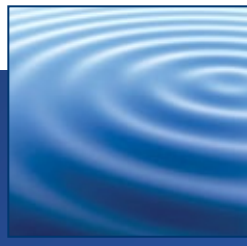
*Life moves us*

SURGICAL TECHNIQUE



# PROTEX®-CT

## Occipito-Cervico-Thoracic Stabilization System

GLOBUS MEDICAL

*Life moves us*

At Globus, we move with a sense of urgency to deliver innovations that improve the quality of life for patients with spinal disorders. We are inspired by the needs of these patients and also the needs of the surgeons and health care providers who treat them.

This passion combined with Globus' world class engineering transforms clinical insights into tangible spine care solutions. We are driven to provide the highest quality products to improve the techniques and outcomes of spine surgery so patients can resume their lives as quickly as possible. We extend our reach beyond our world class implants, instrumentation, and service by partnering with researchers and educators to advance the science and knowledge of spine care.

The energy and enthusiasm each of us bring everyday to Globus is palpable. We are constantly in the pursuit of better patient care and understand that speed is critical because life cannot wait.

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# PROTEX®-CT

## Occipito-Cervico-Thoracic Stabilization System

PROTEX®-CT is an occipito-cervico-thoracic stabilization system with a full line of hooks, polyaxial screws, rods, connectors, and occipital clamps and screws. The self-tapping polyaxial screws provide 40° of angulation in all directions for maximum intraoperative flexibility.

A preassembled set screw in a non-threaded locking cap prevents cross-threading. The unique occipital clamps provide a low-profile alternative to plating, requiring no bending and allowing optimal occipital screw placement.

# PROTEX®-CT

## OCCIPITO-CERVICO-THORACIC STABILIZATION SYSTEM

### Non-Threaded Locking Cap

A simple 90° rotation captures the rod and eliminates cross-threading by directing set screw forces axially against the rod, unlike threaded systems which direct forces radially against the screw head.

### Simplified Rod Placement

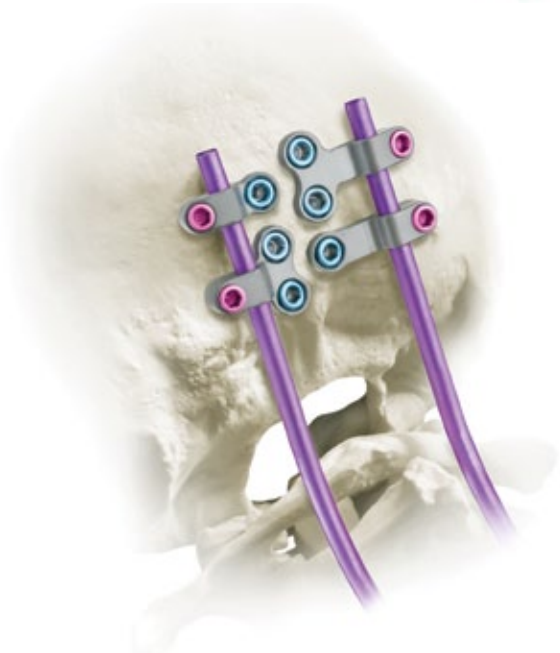
This low-profile top-loading screw design provides intraoperative flexibility and 80° screw angulation (±40°).

### Robust Rod Diameter

The 3.7mm diameter rod provides strength and can be linked to preexisting titanium rod systems of common diameters by way of parallel connectors.

### Low-Profile Occipital Fixation

The versatility of occipital clamps provides customization for various anatomies and allows for a low-profile midline placement that requires no bending.



# CONTENTS



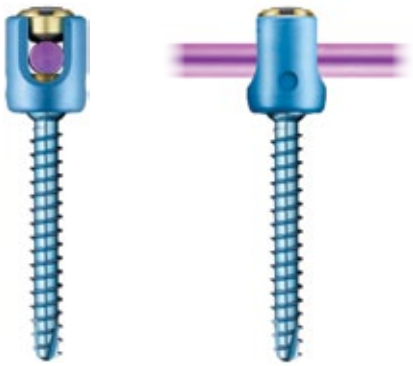
The Surgical Technique shown is for illustrative purposes only. The technique(s) actually employed in each case always depends on the medical judgment of the surgeon exercised before and during surgery as to the best mode of treatment for each patient. Additionally, as instruments may occasionally be 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.

# IMPLANT OVERVIEW

## Non-Threaded Locking Cap

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

## Polyaxial Screws*

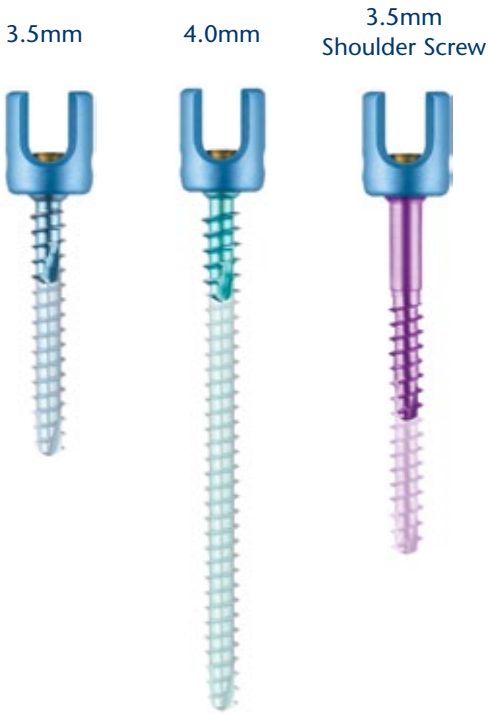


- 80° screw angulation (±40°) provides intraoperative versatility
- Low-profile, top-loading screw design
- Titanium alloy

## Screw Thread

- Self-tapping design
- Blunt tip for bicortical purchase
- Constant outer diameter for maximum bone purchase

## Variety of Options




- Multiple sizes to accommodate patient anatomy
- Screw diameters 3.5mm, 4.0mm and 4.5mm
- Screw lengths from 8mm to 50mm
- Shoulder screws also available

**For use in the thoracic spine (T1-T3) only*

# IMPLANT OVERVIEW

## PROTEX®-CT Rods and Connectors

**Rods**

- 3.2mm or 3.7mm diameter
- Tapered rod transitions from a diameter of 3.7–6.5mm, 3.2–3.7mm or 3.5–3.7mm
- Titanium alloy

**Hooks**

- For use in the cervico-thoracic spine (C1-T3)
- Straight, left and right hook options
- 5.0mm and 7.0mm offset hooks

**Adjustable T-Connector**

- Enhances construct stability
- Unique design offers low-profile position
- Adjusts to avoid contact with the dura
- Dual action set screw reduces steps
- Clamp snaps on rod for controlled insertion

**Lateral Connectors**

- Available for construct versatility
  - *Textured rod surface enhances rotational stability*
  - *May be cut to appropriate length*

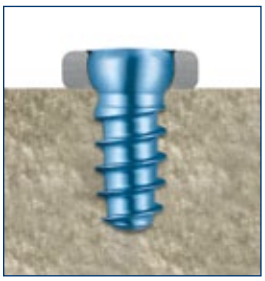
**Parallel Connectors**

- Allow attachment of PROTEX®-CT to titanium rod systems, from 3.7mm to 6.5mm in diameter

# IMPLANT OVERVIEW

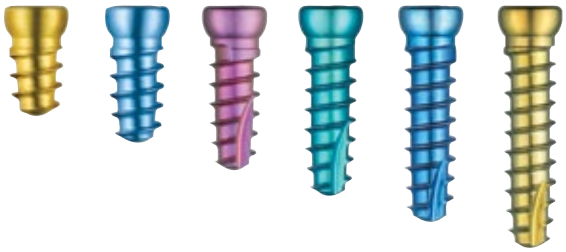
## Occipital Clamps

- Low-profile design
- Single, double and triple anchor configurations
- 5mm and 7mm offsets allow ideal screw placement
- Features the ASSURE® one-step automatic blocking mechanism to resist screw backout
- Design allows clamp to lag to occipital bone
- Variable screw insertion angles (±18°)



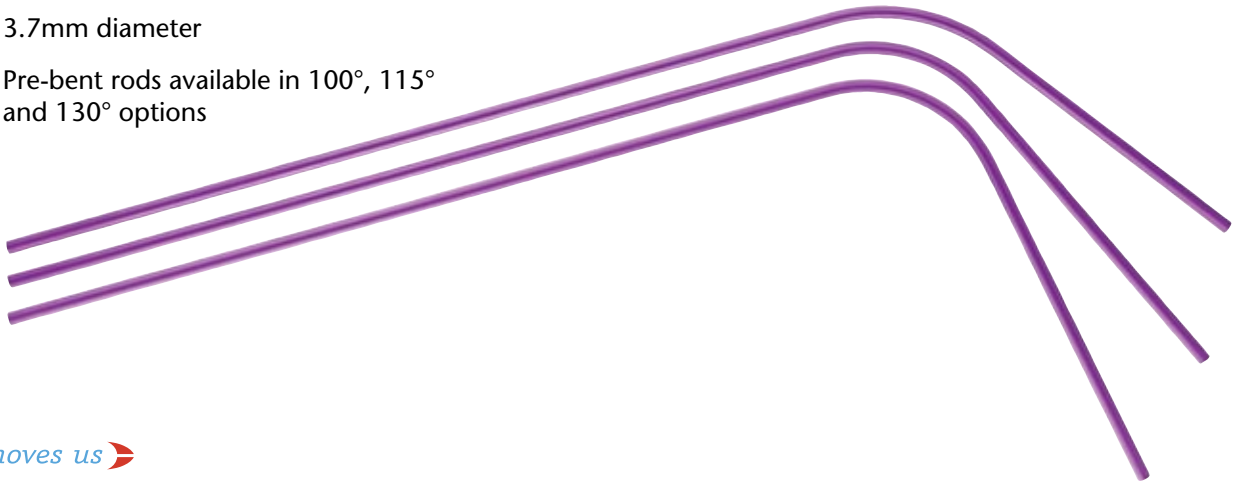
## Occipital Screws

- Standard and rigid self-tapping screws available in 4.0mm and 4.5mm diameters
- Lengths ranging from 6mm to 16mm, in 2mm increments



## Occipital Rods

- 3.7mm diameter
- Pre-bent rods available in 100°, 115° and 130° options



# INSTRUMENT OVERVIEW

## Preparation Instruments

Drill Guide with Adjustable Stop, 6–50mm 615.102

Drill Guide with 14mm Stop, 615.103

Awl, 2.0mm 615.113

Pedicle Probe, Straight 615.114

# Preparation Instruments (cont'd)


Depth Gauge 615.112

Ball Tip Probe 615.115

Drill for Ø3.5mm Screws (2.4mm diameter) 615.104
Drill for Ø4.0mm Screws (2.9mm diameter) 615.105

Tap for Ø3.5mm Screws 615.106
Tap for Ø4.0mm Screws 615.107

Tap Sleeve 615.108

Quick Connect Handle, Small 610.702

*Quick Connect Handle, Small 610.702*
*Drill for Ø3.5mm Screws (2.4mm diameter) 615.104*
*(Assembled)*

*Tap Sleeve 615.108*
*Quick Connect Handle, Small 610.702*
*Tap for Ø3.5mm Screws 615.106*
*(Assembled)*

## Screw Insertion Instruments

Polyaxial Screwdriver with Sleeve 615.202

Screw Head Positioner 615.204

Screwdriver, 2.5mm Hex Self-Retaining 615.205

## Hook Instruments

Lamina Finder 615.111

Cervical Hook Forceps 615.206

# Rod Manipulation Instruments


Rod Template, 240mm 615.301

Rod Cutter, 3.7mm Rod 615.303

Rod Bender, 3.7mm Rod 615.304

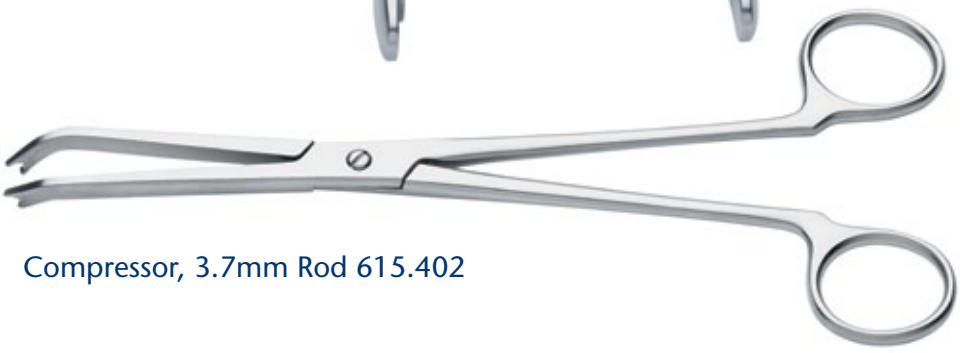
Rod Holder, 3.7mm Rod 615.305

# Rod Manipulation Instruments (cont'd)

*In Situ* Benders, 3.7mm Rods Left 615.306
*In Situ* Benders, 3.7mm Rods Right 615.307

Rod Holding Forceps, 3.7mm Rod 615.308

Rod Reducer 615.401



Compressor, 3.7mm Rod 615.402

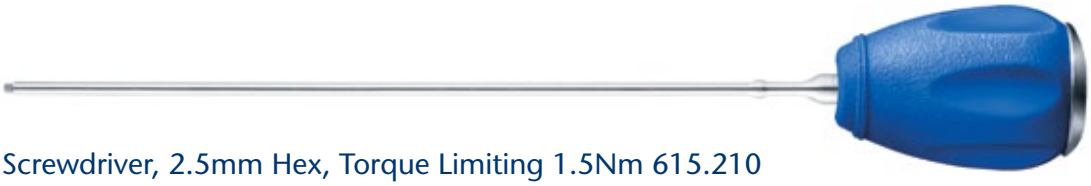
## Locking Instruments

Cap Driver 615.201

Final Tightening Instrument 615.209

Rod Counter Torque 615.403

Screwdriver 2.5mm Hex, Torque Indicating 615.208



Screwdriver, 2.5mm Hex, Torque Limiting 1.5Nm 615.210

## Other Instruments

T-Connector Holder 615.309

# PROTEX®-CT SURGICAL TECHNIQUE

## 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 occipito-cervico-thoracic (CO-T3) construct is described.

## Step 2 Screw Insertion

### Pedicle Preparation

Locate thoracic pedicles (T1-T3) and remove bone and/or soft tissue as needed using standard instruments.

Use the **Awl, 2.0mm** to perforate the cortex and create a pilot hole.

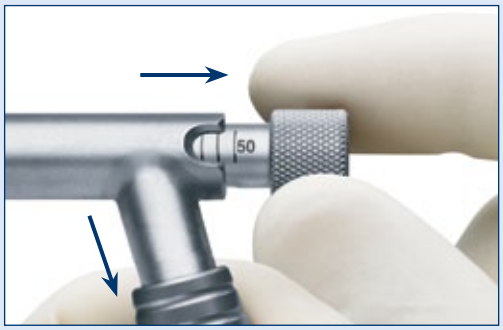
The **Pedicle Probe, Straight** may be used to open the pedicle pathway. Demarcations every 10mm on the probe indicate depth and help determine proper screw length. If the pedicle pathway requires further opening, choose the desired drill bit and guide.

Preparing the pedicle pathway

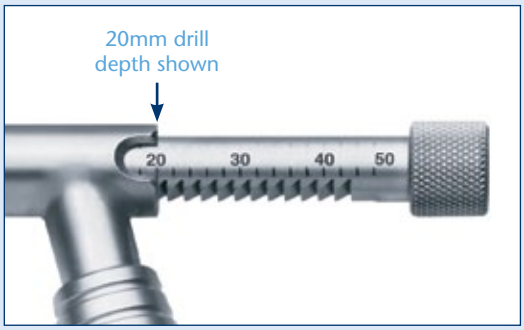
# Screw Insertion (cont'd)

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

## Using the Drill Guide with Adjustable Stop




Pull down the tapered sleeve to release the ratchet. Adjust the drill stop until the appropriate depth indicator is aligned with the back end of the outer tube.



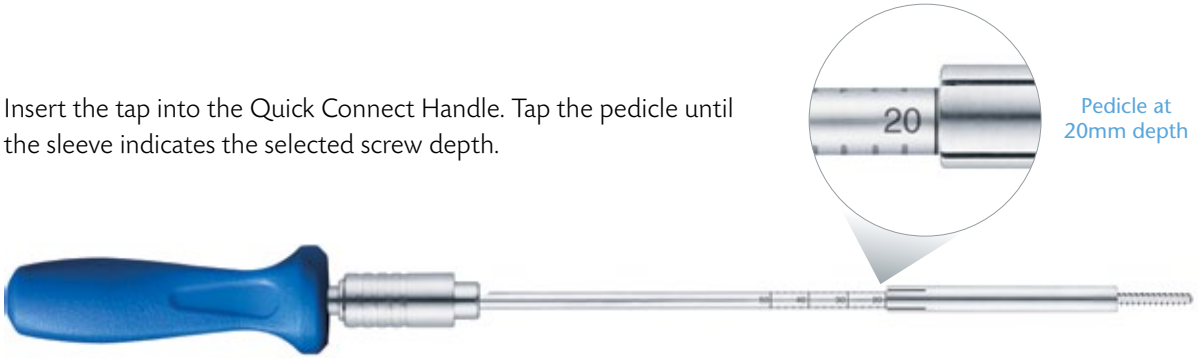

Release the sleeve to lock the drill guide at the appropriate depth. Ensure that the ratchet is fully engaged by pressing on the drill stop.

Attach the drill bit to the **Quick Connect Handle** 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 pathway are not violated. PROTEX®-CT polyaxial screws are self-tapping; however pedicles may be pre-tapped using the **Tap** and **Tap Sleeve**. The sleeve should be used to indicate depth.

Slide the large opening (the end without slots) of the sleeve over the distal end of the appropriate tap.


Insert the tap into the Quick Connect Handle. Tap the pedicle until the sleeve indicates the selected screw depth.



## Loading the Screw

Select the appropriate polyaxial screw diameter and length. Align the **Polyaxial Screwdriver with Sleeve** with the screw head and apply axial pressure, while rotating the handle, to ensure that the hex is fully engaged in the screw head. 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.


Verifying screw length

Polyaxial screwdriver inserted in screw head

Polyaxial screw loaded onto screwdriver

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

Polyaxial screw loaded onto Screwdriver, 2.5mm Hex Self-Retaining

# Screw Insertion (cont'd)

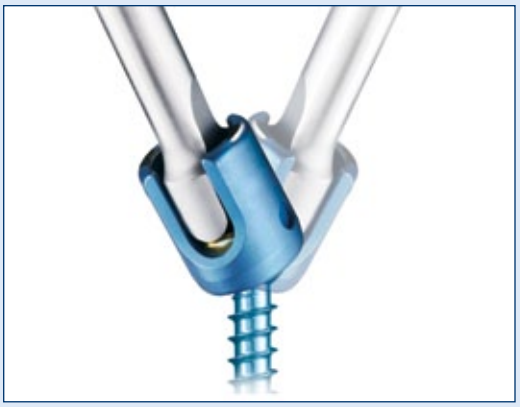
Insert screws into the prepared pedicle. Remove screwdriver from screw head. Ensure that the screw head is mobile and free of bone obstruction. If screws need to be removed or repositioned, the 2.5mm Hex, Self-Retaining Screwdriver should be used. Once the screws are fully inserted, the screw heads may be oriented to better receive the rod using the **Screw Head Positioner**, as described below.

Insertion of polyaxial screws

Screws inserted

## Using the Screw Head Positioner

The 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.



Positioning screws using Screw Head Positioner

# Step 3 Rod Insertion and Locking Cap Delivery

## 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 **Rod Cutter** as described below.

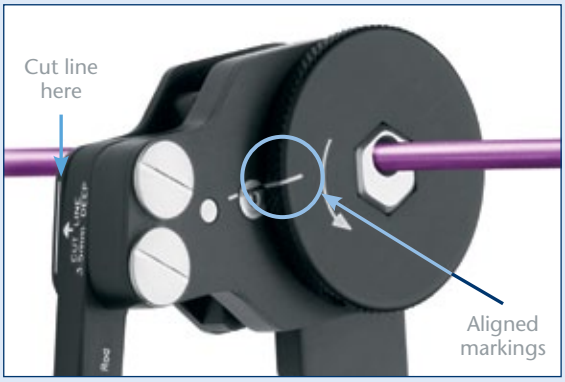
### Using the Rod Cutter

Rotate the dial to align the markings as shown at right. Insert the rod through the opening in the dial. The cut line indicates where the rod will be sectioned.

*Note: The rod may be inserted through the opposite side for smaller cuts, as that side is closer to the cut line.*

Compress the handles several times until the rod is cut and can be easily removed.

*Note: the ratcheting mechanism requires that the handles be compressed several times to fully cut the rod.*




Rod Cutter with algined markings and rod inserted

Rod Cutter after rod has been cut

## Rod Preparation (cont'd)

Rods may be contoured using the **Rod Bender** as described below. After rod contouring, straight sections of the rod can be reinserted into the cutter if additional trimming is needed.

### Using the Rod Bender

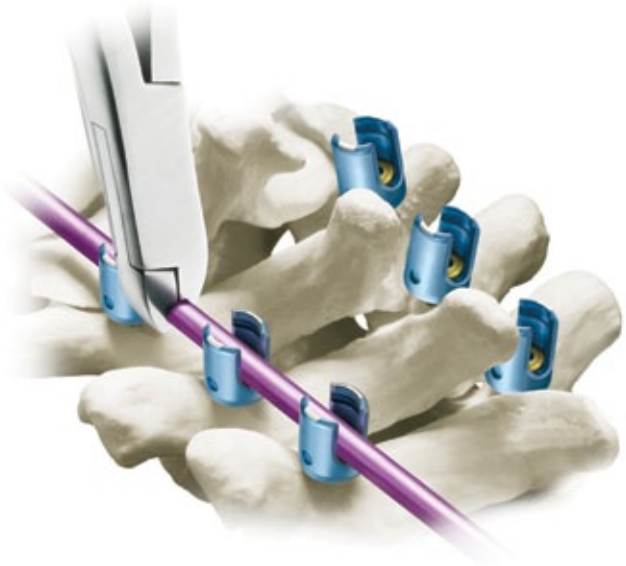
Place the rod into the Rod Bender and compress the handles to achieve the desired curvature.

The opposite side of the bender can be used for further contouring.

# Rod Insertion and Locking Cap Delivery (cont'd)

## Rod Insertion

Using the **Rod Holder**, grasp the rod and insert into the polyaxial screws.



Rod insertion

## Locking Cap Insertion

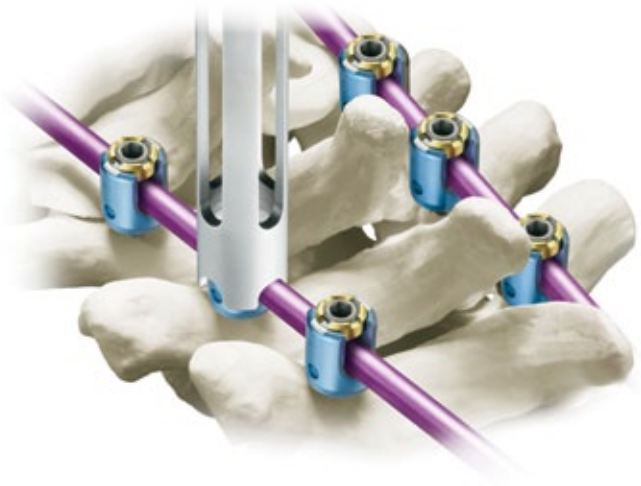
Locking caps can be inserted with or without reduction instruments. To insert a locking cap without a reduction tool, load the **Cap Driver,** as shown at left, and insert into the screw head as described on page 19. The construct is not completely locked until final tightening (see Step 8, Page 29).

## Rod Reduction

PROTEX®-CT has two 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** instrument can be used for rod reduction. This instrument aids in reducing small gaps between the rod and the screw head. Place the counter torque over the rod and screw head and apply downward pressure.



Rod reduction using the Rod Counter Torque

## Loading the Cap Driver

Align the tabs on the Cap Driver with the indentations on the locking cap within the module. Push the driver down over the locking cap while rotating, until fully seated. Ensure that the cap is seated on the driver before insertion.

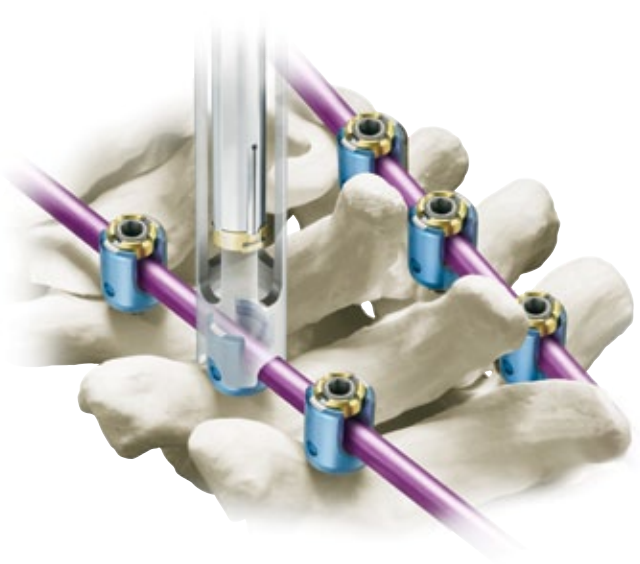
Aligning Cap Driver with the locking cap

Cap Driver loaded

## *Option A: Rod Counter Torque (cont'd)*

Once the rod is fully seated within the screw head, insert the loaded Cap Driver into the Rod Counter Torque and install the locking cap as shown at right.

The construct is not completely locked until final tightening (See Step 8, Page 29).



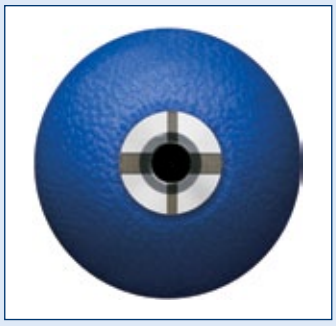
Locking cap insertion through Rod Counter Torque

## Cap Insertion with Rod Counter Torque

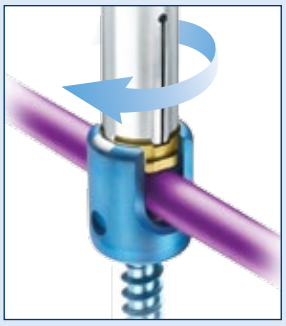
With a loaded cap driver, insert the locking cap into the polyaxial screw head and rotate clockwise 90° to capture the rod. Ensure that the axes of the locking cap and polyaxial screw head are aligned with each other during cap insertion.

*Note: Locking cap insertion requires minimal effort. If the locking cap is difficult to turn, the rod may not be seated properly, or the set screw may have advanced below the cap's undersurface, causing interference with the rod.*

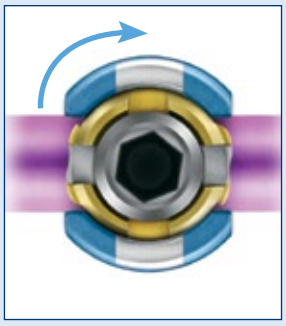
*Indicates change of position only, instrument not keyed to locking cap.



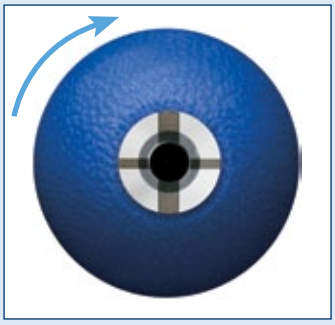
Cap Driver shown in starting position*



Rotate driver 90°



Locking cap INSERTED



Cap Driver rotated 90°*

Rod captured by screw and cap

Locking cap ENGAGED

Remove any instruments used to aid in insertion. The rod is now captured by the screw and cap, but the construct is not completely locked until final tightening.

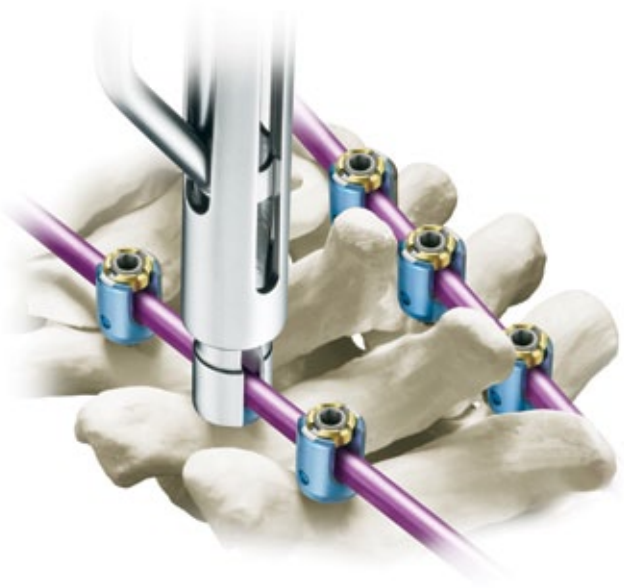
# Rod Insertion and Locking Cap Delivery (cont'd)

## *Option B: Rod Reducer*

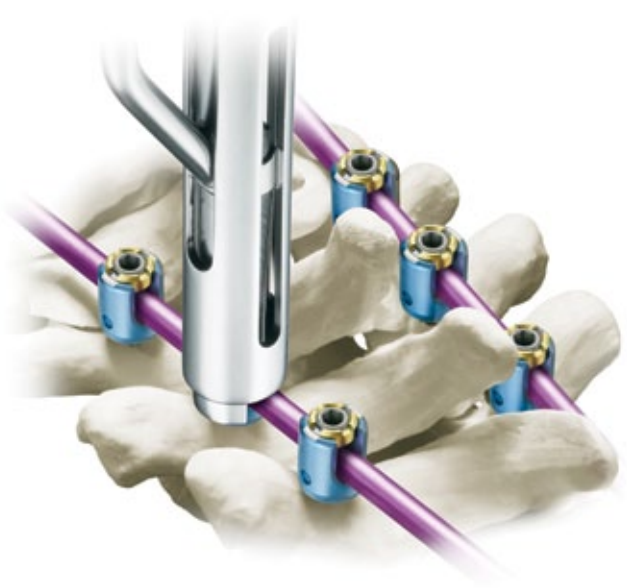
The **Rod Reducer** can also be used to reduce the rod into position. This instrument provides strong reduction and should be used with care. Place the reducer over the screw head until the reducer pins are seated within the dimples. Pull up on the reducer to ensure that it is fully engaged with the screw head.

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

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



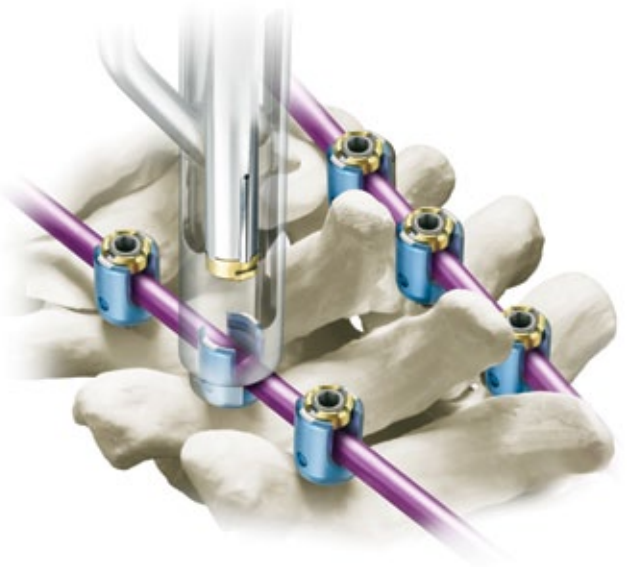
Rod Reducer positioned onto screw head



Rod reduction using the 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 as shown at right. The construct is not fully locked until final tightening (See Step 8, Page 29).

CAUTION: Do not use the reducer in weak and/or osteoporotic or osteopenic bone as it may result in screw loosening.



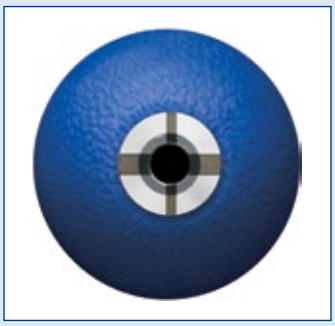
Locking cap insertion through reducer

## Cap Insertion with Rod Reducer

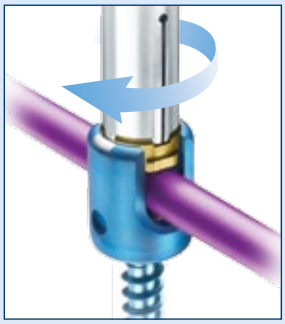
With a loaded Cap Driver, insert the locking cap into the polyaxial screw head and rotate clockwise 90° to capture the rod. Ensure that the axes of the locking cap and polyaxial screw head are aligned with each other during cap insertion.

*Note: Locking cap insertion requires minimal effort. If the locking cap is difficult to turn, the rod may not be seated properly, or the set screw may have advanced below the cap's undersurface, causing interference with the rod.*

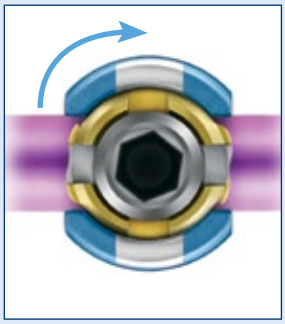
*Indicates change of position only, instrument not keyed to locking cap.



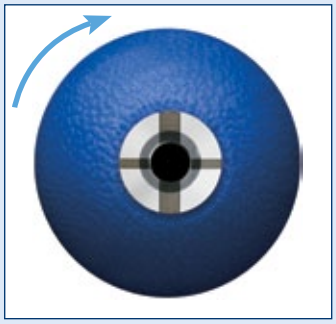
Cap Driver shown in starting position*



Rotate driver 90°

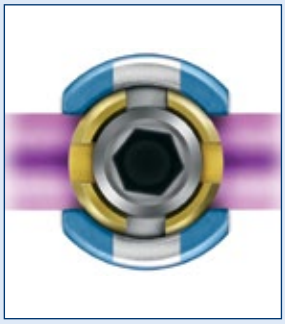


Locking cap INSERTED



Cap Driver rotated 90°*

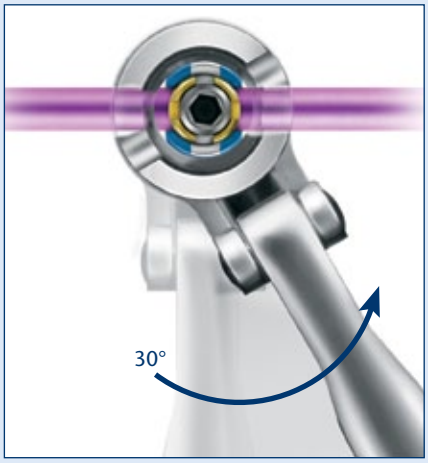
Rod captured by screw and cap



Locking cap ENGAGED

Remove the driver. Release the reducer by pressing the lever. Remove by rotating the reducer approximately 30° about the axis of the screw head (as shown at right). While maintaining this 30° position, pull up to remove the reducer.

The rod is now captured by the screw and cap, but the construct is not completely locked until final tightening.




Release the ratchet and rotate 30° to remove

# Step 4 Hook Placement

PROTEX®-CT Hooks can be used for stabilization of the cervical and thoracic spine (C1-T3). Use the **Lamina Finder** to determine ideal hook placement.

The **Cervical Hook Forceps** can be used to place hooks beneath the rod. Insert the locking cap as described below.

Right | Left | Straight | Hook profile

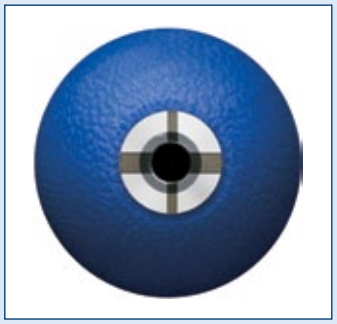
## Cap Insertion through Cervical Hook Forceps

With a loaded Cap Driver, insert the locking cap through the grooves of the Cervical Hook Forceps and into the hook head. Rotate clockwise 90°. Ensure that the axes of the locking cap and hook head are aligned with each other during cap insertion.

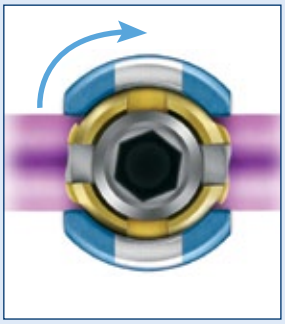
*Note: Locking cap insertion for hooks requires minimal effort, but is slightly more than that required for screws. If the locking cap is difficult to turn, the rod may not be seated properly, or the set screw may have advanced too far below the cap's undersurface, causing interference with the rod.*

*Indicates change of position only, instrument not keyed to locking cap.

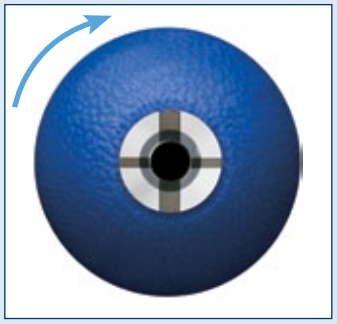
Driver inserting locking cap through forceps



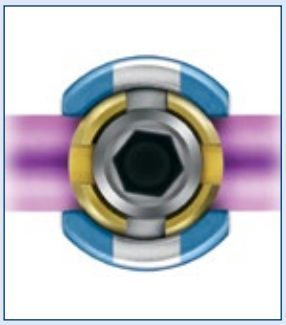
Cap Driver shown in starting position*



Locking cap INSERTED



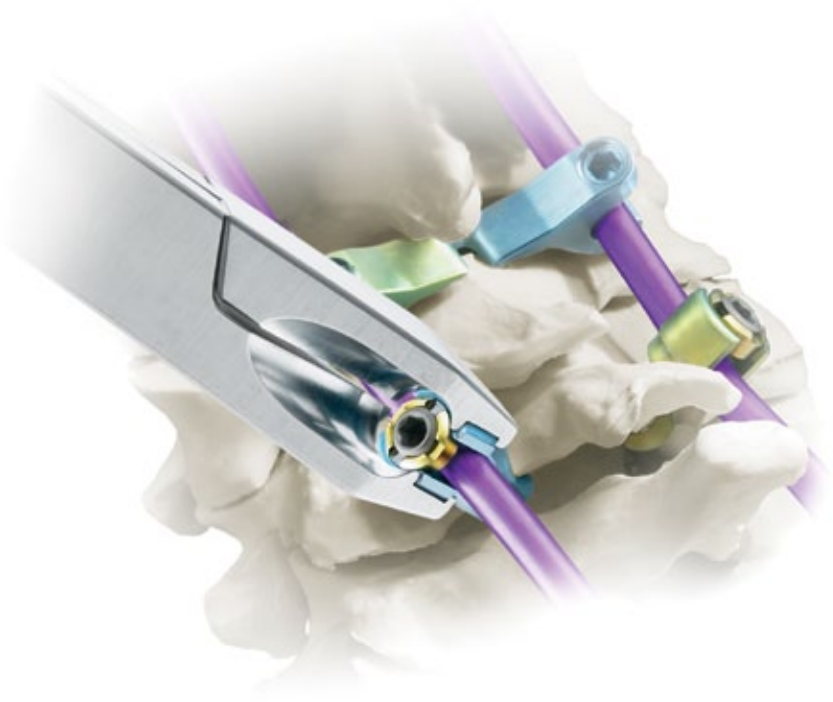
Cap Driver rotated 90°*



Locking cap LOCKED

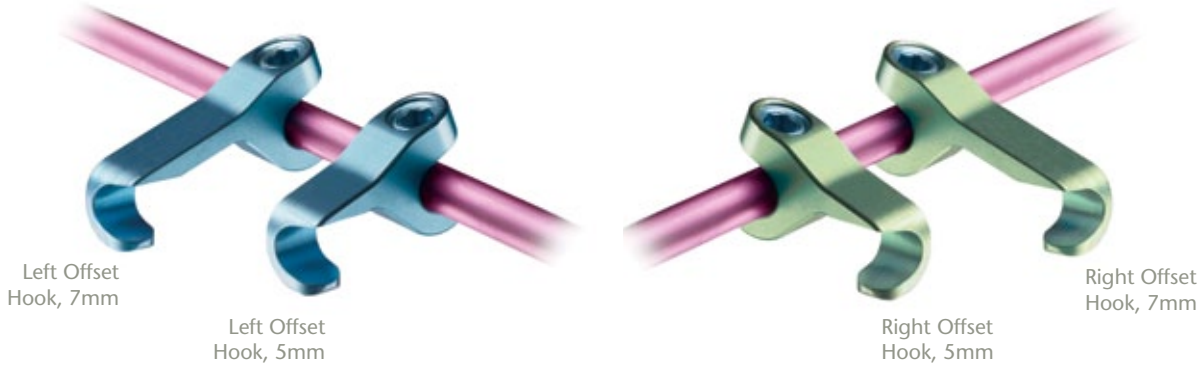
Remove the driver. The rod is now captured by the hook and cap.

The Cervical Hook Forceps can be used to move the hook along the rod and to position onto the lamina.



Offset hooks can be inserted with forceps and provisionally secured with the 2.5mm Hex, Self-Retaining Screwdriver. The pre-loaded set screw may need to be backed out slightly, using the 2.5mm hex driver, before placement.

These hooks are available in right and left versions, with offsets of 5mm or 7mm.

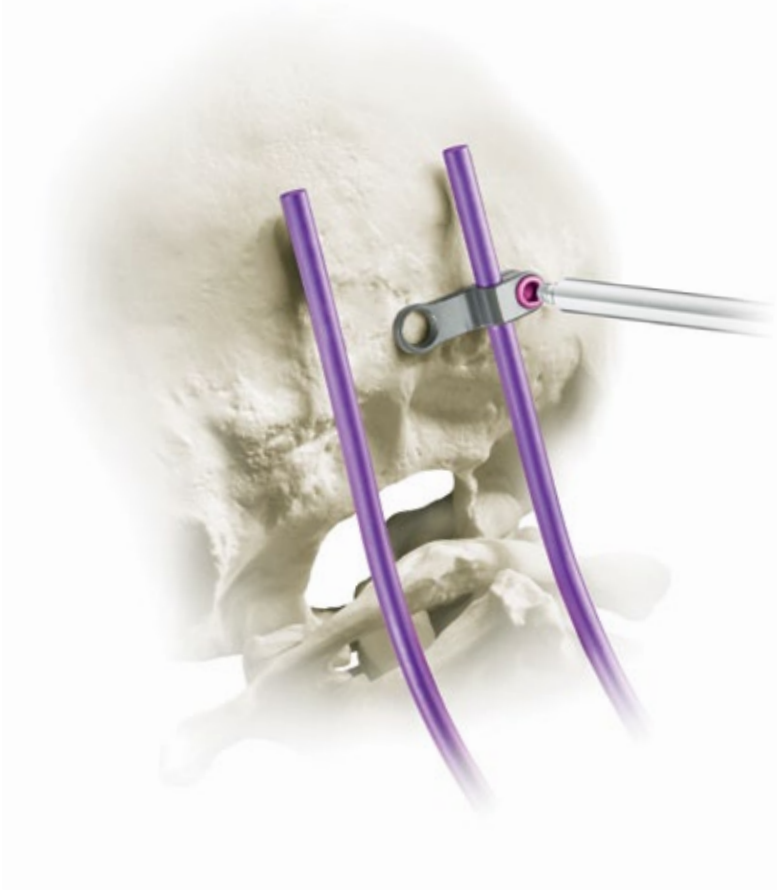



Offset Hooks

The construct is not fully locked until final tightening (See Step 8, Page 29).

# Step 5 Occipital Fixation

Occipital clamps are available in single, double and triple anchor hole configurations. The pre-loaded set screws may need to be backed out slightly, using the Screwdriver 2.5mm Hex, Torque Indicating, before sliding the clamp over the rod end. Slide each clamp over the rod and determine the desired screw location. The clamps may be provisionally secured by tightening the set screw.



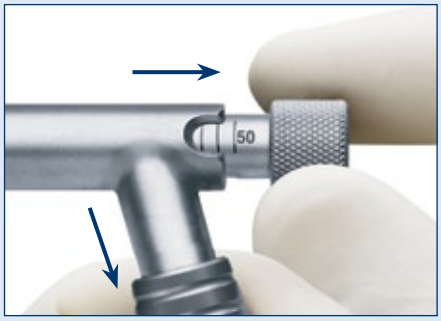
The Drill Guide with Adjustable Stop allows drill depth from 6mm to 16mm, in 2mm increments. Adjust the drill guide depth as described below.

Attach the desired drill bit to the Quick Connect Handle and insert the assembly through the drill guide. Drill to the appropriate trajectory and depth. 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.

*Note: It is recommended that at least two clamps are attached to each side of the construct.*

## Using the Drill Guide with Adjustable Stop

Pull down the tapered sleeve to release the ratchet. Adjust the drill stop until the appropriate depth indicator is aligned with the back end of the outer tube.



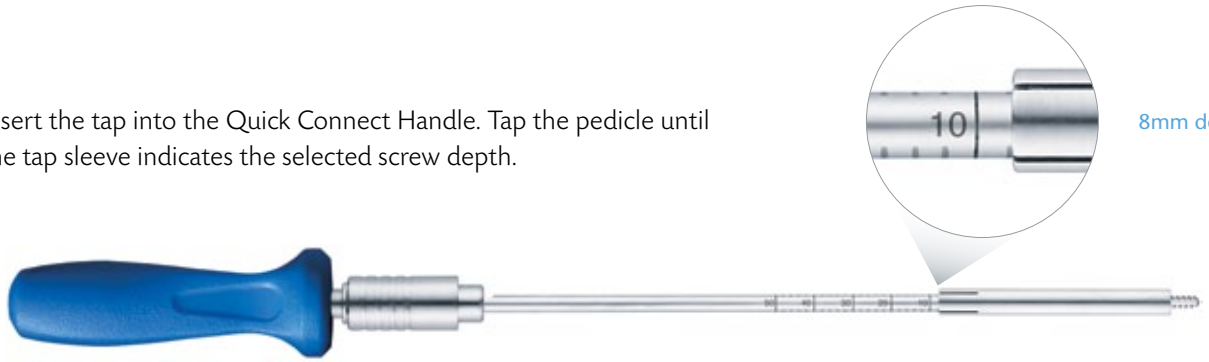


Release the sleeve to lock the drill guide at the desired depth. Ensure that the ratchet is fully engaged by pressing on the drill stop.

PROTEX®-CT occipital screws are self-tapping; however the occiput may be pre-tapped if desired using the Tap and Tap Sleeve. The sleeve should be used to indicate depth.

Slide the large opening (the end without slots) of the sleeve over the distal end of the appropriate tap.

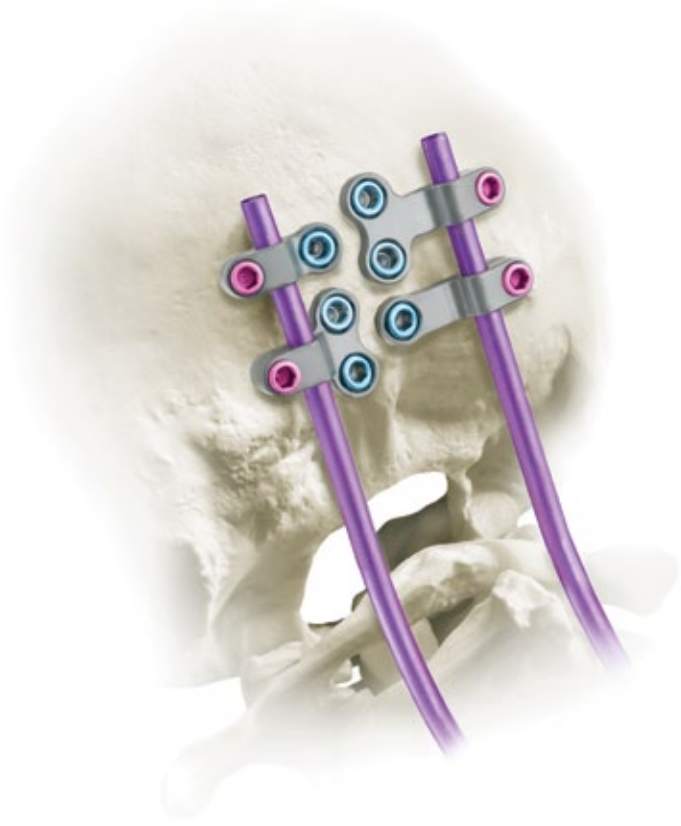

Insert the tap into the Quick Connect Handle. Tap the pedicle until the tap sleeve indicates the selected screw depth.




Remove occipital screws from the occipital module using the 2.5mm Hex, Self-Retaining Screwdriver. The screws should be inserted until the screw head makes contact with the top surface of the clamp. Apply slight downward force while continuing to advance the screw past the interference region. Once the screw is seated, the clamp may be lagged to the occiput, by further rotating the screw for a secure fit. The screw is locked and automatically blocked from backing out, when it is flush with the clamp after full insertion.

To remove and release the screw from the clamp, the **Screw Removal Tool** should be used.

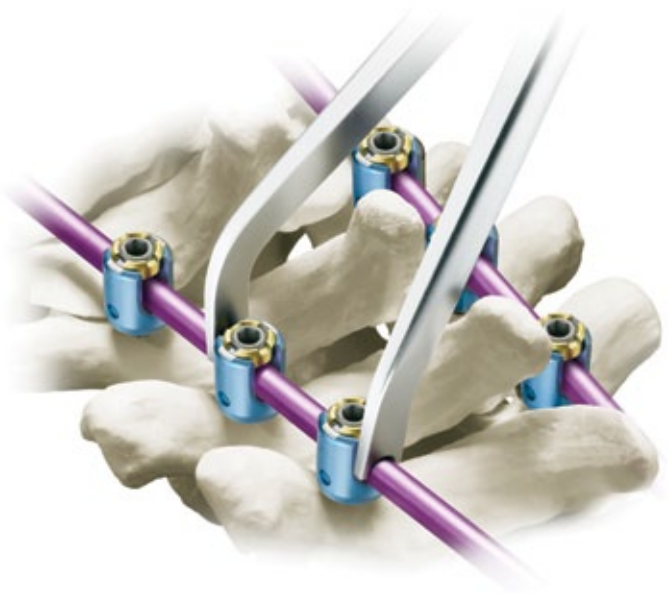
If rigid screws are preferred, they can be inserted using the **Screwdriver for Rigid Screws** and the **Screwdriver for Set Screws**. If rigid screw removal is required, the **Rigid Screw Extractor** can be used.



Occipital clamps secured to the construct

# Step 6 Compression or Distraction

PROTEX®-CT Polyaxial Screws can be compressed or distracted along the rod as necessary using the **Compressor, 3.7mm Rod**.



Compression

Distraction

# Step 7 Optional Connectors

## Parallel Connectors

Parallel connectors can be used to aid in transitions between screw or hook locations and to minimize rod contouring. They can also enable connections to preexisting titanium rod systems of various diameters. The PROTEX®-CT 3.7mm diameter rod can be linked to another titanium 3.7mm rod or to a 6.5mm rod in the PROTEX® System. The 3.7mm rods may also be connected to a 4.0mm, 4.5mm, 5.0mm, 5.5mm, or 6.0mm diameter titanium rod system using the corresponding parallel connector.

The pre-loaded set screws should not be advanced into the rod placement area; if obstructing rod insertion, screws must be backed out slightly using a 2.5mm hex driver. Slide the parallel connector onto the rods to be connected. Once the parallel connector is attached to both rods, the screws can be tightened using the 2.5mm Hex, Torque-Limiting Screwdriver.

## Lateral Connectors

Lateral connectors are used to aid in transitions between screw or hook locations and to minimize rod contouring. Place the opening of the lateral connector over the rod. Introduce the textured rod portion into the opening of the polyaxial screw or hook. Insert the locking cap (see Step 3, Page 17) and provisionally tighten the pre-loaded screw onto the rod with the 2.5mm Hex, Self-Retaining Screwdriver. The lateral connector is now connected to the construct, which is not completely locked until final tightening (see Step 8, Page 29 for final tightening instructions).

*Note: Lateral connectors may be cut to length using the Rod Cutter as described in Step 3, Page 17. Ensure that the rod length will pass completely through the screw or hook head.*

# Optional Connectors (cont'd)

## T-Connectors

To enhance construct stability, the Adjustable T-Connector may be used as a transverse connector between two rods.

Use the **T-Connector Holder** or Rod Holder to grasp the T-connector and insert between the two rods. Adjust the telescoping assembly to obtain approximate length and position. Provisionally tighten the set screws using a 2.5mm hex driver until the end clamps are positioned on the rod.

Using the 2.5mm Hex, Torque-Limiting Screwdriver, tighten both set screws bearing on the rod, then tighten both clamps adjacent to the rod.

Adjusted to avoid dural contact

Low-profile

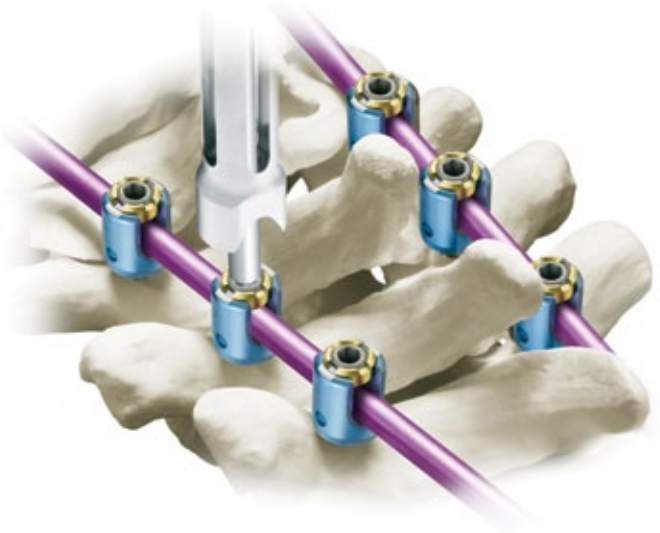
Placing the Adjustable T-Connector

# Step 8 Final Tightening

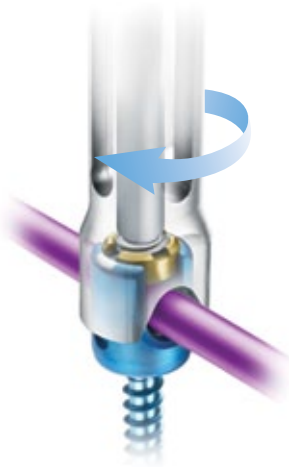
Final tightening of the set screws is necessary to secure the construct, and is accomplished using the 2.5mm Hex, Torque-Limiting Screwdriver. The screwdriver should be used to final tighten all set screws on the offset hooks, T-connectors, parallel connectors, lateral connectors and occipital clamps.

## Polyaxial Screws and Hooks

Insert the 2.5mm hex screwdriver into the **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 2.5mm hex clockwise until it reaches its torque limit of 1.5Nm. Repeat for all locking caps.



Placing the T-connector with the T-Connector Holder



Tightening the set screw

Before final tightening

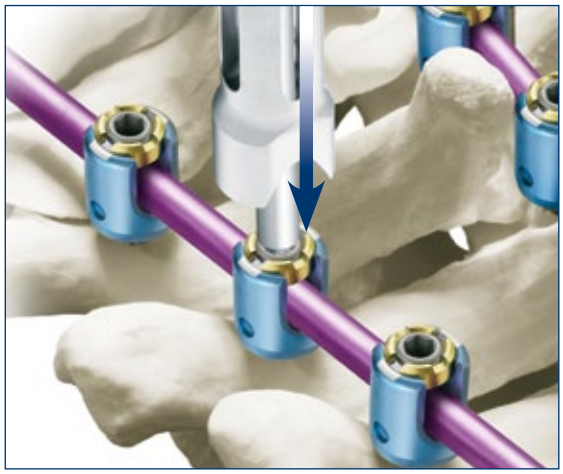
After final tightening

# Final Construct

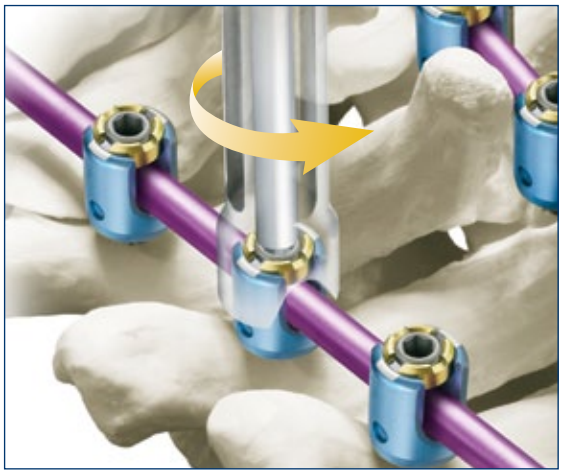
Occiput to T3 is shown. Fixation below T3 can be accomplished using the PROTEX® Stabilization System.

# Optional Technique: Implant Removal

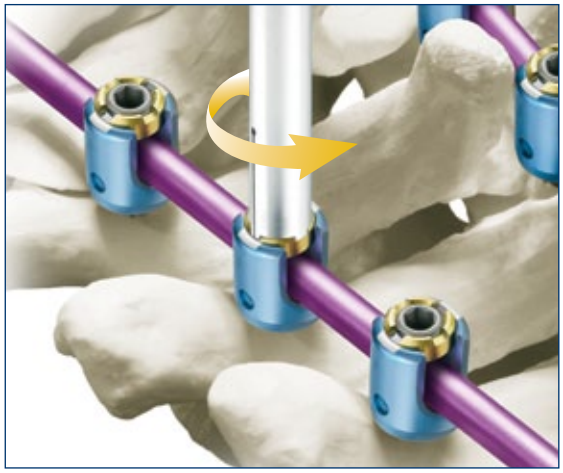
To loosen or remove a screw, insert the 2.5mm Hex, Torque-Limiting Screwdriver into the Final Tightening Instrument. Engage the 2.5mm hex into the set screw and position the Final Tightening Instrument over the polyaxial screw head, ensuring that the sleeve is fully seated on the screw head and cap. Rotate the 2.5mm hex counterclockwise one full turn to loosen the set screw.



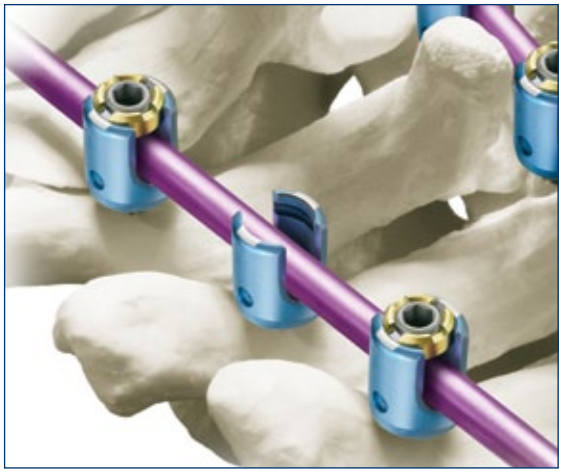
Insert 2.5mm hex and
Final Tightening Instrument



Rotate 2.5mm hex counterclockwise



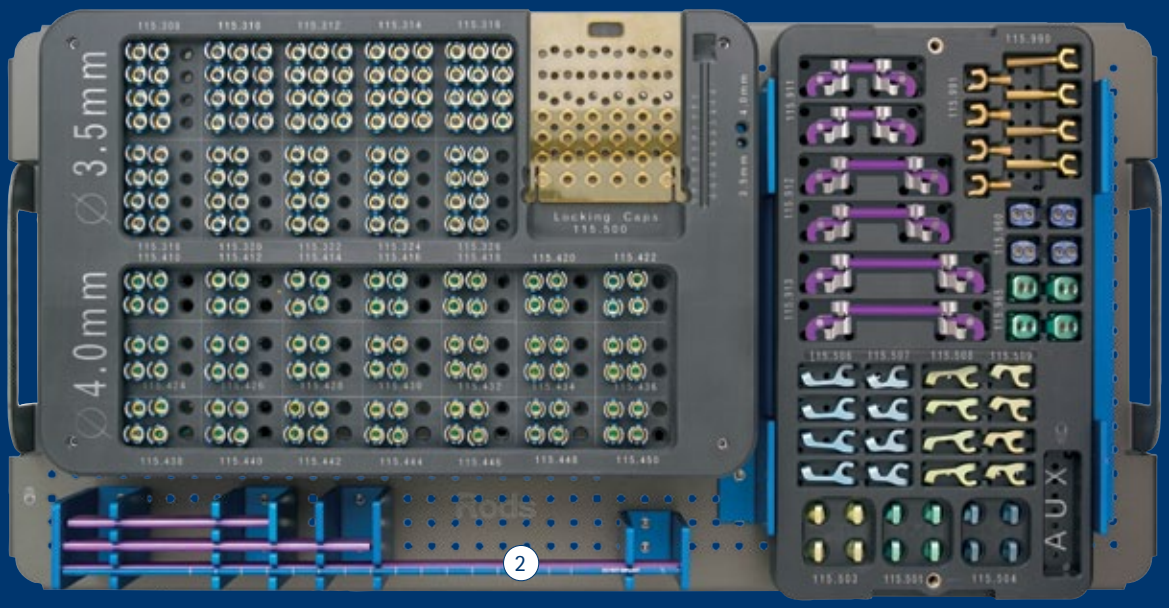
Insert Cap Driver and rotate
counterclockwise 90°

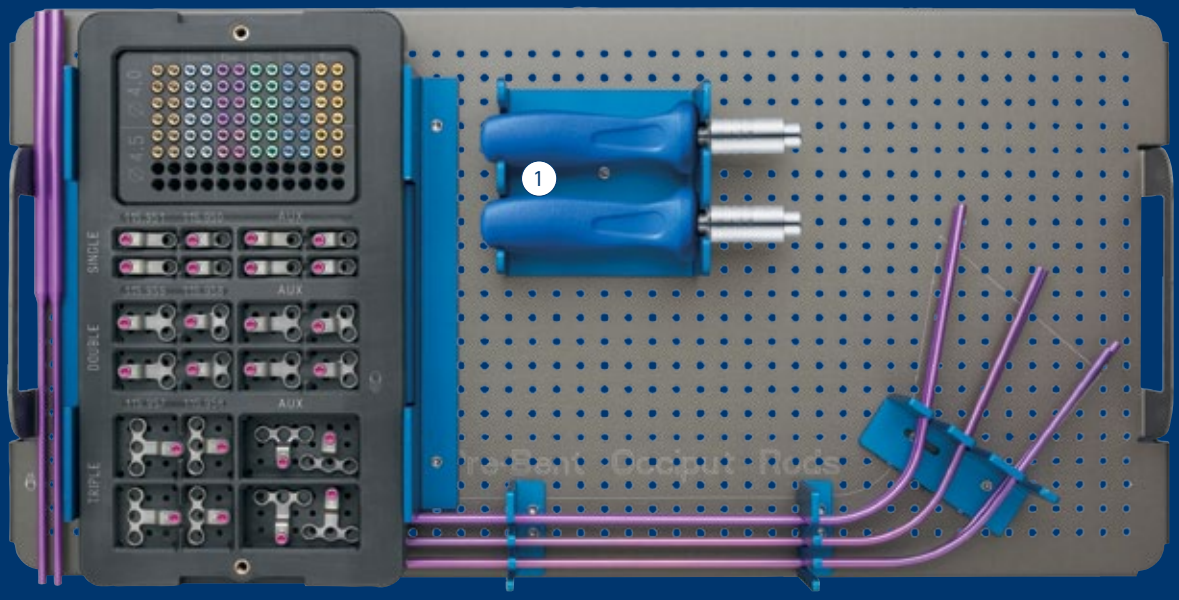


Locking cap removed

Repeat these steps to remove locking caps from adjacent screws. Remove the rod using the Rod Holder, and use the 2.5mm Hex, Self-Retaining Screwdriver to remove the polyaxial screws.

# PROTEX®-CT IMPLANT SET



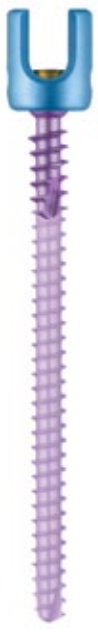
# PROTEX®-CT Implant Set 915.902

## Polyaxial Screws

| Length | Ø3.5mm | Qty |
|---|---|---|
| 8mm | 115.308 | 8 |
| 10mm | 115.310 | 12 |
| 12mm | 115.312 | 12 |
| 14mm | 115.314 | 12 |
| 16mm | 115.316 | 12 |
| 18mm | 115.318 | 8 |
| 20mm | 115.320 | 8 |
| 22mm | 115.322 | 8 |
| 24mm | 115.324 | 8 |
| 26mm | 115.326 | 8 |
| 28mm | 115.328 | |
| 30mm | 115.330 | |
| 32mm | 115.332 | |
| 34mm | 115.334 | |
| 36mm | 115.336 | |
| 38mm | 115.338 | |
| 40mm | 115.340 | |
| 42mm | 115.342 | |
| 44mm | 115.344 | |
| 46mm | 115.346 | |
| 48mm | 115.348 | |
| 50mm | 115.350 | |

| Length | Ø4.0mm | Qty |
|---|---|---|
| 10mm | 115.410 | 4 |
| 12mm | 115.412 | 4 |
| 14mm | 115.414 | 4 |
| 16mm | 115.416 | 4 |
| 18mm | 115.418 | 4 |
| 20mm | 115.420 | 4 |
| 22mm | 115.422 | 4 |
| 24mm | 115.424 | 4 |
| 26mm | 115.426 | 4 |
| 28mm | 115.428 | 4 |
| 30mm | 115.430 | 4 |
| 32mm | 115.432 | 4 |
| 34mm | 115.434 | 4 |
| 36mm | 115.436 | 4 |
| 38mm | 115.438 | 4 |
| 40mm | 115.440 | 4 |
| 42mm | 115.442 | 4 |
| 44mm | 115.444 | 4 |
| 46mm | 115.446 | 4 |
| 48mm | 115.448 | 4 |
| 50mm | 115.450 | 4 |

| Length | Ø4.5mm |
|---|---|
| 10mm | 115.510 |
| 12mm | 115.512 |
| 14mm | 115.514 |
| 16mm | 115.516 |
| 18mm | 115.518 |
| 20mm | 115.520 |
| 22mm | 115.522 |
| 24mm | 115.524 |
| 26mm | 115.526 |
| 28mm | 115.528 |
| 30mm | 115.530 |
| 32mm | 115.532 |
| 34mm | 115.534 |
| 36mm | 115.536 |
| 38mm | 115.538 |
| 40mm | 115.540 |
| 42mm | 115.542 |
| 44mm | 115.544 |
| 46mm | 115.546 |
| 48mm | 115.548 |
| 50mm | 115.550 |



## Polyaxial Shoulder Screws

| Length | Ø3.5mm |
|---|---|
| 22mm | 115.222 |
| 24mm | 115.224 |
| 26mm | 115.226 |
| 28mm | 115.228 |
| 30mm | 115.230 |
| 32mm | 115.232 |
| 34mm | 115.234 |
| 36mm | 115.236 |

## Locking Caps

| Part No. | Description | Qty |
|---|---|---|
| 115.500 | PROTEX®-CT Locking Cap | 24 |

## Instruments

| | Part No. | Description | Qty |
|---|---|---|---|
| 1 | 610.702 | Quick Connect Handle, Small | 2 |
| 2 | 615.301 | Rod Template, 240mm | 2 |
| | 915.002 | Graphic Case | |

*Items highlighted in gray are additionally available.*

# PROTEX®-CT Implant Set 915.902 (cont'd)

## Parallel Connectors

| Part No. | Description | Qty |
|---|---|---|
| 115.960 | 3.7mm Rod to 3.7mm Rod | 4 |
| 115.961 | 3.7mm Rod to 4.5mm Rod | |
| 115.962 | 3.7mm Rod to 5.0mm Rod | |
| 115.963 | 3.7mm Rod to 5.5mm Rod | 4 |
| 115.964 | 3.7mm Rod to 6.0mm Rod | |
| 115.965 | 3.7mm Rod to 6.5mm Rod | |
| 115.966 | 3.7mm Rod to 4.0mm Rod | |

## Lateral Connectors

| Part No. | Description | Qty |
|---|---|---|
| 115.990 | Lateral Connector | 2 |
| 115.991 | Lateral Connector, Short | 4 |

## T-Connectors

| Part No. | Description |
|---|---|
| 115.911 | 3.7mm Rod, 32-41mm |
| 115.912 | 3.7mm Rod, 41-56mm |
| 115.913 | 3.7mm Rod, 54-71mm |
| 115.918 | 3.2mm Rod, 21-33mm, Straight |
| 115.919 | 3.2mm Rod, 26-46mm, Curved |
| 115.920 | 3.2mm Rod, 26-46mm, Straight |
| 115.921 | 3.2mm Rod, 36-56mm, Curved |

| Part No. | Description | |
|---|---|---|
| 115.922 | 3.2mm Rod, 36-56, Straight | |
| 115.923 | 3.7mm Rod, 21-33mm, Straight | 2 |
| 115.924 | 3.7mm Rod, 26-46mm, Curved | |
| 115.925 | 3.7mm Rod, 26-46mm, Straight | 2 |
| 115.926 | 3.7mm Rod, 36-56mm, Curved | |
| 115.927 | 3.7mm Rod, 36-56, Straight | 2 |



*Items highlighted in gray are additionally available.*

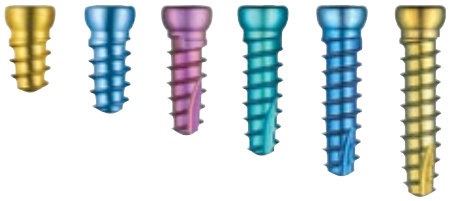
# PROTEX®-CT Implant Set 915.902 (cont'd)

## Hooks

| Part No. | Description | Qty |
|---|---|---|
| 115.501 | PROTEX®-CT Hook | 2 |
| 115.503 | PROTEX®-CT Hook, Right | 2 |
| 115.504 | PROTEX®-CT Hook, Left | 2 |
| 115.506 | PROTEX®-CT Hook, 7mm Offset, Left | |
| 115.507 | PROTEX®-CT Hook, 5mm Offset, Left | |
| 115.508 | PROTEX®-CT Hook, 7mm Offset, Right | |
| 115.509 | PROTEX®-CT Hook, 5mm Offset, Right | |


915.004 PROTEX®-CT Hook and Connector Module

# PROTEX®-CT Implant Set 915.902 (cont'd)



## Standard Screws, Self-Tapping

| Length | Ø4.0mm | Qty |
|---|---|---|
| 6mm | 110.806 | 8 |
| 8mm | 110.808 | 8 |
| 10mm | 110.810 | 8 |
| 12mm | 110.812 | 8 |
| 14mm | 110.814 | 8 |
| 16mm | 110.816 | 8 |

| Length | Ø4.5mm | Qty |
|---|---|---|
| 6mm | 110.906 | 4 |
| 8mm | 110.908 | 4 |
| 10mm | 110.910 | 4 |
| 12mm | 110.912 | 4 |
| 14mm | 110.914 | 4 |
| 16mm | 110.916 | 4 |

## Occipital Clamps

| Part No. | Description | Qty |
|---|---|---|
| 115.950 | Occipital Clamp, Single, Short | 4 |
| 115.951 | Occipital Clamp, Single, Long | 4 |
| 115.956 | Occipital Clamp, Triple, Short | 4 |
| 115.957 | Occipital Clamp, Triple, Long | 4 |
| 115.958 | Occipital Clamp, Double, Short | 4 |
| 115.959 | Occipital Clamp, Double, Long | 4 |


915.005 PROTEX®-CT Occiptal Implant Module



*Items highlighted in gray are additionally available.*

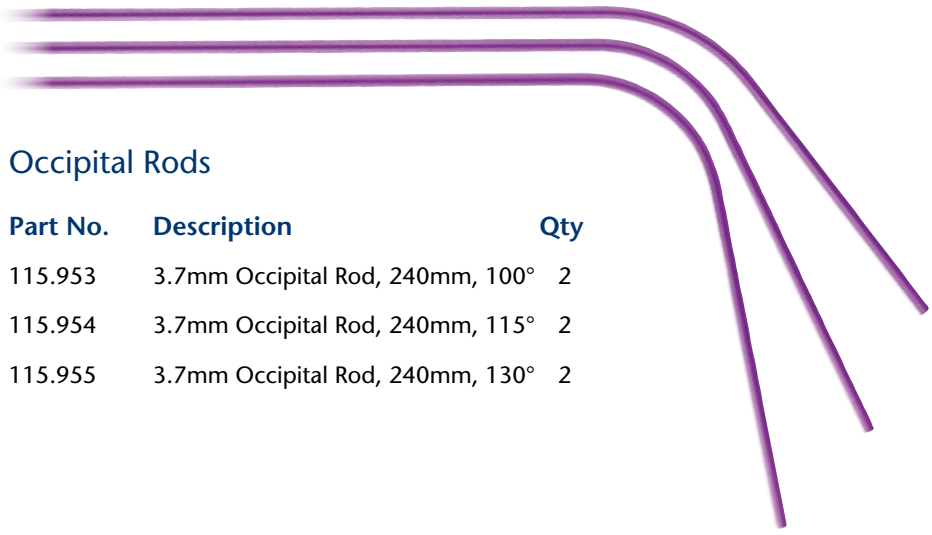
# PROTEX®-CT Implant Set 915.902 (cont'd)

## Straight Rods

| Part No. | Description | Qty |
|---|---|---|
| 115.701 | 3.2mm Straight Ti Rod, 80mm | |
| 115.702 | 3.2mm Straight Ti Rod, 120mm | |
| 115.703 | 3.2mm Straight Ti Rod, 240mm | |
| 115.704 | 3.2mm Straight Ti Rod, 40mm | |
| 115.801 | 3.7mm Straight Rod, 80mm | 4 |
| 115.802 | 3.7mm Straight Rod, 120mm | 4 |
| 115.803 | 3.7mm Straight Rod, 240mm | 4 |
| 115.804 | 3.7mm Straight Rod, 40mm | 4 |

## Tapered Rods

| Part No. | Description | Qty |
|---|---|---|
| 115.979 | 3.2mm to 3.7mm, 240mm | |
| 115.980 | 3.7mm to 6.5mm, 240mm | |
| 115.981 | 3.7mm to 6.5mm, 350mm | |
| 115.982 | 3.7mm to 6.5mm, 300mm | |
| 115.983 | 3.7mm to 6.0mm, 350mm | |
| 115.984 | 3.7mm to 5.5mm, 350mm | 2 |
| 115.985 | 3.7mm to 5.0mm, 350mm | |
| 115.986 | 3.7mm to 4.5mm, 350mm | |
| 115.987 | 3.7mm to 4.0mm, 350mm | |
| 115.988 | 3.2mm to 5.5mm, 350mm | |
| 115.989 | 3.7mm to 5.5mm, 500mm | |

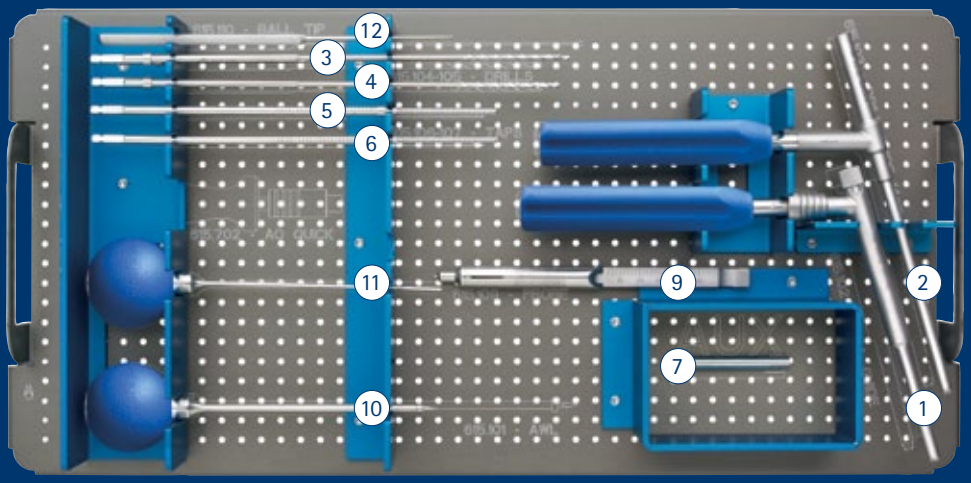


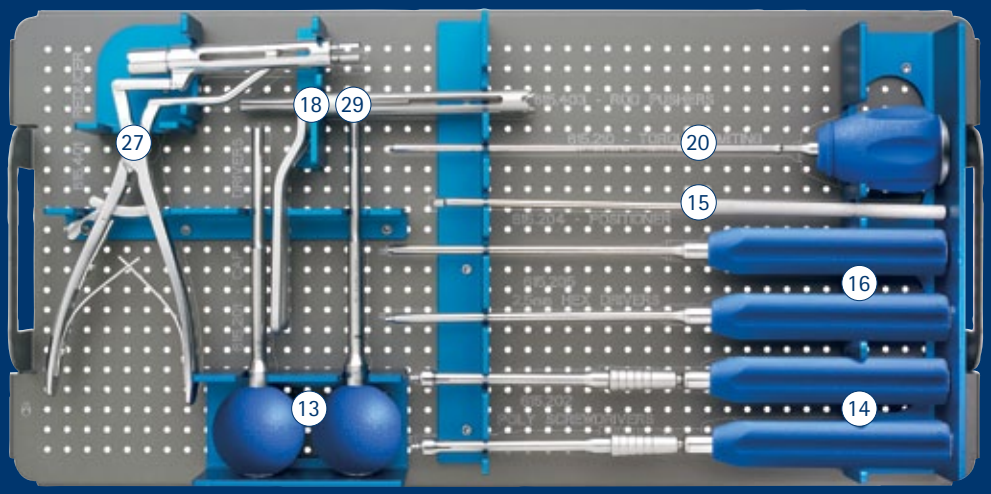
## Occipital Rods

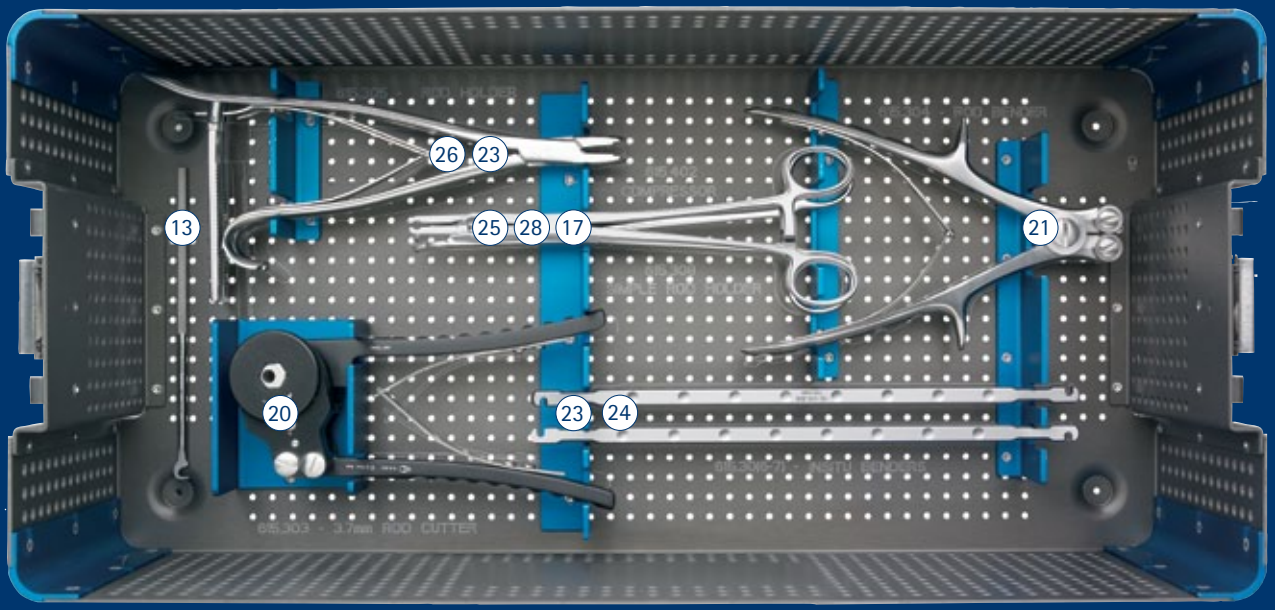
| Part No. | Description | Qty |
|---|---|---|
| 115.953 | 3.7mm Occipital Rod, 240mm, 100° | 2 |
| 115.954 | 3.7mm Occipital Rod, 240mm, 115° | 2 |
| 115.955 | 3.7mm Occipital Rod, 240mm, 130° | 2 |

*Items highlighted in gray are additionally available.*

# PROTEX®-CT INSTRUMENT SET



# PROTEX®-CT Instrument Set 915.901

| | Instruments | | Qty |
|---|---|---|---|
| 1 | 615.102 | Drill Guide with Adjustable Stop, 6-50mm | 1 |
| 2 | 615.103 | Drill Guide with 14mm Stop | 1 |
| 3 | 615.104 | Drill for 3.5mm Screw | 2 |
| 4 | 615.105 | Drill for 4.0mm Screw | 1 |
| 5 | 615.106 | Tap for 4.0mm Screw | 1 |
| 6 | 615.107 | Tap for 3.5mm Screw | 1 |
| 7 | 615.108 | Tap Sleeve | 1 |
| 8 | 615.111 | Lamina Finder | 1 |
| 9 | 615.112 | Depth Gauge | 1 |
| 10 | 615.113 | Awl, 2.0mm | 1 |
| 11 | 615.114 | Pedicle Probe, Straight | 1 |
| 12 | 615.115 | Ball Tip Probe | 1 |
| 13 | 615.201 | Cap Driver | 2 |
| 14 | 615.202 | Polyaxial Screwdriver with Sleeve | 2 |
| 15 | 615.204 | Screw Head Positioner | 1 |
| 16 | 615.205 | Screwdriver, 2.5mm Hex, Self-Retaining | 2 |
| 17 | 615.206 | Cervical Hook Forceps | 1 |
| | 615.208 | Screwdriver, 2.5mm Hex, Torque-Indicating | 1 |
| 18 | 615.209 | Final Tightening Instrument | 1 |
| 19 | 615.210 | Screwdriver, 2.5mm Hex, Torque-Limiting, 1.5Nm | 1 |
| 20 | 615.303 | Rod Cutter, 3.7mm Rod | 1 |
| 21 | 615.304 | Rod Bender | 1 |
| 22 | 615.305 | Rod Holder, 3.7mm Rod | 1 |
| 23 | 615.306 | *In Situ* Bender, Left, 3.7mm Rod | 1 |
| 24 | 615.307 | *In Situ* Bender, Right, 3.7mm Rod | 1 |
| 25 | 615.308 | Rod Holding Forceps, 3.7mm Rod | 1 |
| 26 | 615.309 | T-Connector Holder | 1 |
| | 615.400 | Lateral Rod Reducer | 1 |
| 27 | 615.401 | Rod Reducer | 1 |

| | Instruments | | Qty |
|---|---|---|---|
| 28 | 615.402 | Compressor, 3.7mm Rod | 1 |
| 29 | 615.403 | Rod Counter Torque | 1 |
| | 915.001 | PROTEX®-CT System Instrument Graphic Case | |

### Additionally Available

| | |
|---|---|
| 610.740 | ACDF Tap |
| 615.101 | Awl, Long |
| 615.109 | Pedicle Probe, Straight, Long |
| 615.110 | Ball Tip Probe, Long |
| 615.116 | Pedicle Probe, Curved Tip |
| 615.120 | Tap Stop, 6mm |
| 615.121 | Tap Stop, 8mm |
| 615.122 | Tap Stop, 10mm |
| 615.123 | Tap Stop, 12mm |
| 615.124 | Tap Stop, 14mm |
| 615.125 | Tap Stop, 16mm |
| 615.200 | Cap Driver, Knurled |
| 615.211 | Screwdriver, 2.5mm Hex, Torque-Limiting, 1.5Nm, Short |
| 615.215 | Internal Sleeve, Polyaxial Screw Driver |
| 615.300 | *In Situ* Rod Cutter |
| 615.302 | Rod Cutter, 3.7mm Rod, Shear-Action |
| 615.310 | 3.7mm Rod Gripper |
| 615.311 | 3.2mm Rod Gripper |
| 615.405 | Screw Distractor |
| 615.504 | Drill Bit, Small, for 3.5mm Screws |
| 615.505 | Drill Bit, Small, for 4.0mm Screws |

*Items highlighted in gray are additionally available.*

# IMPORTANT INFORMATION ON THE PROTEX® STABILIZATION SYSTEM

## DESCRIPTION

The PROTEX® CT Occipito-Cervico-Thoracic Spinal System consists of rods, polyaxial screws, hooks, locking caps, t-connectors, lateral connectors, parallel connectors, and occipital clamps. The implants are composed of titanium alloy (per ASTM F136, F1472, or F1295) or stainless steel (per ASTM F138). Due to the risk of galvanic corrosion following implantation, stainless steel implants should not be connected to titanium or titanium alloy implants.

## INDICATIONS (WITHIN THE UNITED STATES)

The PROTEX® CT Occipito-Cervico-Thoracic Spinal System is intended to be used in skeletally mature patients as an adjunct to fusion using autograft or allograft, for stabilization of the cervical spine and occipito-cervico-thoracic junction (occiput-T3) for the following conditions: degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), spondylolisthesis, spinal stenosis, fracture, dislocation, atlanto/axial fracture with instability, occipitocervical dislocation, revision of previous cervical spine surgery, and tumors.

The use of polyaxial screws is limited to placement in the upper thoracic spine (T1-T3) in treating thoracic conditions only. They are not intended to be placed in the cervical spine. Occipital bone screws are limited to occipital fixation; they are not intended for fixation of the posterior cervical spine. The 3.2mm rod implants are for use in the cervical and upper thoracic spine and are not intended for occipital fixation.

The PROTEX® CT Occipito-Cervico-Thoracic Spinal System 3.7mm rods can also be linked to rod systems ranging in diameter from 3.7mm to 6.5mm, including the PROTEX® or REVERE® System, using corresponding parallel connectors.

## INDICATIONS (OUTSIDE THE UNITED STATES)

The PROTEX® CT Occipito-Cervico-Thoracic Spinal System is intended to be used in skeletally mature patients as an adjunct to fusion using autograft or allograft, for stabilization of the cervical spine and occipito-cervico-thoracic junction (occiput-T3) for the following conditions: degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), spondylolisthesis, spinal stenosis, fracture, dislocation, atlanto/axial fracture with instability, occipitocervical dislocation, revision of previous cervical spine surgery, and tumors.

The use of polyaxial screws is limited to placement in the upper thoracic spine (T1-T3) or placement in the cervical spine (C2-C7) in treating cervical conditions. Occipital bone screws are limited to occipital fixation; they are not intended for fixation of the posterior cervical spine. The 3.2mm rod implants are for use in the cervical and upper thoracic spine and are not intended for occipital fixation.

The PROTEX® CT Occipito-Cervico-Thoracic Spinal System 3.7mm rods can also be linked to rod systems ranging in diameter from 3.7mm to 6.5mm, including the PROTEX® or REVERE® System, using corresponding parallel connectors.

## 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

This device is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical spine. 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 or stainless steel. Dissimilar metals in contact with each other can accelerate the corrosion process due to galvanic corrosion effects. Mixing of implant components with different materials is not recommended, for metallurgical, mechanical and functional reasons. Components of this system should not be used with components of any other system or manufacturer, unless specifically stated.

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.

## PRECAUTIONS

The implantation of pedicle screw spinal systems should be performed only by experienced spinal surgeons with specific training in the use of this pedicle screw spinal system because this is a technically demanding procedure presenting a risk of serious injury to the patient. Preoperative planning and patient anatomy should be considered when selecting implants.

The use of polyaxial screws is limited to placement in the upper thoracic spine (T1-T3) in treating thoracic conditions only. They are not intended to be placed in the cervical spine.

The implants are provided non-sterile and 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.

## CLEANING

Cleaning instruments by hand, when properly carried out, causes less damage than mechanical cleaning. When cleaning instruments by hand, the following should be observed:

1. Clear any corners or recesses of all debris. (Note: extra care should be taken to clean out any cannulated areas by using an appropriate cleaning stylet and rinsing immediately.)
2. Remove all traces of blood and other such residues immediately. Do not allow these to dry.
3. The instruments should be submerged (if applicable) and cleaned with a commercially available manual cleaner (i.e. Instraclean from Calgon or Medline High Suds Detergent) prepared according to the manufacturer's recommendation.
4. A soft nylon bristled brush is then used to manually clean the devices while immersed in the cleaning solution. Never use steel brushes or abrasive pads, as these rupture the passive layer of the instrument surface which can lead to corrosion.
5. The instruments should be thoroughly rinsed after cleaning. Distilled water should be used.
6. Dry instruments immediately after cleaning.

# IMPORTANT INFORMATION ON THE REVERE® STABILIZATION SYSTEM

**Implants:**

These devices are supplied NONSTERILE. Sterilization is recommended as follows:

| Method | Cycle | Temperature | Exposure Time |
|---|---|---|---|
| Steam | Gravity Displacement (Wrapped) | 132°–135°C (270°–275°F) | 10 Minutes |
| Steam | Pre-Vacuum (Wrapped) Preconditioning Pulses: 3 | 132°–135°C (270°–275°F) | 4 Minutes |

**Instruments:**

These devices are supplied NONSTERILE. Sterilization is recommended as follows:

| Method | Cycle | Temperature | Exposure Time |
|---|---|---|---|
| Steam | Gravity Displacement (Wrapped) | 132°–135°C (270°–275°F) | 20 Minutes |
| Steam | Pre-Vacuum (Wrapped) Preconditioning Pulses: 3 | 132°–135°C (270°–275°F) | 4 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 autoclave must be properly installed, maintained, and calibrated. Ongoing testing must be performed to confirm inactivation of all forms of viable microorganisms.*

**CAUTION:** Federal (USA) Law Restricts this Device to Sale by or on the order of a Physician.

REV D

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