GLOBUS MEDICAL

ELLIPSE™

Occipito-Cervico-Thoracic Stabilization System

Life moves us

The Surgical Technique shown is for illustrative purposes only. The technique(s) actually employed in each case always depends on the medical judgment of the surgeon exercised before and during surgery as to the best mode of treatment for each patient. Additionally, as instruments may occasionally be updated, the instruments depicted in this Surgical Technique may not be exactly the same as the instruments currently available. Please consult with your sales representative or contact Globus directly for more information.

SURGICAL TECHNIQUE GUIDE

ELLIPSE™

Overview 4
Implant Overview 6
Instrument Overview 9
Surgical Technique 19
1. Approach 19
2. Screw Insertion 19
3. Rod and Cap Insertion 23
Option A: Rod Counter Torque 25
Option B: Rocker Arm 26
Option C: Lateral Rod Reducer 27
Option D: Top Loading Ratcheting Rod Reducer 28
4. Hook Placement 29
5. Occipital Fixation 30
6. Compression or Distraction 36
7. Optional Connectors 37
8. Final Tightening 40
Final Position 41
Optional: Implant Removal 41
ELLIPSE™ Implant Set 982.902 42
ELLIPSE™ Instrument Set 982.901 47
ELLIPSE™ Occipital Implant and Instrument Set 982.910 49
ELLIPSE™ Auxiliary Screw Set 982.906 50
ELLIPSE™ CoCr Rod Set 982.909 51
Important Information 52

ELLIPSE™

Occipito-Cervico-Thoracic Stabilization System

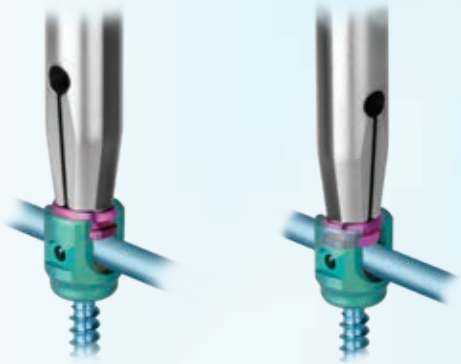
The ELLIPSE™ Occipito-Cervico-Thoracic (OCT) Stabilization System has been designed to eliminate the challenges associated with posterior OCT fusion for easier construct assembly. A wide range of instruments, including flexible and jointed occipital instruments, assist in swift installation of the implants which makes this system a comprehensive, easy-to-use solution for the toughest of cases.

EllipticClick

Drop, Click and Lock — rod retention feature retains the rod within the screw head to stabilize the construct during locking cap insertion.

Non-Threaded Locking Cap

Robust design that eliminates cross-threading and directs set screw forces axially against the rod, unlike threaded systems which direct forces radially against the screw head.



Novel Instruments

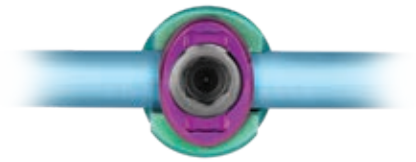
Refined instruments, from an easy release screwdriver, to the flexible, jointed and angled occipital drivers, ensure smooth construct assembly.

IMPLANT OVERVIEW

ELLIPSE™ Polyaxial Screws

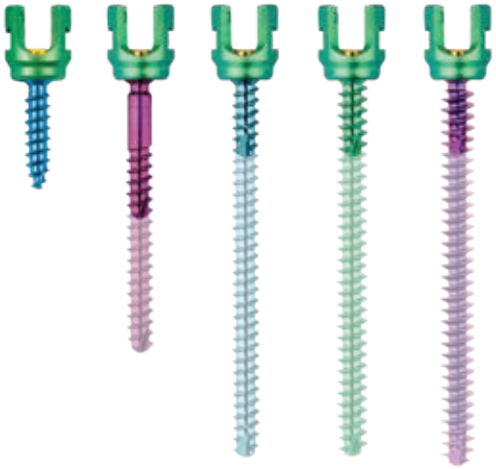
Polyaxial Screws

- 80° screw angulation (±40°) provides intraoperative versatility
- ElliptiClick® feature retains rod once inserted into screw for easier cap insertion
- Elliptical shape provides additional resistance against screw head splaying



Screw Thread

- Self-tapping design
- Blunt tip for bicortical purchase
- Constant outer diameter for maximum bone purchase
- 8, 10 and 12mm non-fluted screws additionally available
- Tapered Tip Screw design available (10–26mm lengths)

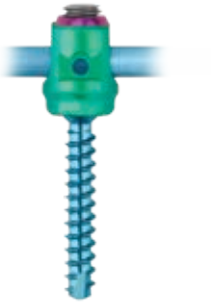


Variety of Options

- Multiple sizes to accommodate patient anatomy
- Screw diameters 3.5, 4.0 and 4.5mm
- Screw lengths from 8–50mm
- Shoulder screws also available (9mm smooth portion)

Non-Threaded Locking Cap

- Eliminates cross-threading
- 90° rotation of locking cap captures rod
- Set screw locks screw angle
- Low-torque locking mechanism



ELLIPSE™ Rods and Connectors

Rods

- 3.5mm titanium and cobalt chrome rods available in a range of lengths
- Tapered rod transitions from 3.5mm to 4.0, 4.5, 5.0, 5.5, 6.0, 6.35 or 6.5mm diameter
- 3.5mm curved rods available in 40–120mm lengths

Top-Loading T-Connector

- One set screw tightens clamp onto rod and secures medial-lateral position
- Multiple implant sizes and sliding clamps eliminate need for rod cutting
- Clamp snaps over rod for controlled insertion
- Friction bushing holds clamp position during insertion
- Adjusts to avoid contact with the dura or for lower profile
- Straight and curved to accommodate patient anatomy

Head-to-Head T-Connector

- Allows insertion when screws are directly adjacent
- Curved design accommodates patient anatomy
- Available in a range of sizes

Lateral Connector

- Utilizes ElliptiClick® feature for easier insertion
- May be cut to appropriate length

Parallel Connectors

- Allow attachment of ELLIPSE™ to titanium rod systems from 3.5–6.5mm in diameter

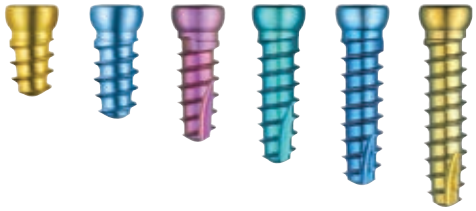
Hooks

- Utilizes ElliptiClick® feature for easier insertion
- Straight, left and right hook options
- 5.0mm and 7.0mm Offset Hooks

ELLIPSE™ Occipital Fixation

Occipital Plate

- Rod acceptors rotate and translate to accommodate rod position
- Seven points of screw insertion for optimal screw placement
- Bend zones for contouring
- Design allows plate to lag to the bone
- Variable screw insertion angles (±18°)
- Utilizes EllipticClick® feature for easier locking cap insertion
- Multiple plate sizes available

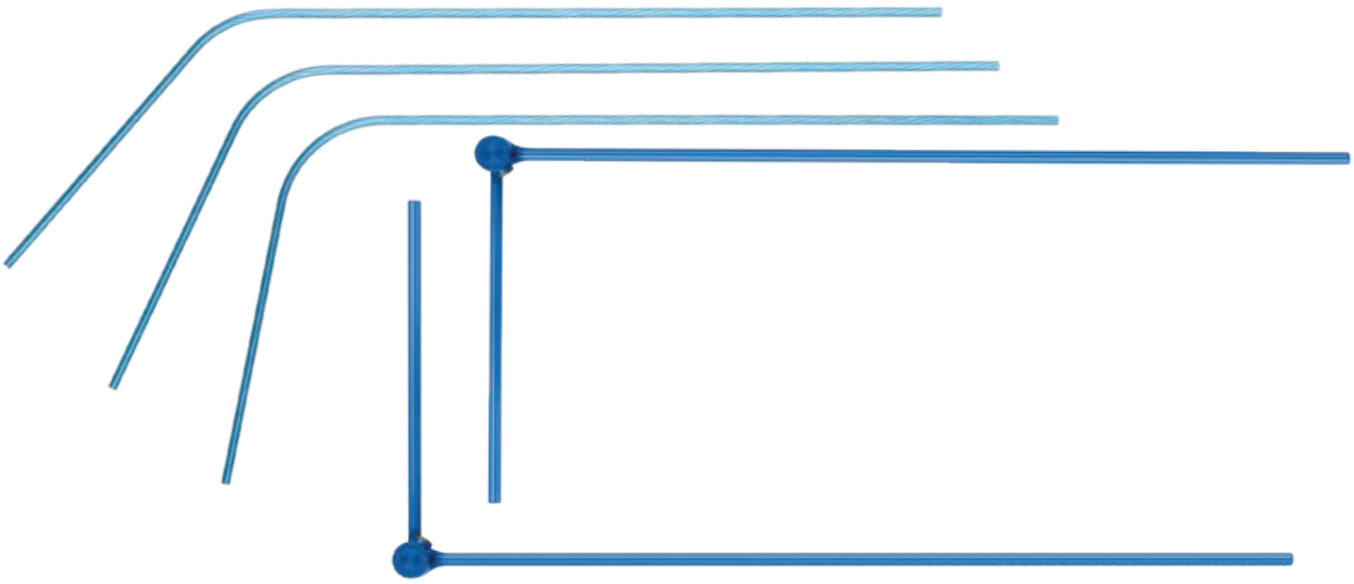


Screws

- Variable self-tapping screws available in 4.0mm and 4.5mm diameters
- Lengths ranging from 6–16mm, in 2mm increments

Rods

- 3.5mm diameter
- Pre-bent rods available in 100°, 115° and 130° options
- 3.5mm Jointed Occipital Rods (left or right)



INSTRUMENT OVERVIEW

PREPARATION INSTRUMENTS

Awl, 2.4mm 682.113

Pedicle Probe, Straight 682.114

Drill Bits
Drill for Ø3.5mm Screws (2.4mm diameter) 682.104 (S) Sterile Packed 682.108S
Drill for Ø4.0mm Screws (2.9mm diameter) 682.105 (S) Sterile Packed 682.109S

Quick-Connect Handle, Swivel 636.450

Taps
Taps for Ø3.5mm Screws 682.106
Taps for Ø4.0mm Screws 682.107

Tap Sleeve 682.110

Tap Sleeve Adjustable Stop 682.111

Ball Tip Probe 682.115

Items in gray are additionally available.

PREPARATION INSTRUMENTS (CONT'D)

Drill Guide with Adjustable Stop, 6–50mm 682.102

Drill Guide with 14mm Stop 682.103

Depth Gauge 682.112

SCREW INSTRUMENTS

ELLIPSE™ Polyaxial Screwdriver, with Cap 682.202

ELLIPSE™ Screw Head Positioner 682.204

Screwdriver, 2.5mm Hex, Self-Retaining, Small Handle 682.205

ELLIPSE™ Pushbutton Hex Driver, 2.5mm 682.700

Items in gray are additionally available.

ROD INSTRUMENTS

Rod Template, 240mm 615.301

In Situ Rod Cutter 615.300

In Situ Bender, Left, 3.5mm Rod 682.306

In Situ Bender, Right, 3.5mm Rod 682.307

Rod Bender 615.304

ROD INSTRUMENTS (CONT'D)

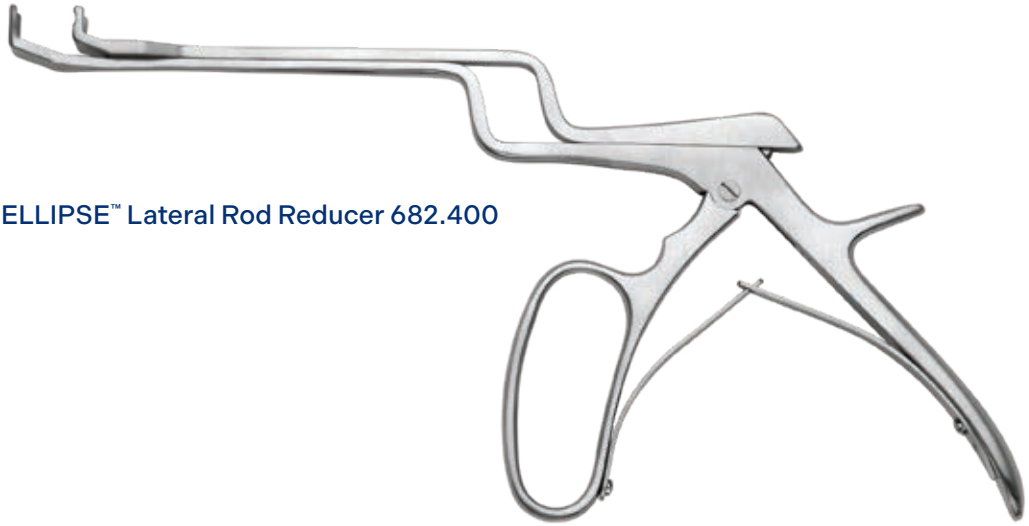
Rod Holding Forceps, 3.5mm Rod 682.308

Compressor, 3.5mm Rod 682.404

Distractor, 3.5mm Rod 682.405

ELLIPSE™ Rocker Arm 682.402

ROD INSTRUMENTS (CONT'D)



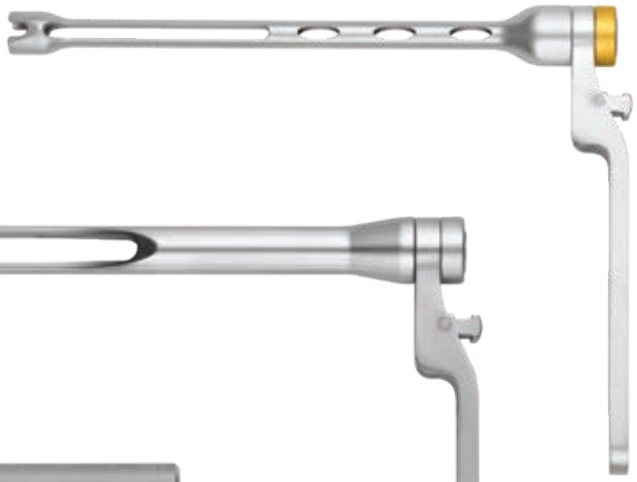
ELLIPSE™ Lateral Rod Reducer 682.400

ELLIPSE™ Threaded Reducer 682.398

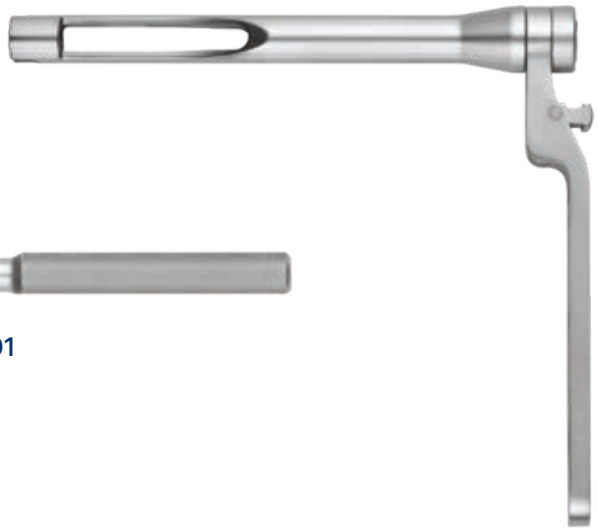
ELLIPSE™ Top-Loading Ratcheting Rod Reducer 682.399

LOCKING INSTRUMENTS

ELLIPSE™ Final Tightening Instrument 682.209



ELLIPSE™ Rod Counter Torque 682.403



ELLIPSE™ Cap Driver, Small Handle 682.201

ELLIPSE™ Head-to-Head Locking Cap Driver 682.901

Screwdriver Shaft, 2.5mm Hex 682.210

Torque-Limiting Quick Connect Handle, 1.5Nm 682.212

OTHER INSTRUMENTS

ELLIPSE™ Cervical Hook Forceps 682.206

Head-to-Head T-Connector Nut Inserter 682.312

Head-to-Head Benders
Left 682.313
Right 682.314

T-Connector Holder 615.309

Locking Nut Removal Tool 682.420

OCCIPITAL INSTRUMENTS

Occipital Plate Holder 682.603

Occipital Positioner, Rod Acceptor 682.604

Flexibile Drill Bit, 2.9mm 682.622

Occipital Adjustable Depth Drill Guide 682.644

Occipital CV Joint Tap, 4.0mm Screws 682.627

Occipital CV Joint Tap, 4.5mm Screws 682.628

Occipital CV Joint Screwdriver 682.647

OCCIPITAL INSTRUMENTS (CONT'D)

Sleeve, CV Joint for 4.5mm Tap 682.629

Sleeve, CV Joint 682.648

Offset Handle, Occipital CV Joint 682.620

Socket Driver 682.602

Offset Handle, Locking Ring 682.619

Occipital Cap Driver 682.650

Occipital Rocker Arm 682.651

Occipital Counter-Torque, Rod Acceptor 682.652

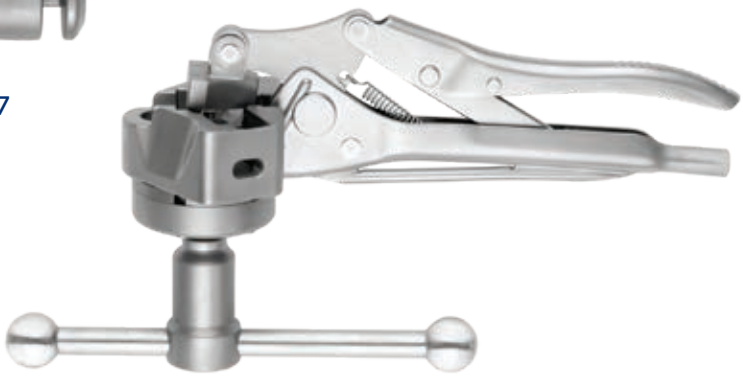
Occipital Screw Counter-Torque, Rod Acceptor 682.653

OCCIPITAL INSTRUMENTS (CONT'D)

Screwdriver, 2.5mm Hex, Torque Limiting Driver 615.203

Screw Removal Tool 610.819

Angled Screw Removal Tool Counter Torque 682.657



Angled Screw Removal Tool 682.656

Plate Bender 682.661

Occipital Plate Tip Bender 682.622

Jointed Rod Holder 682.715

SURGICAL TECHNIQUE

ELLIPSE™

Refer to the device insert (also printed at the back of this technique guide) for important information on the intended use/ indications, device description, contraindications, precautions, warnings, and potential risks associated with this system.

STEP 1 Approach

The patient is placed under general anesthesia and positioned prone. The operative area is carefully cleaned and an incision is made at the appropriate level(s). Lateral C-arm fluoroscopy or other radiographic methods can be utilized throughout surgery to ensure correct implant placement.

There are various techniques for implant insertion. For the purposes of this surgical technique guide, a standard midline approach and building of an occipital-cervical-thoracic (Occiput to T3) construct is shown.

STEP 2 Screw Insertion

Pedicle or Lateral mass Preparation

Locate thoracic pedicles or lateral mass (C1- T3) and remove bone and/or soft tissue as needed using standard instruments. Use the **Awl, 2.4mm**, to perforate the cortex and create a pilot hole.

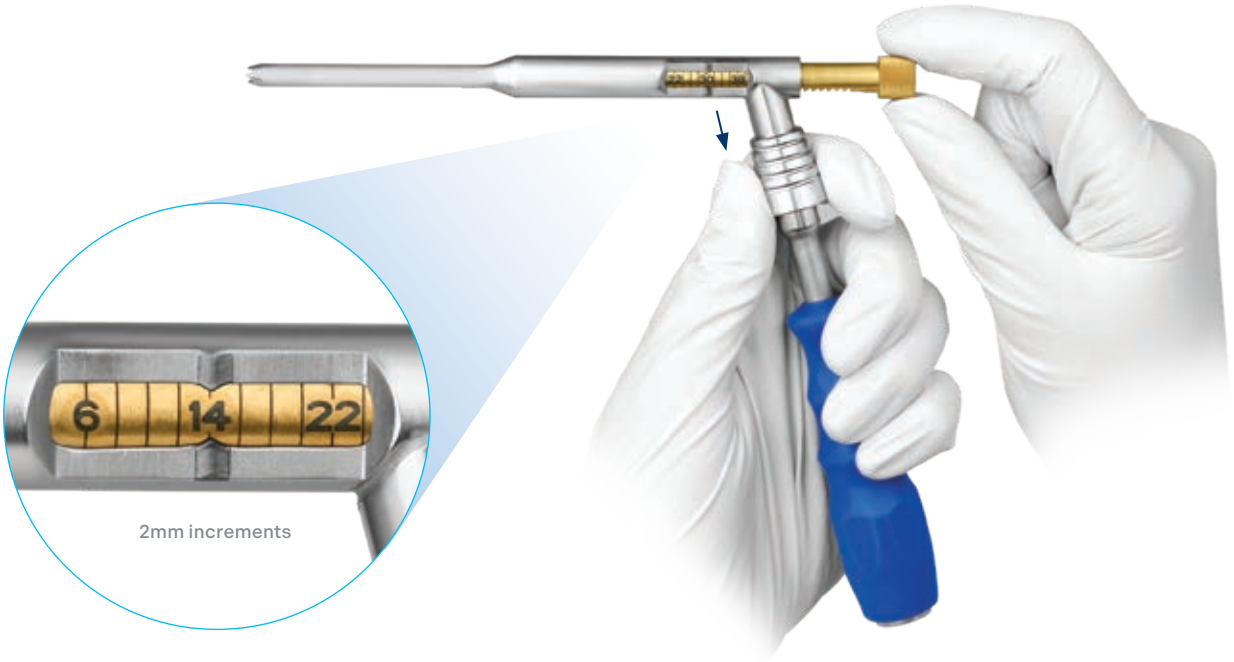
The **Pedicle Probe, Straight** may be used to open the pedicle pathway. Demarcations every 5mm on the probe indicate depth and help determine proper screw length. If the pedicle pathway requires further opening, choose the desired drill bit and guide.

The **Drill Guide with Adjustable Stop, 6–50mm** allows drill depth from 6–50mm, in 2mm increments. Adjust the drill guide depth as described on the next page. If the required depth is 14mm, the **Drill Guide with 14mm Stop** may be used.

Screw Insertion (Cont'd)

Using the Drill Guide with Adjustable Stop

Pull down the tapered sleeve to release the ratchet. Adjust the drill stop until the appropriate depth is indicated. Release the sleeve to lock the drill guide at the appropriate depth. Ensure that the ratchet is fully engaged by pressing on the drill stop.



Attach the **Drill Bit** to the **Quick Connect Handle, Swivel** and insert the assembly through the drill guide. Drill to the stop. The Depth Gauge may be used to verify depth.

The **Ball Tip Probe** may be used to verify that the walls of the prepared pedicle or lateral mass pathway are not violated. ELLIPSE™ polyaxial screws are self-tapping; however pedicles or lateral masses may be pre-tapped using a **Tap**.

Using the Tap Sleeve

The **Tap Sleeve** may be used to indicate depth while tapping the pilot hole. Slide the sleeve onto the tap. The sleeve slides back to the desired depth while tapping.

Tap Sleeve

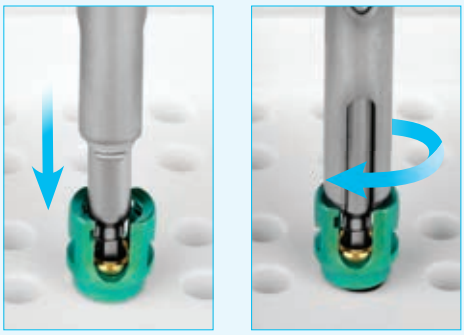
Tap Sleeve with Adjustable Stop
(Note: Sleeve does not slide when locked.)

**Footnote*

LOADING THE POLYAXIAL SCREWDRIVER

OPTION 1

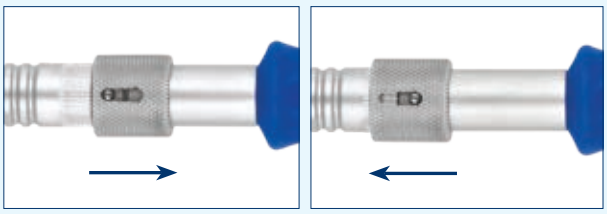
Align the hex of the ELLIPSE™ Polyaxial Screwdriver, with Cap and insert into the screw head. Ensure that the locking collar is in the unlocked position. Press down the screwdriver tapered sleeve and rotate the tabs 90° clockwise into the screw head. Press the locking collar forward to lock the sleeve in place. The screw is now rigidly connected to the screwdriver.



Screwdriver tapered sleeve inserted into screw head

OPTION 2

Push the locking collar forward on the ELLIPSE™ Polyaxial Screwdriver, with Cap. Insert the hex of the screwdriver into the screw head. Rotate the entire screwdriver with the blue handle to rotate the tabs 90° clockwise into the screw head. The screw is now rigidly connected to the screwdriver.

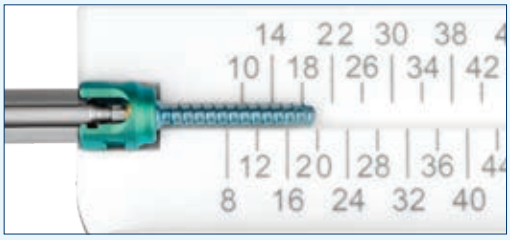


Unlocked Locked

After loading the screw, verify size by checking the length and diameter markings on the screw head in addition to using the gauges provided on the screw module.

To disengage the screwdriver, pull the locking collar back and rotate the sleeve counterclockwise out of the screw head.

Alternately, the **Screwdriver, 2.5mm Hex, Self-Retaining, Small Handle** may be used for screw insertion or repositioning.



Verifying screw length of 20mm

Polyaxial screw loaded onto Polyaxial Screwdriver, with Cap

Polyaxial screw loaded onto optional Self-Retaining Screwdriver

Polyaxial screw loaded onto optional Pushbutton Hex Driver

Screw Insertion (Cont'd)

Insert screws into the prepared pedicle or lateral mass. Remove the screwdriver from the screw head by reversing the insertion steps. Ensure that the screw head is mobile and free of bone obstruction. If required, a **Reamer** is additionally available to prepare the bone at the insertion site for optimal screw head mobility.

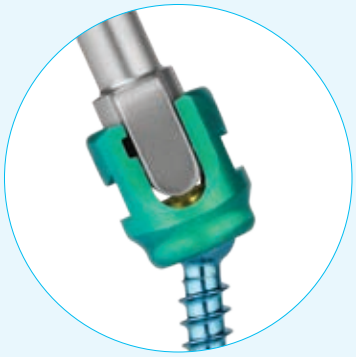
If screws need to be removed or repositioned, the Screwdriver, 2.5mm Hex, Self-Retaining, Small Handle should be used. Once the screws are fully inserted, the screw heads can be oriented to better receive the rod using the **ELLIPSE™ Screw Head Positioner**, as described below.

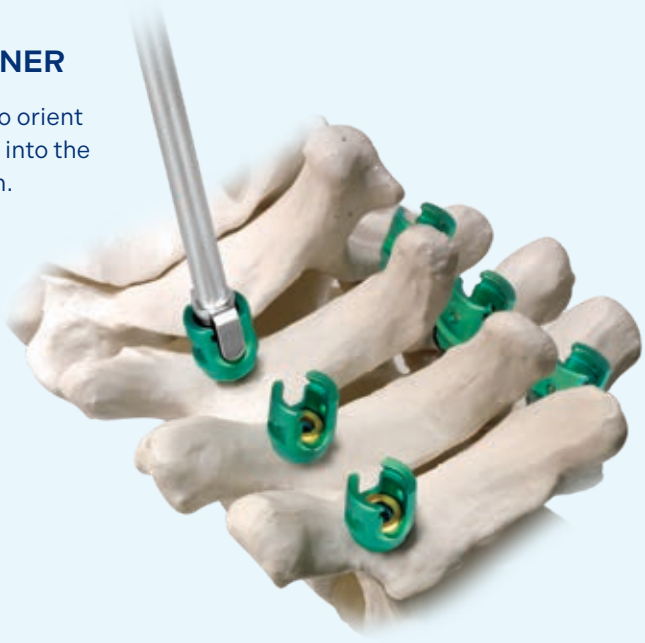
Insertion of polyaxial screws

Screws inserted

USING THE SCREW HEAD POSITIONER

The ELLIPSE™ Screw Head Positioner can be used to orient the screw head after insertion. Insert the positioner into the head of the screw, and rotate to the desired position.





STEP 3 Rod and Cap Insertion

Rod Preparation

Determine the appropriate length and contour of the rod using the **Rod Template**. Rods are available in a variety of lengths, and may be cut using the **In Situ Rod Cutter**. Rods may be contoured using the **Rod Bender**, as described at right.

Rod Insertion

Using the **Rod Holding Forceps**, grasp the rod and insert into the polyaxial screws. Ensure that the rod passes fully through the screw heads.

Apply light downward force to snap the rod past the ElliptiClick® feature, allowing the screw head to retain the rod for easier Locking Cap insertion.

If the rod can not be inserted fully, the rod may need to be contoured or rod reduction may be used, as described on page 25.

Rod insertion

USING THE ROD BENDER

Place the rod into the Rod Bender and squeeze the handles to achieve desired curvature. For further bending, place rod into the opposite side to increase the contour.

Contouring rod

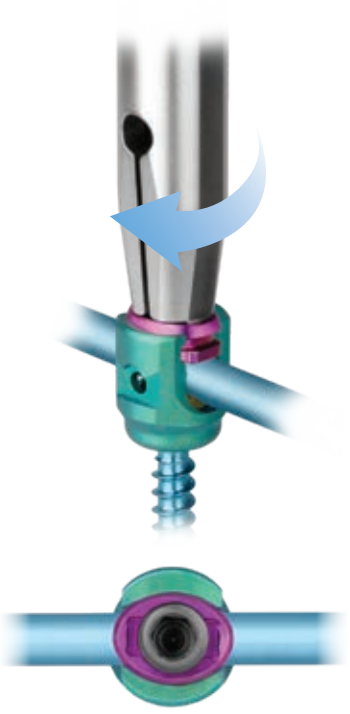
Rod and Cap Insertion (Cont'd)

Locking Cap Insertion

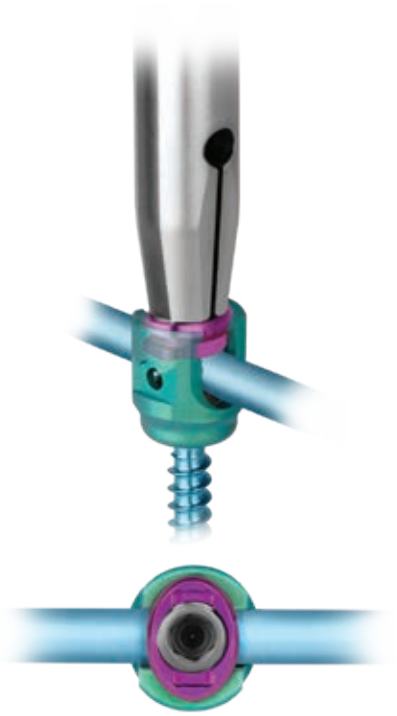
Locking caps can be inserted with or without reduction instruments. To insert a locking cap without reduction, load the **Cap Driver, Small Handle**, as shown below, and insert it into the screw head as shown below. If reduction is needed, refer to page 25.

With a loaded cap driver, insert the locking cap into the polyaxial screw head and rotate clockwise 90° to capture the rod. Note: Locking cap insertion requires minimal effort. If the locking cap is difficult to turn, the rod may not be seated properly.

The construct is not completely locked until final tightening (see Step 8).



UNLOCKED



LOCKED

LOADING THE CAP DRIVER

Align the tabs on the Cap Driver, Small Handle with the indentations on the top of the locking cap within the module. Two laser marked lines on the sides of the cap driver indicate the location of the tabs. Ensure the locking cap is seated on the driver before insertion.

Loading locking cap

Locking cap properly seated

Rod Reduction

The ELLIPSE™ system includes four options for rod reduction. Please note that rod reduction instruments are designed to seat the rod into the screw, not to bend the rod. Ensure that the rod is properly contoured prior to reduction.

Option A: Rod Counter Torque

The **Rod Counter Torque** is useful when the rod is within the screw head but not fully reduced. Place the counter torque over the rod and screw head and apply downward pressure.

The counter torque fits onto the screw head, such that grooves on the instrument tip will fit over the rod. If desired, the handle orientation of the counter torque can be adjusted.

Once the rod is fully seated within the screw head, insert the loaded cap driver into the counter torque. Etched lines on the sides of the cap driver should be aligned with the etched lines on the counter torque. Install the locking cap as shown on page 24.

The construct is not completely locked until final tightening (see Step 8).

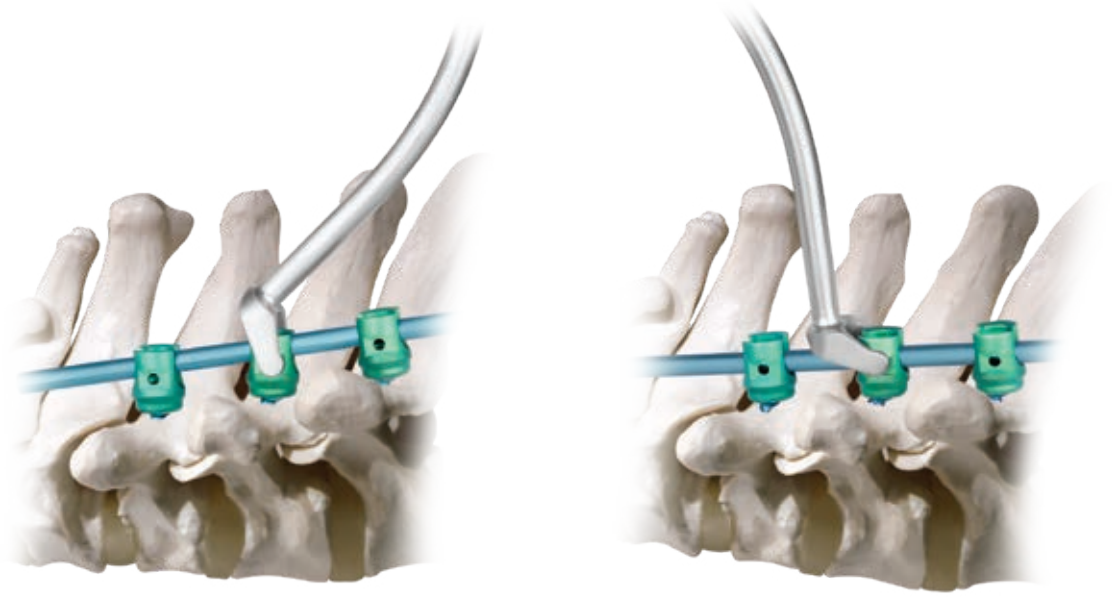
Rod reduction using
ELLIPSE™ Rod Counter Torque

Locking cap insertion through
ELLIPSE™ Rod Counter Torque

Rod and Cap Insertion (Cont'd)

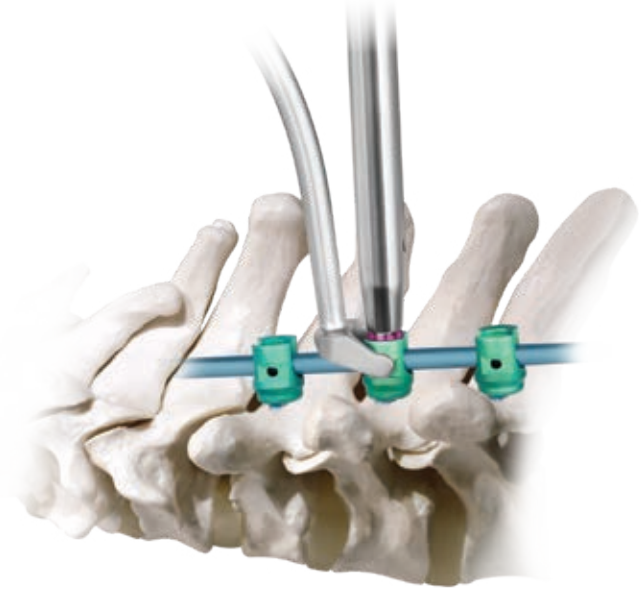
Option B: Rocker Arm

The **ELLIPSE™ Rocker Arm** provides maximum visibility during reduction and may be used when the rod is slightly above the screw head. To engage the screw head, place the rocker arm engagement pins into the screw head reduction slots. Lever the rod down, persuading it into the screw head.



Rod reduction using ELLIPSE™ Rocker Arm

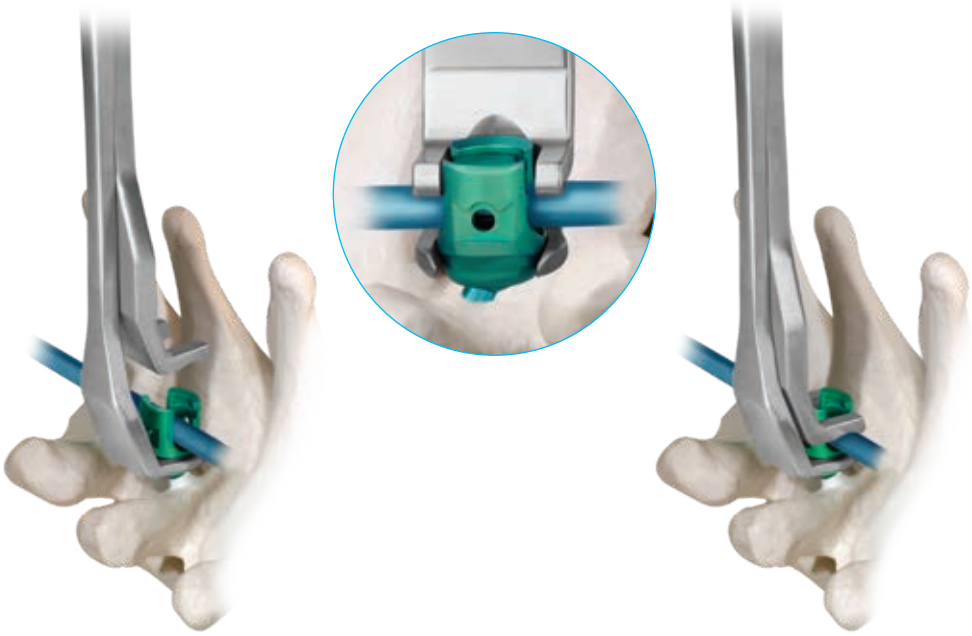
Once the rod is fully seated within the screw head, insert the loaded cap driver to install the locking cap, as shown on page 24. The construct is not completely locked until final tightening (see Step 8).



Locking Cap insertion

Option C: Lateral Rod Reducer

The **ELLIPSE™ Lateral Rod Reducer** can be used when the rod is slightly above the screw head, while maintaining full visibility. Introduce the rod reducer laterally, sliding the bottom jaw under the screw. Compress the handles to place the top jaw against the rod to reduce.



Rod reduction using ELLIPSE™ Lateral Rod Reducer

Once the rod is fully seated within the screw head, insert the loaded cap driver to install the locking cap, as shown on page 24. The construct is not completely locked until final tightening (see Step 8).

Locking Cap insertion

Rod and Cap Insertion (Cont'd)

Option D: Top Loading Ratcheting Rod Reducer

The **ELLIPSE™ Top Loading Ratcheting Rod Reducer** provides strong reduction and should be used with care. Place the rod reducer over the screw head until seated within the screw head reduction slots. Pull up on the reducer to ensure that it is fully engaged with the screw head.

Slowly compress the handles to reduce the rod into the screw head.

Note: For tactile feedback during reduction, press down the ratchet lever while compressing the handle.

Top Loading Ratcheting Rod Reducer positioned onto screw head

Rod reduction using Top Loading Ratcheting Rod Reducer

Once the rod is fully seated within the screw head, insert the loaded cap driver into the rod reducer and install the locking cap. The construct is not completely locked until final tightening (see Step 8).

Note: To release the rod reducer, allow the handles to fully open by releasing the ratchet lever. Then, rotate the instrument a few degrees while gently pulling it off the screwhead.

STEP 4 Hook Placement

ELLIPSE™ hooks can be used for stabilization of the cervical and thoracic spine (C1-T3). The **ELLIPSE™ Cervical Hook Forceps** can be used to place the Inline Hooks. Apply light force to snap the rod past the ElliptiClick® feature within the hook head. This feature will retain the rod for easier locking cap insertion.

The locking cap may be installed through the forceps. Refer to page 26 for details on locking cap installation. The construct is not completely locked until final tightening (see Step 8).

Inline hooks

Cap driver inseting locking cap through Cervical Hook Forceps

ELLIPSE™ Offset Hooks can be inserted with forceps and provisionally secured with the Screwdriver, 2.5mm Hex, Self-Retaining. Apply light force to snap the offset hook onto the rod. These hooks are available in right and left variations, with offsets of 5mm or 7mm.

The construct is not completely locked until final tightening (see Step 8).

Right Offset Hook, 7mm

Right Offset Hook, 5mm

Left Offset Hook, 7mm

Left Offset Hook, 5mm

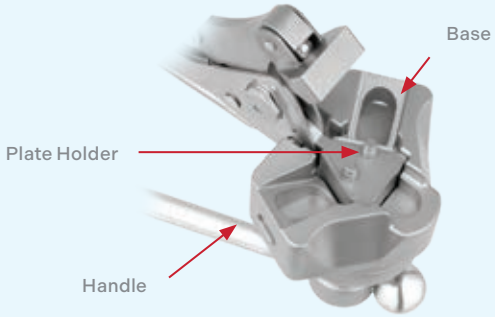
STEP 5 Occipital Fixation

Occipital plates are available in two sizes. Use the **Occipital Plate Holder** to place the appropriate plate on the occiput. If it is necessary to increase the plate contour, the **Occipital Plate Bender** may be used to bend the plate within the indicated bend zones. Determine optimal occipital plate placement and begin screw hole preparation. It is recommended that at least five points of fixation are achieved; two in the rod acceptors and three midline.

USING THE OCCIPITAL PLATE BENDER

STEP 1

Rotate the handle counterclockwise. This will set the plate holder in the base upwards for plate insertion.

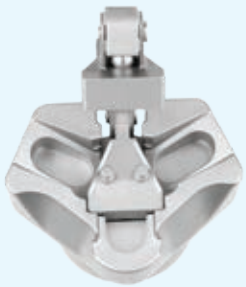


Correct

Incorrect

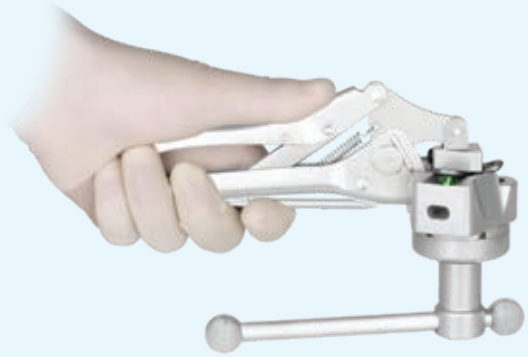
STEP 2

Insert the OC plate into the jaws of the plate bender so that the two plate locator pins fit into the two lateral holes of the OC plate.



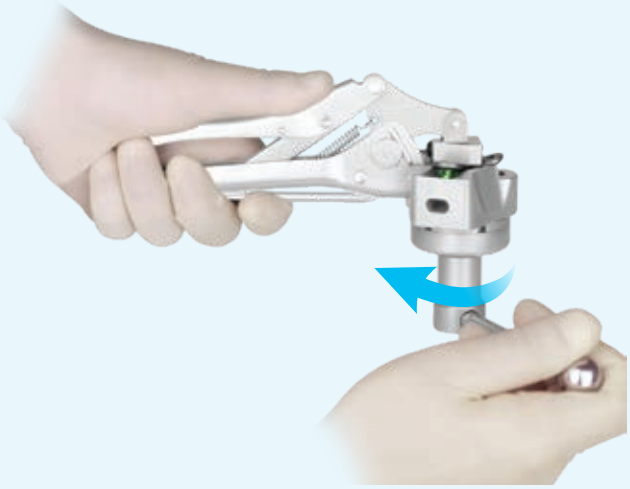
Note: To make the plate more convex, install the plate's top surface facing the bender, as shown above. To make the plate more concave install the plate so that the top surface is facing up, opposite of the image above.

USING THE OCCIPITAL PLATE BENDER (CONT'D)



STEP 3

Retain the plate by compressing the handles to securely hold the plate while bending.



STEP 4

While the OC plate is in the plate holder, rotate the handle clockwise until the desired plate contour is achieved. The handle will stop rotating when the maximum contour is achieved.

Reverse Steps 4 and 3 to remove the OC plate from the plate bender.

USING THE OCCIPITAL PLATE TIP BENDER

To bend the tip of the plate, ensure that the OC plate is inserted with the top of the plate facing downward in the jaws of the plate bender. The plate holder should be at the top of the base, as described in step 1 on the previous page.

Slide the **Occipital Plate Tip Bender** completely over the tip of the plate and compress until the tip bender hits the handle of the plate bender.

Note: The tip of the plate should only be bent in the direction towards the bottom of the plate, as shown at left.

Stay within these guidelines to ensure that bending does not compromise structural integrity of the plate.

Occipital Fixation (Cont'd)

Screw Hole Preparation

The Awl, 2.4mm may be used to perforate the cortex of the occiput. The **Occipital Adjustable Depth Drill Guide** allows drill depth from 6mm to 16mm, in 2mm increments. Adjust the drill guide depth as described below.

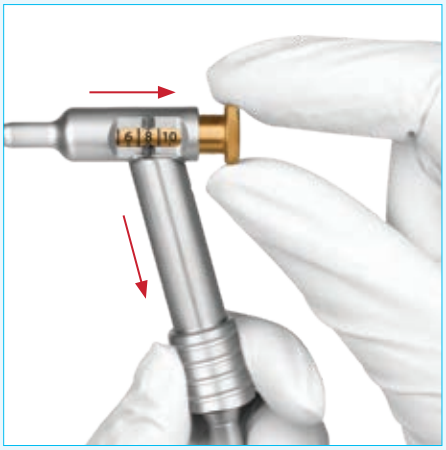
The **Flexible Drill Bit, 2.9mm** allows up to 90° insertion angle when needed in the occiput. Insert the drill bit and drill through the drill guide.

Screws up to 12mm may be safely inserted into occipital bone, close to the external occipital protuberance (EOP). Longer screws up to 16mm may be used if they are angled medially, toward the EOP. Care must be taken not to penetrate the far cortex of the occipital bone. Occipital bone screws are limited to occipital fixation; they are not intended for use in the posterior elements of the cervical spine.

USING THE OCCIPITAL ADJUSTABLE DEPTH DRILL GUIDE

Pull the tapered sleeve down to release the ratchet. Adjust the drill stop until the appropriate depth is indicated.

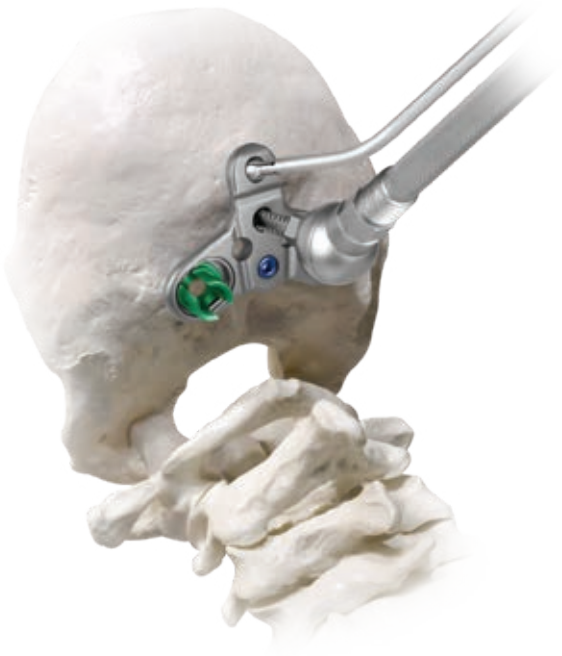
Release the sleeve to lock the drill guide at the appropriate depth. Ensure that the ratchet is fully engaged by pressing on the drill stop.



14mm drill depth down

ELLIPSE™ occipital screws are self-tapping; however it is recommended to tap due to the density of occipital bone.

Choose the **Occipital CV Joint Tap** of appropriate diameter and assemble with the appropriate Sleeve, CV Joint as shown below. The sleeve will maintain the angle of the tap during insertion. Attach the tap assembly to a quick connect handle and tap to the desired depth.



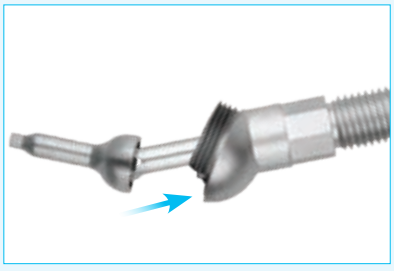
Tapping occiput

ASSEMBLING CV JOINT SLEEVE

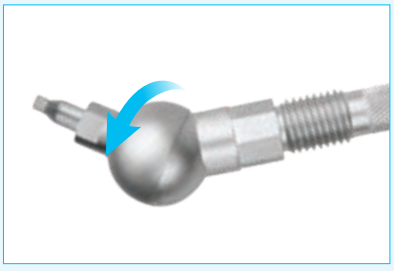
The **Sleeves, CV Joint** are color-coded to match the corresponding tap or screwdriver. Identify the appropriate sleeve and disassemble into two pieces as shown below.

If needed, a **Socket Driver** aids in threading and unthreading the sleeve.

Disassemble the sleeve



Slide cannulated tube over back end of the tap or screwdriver.



Insert angled portion of sleeve over tip of tap or screwdriver. Thread cannulated tube and angle tip together to complete assembly.

Occipital Fixation (Cont'd)

Screw Insertion

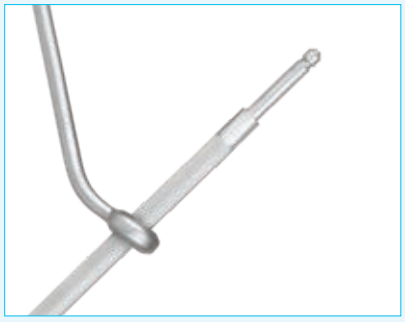
Select the desired occipital screw, and insert using the **Occipital CV Joint Screwdriver**. A CV joint sleeve is provided to maintain the angle of the screw during insertion.

An additional **Offset Handle** may be used to gain leverage during tapping or screw insertion. Assemble the Offset Handle to the CV joint sleeve, as shown below.

Screw insertion using Occipital CV Joint Screwdriver, sleeve and Offset Handle

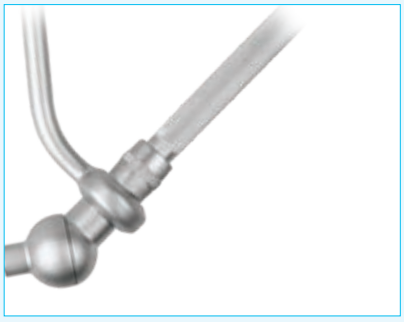
Note: If screw removal is necessary, use the Screw Removal Tool. Refer to the **ASSURE™ Surgical Technique Guide (GMTGD06)** *for instruction.*

OFFSET HANDLE ASSEMBLY



Before attaching the quick connect handle to the tap or screwdriver, slide the Offset Handle over the back end of the CV joint sleeve.

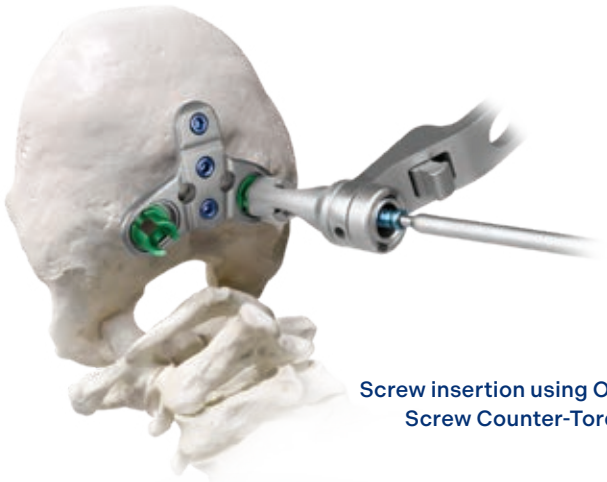
Position the opening of the Offset Handle at the desired angle.



Secure the Offset Handle to the sleeve by sliding the **Offset Handle Locking Ring** over the back end of the sleeve and rotating it clockwise until tight against the Offset Handle.

Use the **Occipital Rod Positioner** to orient the rod acceptors to receive the rod.

The **Occipital Screw Counter Torque, Rod Acceptor** may be used to stabilize the acceptors during screw insertion. Ensure that the rod acceptors are in the optimal orientation prior to screw insertion as they no longer rotate or translate once the screw is in place.



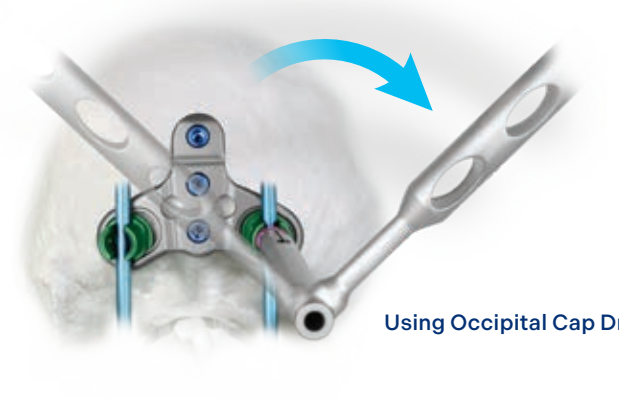
Screw insertion using Occipital Screw Counter-Torque

Rod Selection

Select the desired pre-bent or jointed Occipital Rods. Pre-bent rods accommodate various angles in the occipito-cervical junction and may be adjusted and contoured to match the patient anatomy. Rods are available in 100°, 115° and 130° options.

The jointed rod portion adjusts angulation in the sagittal plane to accommodate more severe angles in the occipito-cervical junction. The straight portions of the rod may be contoured to match the patient anatomy.

Jointed rods accommodate angles from 60° to 150° and are available in both left and right configurations.



Using Occipital Cap Driver

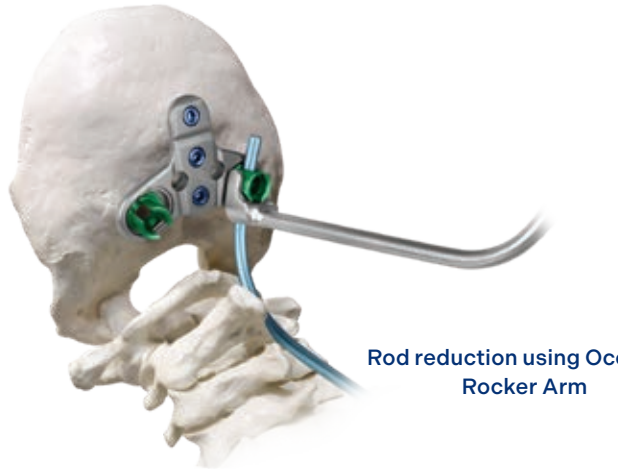
Rod and Cap Insertion

Place the rod in the acceptors, applying light downward force to snap the rod past the ElliptiClick® feature. This allows the rod acceptor to hold the rod for easier locking cap insertion. Insert the locking caps using the **Occipital Cap Driver**.

Locking caps may be inserted with or without reduction instruments. Two reduction tools are provided for use with the Occipital Plate, as shown at right. The **Occipital Rod Counter Torque** and the **Occipital Rocker Arm** are used in the same manner as the ELLIPSE™ Rod Counter Torque and ELLIPSE™ Rocker Arm, described on page 25 and 26 of this technique guide.

The construct is not completely locked until final tightening (see Step 8). The Torque Limiting Handle may be attached to the CV Joint Screwdriver to lock.

Note: ELLIPSE™ Rocker Arm and Occipital Rocker Arm are not interchangeable.

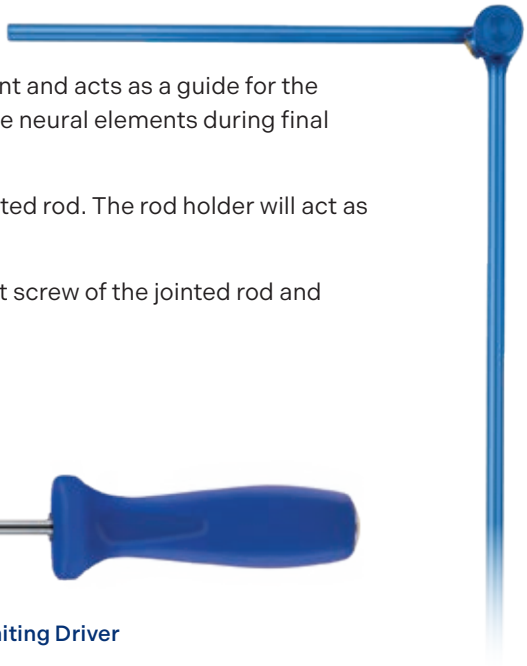


Rod reduction using Occipital Rocker Arm

Rod reduction using Occipital Counter Torque

Occipital Fixation (Cont'd)

Final Tightening Occipital Jointed Rods



The **Jointed Rod Holder** may be used to achieve proper rod placement and acts as a guide for the **Screwdriver, 2.5mm Hex, Torque Limiting Driver** while protecting the neural elements during final tightening.

Place the Jointed Rod Holder around the locking set screw of the jointed rod. The rod holder will act as a counter torque during final tightening.

Insert the Screwdriver, 2.5mm Hex, Torque Limiting Driver into the set screw of the jointed rod and final tighten to 2.5Nm. This locks the angle of the jointed rod in place.

Screwdriver, 2.5mm Hex, Torque Limiting Driver

STEP 6 Compression or Distraction

ELLIPSE™ Polyaxial Screws can be compressed or distracted along the rod as necessary using the **Compressor, 3.5mm Rod** and **Distractor, 3.5mm Rod**. The tips of the compressor and distractor are grooved to grip the screw heads. Once compression or distraction is completed, provisionally tighten the set screws using a 2.5mm hex screwdriver.

Compression

Distraction

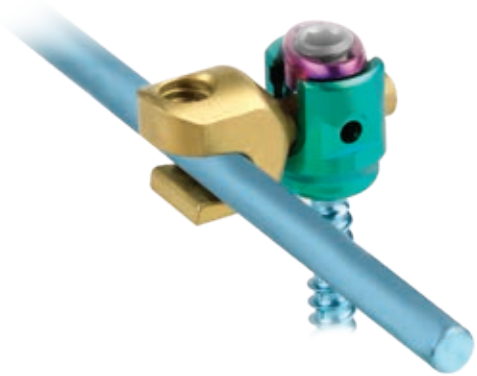
STEP 7 Optional Connectors

Parallel Connectors can be used to aid in transitioning between screw or hook locations and to minimize rod contouring. They can also enable connections to pre-existing titanium rods systems of various diameters. The ELLIPSE™ 3.5mm rod can be linked to another titanium 3.5mm rod or to a 5.5mm rod in the REVERE™ System. The 3.5mm rods may also be connected to a 4.0mm, 4.5mm, 5.0mm, 5.5mm, 6.0mm, 6.35mm or 6.5mm diameter titanium rod system using the corresponding connectors. Slide the Parallel Connectors onto the rods to be connected. Once the Parallel Connector is attached to both rods, the screws should be final tightened as described in Step 8.

Lateral Connectors

Lateral Connectors are used to aid in transitioning between screw or hook locations and to minimize rod contouring. The Lateral Connectors contain the ElliptiClick® feature. Apply light pressure as the connector is loaded onto the rod. The connector will snap onto the rod. Introduce the rod portion of the connector into the opening of the polyaxial screw or inline hook. Insert the locking cap (see Step 3) and provisionally tighten the pre-loaded screw onto the rod with a 2.5mm hex screwdriver. The Lateral Connector is now connected to the construct, which is not completely locked until final tightening (see Step 8 for final tightening instructions).

Note: Lateral Connectors may be cut to length using the *In Situ* Rod Cutter. Ensure that the rod length will pass completely through the screw or hook head.



Optional Connectors (Cont'd)

T-Connectors

To enhance construct stability, a transverse connector may be used between two rods. There are two different T-connector styles available.

Top-loading T-Connector

Head-to-Head
T-Connector

Top-Loading T-Connectors

Use the T-Connector Holder to clamp around one set screw on the Top-Loading T-Connector. Insert a 2.5mm hex driver in the set screw on the opposite side of the connector, and insert the connector between the two rods. Place one side of the T-connector onto the rod. It will gently snap onto the rod. Adjust the telescoping assembly to obtain approximate length and position. Gently snap the other side of the T-connector onto the contralateral rod. The construct is not completely locked until final tightening (see Step 8).

Placing Top-loading T-Connector

Head-to-Head T-Connectors

The Head-to-Head T-Connectors are used only with polyaxial screws; both are only to be used in the upper thoracic spine (T1-T3).

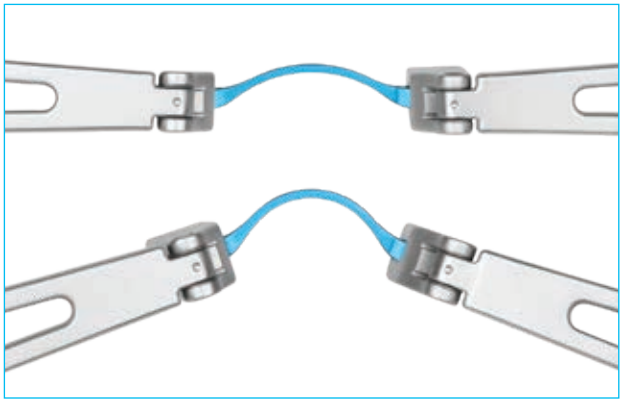
The Head-to-Head T-Connectors attach to contralateral polyaxial screw heads and are particularly useful when screw heads are close together and a traditional T-connector can not be used.

For this Head-to-Head T-Connector, a special locking cap must be used to capture the rod within the polyaxial screw head. Install the Locking Cap for Head-to-Head T-Connector using the **Head-to-Head Locking Cap Driver**. Ensure that the locking cap is rotated a full 90°. Final tighten using the 1.5Nm Torque Limiting Screwdriver Assembly before installing the T-connector.

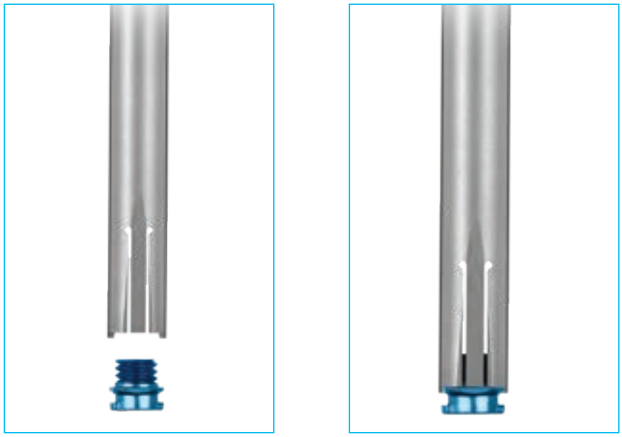
The Head-to-Head T-Connectors are precurved, however, if more curvature is desired, the **Head-to-Head Benders** may be used. Choose the appropriate length connector and place it onto the screw heads using a pair of forceps.

Install the Locking Nut for Head-to-Head T-Connector onto each locking cap set screw using the **Head-to-Head T-Connector Nut Inserter** and Torque-Limiting Quick Connect Handle, 1.5Nm Assembly.

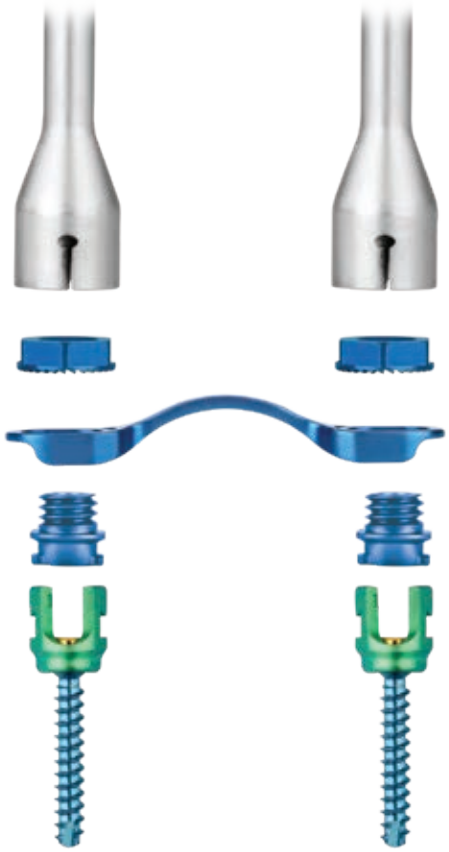
Note: The standard locking cap (fuchsia) will not accept the Head-to-Head T-Connector.



Head-to-Head T-Connector Benders



Head-to-Head Locking Cap Driver



Placement of Head-to-Head T-Connector

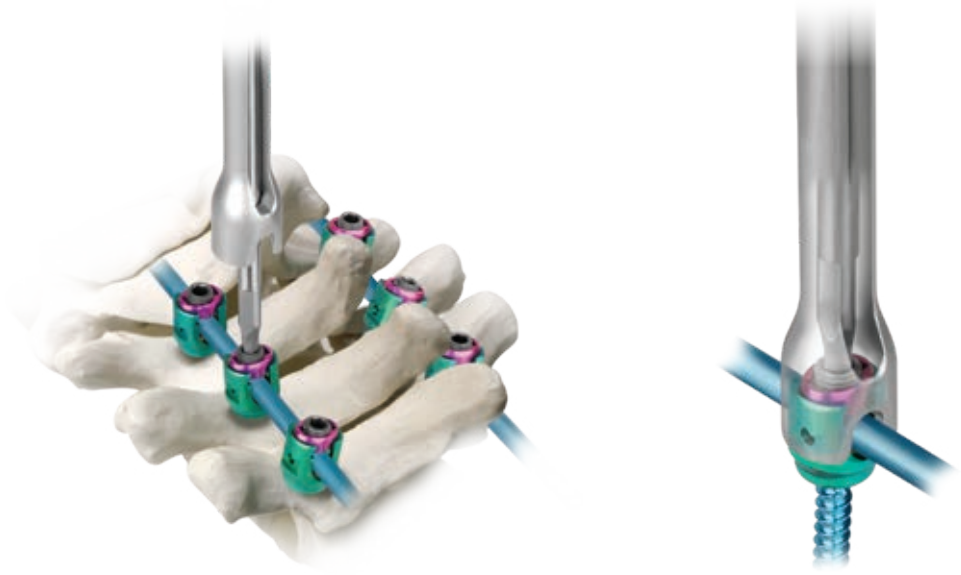
STEP 8 Final Tightening

Final tightening of the set screws is necessary to secure the construct, and is accomplished using the Torque-Limiting Quick Connect Handle, 1.5Nm and **Screwdriver Shaft, 2.5mm Hex**.

Polyaxial Screws and Hooks

Insert the Torque-Limiting Quick Connect Handle, 1.5Nm and Screwdriver Shaft, 2.5mm Hex Assembly into the **ELLIPSE™ Final Tightening Instrument**. Fully engage the 2.5mm hex into the set screw and position the final tightening instrument over the screw or hook head, ensuring that the sleeve is fully seated on the head and cap. Rotate the screwdriver clockwise until it reaches its torque limit of 1.5Nm (13.3 in-lbs). Repeat for all locking caps.

Note: Ensure hex is fully seated into the screw head to avoid stripping.



Occipital Locking Caps

The Torque-Limiting Quick Connect Handle, 1.5Nm may be connected to the Occipital CV Joint Screwdriver and used to final tighten the set screws in the occipital locking caps.

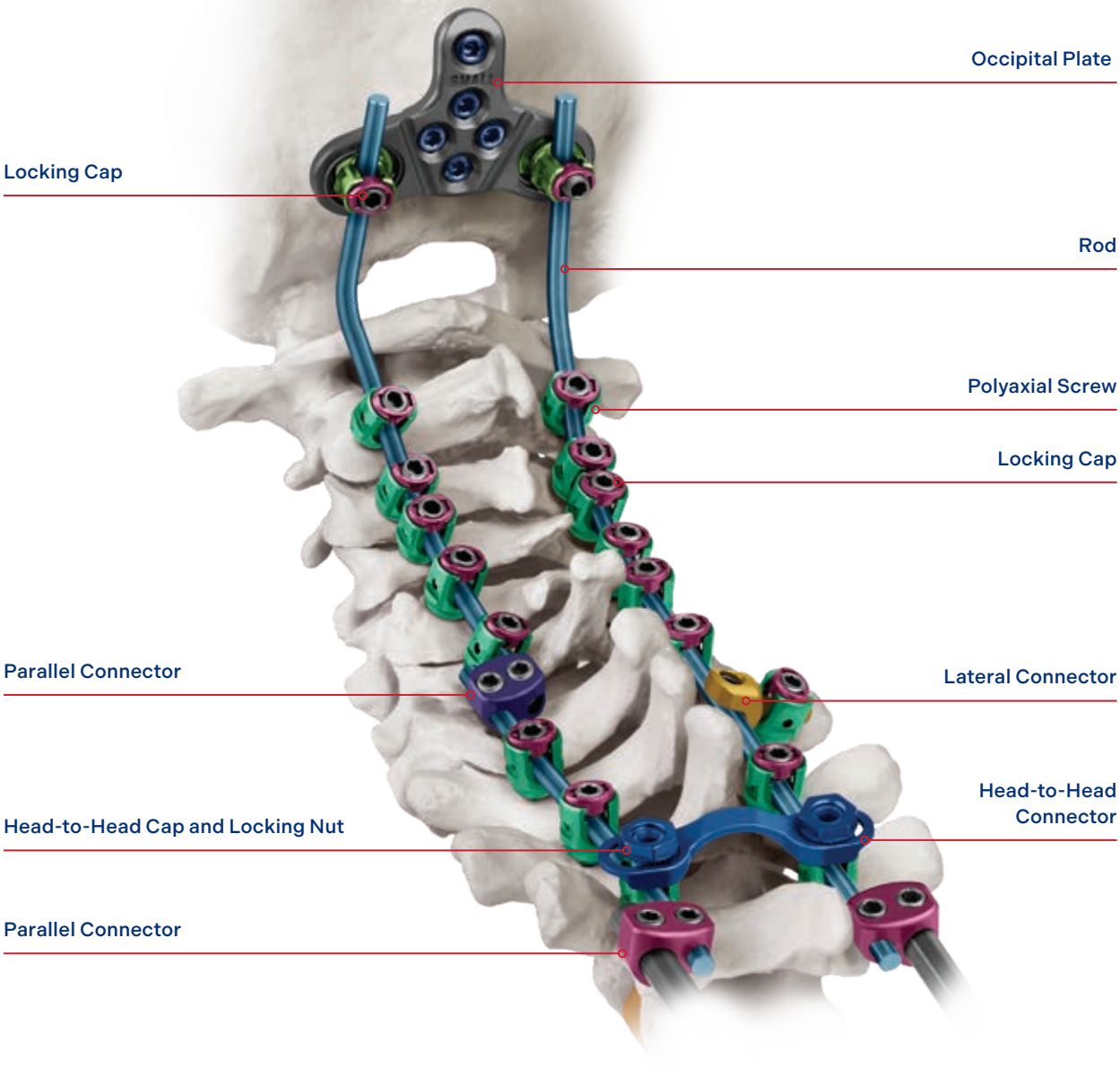
Head-to-Head T-Connectors

The Torque-Limiting Quick Connect Handle, 1.5Nm may be connected to the Head-to-Head T-Connector Nut Inserter and used to final tighten the Locking Nut on the Head-to-Head T-Connector.

All Other Implants

The Torque-Limiting Quick Connect Handle, 1.5Nm and Screwdriver Shaft, 2.5mm Hex Assembly should be used to final tighten all set screws on the Offset Hooks, Parallel Connectors, Lateral Connectors and Top- Loading T-Connectors. The Occipital Jointed Rods must be final tightened with the Screwdriver, 2.5mm Hex, Torque Limiting.

Final Construct



Optional: Implant Removal

For revision or removal of ELLIPSE™ implants, reverse the insertion steps until the desired implants are removed. Loosen all set screws using a 2.5mm hex screwdriver, and remove locking caps using the Locking Cap Driver. Once the set screws are loosened and the caps are removed, grasp the rod and remove from the screws or hooks. Remove all screws using a 2.5mm hex screwdriver. T-connectors and other connectors may remain connected on the rods for removal, or may be removed separately.

ELLIPSE™
Implant Set 982.902

ELLIPSE™ Polyaxial Screws

Length	3.5mm Part No.	Qty	4.0mm Part No.	Qty
8mm	182.308	8	–	–
10mm	182.310	12	182.410	4
12mm	182.312	12	182.412	4
14mm	182.314	12	182.414	4
16mm	182.316	12	182.416	4
18mm	182.318	8	182.418	4
20mm	182.320	8	182.420	4
22mm	182.322	8	182.422	4
24mm	182.324	8	182.424	4
26mm	182.326	8	182.426	4
28mm	182.328	0	182.428	4
30mm	182.330	0	182.430	4
32mm	182.332	0	182.432	4
34mm	182.334	0	182.434	4
36mm	182.336	0	182.436	4
38mm	182.338	0	182.438	4
40mm	182.340	0	182.440	4
42mm	182.342	0	182.442	4
44mm	182.344	0	182.444	4
46mm	182.346	0	182.446	4
48mm	182.348	0	182.448	4
50mm	182.350	0	182.450	4

3.5mm Polyaxial Screw, Tapered Tip

Part No.	Description	Qty
182.010	3.5mm, 10mm Tapered Tip	0
182.012	3.5mm, 12mm Tapered Tip	0
182.014	3.5mm, 14mm Tapered Tip	0
182.016	3.5mm, 16mm Tapered Tip	0
182.018	3.5mm, 18mm Tapered Tip	0
182.020	3.5mm, 20mm Tapered Tip	0
182.022	3.5mm, 22mm Tapered Tip	0
182.024	3.5mm, 24mm Tapered Tip	0
182.026	3.5mm, 26mm Tapered Tip	0

Non-Fluted Polyaxial Screws

Length	3.5mm Part No.	4.0mm Part No.	4.5mm Part No.
8mm	582.308	582.310	582.312
10mm	–	582.410	582.412
12mm	–	582.510	582.512

Locking Caps

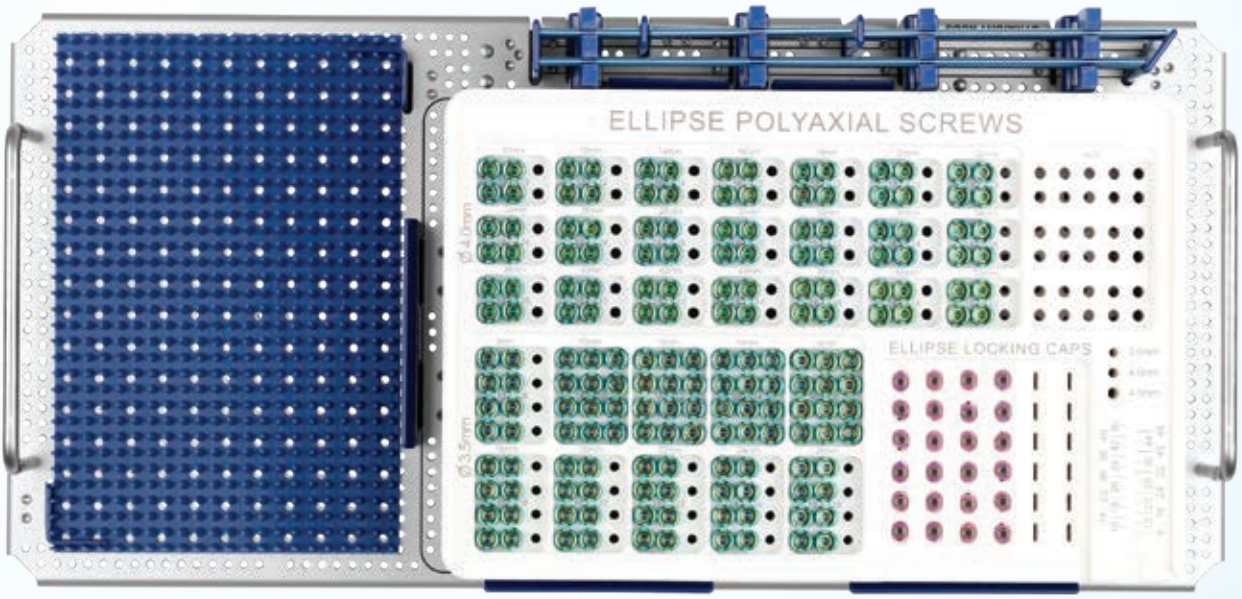
Part No.	Description	Qty
182.500	Locking Caps	24

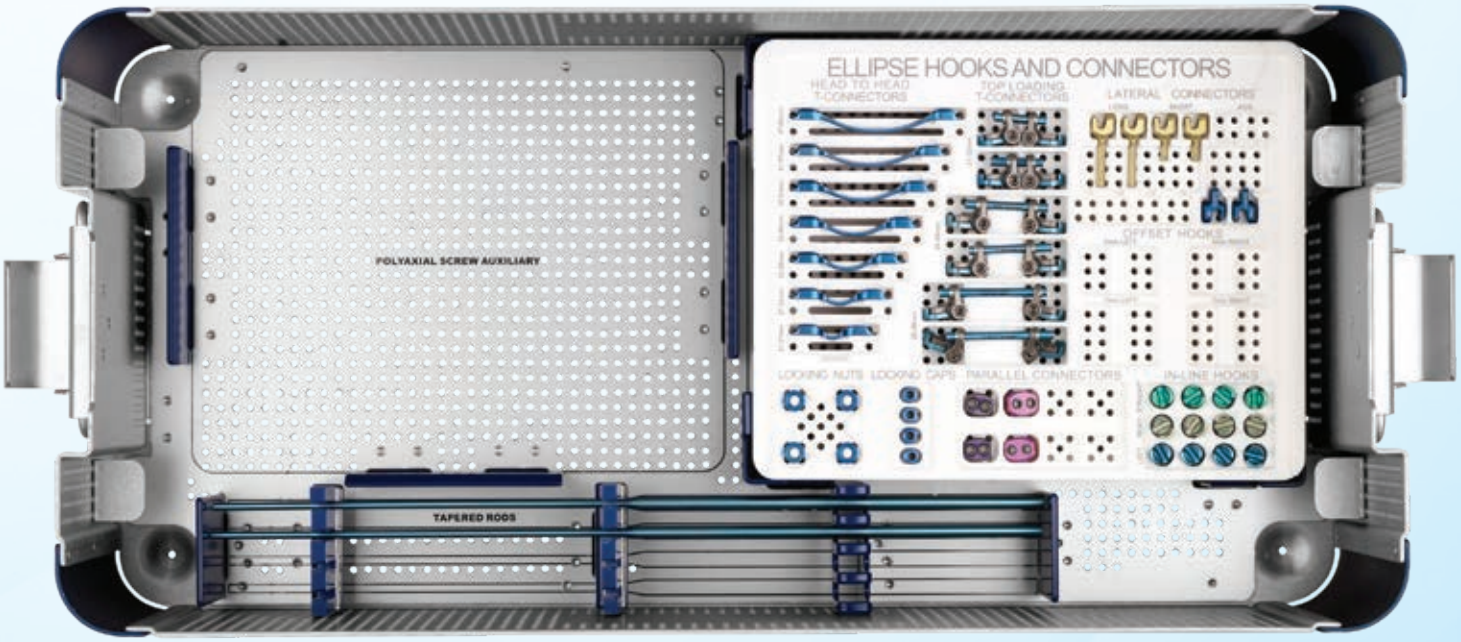
ELLIPSE™ 3.5mm Diameter Rods

Part No.	Description	Qty
182.801	3.5mm Rod, 80mm	4
182.802	3.5mm Rod, 120mm	4
182.803	3.5mm Rod, 240mm	4
182.804	3.5mm Rod, 40mm	4
182.980	Tapered Rod, 3.5mm to 4.0mm, 350mm	0
182.981	Tapered Rod, 3.5mm to 4.5mm, 350mm	0
182.982	Tapered Rod, 3.5mm to 5.0mm, 350mm	0
182.983	Tapered Rod, 3.5mm to 5.5mm, 350mm	2
182.984	Tapered Rod, 3.5mm to 6.0mm, 350mm	0
182.985	Tapered Rod, 3.5mm to 6.35mm, 350mm	0
182.986	Tapered Rod, 3.5mm to 6.5mm, 350mm	0
182.989	Tapered Rod, 3.5mm to 5.5mm, 500mm	0

Items in gray are additionally available.

ELLIPSE™
Implant Set 982.902





ELLIPSE™
Implant Set 982.902 (Cont'd)

Head-to-Head T-Connectors

Part No.	Description	Qty
182.911	Head–to–Head T–Connector, 21–27mm	1
182.912	Head–to–Head T–Connector, 27–33mm	1
182.913	Head–to–Head T–Connector, 33–39mm	1
182.914	Head–to–Head T–Connector, 39–45mm	1
182.915	Head–to–Head T–Connector, 45–51mm	1
182.916	Head–to–Head T–Connector, 51–57mm	1
182.917	Head–to–Head T–Connector, 57–63mm	1
182.900	Locking Cap for Head-to-Head T-Connector	4
182.901	Locking Nut for Head-to-Head T-Connector	4

Top-Loading T-Connectors

Part No.	Description	Qty
182.923	Top-Loading T-Connector, 21–33mm, Straight	2
182.924	Top-Loading T-Connector, 26–46mm, Curved	0
182.925	Top-Loading T-Connector, 26–46mm, Straight	2
182.926	Top-Loading T-Connector, 36–56mm, Curved	0
182.927	Top-Loading T-Connector, 36–56mm, Straight	2

Other Connectors

Part No.	Description	Qty
182.960	Parallel Connector 3.5mm Rod to 3.5mm Rod	2
182.961	Parallel Connector3.5mm Rod to 4.0mm Rod	0
182.962	Parallel Connector 3.5mm Rod to 4.5mm Rod	0
182.963	Parallel Connector 3.5mm Rod to 5.0mm Rod	0
182.964	Parallel Connector 3.5mm Rod to 5.5mm Rod	2
182.965	Parallel Connector 3.5mm Rod to 6.0mm Rod	0
182.966	Parallel Connector 3.5mm Rod to 6.35mm Rod	0
182.967	Parallel Connector 3.5mm Rod to 6.5mm Rod	0
182.975	Lateral Connector	2
182.990	Lateral Connector, Long	2
182.991	Lateral Connector, Short	2
182.992	Lateral Connector, Angled	0

CAPITOL™ Curved Rods

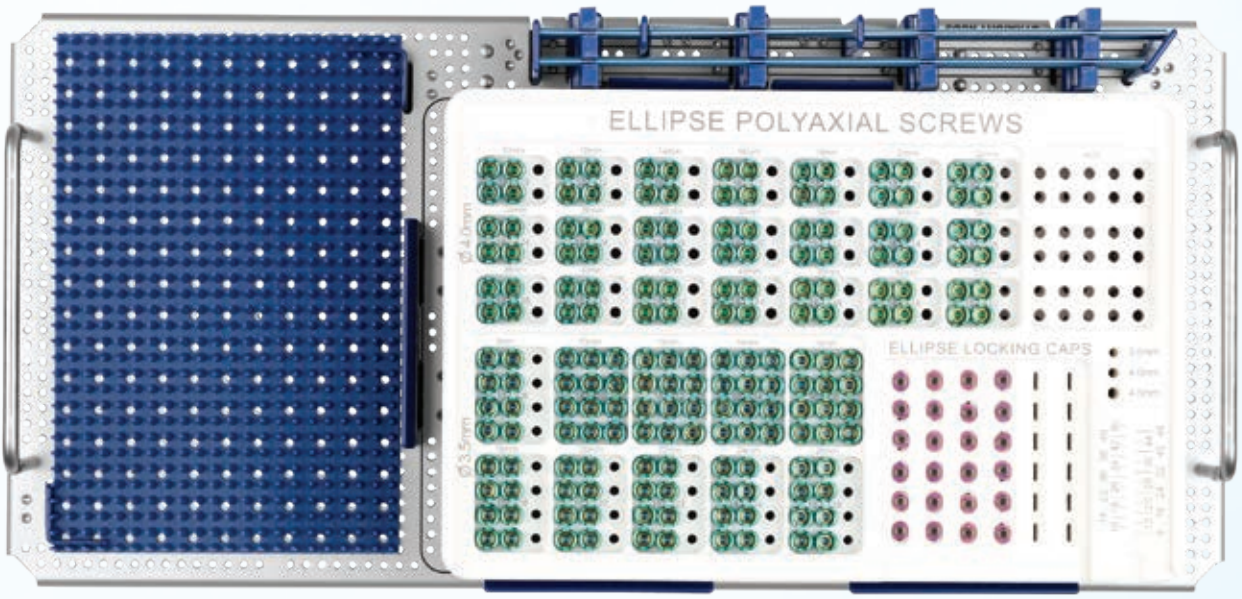
Length	Part No.
40mm	111.840
50mm	111.850
60mm	111.860
70mm	111.870
80mm	111.880
90mm	111.890
100mm	111.900
110mm	111.910
120mm	111.920

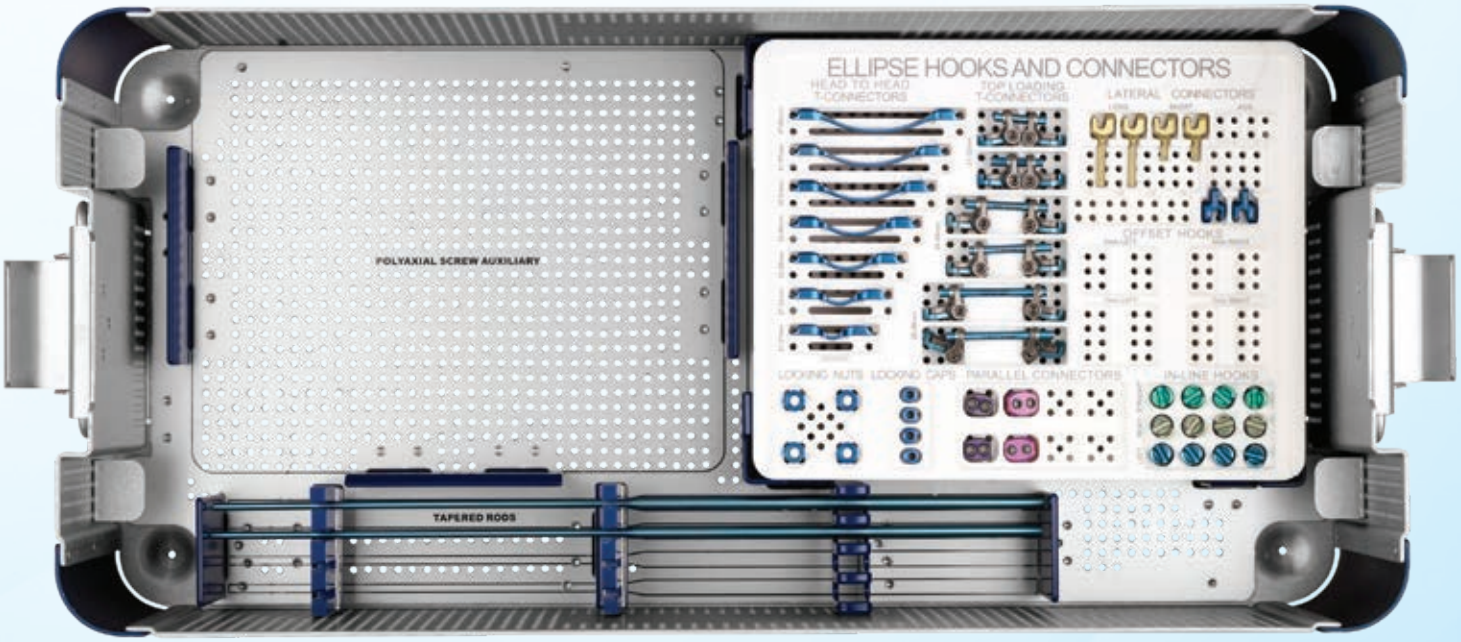
Hooks

Part No.	Description	Qty
182.488	Hook Left, 3mm	0
182.489	Hook Left, 5mm	0
182.490	Hook Left, 7mm	0
182.491	Hook Left, 9mm	0
182.492	Hook Right, 3mm	0
182.493	Hook Right, 5mm	0
182.494	Hook Right, 7mm	0
182.495	Hook Right, 9mm	0
182.501	Inline Hook	4
182.503	Inline Hook, Right	4
182.504	Inline Hook, Left	4
182.506	Offset Hook, Left, 7mm	0
182.507	Offset Hook, Left, 5mm	0
182.508	Offset Hook, Right, 7mm	0
182.509	Offset Hook, Right, 5mm	0

Items in gray are additionally available.

ELLIPSE™
Implant Set 982.902 (Cont'd)





ELLIPSE™
Instrument Set 982.901

	Part No.	Description	Qty
1	636.450	Quick-Connect Handle, Swivel	2
2	682.112	Depth Gauge	1
3	682.113	Awl, 2.4mm	1
4	682.114	Pedicle Probe, Straight	1
5	682.115	Ball Tip Probe	1
6	682.104	Drill Bit for 3.5mm Screw	2
7	682.105	Drill Bit for 4.0mm Screw	1
8	682.102	Drill Guide with Adjustable Stop, 6–50mm	1
9	682.103	Drill Guide with 14mm Stop	1
10	682.106	Tap for 3.5mm Screw	1
11	682.107	Tap for 4.0mm Screw	1
12	682.110	Tap Sleeve	1
13	682.202	ELLIPSE™ Polyaxial Screwdriver, with Cap	2
14	682.204	ELLIPSE™ Screw Head Positioner	1
15	682.205	Screwdriver, 2.5mm Hex, Self-Retaining, Small Handle	2
16	615.301	Rod Template, 240mm	2
17	615.300	*In Situ* Rod Cutter	1
18	615.304	Rod Bender	1
19	682.308	Rod Holding Forceps, 3.5mm	1
20	682.399	ELLIPSE™ Top Loading Ratcheting Rod Reducer	1
21	682.400	ELLIPSE™ Lateral Rod Reducer	1
22	682.402	ELLIPSE™ Rocker Arm	1
23	682.403	ELLIPSE™ Rod Counter Torque	1
24	682.404	Compressor, 3.5mm Rod	1
25	682.405	Distractor, 3.5mm Rod	1
26	682.201	ELLIPSE™ Cap Driver, Small Handle	4
27	682.209	ELLIPSE™ Final Tightening Instrument	1
28	682.210	Screwdriver Shaft, 2.5mm Hex	2
29	682.212	Torque-Limiting Quick Connect Handle, 1.5Nm	1
30	682.306	*In-Situ* Bender, Left, 3.5mm Rod	1
31	682.307	*In-Situ* Bender, Right, 3.5mm Rod	1
32	615.309	T-Connector Holder	1
33	682.312	Head-to-Head T-Connector Nut Inserter	1
34	682.313	Head-to-Head Bender, Left	1
35	682.314	Head-to-Head Bender, Right	1
36	682.206	ELLIPSE™ Cervical Hook Forceps	1
37	682.420	ELLIPSE™ Locking Nut Remover	1
38	682.901	ELLIPSE™ Head-to-Head Locking Cap Driver	1

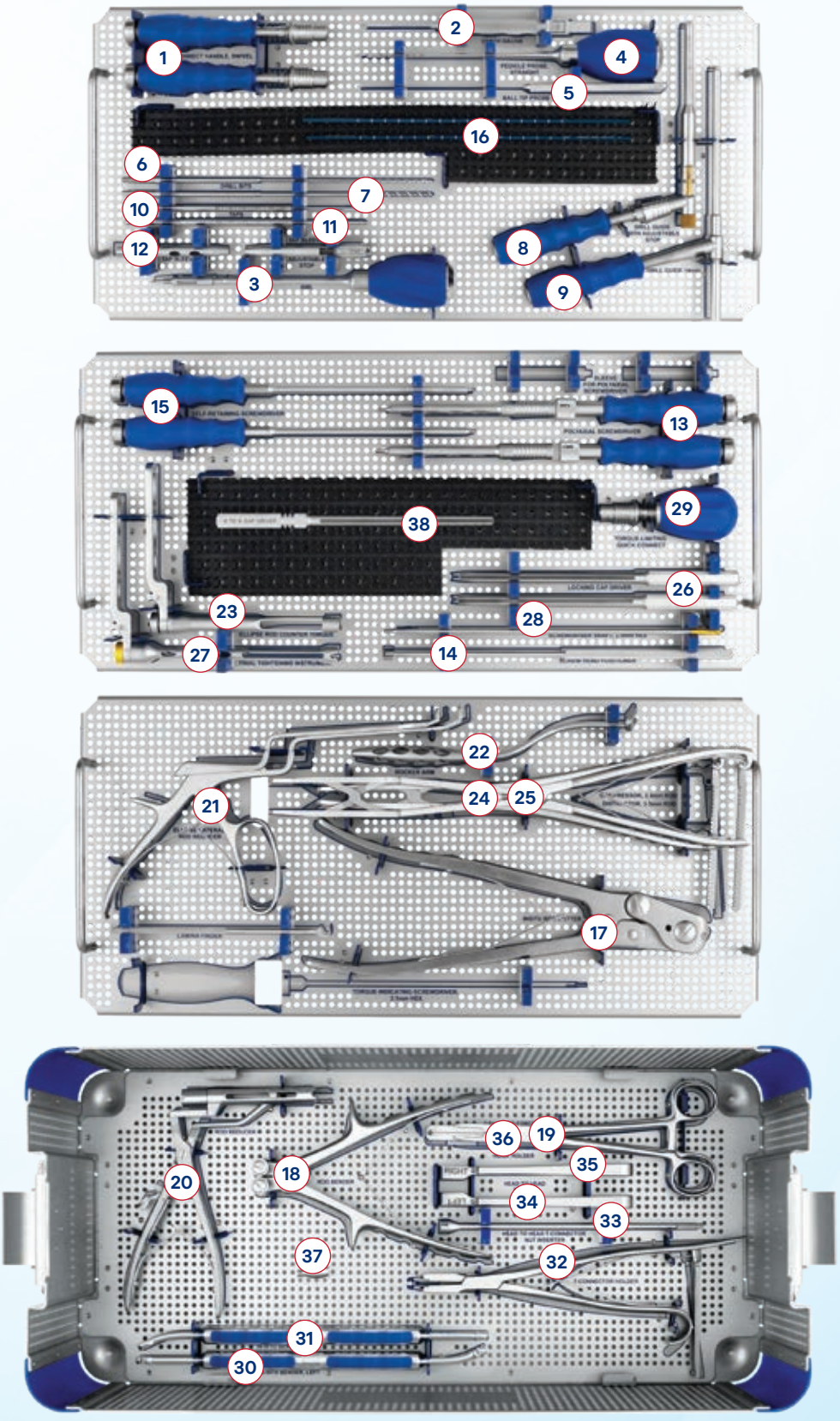
Additionally Available

615.111	Lamina Finder
615.116	Pedicle Probe, Curved Tip
682.123	Awl, 2.4mm, Long
682.124	Pedicle Probe, Straight, Long
682.198	ELLIPSE™ Cap Driver, Dual Handle
682.199	ELLIPSE™ Cap Driver, Large Handle
682.310	3.5mm Rod Gripper
682.410	Reamer
615.112	Depth Gauge [PROTEX®-CT]
615.115	Ball Tip Probe [PROTEX®-CT]
682.108S	Drill Bit for 3.5mm Screw [Sterile Packed]
682.109S	Drill Bit for 4.0mm Screw [Sterile Packed]
682.111	Tap Sleeve, Adjustable Stop
682.401	ELLIPSE™ Inline Reducer
682.700	ELLIPSE™ Pushbutton Hex Driver, 2.5mm
682.398	Threaded Reducer

Items in gray are additionally available.

ELLIPSE™

Instrument Set 982.901



ELLIPSE™
Occipital Implant and Instrument Set 982.910

	Part No.	Description	Qty
1	682.602	Socket Driver	1
2	682.603	Occipital Plate Holder	1
3	682.604	Occipital Positioner, Rod Acceptor	1
4	682.619	Offset Handle Locking Ring	2
5	682.620	Offset Handle, Occipital CV Joint	2
6	682.622	Flexible Drill Bit, 2.9mm	1
7	682.627	Occipital CV Joint Tap, 4.0 Screws	1
8	682.628	Occipital CV Joint Tap, 4.5mm Screws	1
9	682.629	Sleeve, CV Joint for 4.5mm Tap	1
10	682.644	Occipital Adjustable Depth Drill Guide	1
11	682.647	Occipital CV Joint Screwdriver	2
12	682.648	Sleeve, CV Joint	2
13	682.650	Occipital Cap Driver	1
14	682.651	Occipital Rocker Arm	1
15	682.652	Occipital Counter Torque, Rod Acceptor	1
16	682.653	Rod Acceptor, Screw Counter Torque	1
17	682.661	Occipital Plate Bender	1
18	682.662	Occipital Plate Tip Bender	1
19	610.819	Screw Removal Tool	1
20	682.656	Angled Screw Removal Tool	1
21	682.657	Angled Screw Removal Tool Counter Torque	1
22	682.715	Jointed Rod Holder	1
	615.203	Torque-Limiting 2.5mm Hex Driver	1

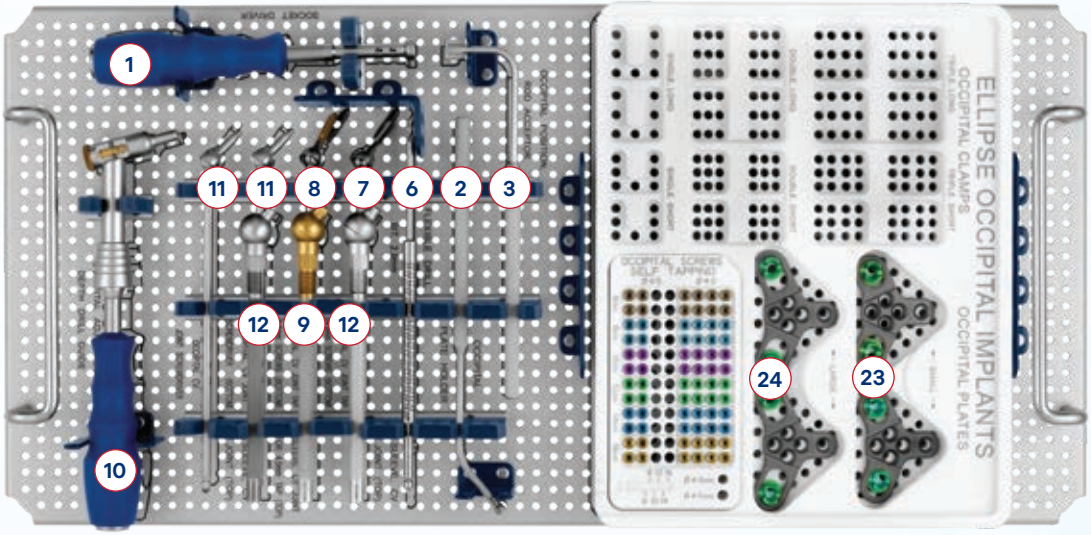
	Part No.	Description	Qty
23	182.950	Occipital Plate, Small	2
24	182.952	Occipital Plate, Large	2
25	182.953	Occipital Rod, 240mm, 100	2
26	182.954	Occipital Rod, 240mm, 115	2
27	182.955	Occipital Rod, 240mm, 130	2
28	182.956	Occipital Jointed Rod, Right	2
29	182.957	Occipital Jointed Rod, Left	2

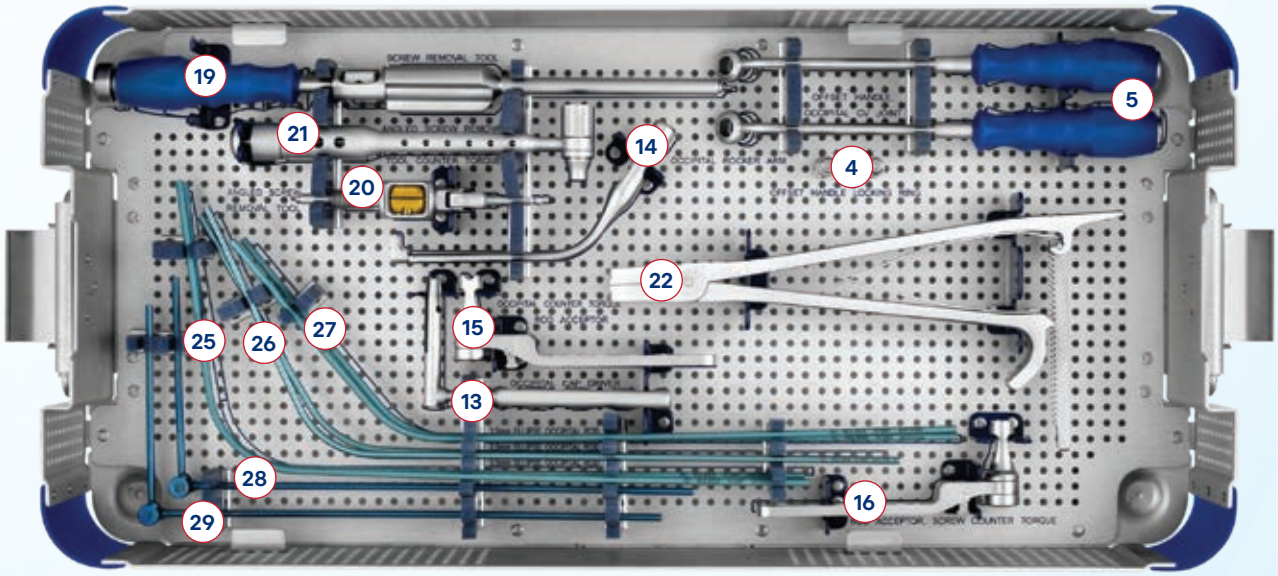
Screws

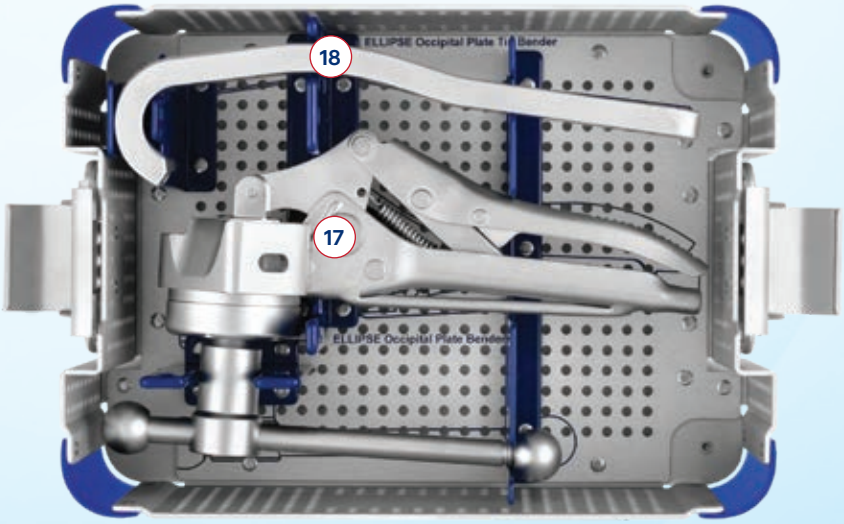
Length	4.0mm Part No.	Qty	4.5mm Part No.	Qty
6mm	110.806	8	110.906	4
8mm	110.808	8	110.908	4
10mm	110.810	8	110.910	4
12mm	110.812	8	110.912	4
14mm	110.814	8	110.914	4
16mm	110.816	8	110.916	4

ELLIPSE™

Occipital Implant and Instrument Set 982.910







ELLIPSE™
Auxiliary Screw Set 982.906

	Shoulder Screws		Polyaxial Screws	
Length	**4.0mm Part No.**	**Qty**	**4.5mm Part No.**	**Qty**
10mm	–	–	182.510	4
12mm	–	–	182.512	4
14mm	–	–	182.514	4
16mm	–	–	182.516	4
18mm	–	–	182.518	4
20mm	–	–	182.520	4
22mm	182.222	4	182.522	4
24mm	182.224	4	182.524	4
26mm	182.226	4	182.526	4
28mm	182.228	4	182.528	4
30mm	182.230	4	182.530	4
32mm	182.232	4	182.532	4
34mm	182.234	4	182.534	4
36mm	182.236	4	182.536	4
38mm	–	–	182.538	4
40mm	–	–	182.540	4
42mm	–	–	182.542	4
44mm	–	–	182.544	4
46mm	–	–	182.546	4
48mm	–	–	182.548	4
50mm	–	–	182.550	4

982.006 ELLIPSE™ Auxiliary Screw Module

ELLIPSE™
CoCr Rod Set 982.909

Cobalt Chrome Rods

Part No.	Description	Qty
782.801	3.5mm CoCr Rod, 80mm	4
782.802	3.5mm CoCr Rod, 120mm	4
782.803	3.5mm CoCr Rod, 240mm	4
782.804	3.5mm CoCr Rod, 40mm	4
782.953	3.5mm CoCr Occipital Rod 240mm, 100°	2
782.954	3.5mm CoCr Occipital Rod 240mm, 115°	2
782.955	3.5mm CoCr Occipital Rod 240mm, 130°	2
782.979	CoCr Tapered Rod, 3.5mm to 3.7mm, 350mm	0
782.980	CoCr Tapered Rod, 3.5mm to 4.0mm, 350mm	0
782.981	CoCr Tapered Rod, 3.5mm to 4.5mm, 350mm	0
782.982	CoCr Tapered Rod, 3.5mm to 5.0mm, 350mm	0
782.983	CoCr Tapered Rod, 3.5mm to 5.5mm, 350mm	2
782.984	CoCr Tapered Rod, 3.5mm to 6.0mm, 350mm	0
782.985	CoCr Tapered Rod, 3.5mm to 6.35mm, 350mm	0
782.986	CoCr Tapered Rod, 3.5mm to 6.5mm, 350mm	0
782.989	CoCr Tapered Rod, 3.5mm to 5.5mm, 500mm	0

Items in gray are additionally available.

IMPORTANT INFORMATION ON THE ELLIPSE™ OCCIPITO-CERVICO-THORACIC SPINAL SYSTEM

DESCRIPTION

The ELLIPSE® Occipito-Cervico-Thoracic Spinal System consists of 3.5mm jointed, straight and pre-bent rods, tapered rods, polyaxial screws, hooks, locking caps, t-connectors, lateral connectors, parallel connectors, in-line connectors, rod-to-rod connectors, rod extension clamps and occipital plates. CAPITOL™ screws and rods are also available as components of the ELLIPSE® system. The implants are composed of titanium alloy (per ASTM F136, F1472, or F1295), stainless steel (per ASTM F138) or cobalt chromium molybdenum alloy (CoCr) (per ASTM F1537). Mixing of stainless steel implant components with different materials is not recommended for metallurgical, mechanical and functional reasons.

ELLIPSE® constructs may be connected to CREO®, REVERE®, BEACON®, PROTEX®, or PROTEX® CT constructs using corresponding connectors.

The ELLIPSE® System includes manual surgical instruments manufactured from stainless steel, as specified in ASTM F899. Navigation Instruments are nonsterile, reusable instruments that can be operated manually or under power using a power drill such as POWEREASE™, that are intended to be used with the Medtronic StealthStation® System.

INDICATIONS

The ELLIPSE® Occipito-Cervico-Thoracic Spinal System implants are intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of the craniocervical junction, the cervical spine (C1-C7) and the thoracic spine (T1-T3): traumatic spinal 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 disease of the facets with instability. These implants are 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, rods may be connected to occipital cervical thoracic or thoracolumbar stabilization systems ranging in diameter from 3.2mm to 6.5mm, using corresponding connectors.

Globus Navigation Instruments are intended to be used during the preparation and placement of ELLIPSE® screws during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open or minimally invasive procedures. These instruments are designed for use with the Medtronic StealthStation® System, which is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as a skull, a long bone, or vertebra, can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks of the anatomy.

CONTRAINDICATIONS

Certain degenerative diseases or underlying physiological conditions such as diabetes or rheumatoid arthritis may alter the healing process, thereby increasing the risk of implant breakage.

Mental or physical impairment which compromises a patient's ability to comply with necessary limitations or precautions may place that patient at a particular risk during postoperative rehabilitation.

Factors such as the patient's weight, activity level, and adherence to weight bearing or load bearing instructions have an effect on the stresses to which the implant is subjected.

WARNINGS

The safety and effectiveness of pedicle screw spinal systems have been established only for spinal conditions with significant mechanical instability or deformity requiring fusion with instrumentation. These conditions are significant mechanical instability or deformity of the thoracic spine secondary to degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, spinal tumor, and failed previous fusion (pseudoarthrosis). The safety and effectiveness of these devices for any other conditions are unknown.

Possible adverse effects which may occur and may require additional surgery include: failed fusion or pseudarthosis leading to implant breakage; allergic reaction to implant materials; device fracture or failure; device migration or loosening; loss of fixation; vertebral fracture; decrease in bone density; pain, discomfort, or abnormal sensations due to the presence of the device; injury to nerves, vessels, and organs; venous thrombosis, lung embolism and cardiac arrest; and death.

The components of this system are manufactured from titanium alloy, stainless steel or cobalt chromium alloy. Dissimilar metals in contact with each other can accelerate the corrosion process due to galvanic corrosion effects. Mixing of implant components of titanium or cobalt chromium with stainless steel is not recommended, for metallurgical, mechanical and functional reasons.

Certain degenerative diseases or underlying physiological conditions such as diabetes, rheumatoid arthritis, or osteoporosis may alter the healing process, thereby increasing the risk of implant breakage or spinal fracture.

These warnings do not include all adverse effects which could occur with surgery in general, but are important considerations particular to orthopedic implants. General surgical risks should be explained to the patient prior to surgery.

Use this device as supplied and in accordance with the handling and use information provided below.

PRECAUTIONS

The implantation of posterior screw spinal systems should be performed only by experienced spinal surgeons with specific training in the use of this posterior screw spinal system because this is a technically demanding procedure presenting a risk of serious injury to the patient.

Preoperative planning for implant of cervical posterior screw implants should include review of radiographs, CT and/or MRI imaging to evaluate the patient's anatomy, transverse foramen and the course of the vertebral artery. If any findings would compromise the placement of posterior screws, other surgical methods should be considered. In addition, use of intraoperative imaging should be considered to guide and/or verify device placement, as necessary.

The implants are for single use only. Surgical implants must never be reused. An explanted metal implant must never be reimplanted. Even though the device appears undamaged, it may have small defects and internal stress patterns which could lead to breakage.

Correct handling of the implant is extremely important. Contouring of metal implants should be avoided where possible. If contouring is necessary, or allowed by design, the surgeon should avoid sharp bends, reverse bends, or bending the device at a screw hole. The operating surgeon should avoid any notching or scratching of the device when contouring it. These factors may produce internal stresses which may become the focal point for eventual breakage of the implant.

Metallic implants can loosen, fracture, corrode, migrate, cause pain, or stress shield bone even after a fracture has healed, particularly in young, active patients. While the surgeon must have the final decision on implant removal, we recommend that whenever possible and practical for the individual patient, fixation devices should be removed once their service as an aid to healing is accomplished. Implant removal should be followed by adequate postoperative management.

Adequately instruct the patient. Mental or physical impairment which compromises or prevents a patient's ability to comply with necessary limitations or precautions may place that patient at a particular risk during postoperative rehabilitation.

For optimal implant performance, the surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc. which may impact the performance of the system.

MRI SAFETY INFORMATION

These devices have not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of devices in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

PACKAGING

These implants and instruments may be supplied pre-packaged and sterile, using gamma irradiation. The integrity of the sterile packaging should be checked to ensure that sterility of the contents is not compromised. Packaging should be carefully checked for completeness and all components should be carefully checked to ensure that there is no damage prior to use. Damaged packages or products should not be used, and should be returned to Globus Medical. During surgery, after the correct size has been determined, remove the products from the packaging using aseptic technique.

The instrument sets are provided nonsterile and are steam sterilized prior to use, as described in the STERILIZATION section below. Following use or exposure to soil, instruments and instrument trays and cases must be cleaned, as described in the CLEANING section below.

HANDLING

All implants, instruments, and instrument trays and cases should be treated with care. Improper use or handling may lead to damage and/or possible malfunction. Products should be checked to ensure that they are in working order prior to surgery. All products should be inspected prior to use to ensure that there is no unacceptable deterioration such as corrosion, discoloration, pitting, cracked seals, etc. Non-working or damaged products should not be used, and should be returned to Globus Medical.

IMPORTANT INFORMATION ON THE ELLIPSE™ OCCIPITO-CERVICO-THORACIC SPINAL SYSTEM

CLEANING

Instruments should be cleaned separately from instrument trays and cases. Lids should be removed from cases for the cleaning process, if applicable. All instruments that can be disassembled must be disassembled for cleaning. All handles must be detached. Instruments may be reassembled following sterilization. The products should be cleaned using neutral cleaners before sterilization and introduction into a sterile surgical field or (if applicable) return of the product to Globus Medical.

Cleaning and disinfecting can be performed with aldehyde-free solvents at higher temperatures. Cleaning and decontamination must include the use of neutral cleaners followed by a deionized water rinse. Note: certain cleaning solutions such as those containing formalin, glutaraldehyde, bleach and/or other alkaline cleaners may damage some devices, particularly instruments; these solutions should not be used.

The following cleaning methods should be observed when cleaning instruments and instrument trays and cases after use or exposure to soil, and prior to sterilization:

1. Immediately following use, ensure that the instruments are wiped down to remove all visible soil and kept from drying by submerging or covering with a wet towel.
2. Disassemble all instruments that can be disassembled.
3. Rinse the instruments under running tap water to remove all visible soil. Flush the lumens a minimum of 3 times, until the lumens flush clean.
4. Prepare Enzol® (or a similar enzymatic detergent) per manufacturer's recommendations.
5. Immerse the instruments in the detergent and allow them to soak for a minimum of 2 minutes.
6. Use a soft bristled brush to thoroughly clean the instruments. Use a pipe cleaner for any lumens. Pay close attention to hard to reach areas.
7. Using a sterile syringe, draw up the enzymatic detergent solution. Flush any lumens and hard to reach areas until no soil is seen exiting the area.
8. Remove the instruments from the detergent and rinse them in running warm tap water.
9. Prepare Enzol® (or a similar enzymatic detergent) per manufacturer's recommendations in an ultrasonic cleaner.
10. Completely immerse the instruments in the ultrasonic cleaner and ensure detergent is in lumens by flushing the lumens. Sonicate for a minimum of 3 minutes.
11. Remove the instruments from the detergent and rinse them in running deionized water or reverse osmosis water for a minimum of 2 minutes.
12. Dry instruments using a clean soft cloth and filtered pressurized air.
13. Visually inspect each instrument for visible soil. If visible soil is present, then repeat cleaning process starting with Step 3.

CONTACT INFORMATION

Globus Medical may be contacted at 1-866-GLOBUS1 (456-2871). A surgical technique manual may be obtained by contacting Globus Medical.

STERILIZATION

These implants and instruments may be available sterile or nonsterile.

Sterile implants and instruments are sterilized by gamma radiation, validated to ensure a Sterility Assurance Level (SAL) of 10^{-6}. Sterile products are packaged in a heat sealed, double foil pouch. The expiration date is provided on the package label. These products are considered sterile unless the packaging has been opened or damaged. Sterile implants meet pyrogen limit specifications.

Nonsterile implants and instruments have been validated to ensure an SAL of 10^{-6}. The use of an FDA-cleared wrap is recommended, per the Association for the Advancement of Medical Instrumentation (AAMI) ST79, *Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities*. It is the end user's responsibility to use only sterilizers and accessories (such as sterilization wraps, sterilization pouches, chemical indicators, biological indicators, and sterilization cassettes) that have been cleared by the FDA for the selected sterilization cycle specifications (time and temperature).

When using a rigid sterilization container, the following must be taken into consideration for proper sterilization of Globus devices and loaded graphic cases:

- Recommended sterilization parameters are listed in the table below.
- Only FDA-cleared rigid sterilization containers for use with pre-vacuum steam sterilization may be used.
- When selecting a rigid sterilization container, it must have a minimum filter area of 176 in^2 total, or a minimum of four (4) 7.5in diameter filters.
- No more than one (1) loaded graphic case or its contents can be placed directly into a rigid sterilization container.
- Stand-alone modules/racks or single devices must be placed, without stacking, in a container basket to ensure optimal ventilation.
- The rigid sterilization container manufacturer's instructions for use are to be followed; if questions arise, contact the manufacturer of the specific container for guidance.
- Refer to AAMI ST79 for additional information concerning the use of rigid sterilization containers.

For implants and instruments provided NONSTERILE, sterilization is recommended (wrapped or containerized) as follows:

Method	Cycle Type	Temperature	Exposure Time	Drying Time
Steam	Pre-vacuum	132°C (270°F)	4 Minutes	30 Minutes
Steam	Pre-vacuum	134°C (273°F)	3 Minutes	30 Minutes

These parameters are validated to sterilize only this device. If other products are added to the sterilizer, the recommended parameters are not valid and new cycle parameters must be established by the user. The sterilizer must be properly installed, maintained, and calibrated. Ongoing testing must be performed to confirm inactivation of all forms of viable microorganisms.

CAUTION: Federal (U.S.A.) Law restricts this Device to Sale by or on the Order of a Physician.

SYMBOL TRANSLATION			
REF	CATALOGUE NUMBER	STERILE R	STERILIZED BY IRRADIATION
LOT	LOT NUMBER	EC REP	AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY
⚠	CAUTION		MANUFACTURER
	SINGLE USE ONLY		USE BY (YYYY-MM-DD)
QTY	QUANTITY	Rx ONLY	PRESCRIPTION USE ONLY

DI137A Rev L

Globus Medical
Valley Forge Business Center
2560 General Armistead Avenue
Audubon, PA 19403
globusmedical.com

Customer Service:
Phone 1-866-GLOBUS1 (or 1-866-456-2871)
Fax 1-866-GLOBUS3 (or 1-866-456-2873)

GMTGD45
02.25 Rev F