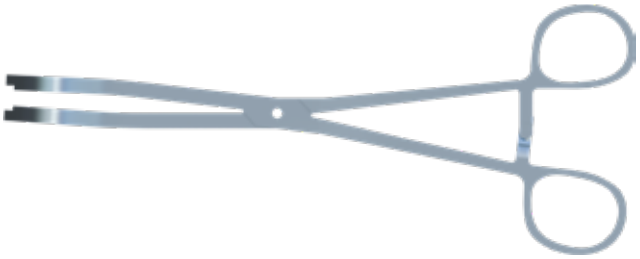


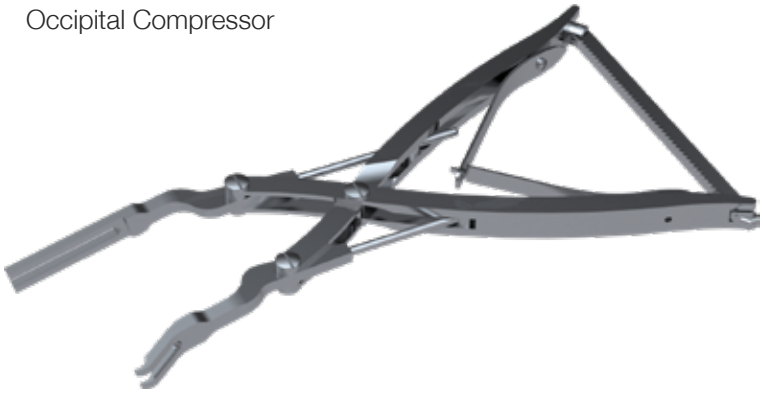
Plate Rotating Body Adjustment Tool



In-situ Rod Bender, left and right

Counter-torque

Occipital Compressor



Quick Connect Silicone Axial Handle, Ratcheting

Quick Connect Silicone T-Handle, Ratcheting

Torque Limiting Silicone Handle, Axial 25inch-lbs

Self-Centering Set Screw Inserter

Rod Persuader

Torque Limiting Handle

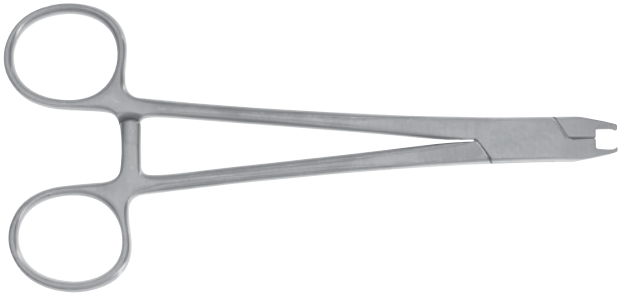
Torque Limiting Shaft

Small Depth Gauge

Counter-torque

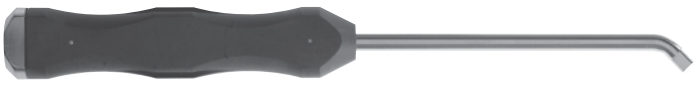
150mm Rod Template 3.0mm

Hook Holder



Hook Trial

Hook Impactor



INSTRUCTIONS FOR USE

SOLANAS® POSTERIOR OCT FIXATION SYSTEM

GENERAL INFORMATION:
The Solanas Posterior OCT Fixation System is a spinal fixation system intended to improve stability of the occipital, cervical, and thoracolumbar areas of the spine (Occiput-T3).

The Solanas Posterior OCT 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 Posterior OCT 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® Posterior OCT 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 of 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 Posterior OCT 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 Posterior OCT 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 Posterior OCT 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:
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 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 not to smoke, consume alcohol, or consume non-steroidals and aspirin, as determined by the surgeon. Complete postoperative management to maintain the desired result should also follow implant surgery.
5. Postoperative patients should be instructed not to use tobacco or nicotine products, consume alcohol, or use non-steroidal anti-inflammatory drugs and aspirin, as determined by the surgeon. Complete postoperative management to maintain the desired result should also follow implant surgery.
6. 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

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