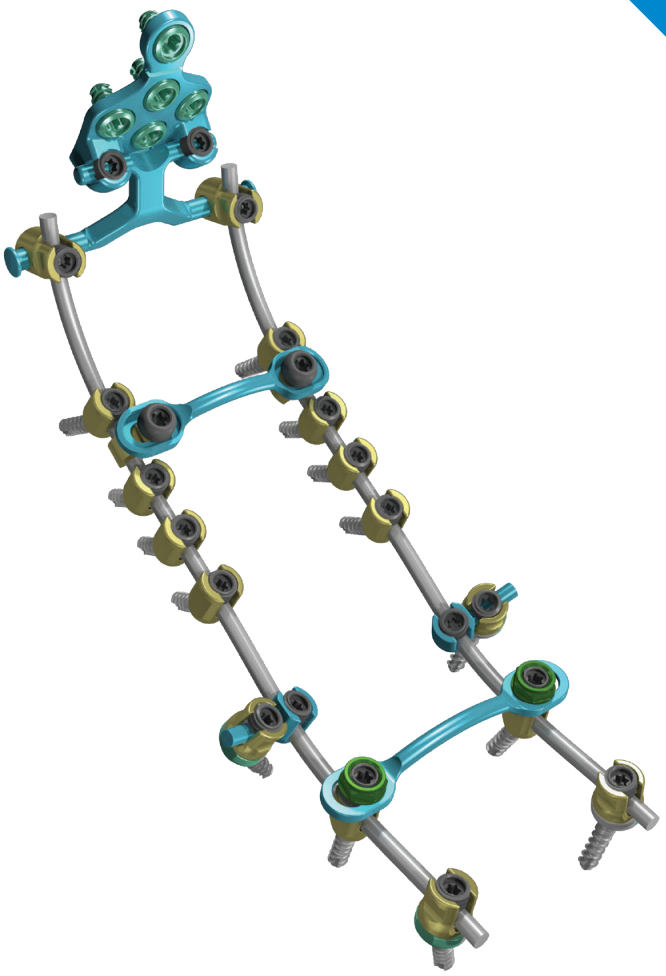
Streamline® OCT

Occipito-Cervico-Thoracic System



SURGICAL TECHNIQUE

DESCRIPTION

The Streamline OCT System consists of a variety of rods, hooks, polyaxial screws, high-angle screws, locking caps, occipital plates, occipital screws, and connecting components used to build an occipito-cervico-thoracic spinal construct. System components are manufactured from ASTM F136 medical grade titanium alloy and ASTM F1537 medical grade cobalt chromium molybdenum alloy. Medical grade titanium alloy and medical grade cobalt chromium molybdenum alloy may be used together. The system should be implanted using only the surgical instruments designed for the system. Cases and caddies are supplied for sterilization and transport of the implants and instruments.

INDICATIONS FOR USE

The Streamline OCT Occipito-Cervico-Thoracic System is intended to provide immobilization and stabilization of the spinal segments as an adjunct to fusion when using autograft and/or allograft for the following acute and chronic instabilities of the craniocervical junction, the cervical spine (C1 to C7) and the thoracic spine (T1 to T3): traumatic spine fractures and/or traumatic dislocations; instability or deformity; failed previous fusions (e.g., pseudoarthrosis); tumors involving the cervical/thoracic 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 disc disease of the facets with instability.

The 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 advanced 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 Streamline OCT System may be connected to the Streamline MIS Spinal Fixation System or Streamline TL Spinal System using connectors and/or transition rods.

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SURGICAL TECHNIQUE

ORDERING GUIDE

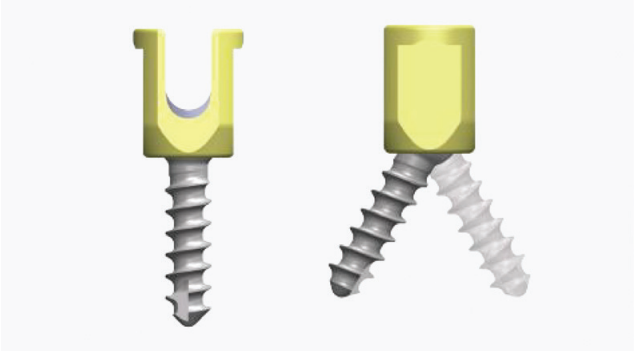
SPECIFICATIONS

INTRODUCTION

System Overview

The Streamline Occipito-Cervico-Thoracic (OCT) System allows a rigid posterior construct to be created in the occipito-cervico-thoracic spine by offering a broad range of implants. These implants provide the ability to tailor treatment to a specific patient for a more efficient, streamlined surgical experience.

Polyaxial Screw



- For use in cervico-thoracic spine, C1-T3
- T-10 hexalobe drive mechanism
- Self-tapping
- 52° conical screw angulation provides intraoperative flexibility
- Friction fit screw head designed for greater control
- Extensive size offering
- Diameters: 3.5, 4.0 and 4.5mm
- Lengths: 10 - 48mm
- Color-coding, by diameter, minimizes risk of improper size selection
- Composed of Ti-6Al-4V ELI

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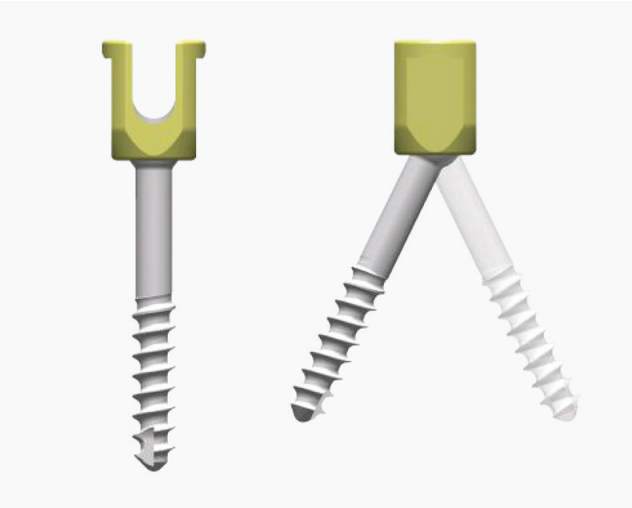
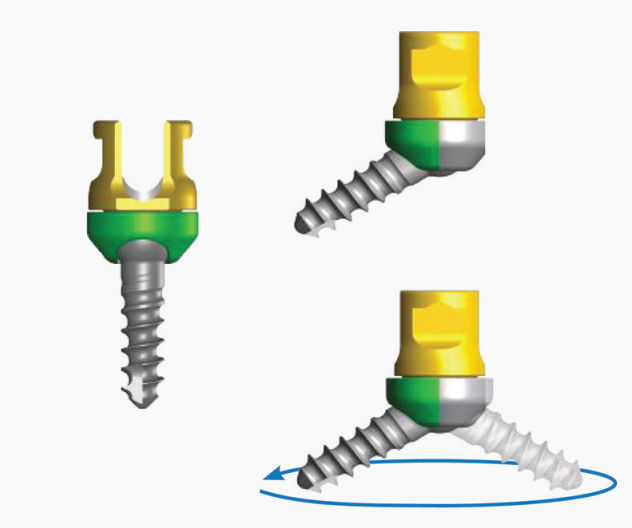
Polyaxial Smooth Shank Screw



- For use in cervico-thoracic spine, C1-T3
- T-10 hexalobe drive mechanism
- Self-tapping
- 52° conical screw angulation provides intraoperative flexibility
- Friction fit screw head designed for greater control
- Extensive size offering
- Diameters: 3.5 and 4.0mm
- Lengths: 24 - 36mm, in 2mm increments
- Color-coding, by diameter, minimizes risk of improper size selection
- Composed of Ti-6Al-4V ELI

High Angle Screw



- For use in cervico-thoracic spine, C1-T3
- T-10 hexalobe drive mechanism
- Self-tapping
- 120° conical screw angulation provides intraoperative flexibility
- Screw thread can be positioned anywhere along a 360°track, irrespective of desired angulation position, offering more versatility than with conventional “favored angle” screws
- Extensive size offering
- Diameters: 3.5 and 4.0mm
- Lengths: 10 - 48mm
- Color-coding, by diameter, minimizes risk of improper size selection
- Composed of Ti-6Al-4V ELI

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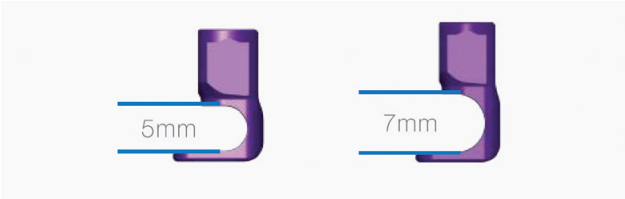
Set Screw

- Designed to reduce potential of cross-threading
- Self-retaining T-15 hexalobe drive mechanism
- Retention feature for secure attachment to cap inserter
- Compatible with the following implants: occipital plate, occipital-cervical assembly, hook, polyaxial screw, high angle screw, rod-to-rod connectors and lateral offset connectors
- Composed of Ti-6Al-4V ELI

Hook

- For use in cervico-thoracic spine, C1-T3
- Available in two sizes with 5 and 7mm mouth openings
- Composed of Ti-6Al-4V ELI



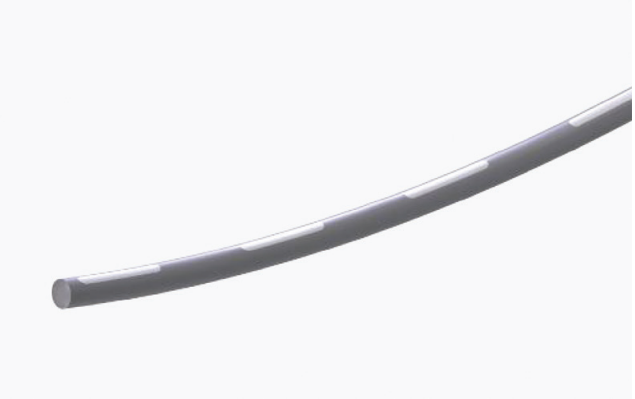
Straight Rod

- For use in cervico-thoracic spine, C1-T3
- Low-profile, 3.2mm diameter with the same ultimate tensile strength (UTS) as a 3.7mm Ti-6Al-4V rod*
- Minimal "spring back" behavior during contouring reduces OR time
- Alignment marks enable consistent contouring along entire rod length
- Available in multiple lengths
- Composed of Co-28Cr-6Mo

** data on file*

INTRODUCTION

Pre-Bent Rod



- For use in cervico-thoracic spine, C1-T3
- Low-profile, 3.2mm diameter with the same ultimate tensile strength (UTS) as a 3.7mm Ti-6Al-4V rod*
- Minimal "spring back" behavior during contouring reduces OR time
- Alignment marks enable consistent contouring along entire rod length
- Available in multiple lengths
- Composed of Co-28Cr-6Mo

Note: Pre-bent rods are not part of the standard Streamline OCT implant set. Please contact Customer Service to special order the Streamline OCT pre-bent rod caddy (26-LS-STRMOCT-PBRD).

Transition Rod

- For use in cervico-thoracolumbar spine, C1-S1
- 3.2mm diameter transitions to 5.5mm diameter†
- Minimal "spring back" behavior during contouring reduces OR time
- Longitudinal alignment mark enables consistent contouring along entire rod length
- Transition zone length minimized to accommodate screw placement
- Composed of Co-28Cr-6Mo

Note: The transition rod is not part of the standard Streamline OCT implant set. Please contact Customer Service to special order.

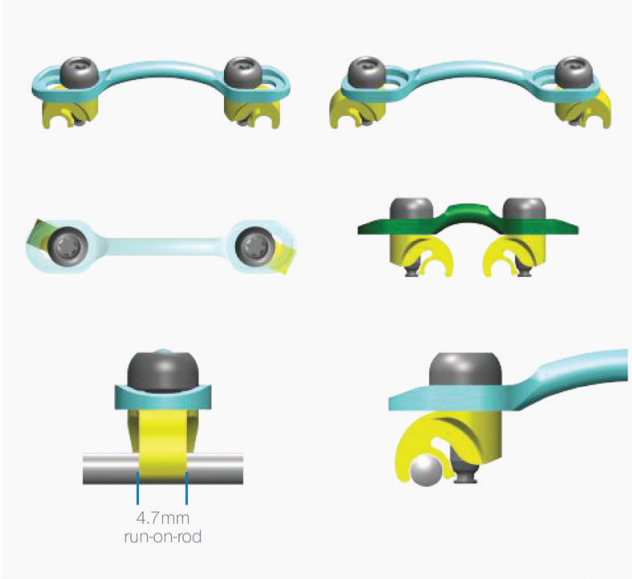
†5.5mm end to be connected to the Streamline® MIS or Streamline® TL Spinal Fixation System.

** data on file*

INTRODUCTION

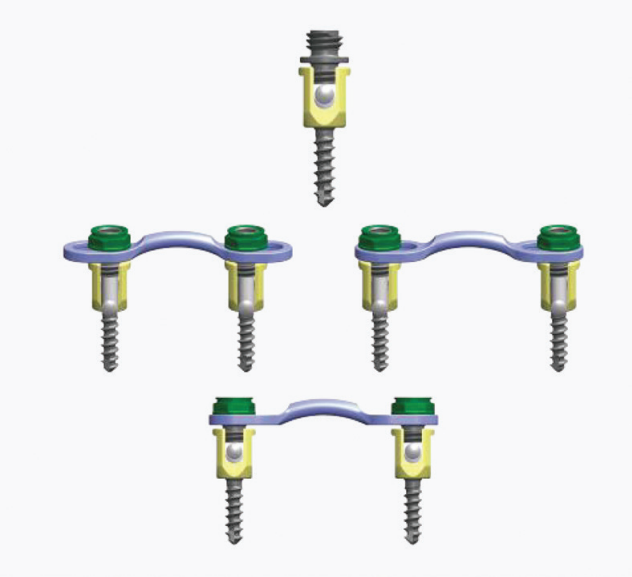
Rod-to-Rod Crosslink

- For use in cervico-thoracic spine, C1-T3
- Provides additional construct stability
- Self-retaining T-15 hexalobe drive mechanism
- Top-loading design for quick placement
- Variable design available in small, medium and large; rod-to-rod attachment range of 11 - 46mm
- Medial/lateral adjustability
- 8mm, with claws oriented laterally
- 23mm, with claws oriented toward midline
- 4.7mm run-on-rod
- Provides full coronal adjustability of claws
- Color-coding for quick selection
- Composed of Ti-6Al-4V ELI



Head-to-Head Crosslink

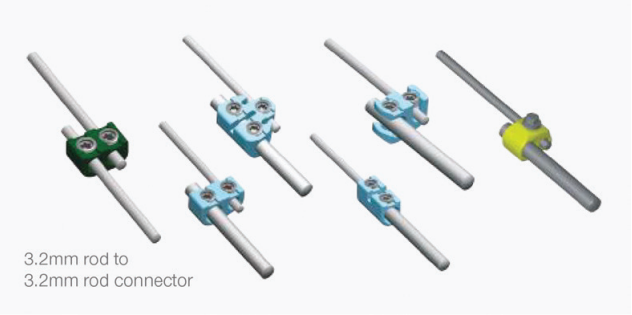
- For use in cervico-thoracic spine, C1-T3
- Provides additional construct stability as an alternative to the rod-to-rod crosslink
- Set screw has a self-retaining T-15 hexalobe drive mechanism
- Variable design available in extra small, small, medium and large; head-to-head range of 20 - 46mm
- 8mm of medial/lateral adjustability
- Color-coding for quick selection
- Composed of Ti-6Al-4V ELI



INTRODUCTION

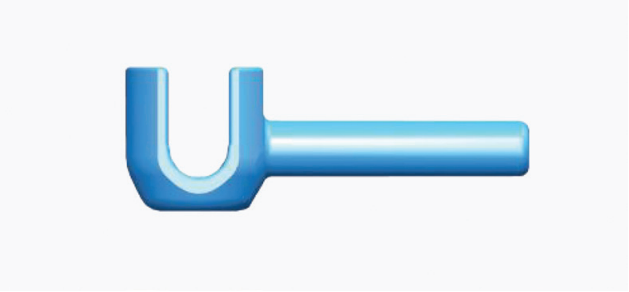
Rod-to-Rod Connectors

- For use in cervico-thoracolumbar spine, C1-T3
- Connect 3.2mm rod to 3.2mm or 5.5mm rod
- Allows a cervico-thoracic construct to be linked to a thoracolumbar construct, such as the Streamline MIS or Streamline TL Spinal Fixation System
- Composed of Ti-6Al-4V ELI



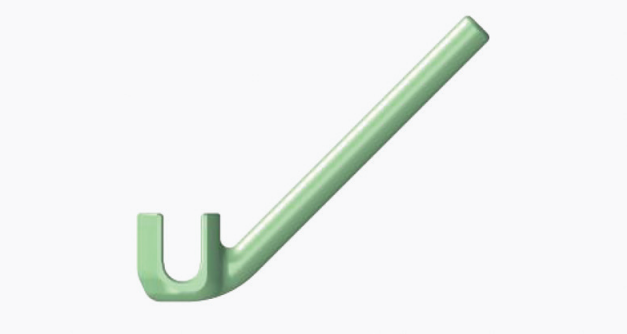
Lateral Offset Connector, Straight

- For use in cervico-thoracic spine, C1-T3
- Accepts 3.2mm Co-28Cr-6Mo rod
- 3.2mm rod, 15mm length
- Composed of Ti-6Al-4V ELI



Lateral Offset Connector, Angled

- For use in cervico-thoracic spine, C1-T3
- Accepts 3.2mm Co-28Cr-6Mo rod
- 3.2mm rod, 30mm length
- 45˚ rod angle
- Composed of Ti-6Al-4V ELI



INTRODUCTION

Occipital Plate

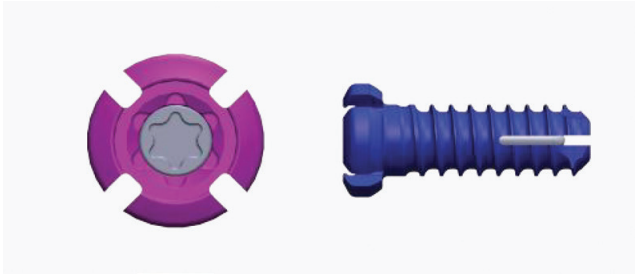
- One size plate: 2.5mm profile x 42mm (H) x 26mm (W)
- Superior and inferior midline screw holes can be removed to create a 5- or 4-hole plate
- Utilizes standard set screws to connect to the cross connector
- Composed of Ti-6Al-4V ELI

Occipital Plate Screws - Standard

- Cortical thread design
- Self-tapping
- Self-retaining T-20 hexalobe drive mechanism
- Available in two diameters: 4.5 and 5.25mm, and lengths ranging from 6 - 16mm
- Color-coding, by length, for quick selection
- Composed of Ti-6Al-4V ELI

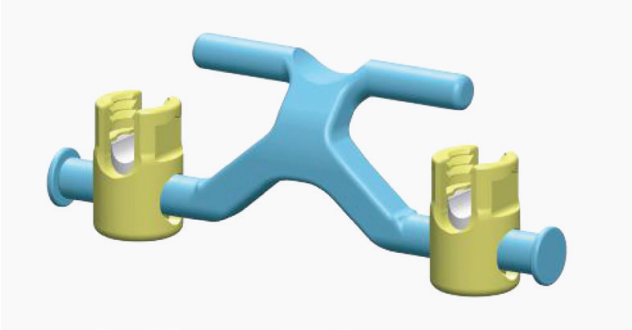
Occipital Plate Screws - Split Tip

- Cortical thread design
- Self-tapping
- Self-retaining T-20 hexalobe drive mechanism
- Inner set screw has a T-8 hexalobe drive pocket; once the set screw is fully seated, the screw tip will expand
- Available in two diameters: 4.5 and 5.25mm, and lengths ranging from 10 - 16mm
- Color-coding, by length, for quick selection
- Composed of Ti-6Al-4V ELI



Occipital - Cervical Assembly

- Available in four heights: 8, 14, 17 and 20mm
- Locking cups
  - Friction fit
  - Utilize standard set screw
  - M/L adjustability of 32 - 44mm (8mm option is 27 - 44mm)
  - 360˚ of sagittal adjustability
- Composed of Ti-6Al-4V ELI



SURGICAL TECHNIQUE

Step 1: Patient Positioning

Place the patient on a radiolucent operating table in the prone position with the head and neck held securely in proper alignment. (Figure 1) Prepare, clean, and drape the operative area in a conventional manner and then make an incision at the appropriate level(s). Apply lateral C-arm fluoroscopy or other radiographic techniques during surgery to ensure correct targeted levels and implant placement.

Figure 1

Step 2: Cortex Preparation

After removing bone and/or soft tissue (as needed) to expose the bone / lateral mass, evaluate the anatomy to determine the appropriate position and orientation for the screw. Use the awl or a burr to perforate the cortex, creating a pilot hole (Figure 2). The tip of the awl is 2mm in diameter and 6mm in length. Repeat for all screw placement sites.

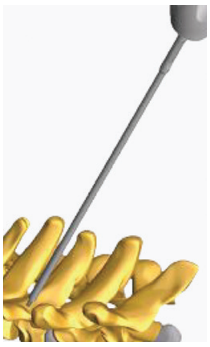


Figure 2

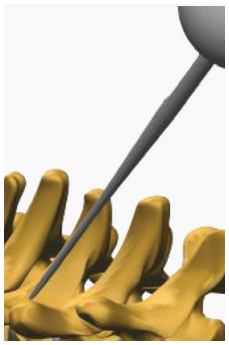


Figure 3A

Figure 3B

Step 3: Screw Hole Preparation

OPTION ONE: Pedicle Finder

Use the straight or curved pedicle finder (Figures 3A and 3B) to dissect the cancellous bone to the appropriate depth for tapping and screw insertion. The diameter of the pedicle finder is 2.5mm and should only be used with 4.0mm and 4.5mm diameter screws. Etched markings on the pedicle finder indicate its depth. The depth markings start at 10mm extending up to 50mm, in 5mm increments.

OPTION TWO: Drill Utilizing Fixed Guide

Position the tip of the fixed guide (Figure 4) where the cortex was perforated with the awl. Align the guide with the intended screw orientation.

Fixed drills are available in 10 - 18mm lengths in 2mm increments

Note: Fixed drills have a colored band to help identify sizes.

OPTION THREE: Drill Utilizing Variable Drill Guide

To set the appropriate depth on the variable drill guide, pull the adjustment knob upward and rotate (Figure 5) until desired depth is completely visible in one of the three windows.

Note: If a number is not centered in the window, that depth is incorrect; verify the correct depth is selected by checking the other windows (Figures 6-8). Once the correct depth is selected, release the knob to lock the depth in place.

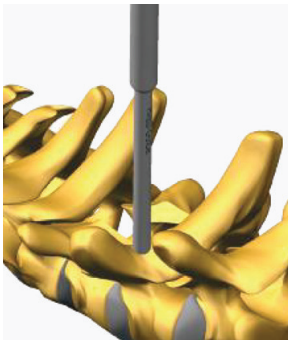


Figure 4

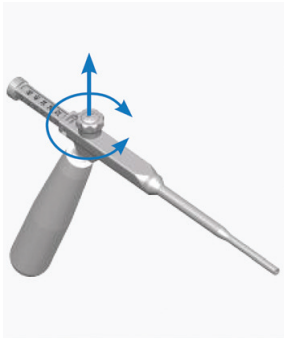


Figure 5

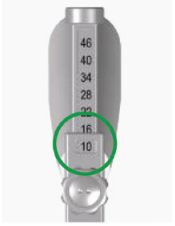


Figure 6

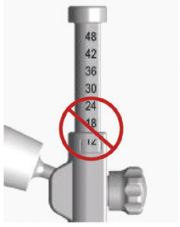


Figure 7

Figure 8

Step 4: Drilling

Attach the fixed or variable drill to one of the following:

- AO to Jacobs Chuck adapter, or,
- Modular AO handle (available in ratcheting or non-ratcheting) for hand drilling

Next, insert drill tip completely through the fixed (Figure 9) or variable drill guide (Figure 10A). First, locate the drill tip into previously prepared pilot hole. Next, lower the distal tip of the guide down until it rests against the bone. Align the guide with the intended screw orientation.

Orient the drill guide and drill at the desired trajectory and drill to the appropriate depth. The integral stop near the proximal end of the drill will bottom out against the proximal end of the guide (Figure 10B). Carefully remove the drill and the guide.

Note: The fixed and variable drills are slightly undersized relative to the 3.5mm screw minor diameter, 0.5mm undersized to the 4.0mm screw minor diameter and 0.8mm undersized to the 4.5mm screw minor diameter.

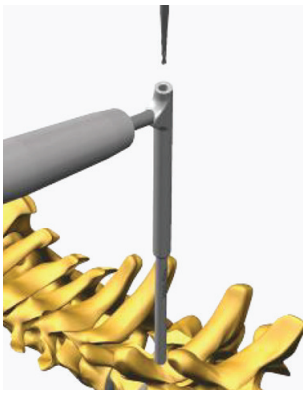


Figure 9

Figure 10A

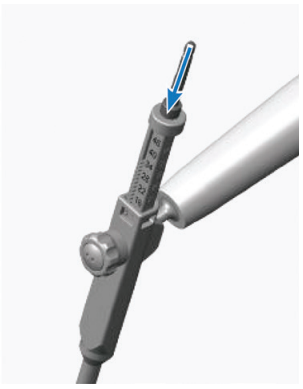


Figure 10B

Step 5: Tapping (Optional)

Attach the appropriate length fixed tap to the desired modular AO handle (available as ratcheting or non-ratcheting). First, locate the tap tip into the previously prepared pilot hole (Figure 11). Align the tap with the intended screw orientation (Figure 12).

Turn the handle clockwise to tap the hole to the appropriate depth. Carefully remove the tap in a counterclockwise fashion (Figure 13).

Note: The fixed taps can be used through the fixed guide. The guidelines are the same as for the fixed drills. They are color-coded by diameter: 3.0 (orange), 3.5 (gold) and 4.0 (dark blue).

Note: The thread length of ALL taps is 10.5mm, regardless of the labeled length. The labeled length only applies when the tap is used through the fixed guide. The depth markings start at 15mm, with the wide band at 20 - 25mm, extending up to 30mm.

Note: For Ø4.5mm screws, use the Ø4.5mm tap (magenta). The thread length of this tap is 10.5mm. The depth markings for the 4.5mm tap also start at 15mm, with the wide band at 20 - 25mm, extending every 5mm up to 45mm.

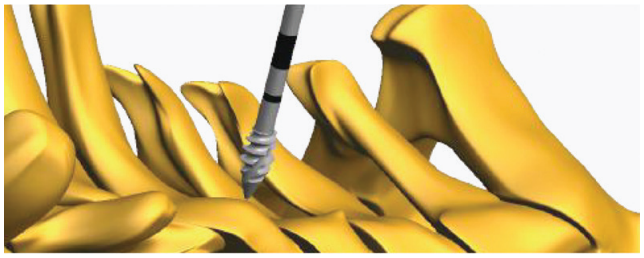


Figure 11

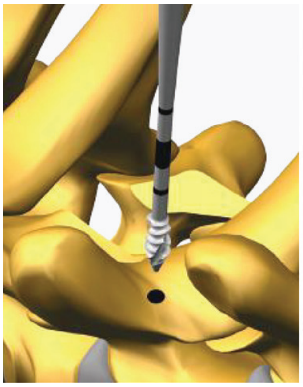


Figure 12

Figure 13

Step 6: Check Cortex Integrity and Hole Depth

- Use a striped ball-tipped probe (Figure 14) to check cortex integrity in all directions. Either use the probe or the depth gage (Figure 15) to verify hole depth. The depth markings for the striped ball-tipped probe start at 10mm, extending every 5mm up to 45mm, with the wide band at 20 - 25mm.

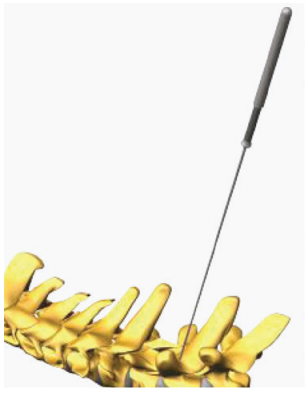


Figure 14

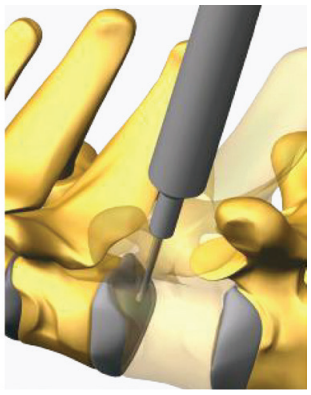


Figure 15

Step 7: Screw Insertion

Insertion instructions are the same for polyaxial, polyaxial smooth shank and high angle screws.

Attach the screw inserter (Figure 16A) to the desired modular AO handle (available as ratcheting or non-ratcheting). Press the tip of the screw inserter into the head of the appropriate size screw (Figure 16B), polyaxial or high angle. Exert downward pressure on the knob until the outer sleeve threads of the inserter engage the opening of the tulip. Maintaining downward pressure, rotate the knob clockwise to thread the outer sleeve into the tulip. Tighten until the knob cannot be rotated further. Before inserting the screw, ensure that the screw shaft is coaxial with the inserter shaft (Figures 16C and 16D).

Insert the screw tip into the previously prepared pilot hole. Rotating the handle clockwise, insert the screw to the appropriate depth. For additional stability, grasp the black sleeve, making sure not to grasp the tightening knob above it (Figure 17). It is important that the outer sleeve be fully threaded into the tulip (Figure 18) until the screw is fully inserted.

Once the screw has reached the desired depth, rotate the knob counterclockwise to disengage the screw inserter from the tulip.

Note: To ensure polyaxial capability is maintained, leave the underside of the tulip (polyaxial screw) or swivel base (high angle screw) slightly proud of the bone (Figure 19). DO NOT bury them into the bone.

Surgical Pearl: Keep the screw inserter completely on axis with the screw shaft when removing the inserter from the implanted screw. To accomplish this, 1) retract any soft tissue that may be impinging against the screw inserter, and, 2) avoid bottoming the tulip head against the bony elements in order to maintain its polyaxial characteristics.

Note: It is recommended that the dorsal height adjuster, not screw inserter, be used to adjust the height of the screw. (Figure 20).

Figure 16A

Figure 16B

Figure 16C

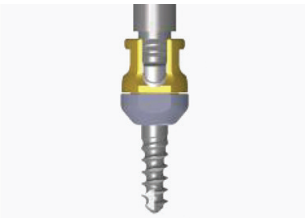


Figure 16D

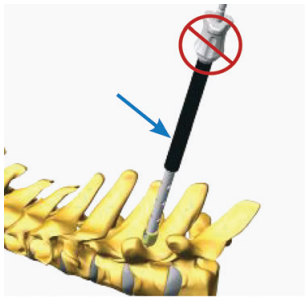


Figure 17

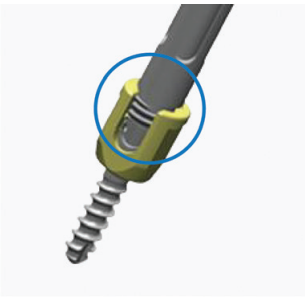


Figure 18

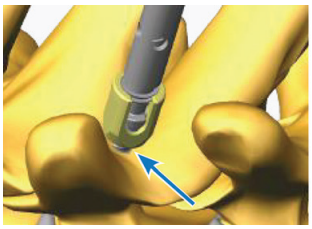


Figure 19

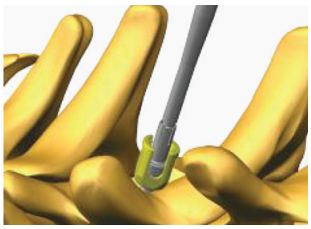


Figure 20

Step 8: Adjust Angle/Orientation of Tulip Assembly

Polyaxial and Polyaxial Smooth Shank Screws

Fit the tip of the yoke manipulator (Figure 21) into the tulip of the polyaxial screw and adjust the angle as needed. Rotate the handle to align the tulip slot with the intended rod orientation. Carefully remove the instrument from the screw.

CAUTION: It is critically important that the yoke manipulator be fully engaged into the bottom of the tulip (Figures 22A & 22B).

High Angle Screw

Fit the tip of the yoke manipulator into the tulip of the high angle screw (Figure 23A). Apply downward pressure and then locate the high angle position/slot (Figure 23B). Once the high angle position/slot is located, swing the manipulator handle toward the direction of where the high angle is desired (Figure 24A).

CAUTION: Minimal force should be required to angulate the tulip assembly.

Note: If polyaxial screw movement is restricted, adjust the height of the screw.

Once the angle is established, rotate the proximal tulip to align with the anticipated rod orientation (Figure 24B). Carefully remove the instrument from the tulip. The design intent is to allow more space for rod placement when the adjacent screw is in close proximity (Figure 24C).

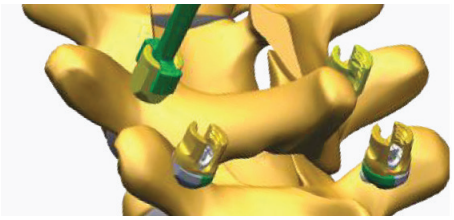


Figure 21

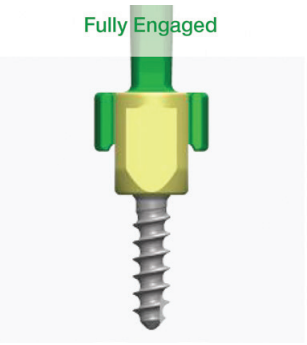


Figure 22A

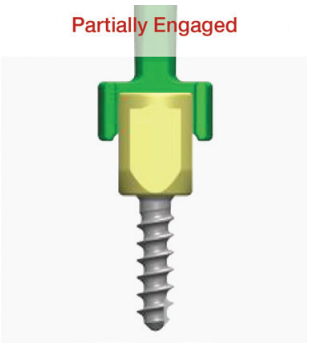


Figure 22B

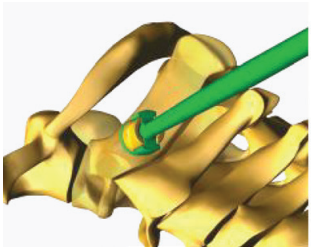


Figure 23A

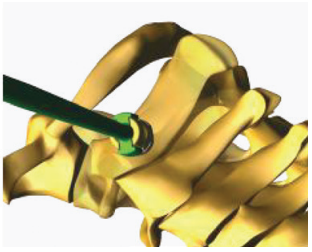


Figure 23B

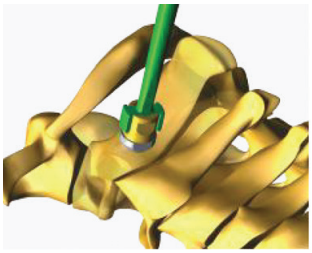


Figure 24A

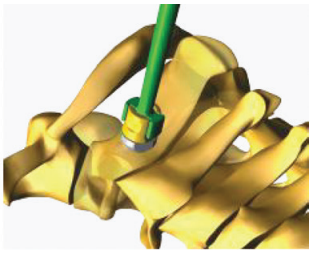


Figure 24B

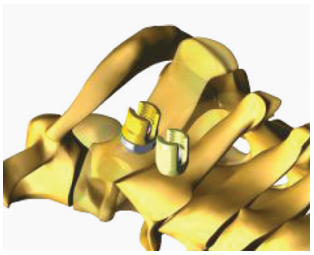


Figure 24C

Step 9: Rod Preparation

There are three rod options: straight, pre-bent and transition. Pre-bent rods are pre-lordosed to help reduce the need for intraoperative rod contouring. Transition rods are offered for constructs that require the linkage of Streamline OCT System implants to Streamline MIS or Streamline TL System implants.

Select the appropriate length rod template and place it into the tulips to provide guidance for the proper length and contour. Utilize the shape of the template and the length markings to cut and contour rod accordingly.

Note: The rod cutter has two different diameter holes; one is for the rod (3.2mm) and the other for the occipital plate cross connector (4.0mm).

Cut the rod to the appropriate length using the 3.2mm openings in the rod cutter (Figure 25A). The rod cutter offers two 3.2mm cut options: the open end, for full visibility, or, the closed hole. The cut point is at the junction between the two halves of the cutter head: 4mm (open end) and 6.5mm (closed hole) (Figure 25B). If needed, utilize the rod deburrer to remove any sharp edges or burrs (Figure 26).

To change the contour of the rod prior to affixing it to the construct, place the rod between the rollers of the rod bender (Figure 27) and squeeze the handles until the desired contour is achieved. Alternatively, the in-situ benders can also be used to bend the rod by utilizing the holes (Figure 28).

Note: There are alignment marks on the rod to help ensure that contouring occurs within the same plane, if that is what is desired.

CAUTION: Avoid creating a sharp bend or reversing a contour in the rod, as this may lead to premature material fatigue of the implant. Do not bend the rod in the reverse direction, as this may introduce micro fractures that compromise its strength. IF REVERSE ROD BENDING OR EXCESSIVE BENDING HAS OCCURRED, THE BENT ROD MUST BE DISCARDED.

Figure 25A

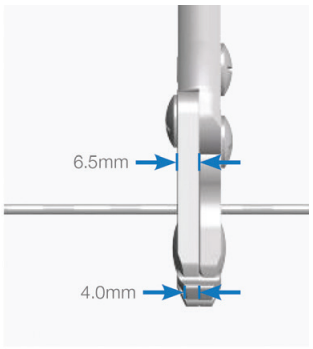


Figure 25B

Figure 26

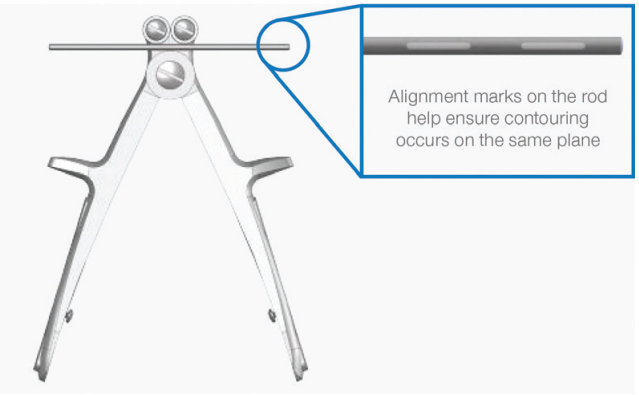


Figure 27

Figure 28

Step 10: Rod Placement

- Grasp the rod with the rod holder and seat it within the screws or hook tulips. (Figure 29).

Rod Reducer

If necessary, use the rod reducer to fully seat the rod. The rod reducer fits around the outside of the tulip and has two pins that fit just under the ears of the tulip to lock rotation and axial movement (Figure 30). Squeeze the handles together to reduce the rod into the base of the tulip (Figure 31).

If needed, the rod reducer has a ratcheting locking bar used to maintain reduction. The locking bar can also be folded out of the way (Figure 32).

Rod Rocker Reducer

Lower the rocker onto the rod. Slide the rocker toward the tulip until it comes to a stop (Figure 33). Depending upon initial orientation, rock the handle either cephalad or caudal (Figure 34) until the rod is fully seated into the bottom of the tulip. Insert set screw.

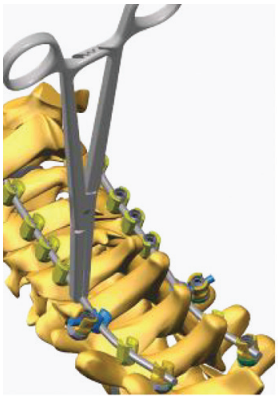


Figure 29

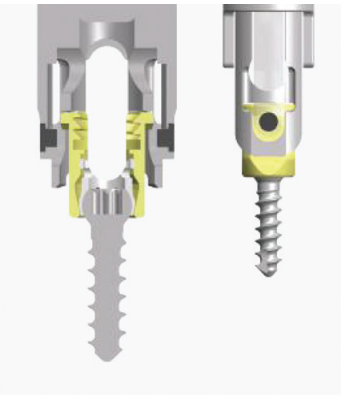


Figure 30

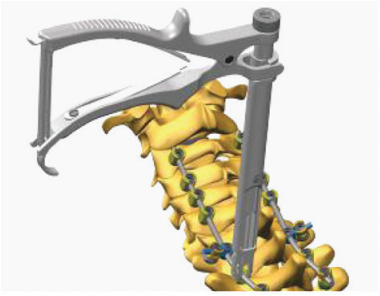


Figure 31

Figure 32

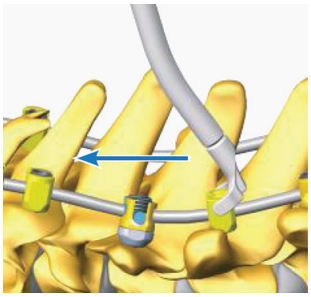


Figure 33

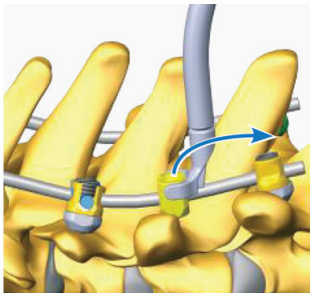


Figure 34

Step 11: Set Screw Insertion

- Use the self-retaining tip of the cap inserter (Figure 35) to pick up a set screw seated in the caddy.

  Insert the set screw into a tulip (Figure 36). To properly engage the threads, while minimizing the risk of cross-threading, rotate the handle a quarter-turn counterclockwise before advancing the set screw. Use a light, "three-finger technique" for initial insertion. Do not apply full locking torque at this time. To remove the cap inserter, pull it straight up to disengage the self-retaining feature.

  If using a rod reducer, place the cap inserter with set screw through the reducer to thread into the tulip (Figure 37). Utilize the same insertion technique as above.

  CAUTION: Do not utilize the set screw to reduce the rod. The rod must be fully reduced prior to inserting the set screw.

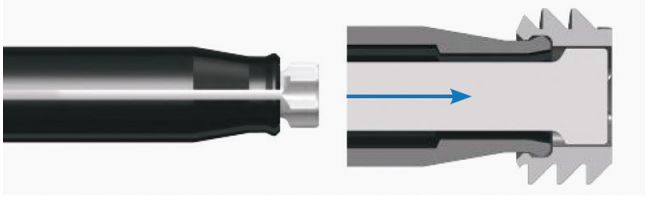


Figure 35

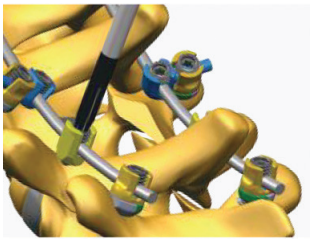


Figure 36

Figure 37

Step 12: Final Tightening

When all implants are securely in place and the rods are fully seated, final tightening is performed. Tighten set screws using the final driver, torque-limiting AO handle, and a counter-torque tube. Assemble the final driver to the torque-limiting AO handle. To perform a final lock of a set screw, seat the counter-torque tube (Figure 38) over the tulip, resting it on top of the rod. The handle can be rotated into one of four positions. To adjust the handle position, pull back on the lock ring (Figure 39) and rotate the handle (Figure 40). When the desired position is reached, release the spring-loaded ring to lock the handle in place (Figure 41A).

Note: An inline counter-torque tube is also available (Figure 41B).

Insert the final driver through the tube and into the set screw drive pocket (Figure 42). Do not apply maximum force at this time. First, ensure the driver is fully seated/on axis by applying a nominal amount of force to gauge the resistance. Stabilizing the counter-torque tube handle, rotate the torque-limiting AO handle clockwise until it emits an audible "click." Follow the same steps for remaining components.

CAUTION: Do not perform a final lock of the set screw without the counter-torque tube.

CAUTION: If removal of a set screw is necessary after previously being final locked, it must be replaced with a new set screw.

Figure 38

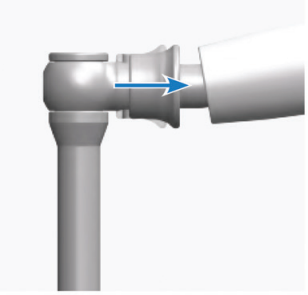


Figure 39

Figure 40

Figure 41A

Figure 41B

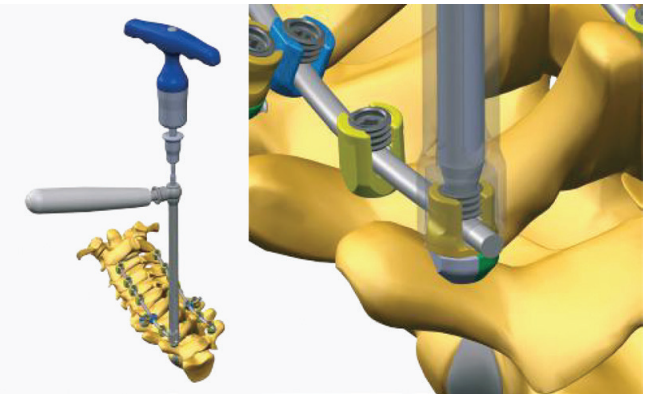


Figure 42

Attaching Optional Devices

Hook

Choose the appropriate size hook and grasp it with the hook holder. Adjust its position to conform to the targeted lamina (Figure 43) and to engage the rod. Hold the hook in position to prepare for insertion of the rod.

Alternatively, the hook may be provisionally attached to the rod with a set screw before the rod and hook are positioned. The set screw should remain loose so that the hooks can be repositioned easily.

Insert the set screw into a tulip (Figure 44). To properly engage the threads, while minimizing the risk of cross-threading, rotate the handle a quarter-turn counterclockwise before advancing the set screw. Use a light, "three-finger technique" for initial insertion. To remove the cap inserter, pull it straight up to disengage the self-retaining feature. Do not apply full locking torque at this time.

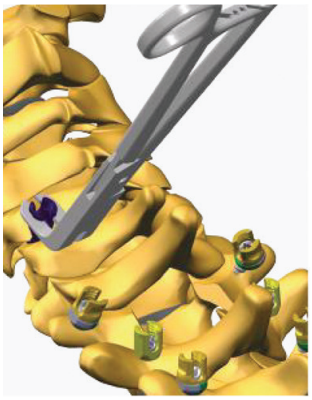


Figure 43

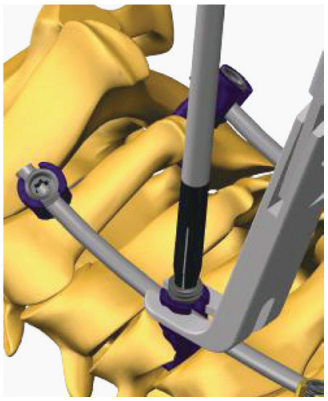


Figure 44

Rod-to-Rod Crosslink

Select the appropriate size rod-to-rod crosslink. Keep in mind that the design offers medial/lateral and coronal adjustability. Attach cap inserters to both of the crosslink set screws. The cap inserters are used to lower and position the crosslink rod clamps (gold) onto the rods (Figure 45). Before provisionally tightening the set screws, make sure the rod clamps are fully seated on the rods

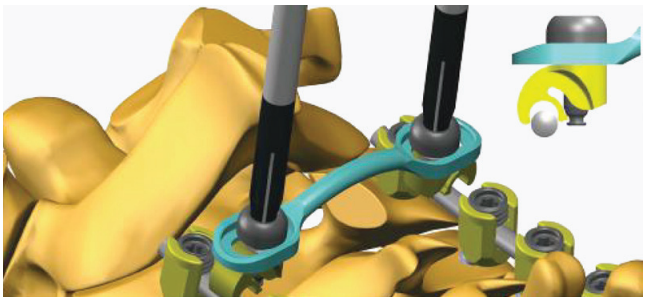


Figure 45

(Figure 46). Once confirmed, provisionally tighten the set screws. To disengage the cap inserter from the set screw self-retaining feature, pull it straight up.

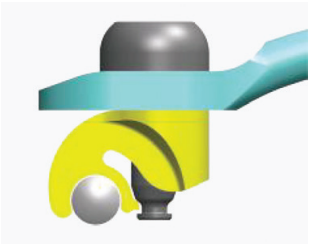


Figure 46

For final locking, assemble the rod-to-rod crosslink final driver (gray) to the torque-limiting AO handle. Lower the crosslink counter-torque tube over the set screw until fully seated. Insert the final driver through the tube and into the set screw drive pocket (Figure 47). Do not apply maximum force at this time. First, ensure the driver is fully seated/on axis by applying a nominal amount of force to gauge the resistance. Holding the counter-torque tube handle, rotate the torque-limiting AO handle clockwise until it emits an audible "click." Repeat these steps for the contralateral set screw.

CAUTION: If a set screw is loosened after it had previously been final locked, the crosslink must be replaced.

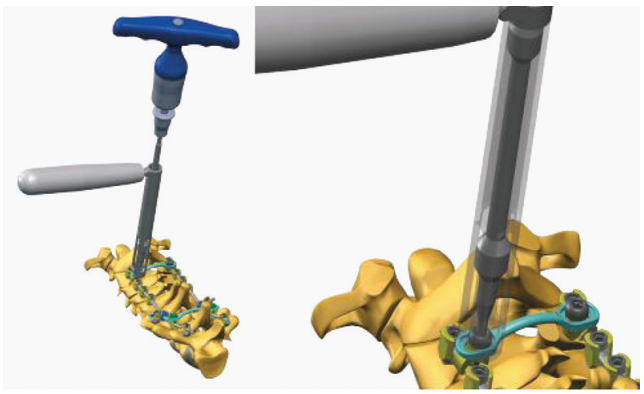


Figure 47

Head-to-Head Crosslink

Close approximation of adjacent screw or hook tulips will often not allow use of the rod-to-rod crosslink. For these situations, a head-to-head crosslink, which connects directly from tulip to tulip (Figure 48), is available.

Note: Set screws for Head-to-Head Crosslinks are different than traditional set screws

Use the self-retaining tip of the cap inserter to pick up a head-to-head set screw seated in the caddy. Utilizing the cap inserter, insert the set screw into the polyaxial screw or hook tulip (Figure 49).

CAUTION: Do not utilize the set screw to reduce the rod. The rod must be fully reduced prior to inserting the set screw.

For final locking, assemble the final driver to the torque-limiting AO handle. Lower the counter-torque tube over the set screw until fully seated. Insert the final driver through the tube (Figure 50) and into the set screw drive pocket (Figure 51). Do not apply maximum force at this time. First, ensure the driver is fully seated/on axis by applying a nominal amount of force to gauge the resistance. Stabilizing the counter-torque tube handle, rotate the torque-limiting AO handle clockwise until it emits an audible "click." Repeat these steps for the contralateral set screw.

CAUTION: Do not perform a final lock of the set screw without the counter-torque tube. Be sure to maintain consistent downward pressure on the handle, during final locking.

CAUTION: If removal of a set screw is necessary after previously being final locked, it must be replaced with a new set screw.

CAUTION: Do not introduce the crosslink or final nut prior to final lock of the set screw.

Select the appropriate size crosslink (the design offers medial/lateral adjustability), and place the slots over the set screws (Figure 52). Using the head-to-head crosslink final driver, load a locking nut, from the caddy, and thread it onto the set screw until it is provisionally tightened against the shoulder of the crosslink (Figure 53). Repeat the same step for the contralateral side.

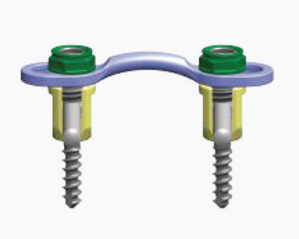


Figure 48

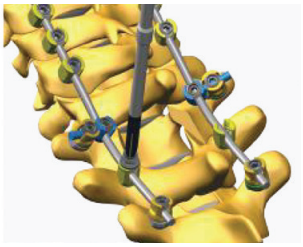


Figure 49

Figure 50

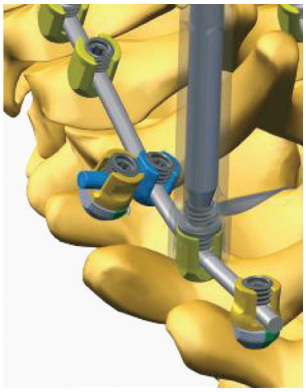


Figure 51

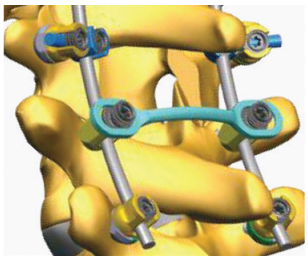


Figure 52

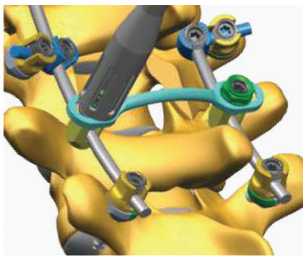


Figure 53

For final locking, assemble the head-to-head crosslink final driver (gray) to the torque-limiting AO handle. Insert the head-to-head crosslink final driver through the crosslink counter-torque tube (Figure 54). Do not apply maximum force at this time. First, ensure the driver is fully seated/on axis by applying a nominal amount of force to gauge the resistance. Stabilizing the counter-torque tube handle, rotate the torque-limiting AO handle clockwise until it emits an audible "click." Repeat these steps for the contralateral locking nut.

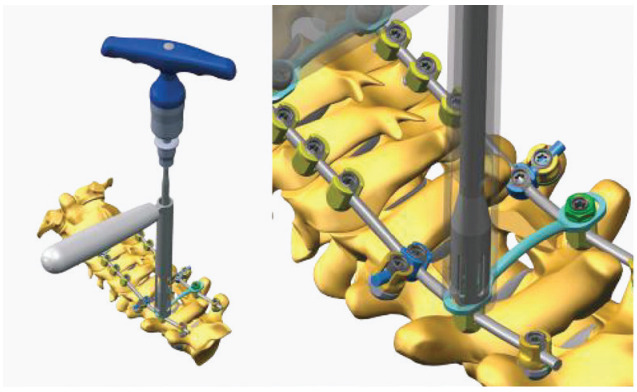


Figure 54

Note: Head-to-head crosslink benders are available in the set.

CAUTION: Avoid creating a sharp bend or reversing a contour in the crosslink. Do not bend the crosslink in the reverse direction as this may introduce micro fractures that compromise strength. If excessive bending or reverse bending has occurred, the device must be discarded.

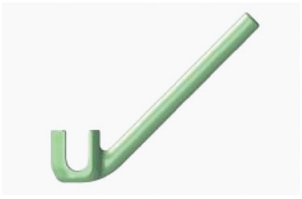


Figure 55

Figure 56

Lateral Offset Connectors - Straight and Angled

In order to accommodate medial/lateral flexibility with challenging rod-screw alignment situations, lateral offset connectors are available in angled and straight configurations (Figures 55 and 56).

Screws are placed in the usual manner. If the offset with a given screw precludes rod placement, a lateral offset connector can be used. Utilizing a set screw, first place the selected lateral offset connector loosely on the rod, near the level of the target screw (Figure 57). Tighten the set screw enough so that the lateral offset connector is secure enough to remain in contact with the rod, but also still able to slide along and rotate around the rod.

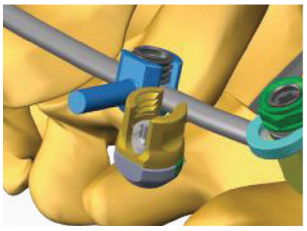


Figure 57

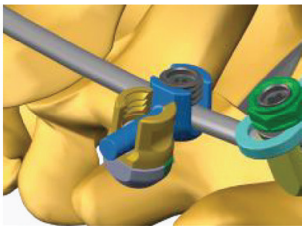


Figure 58

When connecting to a screw, rotate and/or angulate the screw tulip to align it with the lateral offset connector rod. Place the lateral offset connector rod into the tulip of the screw (Figure 58). Insert a set screw over the lateral offset connector rod (Figure 59). Final lock both set screws utilizing the counter-torque tube (same one as for screws), but with the 35 in-lb torque-limiting AO handle (black handle, 23-TORQUE-AO).

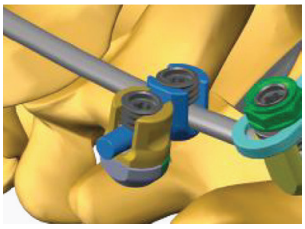


Figure 59

CAUTION: If removal of a set screw is necessary after previously being final locked, it must be replaced with a new set screw.

Rod-to-Rod Connectors (Figure 60)
The Streamline OCT System offers rod connectors to connect a 3.2mm rod to a 3.2 or 5.5mm rod.

Slide the parallel connector over the end of the Streamline OCT Ø3.2mm rod. Rotate the parallel connector and slip it over the end of the Streamline TL Ø5.5mm rod. The parallel connector is designed to accommodate 6mm of lateral offset between the centers of the two rods.

Attach the parallel connector final nut driver (gold) (Figure 61) to one of the modular handles. Provisionally lock the locking nut. Remove the nut driver from the handle and insert it up through the bottom of the parallel connector counter-torque tube (Figure 62). Attach the AO end to the torque-limiting AO handle (black handle, 23-TORQUE-AO)(Figure 63). Keeping the counter-torque tube retracted, seat the nut driver over the locking nut. Once fully seated, lower the counter-torque tube over the parallel connector (Figure 64). Stabilizing the counter-torque tube handle, rotate the torque-limiting AO handle clockwise until it emits an audible "click."

CAUTION: If the locking nut is loosened after it had previously been final locked, the connector must be replaced.

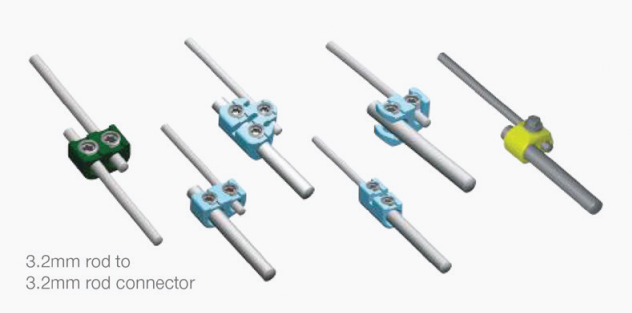


Figure 60

Figure 61

Figure 62

Figure 63

Figure 64

Place the connector onto both rods. Utilizing the cap inserter, provisionally insert a standard set screw (26-SETSCREW) into the threaded holes until fully seated onto each rod (Figures 65 & 66).

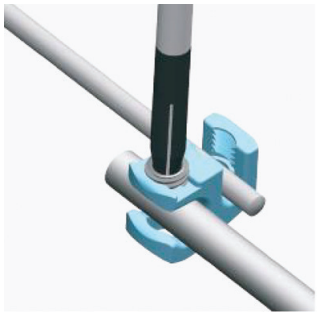


Figure 65

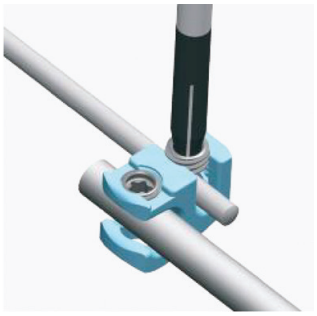


Figure 66

Assemble the final driver to the 35 in-lb torque-limiting AO handle (black handle, 23-TORQUE-AO). To perform a final lock of a set screws, seat the rod-to-rod connector counter-torque tube onto the connector. Insert the final driver through the tube and into the set screw drive pocket (Figure 67). Do not apply maximum force at this time.

First, ensure the driver is fully seated/on axis by applying a nominal amount of force to gauge the resistance (Figure 68). Stabilizing the counter-torque tube handle, rotate the torque-limiting AO handle clockwise until it emits an audible "click."

Figure 67

Figure 68

CAUTION: Do not perform a final lock of the set screw without the counter-torque tube.

CAUTION: If removal of a set screw is necessary after previously being final locked, it must be replaced with a new set screw.

Transition Rod Preparation and Placement

For 3.2mm diameter portion, see Step 9, "ROD PREPARATION." For the 5.5mm diameter portion, see the Streamline MIS or Streamline TL System's Surgical Technique.

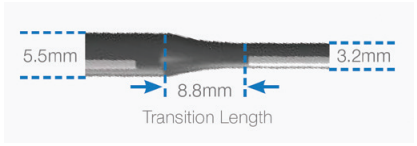


Figure 69

Note: The transition zone from the 3.2mm diameter to the 5.5mm diameter is 8.8mm (Figure 69).

Occipital Plate Selection/Placement

Burr down any bony protuberances on the occiput, while making sure to maintain the integrity of the cortical bone of the outer table. Select the occipital plate from the implant caddy and place it onto the occipital bone (Figure 70). Place the center of the plate along the midline of the occiput (Figure 71). The plate offers six screw placement options, four along the midline and two laterally. Tab breakers provided in the set can be used to remove the most superior and/or most inferior midline screw holes (Figure 72).

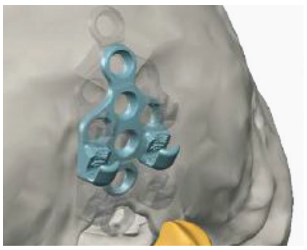


Figure 70

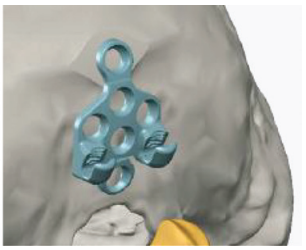


Figure 71

Note: The plate cannot be contoured.

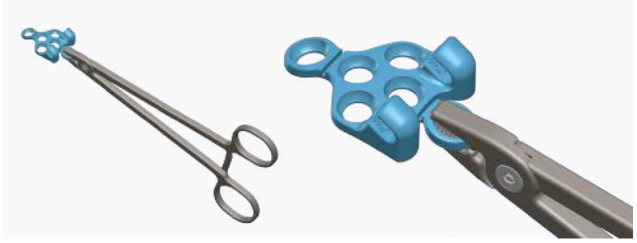


Figure 72

SURGICAL TECHNIQUE

Note: Correct handling of the implant is extremely important. The operating surgeon should avoid any notching or scratching of the plate. Alterations will produce defects in surface finish and internal stresses which may become the focal point for eventual breakage of the implant. If notching or scratching of the plate occurs, discard and do not implant the plate.

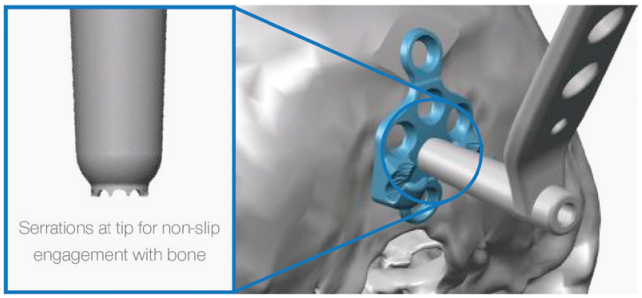


Figure 73

Drill Pilot Holes

Initially drill with the shortest (6/8mm) double-ended occipital guide, then increase one size at a time, until reaching the desired depth. 10/12 and 14/16mm double-ended occipital guides are also available.

Seat the serrated tip of the guide into the plate hole (Figure 73) The serrations keep the guide and plate stable against the occiput. Orient the guide barrel such that the screw is ultimately inserted perpendicular to the plate surface.

Figure 74

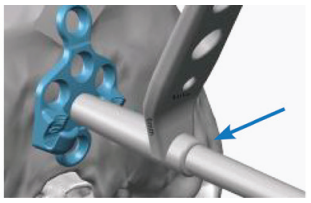


Figure 75

Insert the fixed shaft or flexible shaft drill through the guide barrel (Figure 74). Drill into the occipital bone until the stop on the drill bottoms out on the top of the barrel (Figure 75).

Note: The drill diameter is approximately 0.15mm undersized to the 4.5mm screw minor diameter.

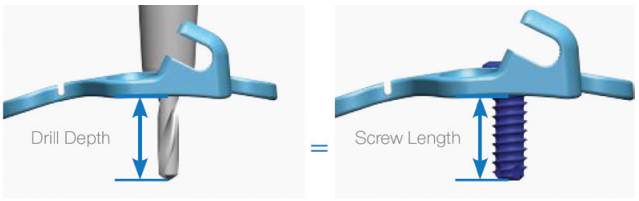


Figure 76

Note: The length labeled next to the guide barrel represents the maximum insertion depth of the drill relative to the underside of the plate. This measurement corresponds with the length of the screw (Figure 76).

Note: If placing the guide directly onto the occiput (without the plate in place), the drill depth will be the same. The distal tip of the guide always sits flush with the occiput regardless of its use with or without the plate in position.

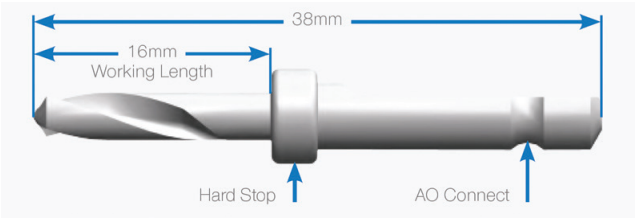


Figure 77

A short, free-hand drill (Figure 77) is also available to accommodate situations with limited access to the occiput. This drill penetrates the bone to a depth of 16mm before the hard stop makes contact with the surface of the occiput.

Note: The first hole drilled should be through the midline screw hole, second from the bottom.

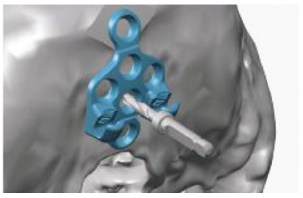


Figure 78

Note: For preparation of the first pilot hole, hold the occipital plate on the occiput to help mark the desired hole location for drilling or tapping (Figure 78). Once the entry point is marked, remove the plate before creating the pilot hole.

SURGICAL TECHNIQUE

Once the hole has been drilled to the desired depth, select the 4.5mm* fixed shaft or flexible shaft tap. Place the double-ended occipital plate guide that matches the depth of the hole just created. Insert the tap through the barrel

(Figure 79). Thread the tap into the bone until the stop makes contact with the top of the guide (Figure 80).

*5.25mm screws are intended for use as a rescue option, therefore a 5.25mm tap is not available in the set.

Note: The tap minor diameter is 0.2mm undersized to the 4.5mm screw minor diameter. The tap major diameter is approximately 0.4mm undersized to the 4.5mm screw major diameter.

Note: The length labeled near the guide barrel represents the maximum insertion depth of the tap relative to the underside of the plate. This measurement corresponds with the length of the screw (Figure 81).

Note: If placing the guide directly onto the occiput, without the plate in place, the tap depth will be the same. The distal tip of the guide always sits flush with the occiput regardless of its use with or without the plate in position.

CAUTION: Tapping under power is not recommended.

Tap Pilot Holes: Short Tap

A short, free-hand tap (Figure 82) is also available to accommodate situations with limited access to the occiput. This tap will penetrate the bone to a depth of 16mm before the hard stop makes contact with the surface of the occiput.

Note: The first hole tapped (Figure 83) should be for the midline screw hole, second from the bottom.

Figure 79

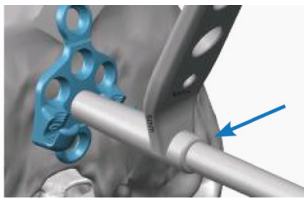


Figure 80

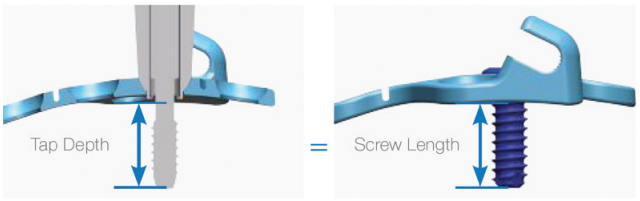


Figure 81

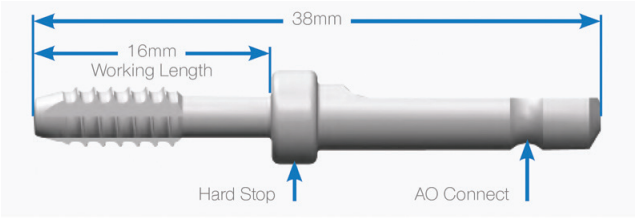


Figure 82

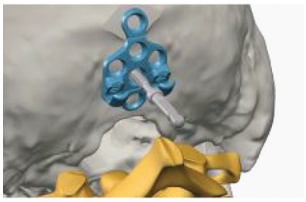


Figure 83

Occipital Plate Screw Placement

The system offers two screw styles, standard and split-tip. They are both available in 4.5mm and 5.25mm diameters with multiple lengths 6-16mm (10-16mm for the split-tip screws) in 2mm increments. Based on the last depth drilled and tapped, select the same length screw using a "stab-n-grab" screw driver (Figure 84). There are three driver options: 1) fixed shaft, 2) flex shaft and 3) short shaft (Figure 85).

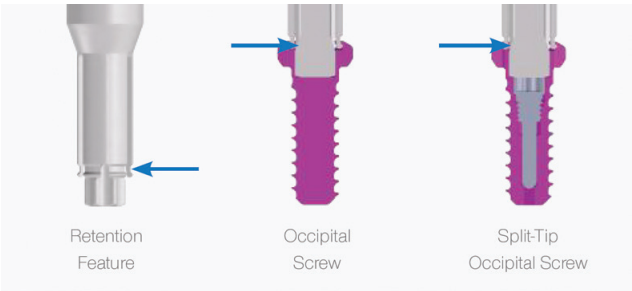


Figure 84

Note: All of these driver options are to be used freehand, i.e., the screws cannot be placed through the guide barrel.

Advance the screw into the bone until the head is fully seated within the screw hole (Figure 86).

To ensure adequate fixation, a minimum of four (4) bone screws must be placed in the central four (4) screw holes. Placing screws in the superior and/or inferior screw holes is optional.

If split-tip screws are selected, proceed to the next page.

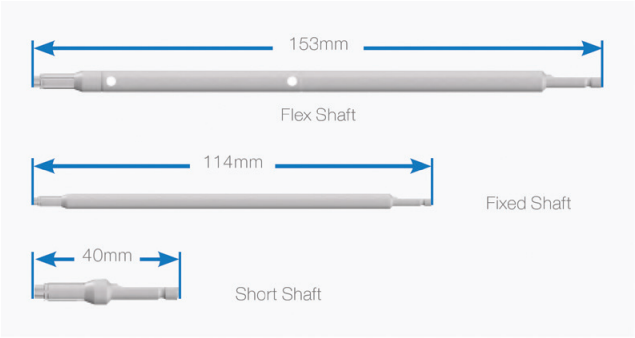


Figure 85

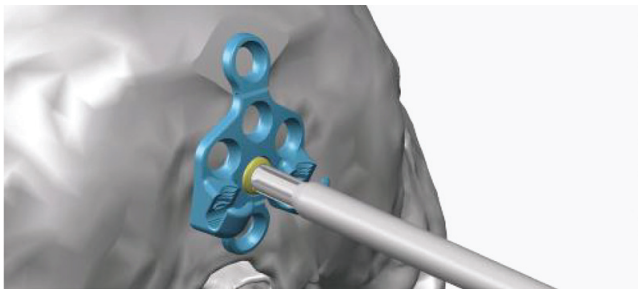


Figure 86

Screw Placement – Split-Tip Screws
Utilize the same insertion technique as for the standard screws.

Note: Do not fully lock the internal set screws until plate and screw placement is confirmed.

Once the split-tip screw is fully inserted and proper positioning is verified, proceed to lock down the set screw. To expand the tip of the split-tip screw, first assemble the split-tip screw final driver to the split-tip screw torque-limiting AO handle.

Insert the tip of the final driver through the opening in the counter-torque wrench (Figure 87). After sliding the counter-torque wrench up the shaft of the final driver, insert the tip of the final driver into the drive pocket of the center set screw. Then slide the counter-torque wrench down (Figure 88) to engage the prongs (Figure 89A) with the slots around the outside of the screw head (Figure 89B). To make sure the driver is fully seated, apply a nominal amount of rotational force and gauge the resistance. Keeping the driver on axis, advance the center set screw until the 10in-lb torque-limiting AO handle clicks off. The set screw is now fully seated and the distal tip expanded. Repeat steps for any additional split-tip screws.

To remove a split-tip screw, repeat the previous steps in reverse.

To ensure adequate fixation, a minimum of four (4) bone screws must be placed in the central four (4) screw holes. Placing screws in the superior and/or inferior screw holes is optional.

Figure 87

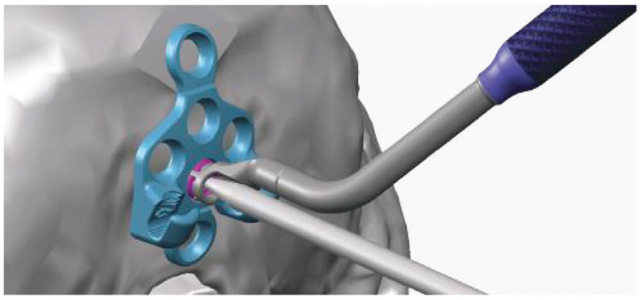


Figure 88

Figure 89A

Figure 89B

Occipital-Cervical Assembly Selection and Placement

The assembly is available in four sizes: 8mm, 14mm, 17mm and 20mm. Sizing is based on the height or distance from the upper (short) to the lower (long) crossbars or size "A" (Figure 90).

Loosen the head holder and rotate the head back to the desired position, locking the head holder in that position. To gauge the correct size, select one of the assemblies (Figure 91), and place the upper (short) crossbar into the fixed tulips on the plate. Gauge the best size option by determining the optimal final location for the lower (longer) crossbar and locking cups.

Note: The occipital-cervical assembly cannot be contoured.

For final placement, insert the upper (short) crossbar of the selected assembly into the fixed tulips of the occipital plate. Insert the set screws into both tulips using the self-retaining locking cap inserter. In order to allow for sagittal adjustment of the assembly (Figure 92), do not fully tighten the set screws against the upper crossbar.

Adjust the lower (long) crossbar to the desired final position. Provisionally tighten both of the set screws onto the upper (short) crossbar until the assembly is provisionally stable (Figure 93). Do not final lock the upper crossbar set screws at this time

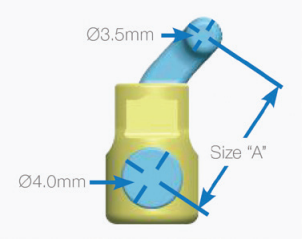


Figure 90

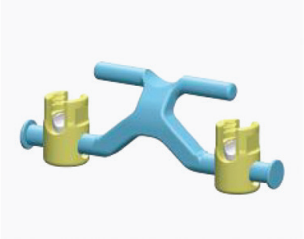


Figure 91

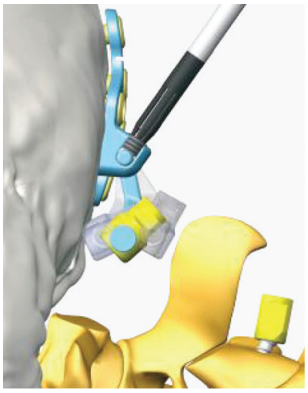


Figure 92

Figure 93

Adjust Position of Occipital-Cervical Assembly Locking Cups

Utilizing the yoke manipulator (Figure 94), adjust the medial/lateral (Figure 95) and sagittal (Figure 96) positions of the assembly locking cups so that they are aligned with the subaxial hooks and pedicle screws (Figure 97). Place rod into the locking cups, linking them to the subaxial components.

Insert the set screws into both locking cups using the self-retaining locking cap inserter. Loosely position the set screws against the rods.

Final Head Adjustments for Occipital Plate

Before final locking the full construct, the head position may be adjusted (Figure 98). Once the head is properly positioned, provisionally tighten the set screws.

Final Lock of Occipital-Cervical Assembly

Seat the counter-torque tube over the assembly locking cup and rest it on top of the rod (Figure 99). The handle can rotate and lock into one of four positions (see Step 12, "FINAL TIGHTENING"). Insert the final driver through the tube and into the set screw drive pocket (Figure 100). Do not apply maximum force at this time. First, ensure the driver is fully seated/on axis by applying a nominal amount of force to gauge the resistance. Stabilizing the counter-torque tube handle, rotate the torque-limiting AO handle clockwise until it emits an audible "click." Follow the same steps for the contralateral locking cup. Proceed caudally, repeating the same steps to lock down the subaxial hooks and screws.

CAUTION: Do not perform a final lock of the set screws without the counter-torque tube.

CAUTION: If removal of a set screw is necessary after previously being final locked, it must be replaced with a new set screw.

Figure 94

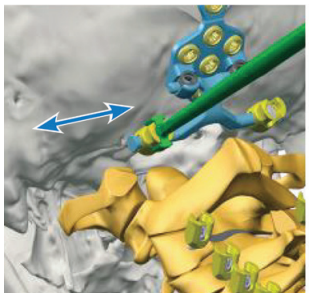


Figure 95

Figure 96

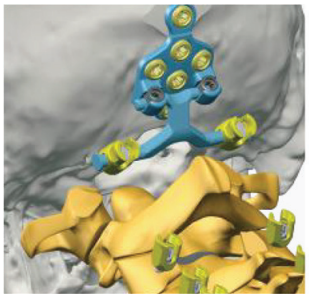


Figure 97

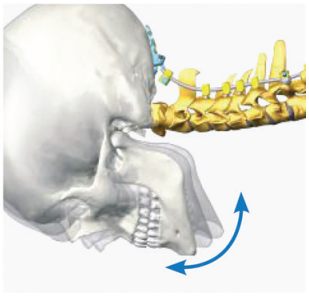


Figure 98

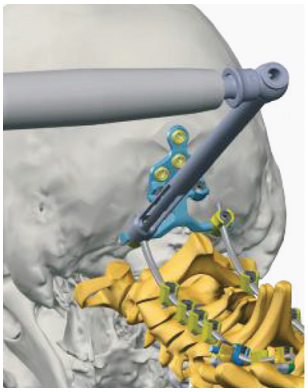


Figure 99

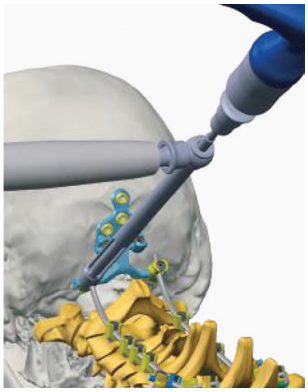


Figure 100

Final Lock of Upper Crossbar

Seat the occipital plate counter-torque tube (Figure 101) over both fixed tulips (Figure 102), ensuring the handle is oriented upward, toward the crown of the head. Insert the final driver through the first tube (Figure 103) and into the set screw drive pocket. Do not apply maximum force at this time. First, ensure the driver is fully seated/on axis by applying a nominal amount of force to gauge the resistance. Stabilizing the counter-torque tube handle, rotate the torque-limiting AO handle clockwise until it emits an audible "click." Repeat these steps for the contralateral set screw.

Figure 101

Note: All set screws must be torque tightened.

CAUTION: Do not perform a final lock of the set screws without the counter-torque tube.

CAUTION: If removal of a set screw is necessary after previously being final locked, it must be replaced with a new set screw.

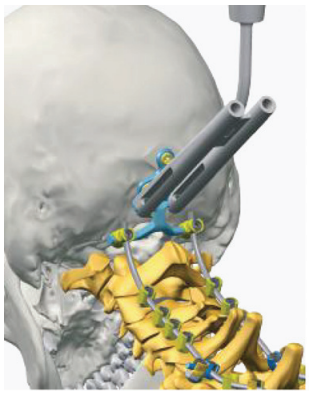


Figure 102

Figure 103

REMOVAL PROCEDURE (IF NECESSARY)

To remove the construct, apply counterclockwise rotation to loosen the components. Remove them in the opposite order in which the construct was built.

DRIVE MECHANISIMS

Polyaxial, High Angle & Smooth Shank screws require a T10 hexalobe drive mechanism. Set Screws & Crosslinks require a T15 hexalobe drive mechanism Occipital Plate Screws require a T20 hexalobe drive mechanism.

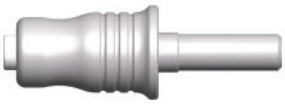
ORDERING GUIDE

INSTRUMENT GUIDE

Part Number	Instrument	Description	
20-MODHANDLE-G	**Cervical Modular Handle, AO**	Can be used with all instruments that have an AO connection	
26-RATCHET-AO	**Modular Ratchet Handle, AO**	Ca n be used with all instruments that have an AO connection	
26-AWL-G	**Awl**	For creating a pilot hole in the pedicle	
26-BALLTIPPRBE	**Striped Ball-Tipped Probe**	For checking the integrity and depth of a previously prepared screw hole	
26-FDRILL-35-X	**Fixed Drill**	Used through fixed guide to create a screw hole in the pedicle Available in 10 - 18mm lengths (2mm increments) (X) 10, 16 and 18mm are special order	10mm 12mm 14mm  16mm  18mm 
26-FGUIDE-G	**Fixed Guide**	Used to guide and control the trajectory and depth of a fixed drill or fixed tap	
26-FTAP-X-Y	**Fixed Tap**	For creating desired pathway for screw placement; color-coded by diameter; can be used through fixed guide Available in 3.0, 3.5 and 4.0 diameters (X), 10 - 18mm lengths (2mm increments) (Y) 14, 16 and 18mm lengths are special order Ø4.0mm taps are special order	3.0mm 3.5mm 4.0mm

ORDERING GUIDE

INSTRUMENT GUIDE

Part Number	Instrument	Description	
26-FTAP-45	**Fixed Tap, Ø4.5mm**	For creating desired pathway for screw placement; color-coded by diameter	
26-JACOBSCHUCK	**Jacobs Chuck Adapter**	For connection of a drill to a Jacobs Chuck	
26-S-FINDER	**Pedicle Finder, Straight**	For creating a screw hole in the pedicle	
26-C-FINDER	**Pedicle Finder, Curved**	For creating a screw hole in the pedicle	
26-SCREWINSRTR-4	**Screw Inserter**	For use with a modular AO handle (ratcheting or non-ratcheting) to insert a polyaxial or high angle screw into the pedicle	
26-VDRILL-35	**Variable Drill**	Used through variable drill guide to create a screw hole in the pedicle	
26-VGUIDE-2	**Variable Drill Guide**	Used to guide and control the trajectory and depth of a variable drill	
23-RODBENDER	**Rod Bender**	For contouring the rod to establish the ultimate construct positioning	
26-CAPINSRTR-2	**Cap Inserter**	For use to retain and insert set screws (standard and head-to-head crosslink) into screws and hooks; for use to retain and provisionally tighten the rod-to-rod crosslink set screws; can be used through a rod reducer	

ORDERING GUIDE

INSTRUMENT GUIDE

Part Number	Instrument	Description	
26-RODTEMP2-120/-240	**Rod Templates 120mm & 240mm**	For use to help establish desired length and curvature of rod	
26-DORSALADJUSTR	**Dorsal Height Adjuster**	For adjusting height, up or down, of a polyaxial or high angle screw	
26-REDUCER-3	**Rod Reducer**	For reducing the rod into a screw, hook or occipital plate locking cup; used in conjunction with the locking cap inserter	
26-ROCKER-2	**Rod Rocker Reducer**	For reducing the rod into a screw, hook or occipital plate locking cup	
26-RODCUTTER-2	**Rod Cutter**	For cutting the 3.2mm rod and the 4.0mm lower crossbar of the occipital plate cross connector	
26-YOKEMANPLTR-3	**Yoke Manipulator**	For adjusting the position of the polyaxial and high angle screw yokes along with the occipital plate cross connector locking cups	
23-HOOKHOLDER	**Hook Holder**	For insertion and positioning of hook	
23-RODHOLDER	**Rod Holder**	For placement of rod into screws, hooks, lateral offset connectors and locking cups	
23-TORQUE-AO	**Torque-Limiting AO Handle (35in-lbs)**	For final locking of set screws and locking nut for the various rod-to-rod connectors and lateral offset connectors	

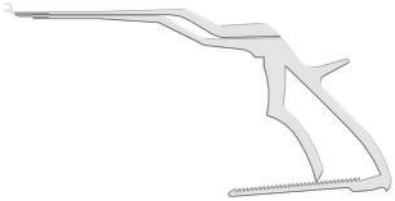
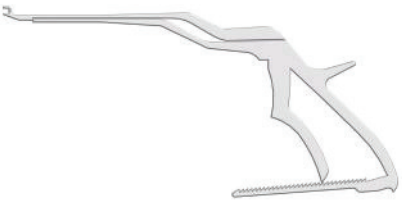
ORDERING GUIDE

INSTRUMENT GUIDE

Part Number	Instrument	Description	
26-TORQUE-AO-23	**Torque-Limiting AO Handle (23in-lbs)**	For final locking of set screws for the various implants with the exception of rod-to-rod connectors and lateral offset connectors.	
26-COUNTER-T-3	**Counter-Torque Tube**	For countering the force generated during final locking of standard and head-to-head set screws	
26-COUNTER-T-INLNE	**Inline Counter-Torque Tube**	For countering the force generated during final locking of standard and head-to-head set screws; designed to fit when tulip heads are touching	
26-COUNTER-T-XLINK	**Crosslink Counter-Torque Tube**	For countering the force generated during final locking of rod-to-rod crosslink set screws or the head- to-head crosslink locking nuts	
26-DEBURRER	**Rod Deburrer**	For removing any sharp edges or burrs from the ends of a rod after it has been cut	
26-FNLDRIVER-2	**Final Driver**	Used with torque-limiting AO handle through the counter-torque tube and the occipital plate counter-torque tube for final locking of standard and head-to-head set screws	
26-R2R-XLINK-DRVR	**Rod-to-Rod Crosslink Final Driver**	Used with torque-limiting AO handle through the crosslink counter-torque tube, for final locking of rod-to-rod crosslink set screws	
26-H2H-XLINK-DRVR	**Head-to-Head Crosslink Final Nut Driver**	Used with torque-limiting AO handle, through the crosslink counter-torque tube, for final locking of head-to-head crosslink locking nuts	

ORDERING GUIDE

INSTRUMENT GUIDE

Part Number	Instrument	Description	
26-H2H-BENDER	**Head-to-Head Crosslink Bender**	For contouring the crossbar to better align with tulips it will attach to. Through holes can be used for bending a 3.2mm rod	
26-DEPTH-GAGE	**Depth Gage**	For establishing screw hole depth to help with screw length selection	
26-COMPRESSOR-SM	**Compressor**	For compressing screws and/ or hooks together, along the previously placed rod, prior to final locking of the set screws	
26-DISTRACTOR-SM	**Distractor**	For distracting screws and/or hooks apart, along the previously placed rod, prior to final locking of the set screws	
26-INSITUBEND-X	**In-Situ Benders, Left and Right (X = L or R)**	For making additional coronal and/or sagittal adjustments to the rod after it has been final locked; through holes can be used for bending the rod prior to placement	
23-NUTDRIVER	**Parallel Connector Final Nut Driver**	Used with torque-limiting AO handle, through the parallel connector counter-torque tube, for final locking of locking nut	
23-C-TORQUE-P	**Parallel Connector Counter-Torque Tube**	For countering the force generated during final locking of parallel connector locking nut	
26-COUNTER-T-CONN	**Rod-to-Rod Connector Counter-Torque Tube**	For countering force generated during final locking of standard set screw when used with the 26- rod-to-rod connectors	

ORDERING GUIDE

INSTRUMENT GUIDE

Part Number	Instrument	Description	
26-OCPTABBREAKER	**Occipital Plate Tab Breakers**	For removing the superior and inferior midline screw holes	
26-OCPGUIDE-X	**Double-Ended Occipital Plate Guide**	Used, within the plate screw holes, to guide and control the trajectory and depth (6 - 16mm) of a drill or tap; depth is marked next to each tube Available in 6 - 8, 10 - 12 and 14 - 16mm (X), with the size referring to the guide tube length	
26-OCPDRILL-2	**Fixed Drill**	Used through double-ended occipital plate guide to create a screw hole in the occiput	
26-OCPFLXDRILL-2	**Flexible Drill**	Used through double-ended occipital plate guide to create a screw hole in the occiput	
26-OCPSTBDRILL-2	**Short Drill**	Used free-hand to create a screw hole in the occiput; has a maximum depth of 16mm	
26-OCPTAP	**Fixed Tap**	Used through double-ended occipital plate guide for creating desired pathway for screw placement	
26-OCPFLXTAP	**Flexible Tap**	Used through double-ended occipital plate guide for creating desired pathway for screw placement	
26-OCPSTBTAP	**Short Tap**	Used free-hand for creating desired pathway for screw placement; has a maximum depth of 16mm	
26-OCPDRVR	**Occipital Plate Fixed Driver**	For retention and insertion of occipital plate screws	

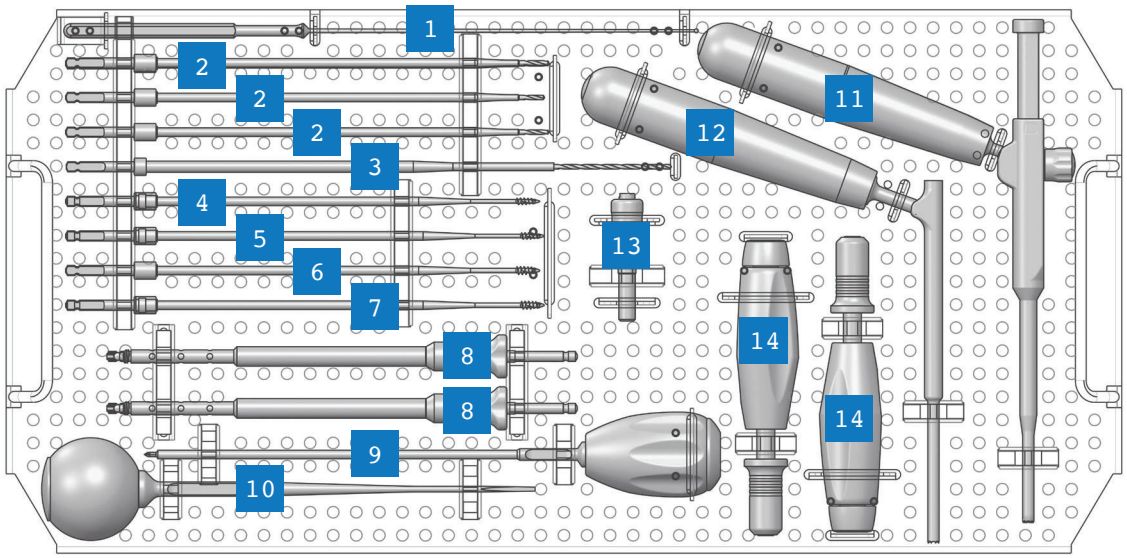
ORDERING GUIDE

INSTRUMENT GUIDE

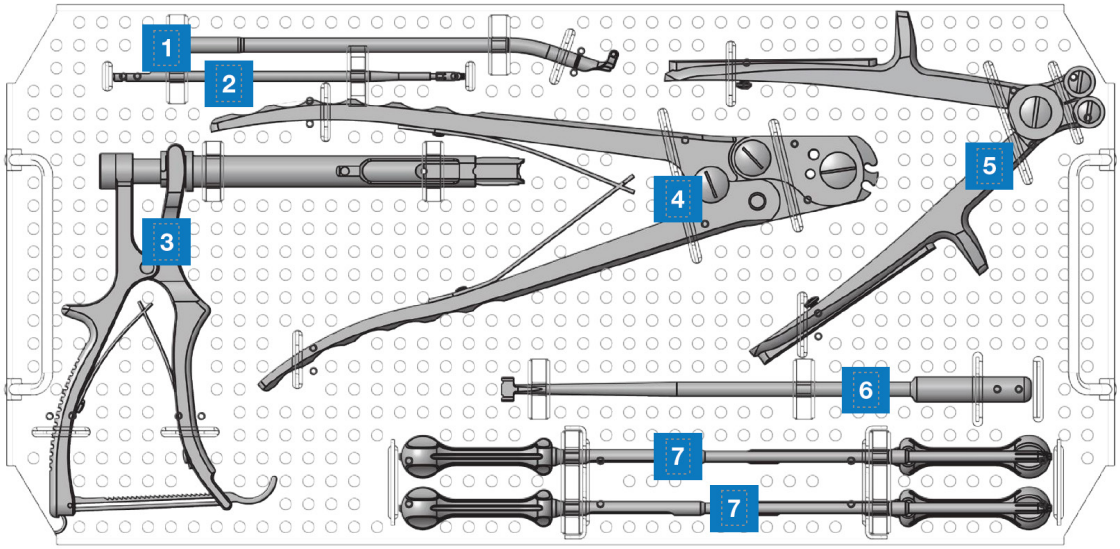
Part Number	Instrument	Description	
26-OCPFLXDRVR	**Occipital Plate Flexible Driver**	For retention and insertion of occipital plate screws	
26-OCPSTBDRVR	**Occipital Plate Short Driver**	For retention and insertion of occipital plate screws	
26-P-HANDLE	**Modular Palm Handle, AO**	For use with drills, taps and drivers	
26-OCPRATCHET	**90° Quick-Connect Ratchet Handle, AO**	For use with drills, taps and drivers	
26-OCPCOUNTER-T	**Occipital Plate Counter-Torque Tube**	For countering the force generated during final locking of the set screws into the occipital plate fixed tulips	
26-OCPSTFLDRVR	**Split-Tip Screw Final Driver**	Used with split-tip torque-limiting handle, through the split-tip counter-torque wrench, for seating and final locking of the split-tip set screw	
26-OCP-TORQUE-AO	**Split-Tip Screw Torque-Limiting AO Handle (10in-lbs)**	Used with split-tip final driver for final locking of split-tip set screws	
26-OCP-CNTRTORQ	**Split-Tip Screw Counter-Torque Wrench**	For countering the force generated during final locking of the split-tip set screws	

ORDERING GUIDE

Standard Instrument Set - Top Tray		
1 Striped Ball-Tipped Probe	6 Fixed Tap, Ø3.5mm x 10mm	11 Variable Drill Guide
2 Fixed Drill	7 Fixed Tap, Ø3.5mm x 12mm	12 Fixed Guide
3 Variable Drill	8 Screw Inserter	13 Jacobs Chuck Adapter
4 Fixed Tap, Ø3.0mm x 10mm	9 Awl	14 Cervical Modular Handle, AO
5 Fixed Tap, Ø3.0mm x 12mm	10 Pedicle Finder, Straight	

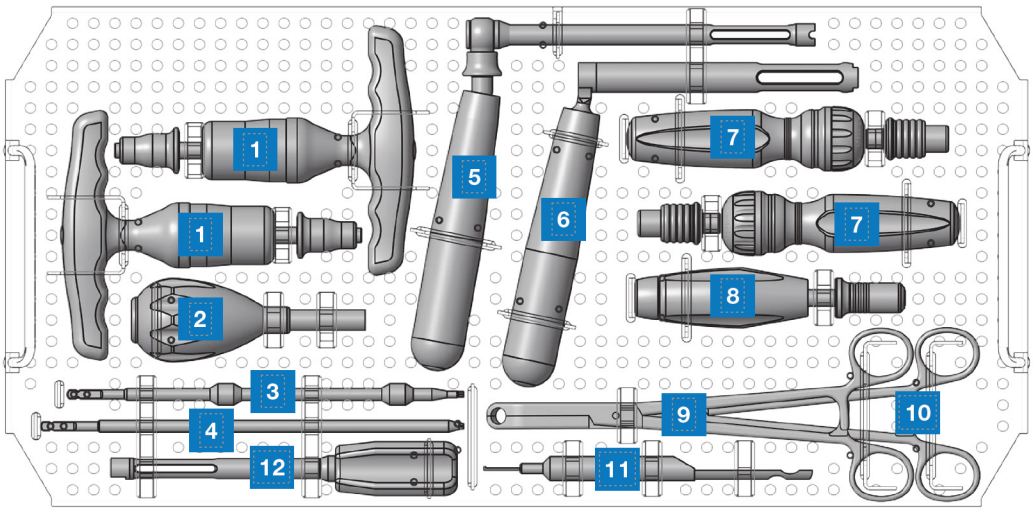


Standard Instrument Set - Middle Tray		
1 Rod Rocker Reducer	4 Rod Cutter	6 Yoke Manipulator
2 Dorsal Height Adjuster	5 Rod Bender	7 Cap Inserter
3 Rod Reducer		



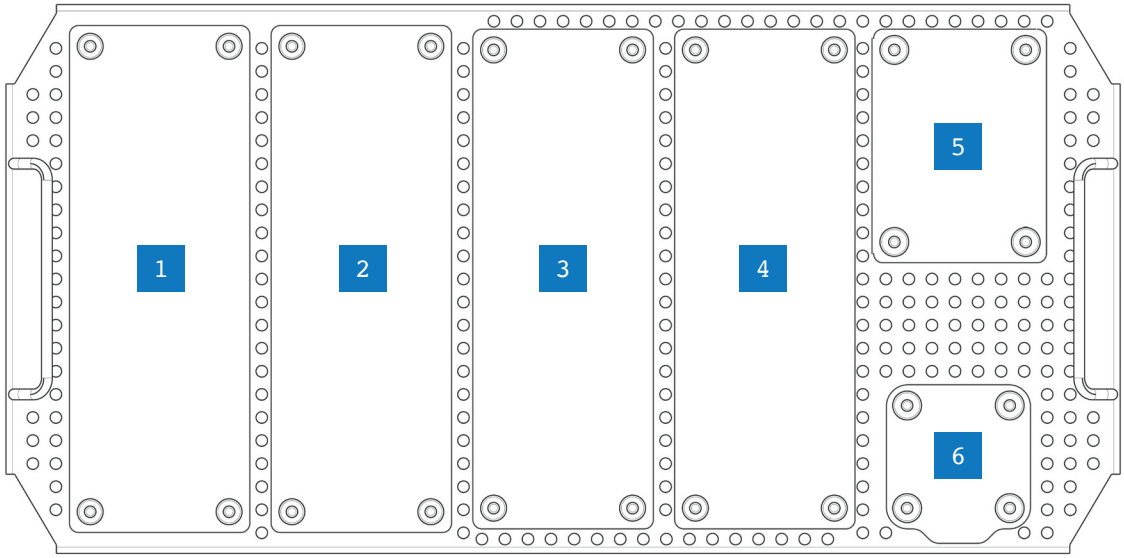
ORDERING GUIDE

Standard Instrument Set - Bottom Tray		
1 Torque-Limiting AO Handle (23in-lbs, blue)	5 Counter-Torque Tube	9 Hook Holder
2 Rod Deburrer	6 Crosslink Counter-Torque Tube	10 Rod Holder
3 Rod-to-Rod Crosslink Final Driver	7 Modular Ratchet Handle, AO	11 Depth Gage
4 Final Driver	8 Cervical Modular Handle, AO	12 Inline Counter-Torque Tube

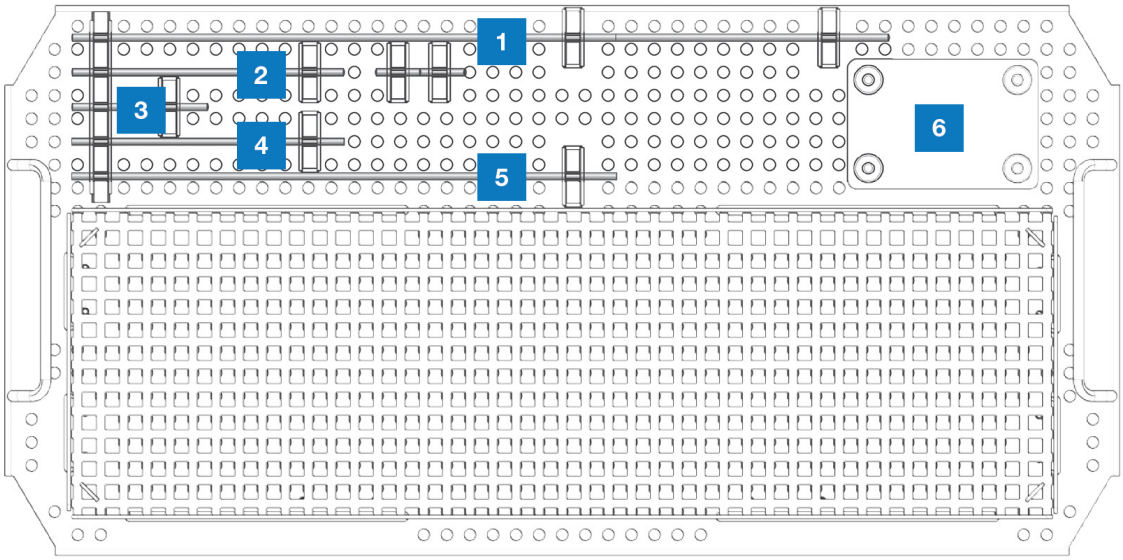


ORDERING GUIDE

Standard Implant Set - Top Tray		
1 Ø3.5mm Polyaxial Screws 10 - 30mm 2 Ø4.0mm Polyaxial Screws 10 - 30mm	3 Ø3.5mm High Angle Screws 10 - 30mm 4 Ø4.0mm High Angle Screws 10 - 30mm	5 Rod-to-Rod Crosslinks 6 Set Screws

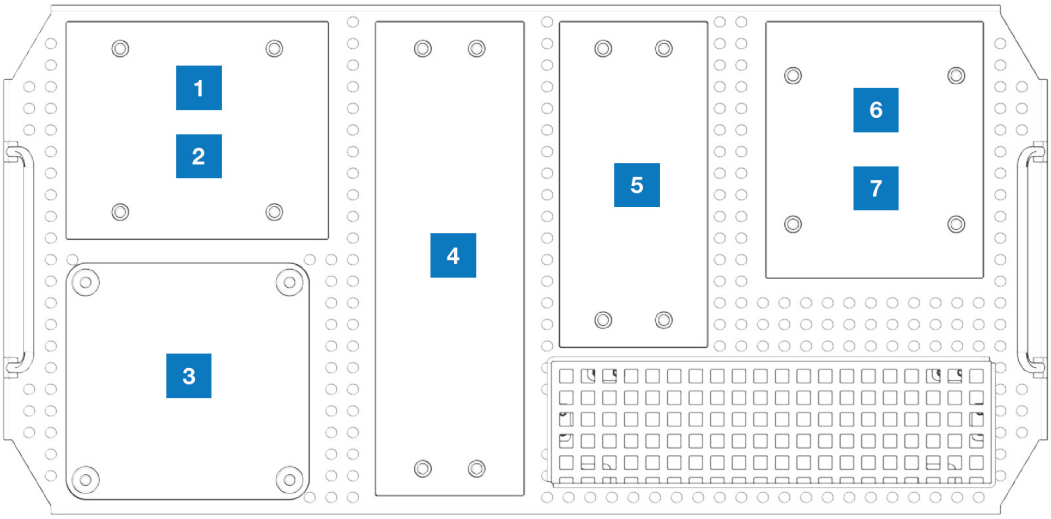


Standard Implant Set - Bottom Tray		
1 Rod, 240mm 2 Rod, 120mm	3 Rod, 60mm 4 Rod Template, 120mm	5 Rod Template, 240mm 6 Hooks

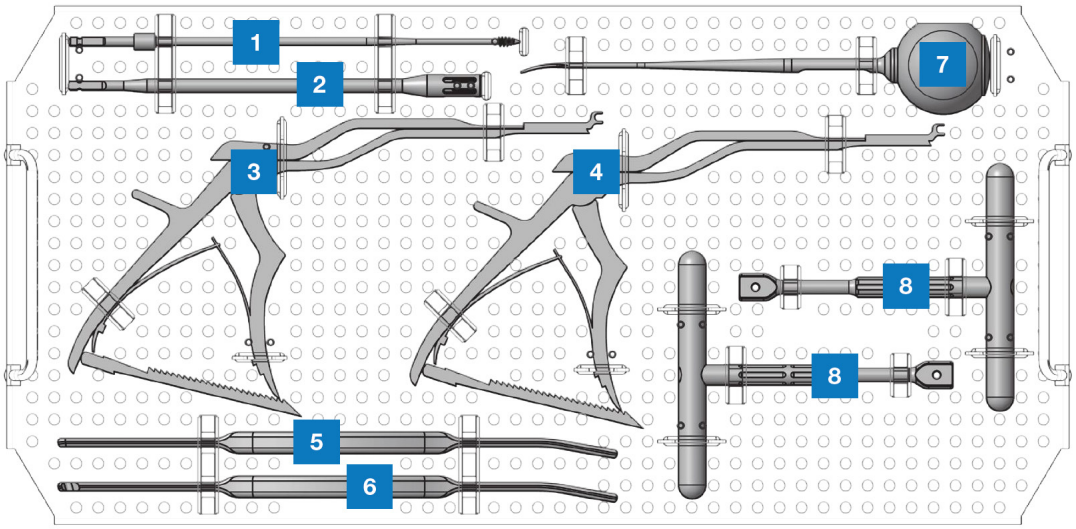


ORDERING GUIDE

Optional Instrument and Implant Set - Implants Top Tray		
1 Ø3.5mm High Angle Screws 36, 42, 48mm 2 Ø4.0mm High Angle Screws 36, 42, 48mm 3 Head-to-Head Crosslinks	4 Ø3.5/4.0mm Polyaxial Smooth Shank Screws 24 - 36mm 5 Ø4.5mm Polyaxial Screws 25 - 45mm	6 Ø3.5mm Polyaxial Screws 36, 42, 48mm 7 Ø4.0mm Polyaxial Screws 36, 42, 48mm

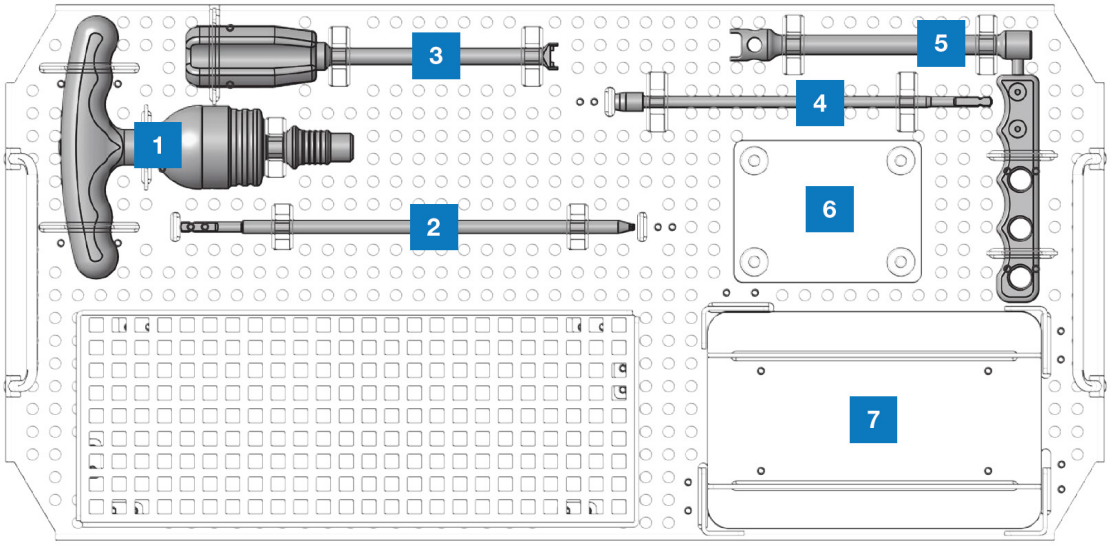


Optional Instrument and Implant Set - Instrument Bottom Tray		
1 Fixed Tap, Ø4.5mm 2 Head-to-Head Crosslink Final Nut Driver 3 Compressor	4 Distractor 5 In-Situ Bender, Right 6 In-Situ Bender, Left	7 Pedicle Finder, Curved 8 Head-to-Head Crosslink Benders



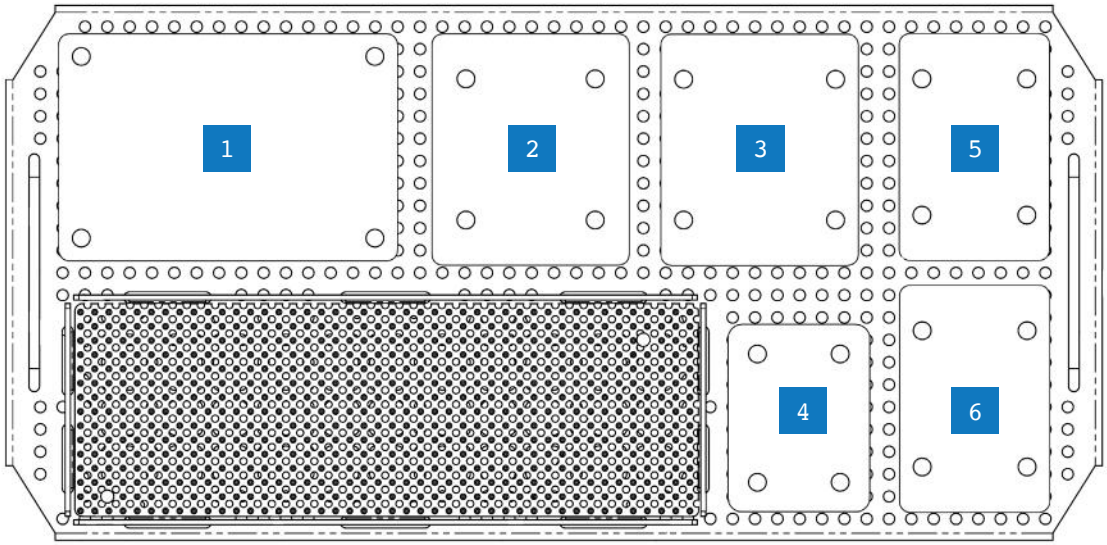
ORDERING GUIDE

Connector Instrument and Implant Set		
1 Torque-Limiting AO Handle (35 in-lbs, black) 2 Final Driver 3 Rod-to-Rod Connector Counter-Torque Tube	4 Parallel Connector Final Nut Driver 5 Parallel Connector Counter-Torque Tube	6 Lateral Offset Connector Caddy 7 Rod-to-Rod Connector Caddy

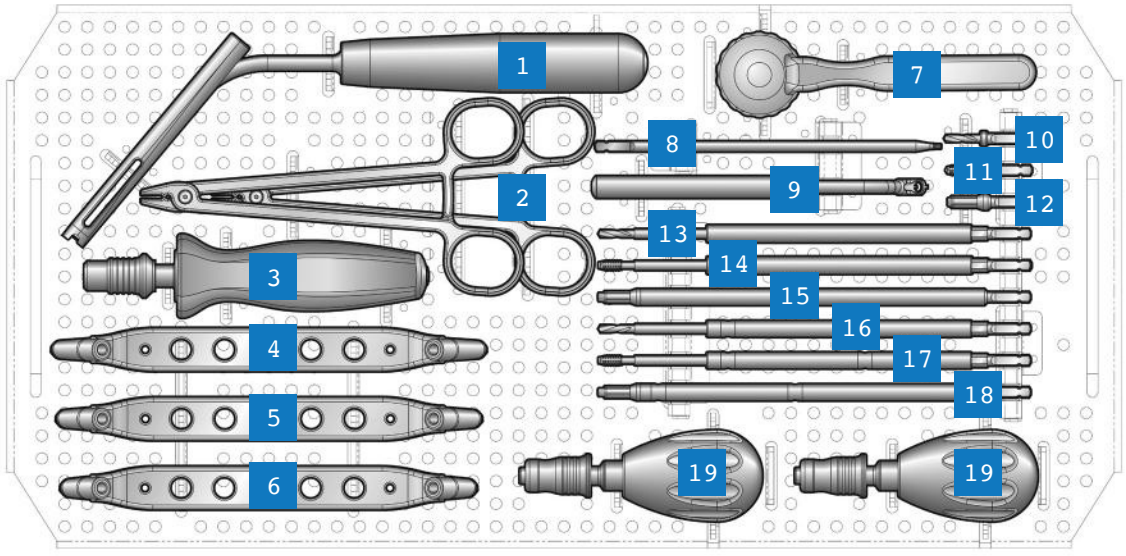


ORDERING GUIDE

Occipital Instrument and Implant Set - Implants Top Tray		
1 Occipital Plates and Occipital-Cervical Assemblies	3 Ø5.25mm Occipital Screws	5 Ø4.5mm Occipital Split-Tip Screws
2 Ø4.0mm Occipital Screws	4 Set Screws	6 Ø5.25mm Occipital Split-Tip Screws



Occipital Instrument and Implant Set - Instruments Bottom Tray		
1 Counter-Torque Tube	6 Fixed Tap, Ø3.5mm x 10mm	11 Variable Drill Guide
2 Tab Breakers	7 Fixed Tap, Ø3.5mm x 12mm	12 Fixed Guide
3 Split-Tip Screw Torque-Limiting AO Handle (10in-lbs)	8 Screw Inserter	13 Jacobs Chuck Adapter
4 Double-Ended Occipital Plate Guide, 14 - 16mm	9 Awl	14 Cervical Modular Handle, AO
5 Double-Ended Occipital Plate Guide,	10 Pedicle Finder, Straight	



ORDERING GUIDE

STANDARD INSTRUMENT SET (26-LS-STRMOCT-INS2)

TOP TRAY INSTRUMENTS

Part Number	Description	Quantity
26-BALLTIPPRBE	Striped Ball-Tipped Probe	1
26-FDRILL-35-12	Fixed Drill, Ø2.0 x 12mm	2
26-FDRILL-35-14	Fixed Drill, Ø2.0 x 14mm	2
26-VDRILL-35	Variable Drill	2
26-VGUIDE-2	Variable Drill Guide	1
26-FTAP-30-10	Fixed Tap, Ø3.0 x 10mm	1
26-FTAP-30-12	Fixed Tap, Ø3.0 x 12mm	1
26-FTAP-35-10	Fixed Tap, Ø3.5 x 10mm	1
26-FTAP-35-12	Fixed Tap, Ø3.5 x 12mm	1
26-SCREWINSRTR-4	Screw Inserter	2
26-AWL-G	Awl	1
26-S-FINDER	Pedicle Finder, Straight	1
26-FGUIDE-G	Fixed Guide	1
26-JACOBSCHUCK	Jacobs Chuck Adapter	1
20-MODHANDLE-G	Cervical Modular Handle, AO	2

MIDDLE TRAY INSTRUMENTS

Part Number	Description	Quantity
26-ROCKER-2	Rod Rocker Reducer	1
26-DORSALADJUSTR	Dorsal Height Adjuster	1
26-REDUCER-3	Rod Reducer	1
26-RODCUTTER-2	Rod Cutter	1
23-RODBENDER	Rod Bender	1
26-YOKEMANPLTR-3	Yoke Manipulator	1
26-CAPINSRTR-2	Cap Inserter	3

BOTTOM TRAY INSTRUMENTS

Part Number	Description	Quantity
26-TORQUE-AO-23	Torque-Limiting AO Handle (23in-lbs)	2
26-DEBURRER	Rod Deburrer	1
26-R2R-XLINK-DRVR	Rod-to-Rod Crosslink Final Driver	1
26-FNLDRIVER-2	Final Driver	2
26-COUNTER-T-3	Counter-Torque Tube	1
26-COUNTER-T-XLINK	Crosslink Counter-Torque Tube	1
26-RATCHET-AO	Modular Ratchet Handle, AO	2
20-MODHANDLE-G	Cervical Modular Handle, AO	1
23-HOOKHOLDER	Hook Holder	1
23-RODHOLDER	Rod Holder	1
26-DEPTH-GAGE	Depth Gage	1
26-COUNTER-T-INLNE	Counter-Torque Tube, Inline	1

ORDERING GUIDE

STANDARD INSTRUMENT SET (26-LS-STRMOCT-INS2)

TOP TRAY IMPLANTS

Part Number	Description	Quantity
26-PA-35-10	Polyaxial Screw, 3.5 x 10mm	6
26-PA-35-12	Polyaxial Screw, 3.5 x 12mm	12
26-PA-35-14	Polyaxial Screw, 3.5 x 14mm	12
26-PA-35-16	Polyaxial Screw, 3.5 x 16mm	6
26-PA-35-18	Polyaxial Screw, 3.5 x 18mm	6
26-PA-35-20	Polyaxial Screw, 3.5 x 20mm	6
26-PA-35-22	Polyaxial Screw, 3.5 x 22mm	6
26-PA-35-24	Polyaxial Screw, 3.5 x 24mm	6
26-PA-35-26	Polyaxial Screw, 3.5 x 26mm	6
26-PA-35-28	Polyaxial Screw, 3.5 x 28mm	6
26-PA-35-30	Polyaxial Screw, 3.5 x 30mm	6
26-PA-40-10	Polyaxial Screw, 4.0 x 10mm	6
26-PA-40-12	Polyaxial Screw, 4.0 x 12mm	6
26-PA-40-14	Polyaxial Screw, 4.0 x 14mm	6
26-PA-40-16	Polyaxial Screw, 4.0 x 16mm	6
26-PA-40-18	Polyaxial Screw, 4.0 x 18mm	6
26-PA-40-20	Polyaxial Screw, 4.0 x 20mm	6
26-PA-40-22	Polyaxial Screw, 4.0 x 22mm	6
26-PA-40-24	Polyaxial Screw, 4.0 x 24mm	6
26-PA-40-26	Polyaxial Screw, 4.0 x 26mm	6
26-PA-40-28	Polyaxial Screw, 4.0 x 28mm	6
26-PA-40-30	Polyaxial Screw, 4.0 x 30mm	6
26-HA-35-10	High Angle Screw, 3.5 x 10mm	4
26-HA-35-12	High Angle Screw, 3.5 x 12mm	4
26-HA-35-14	High Angle Screw, 3.5 x 14mm	4
26-HA-35-16	High Angle Screw, 3.5 x 16mm	4
26-HA-35-18	High Angle Screw, 3.5 x 18mm	4
26-HA-35-20	High Angle Screw, 3.5 x 20mm	4
26-HA-35-22	High Angle Screw, 3.5 x 22mm	4
26-HA-35-24	High Angle Screw, 3.5 x 24mm	4
26-HA-35-26	High Angle Screw, 3.5 x 26mm	4
26-HA-35-28	High Angle Screw, 3.5 x 28mm	4
26-HA-35-30	High Angle Screw, 3.5 x 30mm	4

TOP TRAY IMPLANTS

Part Number	Description	Quantity
26-HA-40-10	High Angle Screw, 4.0 x 10mm	4
26-HA-40-12	High Angle Screw, 4.0 x 12mm	4
26-HA-40-14	High Angle Screw, 4.0 x 14mm	4
26-HA-40-16	High Angle Screw, 4.0 x 16mm	4
26-HA-40-18	High Angle Screw, 4.0 x 18mm	4
26-HA-40-20	High Angle Screw, 4.0 x 20mm	4
26-HA-40-22	High Angle Screw, 4.0 x 22mm	4
26-HA-40-24	High Angle Screw, 4.0 x 24mm	4
26-HA-40-26	High Angle Screw, 4.0 x 26mm	4
26-HA-40-28	High Angle Screw, 4.0 x 28mm	4
26-HA-40-30	High Angle Screw, 4.0 x 30mm	4
26-SETSCREW	Set Screw	30
26-R2R-XLINK-S	Rod-to-Rod Crosslink, S, 26 - 34mm	2
26-R2R-XLINK-M	Rod-to-Rod Crosslink, M, 32 - 40mm	2
26-R2R-XLINK-L	Rod-to-Rod Crosslink, L, 38 - 46mm	2

BOTTOM TRAY INSTRUMENTS

Part Number	Description	Quantity
23-CC-ROD-60	Rod, 60mm	3
23-CC-ROD-120	Rod, 120mm	3
23-CC-ROD-240	Rod, 240mm	3
26-RODTEMP2-120	Rod Template, 120mm	1
26-RODTEMP2-240	Rod Template, 240mm	1
26-HOOK-S-5	Hook, Straight, 5mm	4
26-HOOK-S-7	Hook, Straight, 7mm	4

ORDERING GUIDE

PRE-BENT ROD CADDY (SPECIAL ORDER ONLY) (26-LS-STRMOCT-PBRD)

Part Number	Description	Quantity
26-CC-PB-ROD-60	Pre-Bent Rod, 60mm	3
26-CC-PB-ROD-80	Pre-Bent Rod, 80mm	3
26-CC-PB-ROD-100	Pre-Bent Rod, 100mm	3

TRANSITION ROD (SPECIAL ORDER ONLY)

Part Number	Description
26-CC-TRANS-ROD	Transition Rod, 3.2 to 5.5mm

OPTIONAL INSTRUMENT AND IMPLANT SET (26-LS-STRMOCT-OPT2)

OPTIONAL INSTRUMENTS

Part Number	Description	Quantity
26-COMPRESSOR-SM	Compressor	2
26-DISTRACTOR-SM	Distractor	1
26-FTAP-45	Fixed Tap, Ø4.5	1
26-H2H-XLINK-DRVR	Head-to-Head Crosslink Final Nut Driver	2
26-INSITUBEND-L	In-Situ Bender, Left	1
26-INSITUBEND-R	In-Situ Bender, Right	1
26-C-FINDER	Pedicle Finder, Curved	2
26-H2H-BENDER	Head-to-Head Crosslink Bender	1

OPTIONAL IMPLANTS

Part Number	Description	Quantity
26-PA-35-36	Polyaxial Screw, 3.5 x 36mm	4
26-PA-35-42	Polyaxial Screw, 3.5 x 42mm	4
26-PA-35-48	Polyaxial Screw, 3.5 x 48mm	4
26-PA-40-36	Polyaxial Screw, 4.0 x 36mm	4
26-PA-40-42	Polyaxial Screw, 4.0 x 42mm	4
26-PA-40-48	Polyaxial Screw, 4.0 x 48mm	4
26-PA-45-20*	Polyaxial Screw, 4.5 x 20mm	N/A
26-PA-45-25	Polyaxial Screw, 4.5 x 25mm	4
26-PA-45-30	Polyaxial Screw, 4.5 x 30mm	4
26-PA-45-35	Polyaxial Screw, 4.5 x 35mm	4
26-PA-45-40	Polyaxial Screw, 4.5 x 40mm	4
26-PA-45-45	Polyaxial Screw, 4.5 x 45mm	4

OPTIONAL IMPLANTS (CONTINUED)

Part Number	Description	Quantity
26-HA-35-36	High Angle Screw, 3.5 x 36mm	4
26-HA-35-42	High Angle Screw, 3.5 x 42mm	4
26-HA-35-48	High Angle Screw, 3.5 x 48mm	4
26-HA-40-36	High Angle Screw, 4.0 x 36mm	4
26-HA-40-42	High Angle Screw, 4.0 x 42mm	4
26-HA-40-48	High Angle Screw, 4.0 x 48mm	4
26-PA-SS-35-24	Polyaxial Smooth Shank Screw, 3.5 x 24mm	2
26-PA-SS-35-26	Polyaxial Smooth Shank Screw, 3.5 x 26mm	4
26-PA-SS-35-28	Polyaxial Smooth Shank Screw, 3.5 x 28mm	4
26-PA-SS-35-30	Polyaxial Smooth Shank Screw, 3.5 x 30mm	4
26-PA-SS-35-32	Polyaxial Smooth Shank Screw, 3.5 x 32mm	4
26-PA-SS-35-34	Polyaxial Smooth Shank Screw, 3.5 x 34mm	4
26-PA-SS-35-36	Polyaxial Smooth Shank Screw, 3.5 x 36mm	4
26-PA-SS-40-24	Polyaxial Smooth Shank Screw, 4.0 x 24mm	2
26-PA-SS-40-26	Polyaxial Smooth Shank Screw, 4.0 x 26mm	2
26-PA-SS-40-28	Polyaxial Smooth Shank Screw, 4.0 x 28mm	2
26-PA-SS-40-30	Polyaxial Smooth Shank Screw, 4.0 x 30mm	2
26-PA-SS-40-32	Polyaxial Smooth Shank Screw, 4.0 x 32mm	2
26-PA-SS-40-34	Polyaxial Smooth Shank Screw, 4.0 x 34mm	2
26-PA-SS-40-36	Polyaxial Smooth Shank Screw, 4.0 x 36mm	2
26-H2H-XLINK-XS	Head-to-Head Crosslink, XS	2
26-H2H-XLINK-S	Head-to-Head Crosslink, S	2
26-H2H-XLINK-M	Head-to-Head Crosslink, M	2
26-H2H-XLINK-L	Head-to-Head Crosslink, L	2
26-H2H-SETSCREW	Head-to-Head Crosslink Set Screw	8
26-H2H-LOCKINGNUT	Locking Nut	8

ORDERING GUIDE

CONNECTOR INSTRUMENT AND IMPLANT SET (26-LS-STRMOCT-CONN)

Part Number	Description	Quantity
23-TORQUE-AO	Torque-Limiting AO Handle (35 in-lbs)	1
26-FNLDRIVER-2	Final Driver	1
26-COUNTER-T-CONN	Rod-to-Rod Connector Counter-Torque Tube	1
23-NUTDRIVER	Parallel Connector Final Nut Driver	1
23-C-TORQUE-P	Parallel Connector Counter-Torque Tube	1
26-3232-CLSD11	Rod-to-Rod Connector,3.2-3.2,Closed,1x1	2
26-3255-CLSD11	Rod-to-Rod Connector,3.2-5.5,Closed,1x1	4
26-3255-CLSD21	Rod-to-Rod Connector,3.2-5.5,Closed,2x1	2
26-3255-INLINE11	Rod-to-Rod Connector,3.2-5.5, Inline,1x1	2
26-3255-OPEN11	Rod-to-Rod Connector,3.2-5.5,Open,1x1	4
23-SSCONN-32-55	Parallel Side-by-Side Connector	4
26-OFFSETCONN-S	Lateral Offset Connector, Straight	4
26-OFFSETCONN-A	Lateral Offset Connector, Angle	2

CONNECTOR INSTRUMENT AND IMPLANT SET (26-LS-STRMOCT-CONN)

OCCIPITAL INSTRUMENTS

Part Number	Description	Quantity
26-OCPTABBREAKER	Tab Breakers	2
26-OCPGUIDE 6-8	Double-Ended Occipital Plate Guide 6 - 8mm	1
26-OCPGUIDE-10-12	Double-Ended Occipital Plate Guide, 10 - 12mm	1
26-OCPGUIDE-14-16	Double-Ended Occipital Plate Guide, 14 - 16mm	1
26-OCPDRILL-2	Fixed Drill	2
26-OCPFLXDRILL-2	Flexible Drill	1
26-OCPSTBDRILL-2	Short Drill	1
26-OCPTAP	Fixed Tap	2
26-OCPFLXTAP	Flexible Tap	1
26-OCPSTBTAP	Short Tap	1
26-OCPDRVR	Fixed Driver	2
26-OCPFLXDRVR	Flex Driver	1
26-OCPSTBDRVR	Short Driver	1
26-P-HANDLE	Modular Palm Handle, AO	2
26-OCPRATCHET	90° Quick-Connect Ratchet Handle, AO	1
26-OCPCOUNTER-T	Counter-Torque Tube	1
26-OCPSTFLDRVR	Split-Tip Screw Final Driver	2
26-OCP-TORQUE-AO	Split-Tip Screw Torque-Limiting AO	1
26-OCP-CNTRTORQ	Split-Tip Screw Counter-Torque Wrench	1

OCCIPITAL IMPLANTS

Part Number	Description	Quantity
26-OCPPLATE	Occipital Plate	6
26-OCP-ASSY-08	Occipital-Cervical Assembly, 8mm	12
26-OCP-ASSY-14	Occipital-Cervical Assembly, 14mm	12
26-OCP-ASSY-17	Occipital-Cervical Assembly, 17mm	6
26-OCP-ASSY-20	Occipital-Cervical Assembly, 20mm	6
26-OCPS-45-6	Occipital Screw, 4.5 x 6mm	6
26-OCPS-45-8	Occipital Screw, 4.5 x 8mm	6
26-OCPS-45-10	Occipital Screw, 4.5 x 10mm	6
26-OCPS-45-12	Occipital Screw, 4.5 x 12mm	6
26-OCPS-45-14	Occipital Screw, 4.5 x 14mm	6
26-OCPS-45-16	Occipital Screw, 4.5 x 16mm	6
26-OCPS-525-6	Occipital Screw, 5.25 x 6mm	6
26-OCPS-525-8	Occipital Screw, 5.25 x 8mm	6
26-OCPS-525-10	Occipital Screw, 5.25 x 10mm	6
26-OCPS-525-12	Occipital Screw, 5.25 x 12mm	6
26-OCPS-525-14	Occipital Screw, 5.25 x 14mm	6
26-OCPS-525-16	Occipital Screw, 5.25 x 16mm	6
26-OCPST-45-10	Split-Tip Occipital Screw, 4.5 x 10mm	6
26-OCPST-45-12	Split-Tip Occipital Screw, 4.5 x 12mm	6
26-OCPST-45-14	Split-Tip Occipital Screw, 4.5 x 14mm	6
26-OCPST-45-16	Split-Tip Occipital Screw, 4.5 x 16mm	6
26-OCPST-525-10	Split-Tip Occipital Screw, 5.25 x 10mm	6
26-OCPST-525-12	Split-Tip Occipital Screw, 5.25 x 12mm	4
26-OCPST-525-14	Split-Tip Occipital Screw, 5.25 x 14mm	4
26-OCPST-525-16	Split-Tip Occipital Screw, 5.25 x 16mm	4
26-SETSCREW	Set Screw	4

CLEANING AND STERILIZATION

Implants are not sterile packed
Reusable instruments are provided non-sterile.

For specific cleaning and sterilization instructions, refer to the instructions for use provided with the device or contact Xtant Medical. See back page for contact information.

SPECIFICATIONS

TORQUE AND DRIVER SPECIFICATIONS

Part Number	Description	IN-LBS	N-m	For Usage With
23-TORQUE-AO	Torque-Limiting AO Handle	35	4	For final locking of Rod-to-Rod Connectors and Lateral Offset Connectors
26-TORQUE-AO-23	Torque-Limiting AO Handle	23	2.6	For final locking of all implants with the exception of the rod-to-rod connectors and lateral offset connectors
26-OCP-TORQUE-AO	Split-Tip Screw Torque-Limiting AO Handle	10	1	Occipital Plate Split-Tip Set Screw

Part Number	Description	IN-LBS	For Usage With
23-NUTDRIVER	Parallel Connector Final Nut Driver	4mm Female Hex	Rod-to-Rod Parallel Connector
26-CAPINSRTR-2	Cap Inserter	T-15, Hexalobe	Set Screws
26-FNLDRIVER-2	Final Driver	T-15, Hexalobe	Set Screws
26-SCREWINSRTR-4	Screw Inserter	T-10, Hexalobe	Polyaxial and High Angle Screws
26-H2H-XLINK-DRVR	Head-to-Head Crosslink Final Driver	Custom Hex	Head-to-Head Crosslink Locking Nut
26-R2R-XLINK-DRVR	Rod-to-Rod Crosslink Final Driver	T-15 Hexalobe	Rod-to-Rod Crosslink Set Screw
26-OCPDRVR	Fixed Driver	T-20 Hexalobe	Occipital Plate Screws
26-OCPFLXDRVR	Flexible Driver	T-20 Hexalobe	Occipital Plate Screws
26-OCPSTBDRVR	Short Driver	T-20 Hexalobe	Occipital Plate Screws
26-OCPSTFLDRVR	Split-Tip Screw Final Driver	T-8 Hexalobe	Occipital Plate Split-Tip Set Screw

NOTES

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See Package Insert for a more complete listing of indications, contraindications, warnings, precautions, and other important information.

LIMITED WARRANTY and DISCLAIMER: Xtant Medical products have a limited warranty against defects and workmanship and materials. Any other express or implied warranties, including warranties of merchantability or fitness, are disclaimed.

WARNING: In the USA, this product has labeling limitations. See package insert for complete information. CAUTION: USA Law restricts these devices to sale by or on the order of a physician.