stryker

Yukon®

OCT Spinal System

Surgical technique guide

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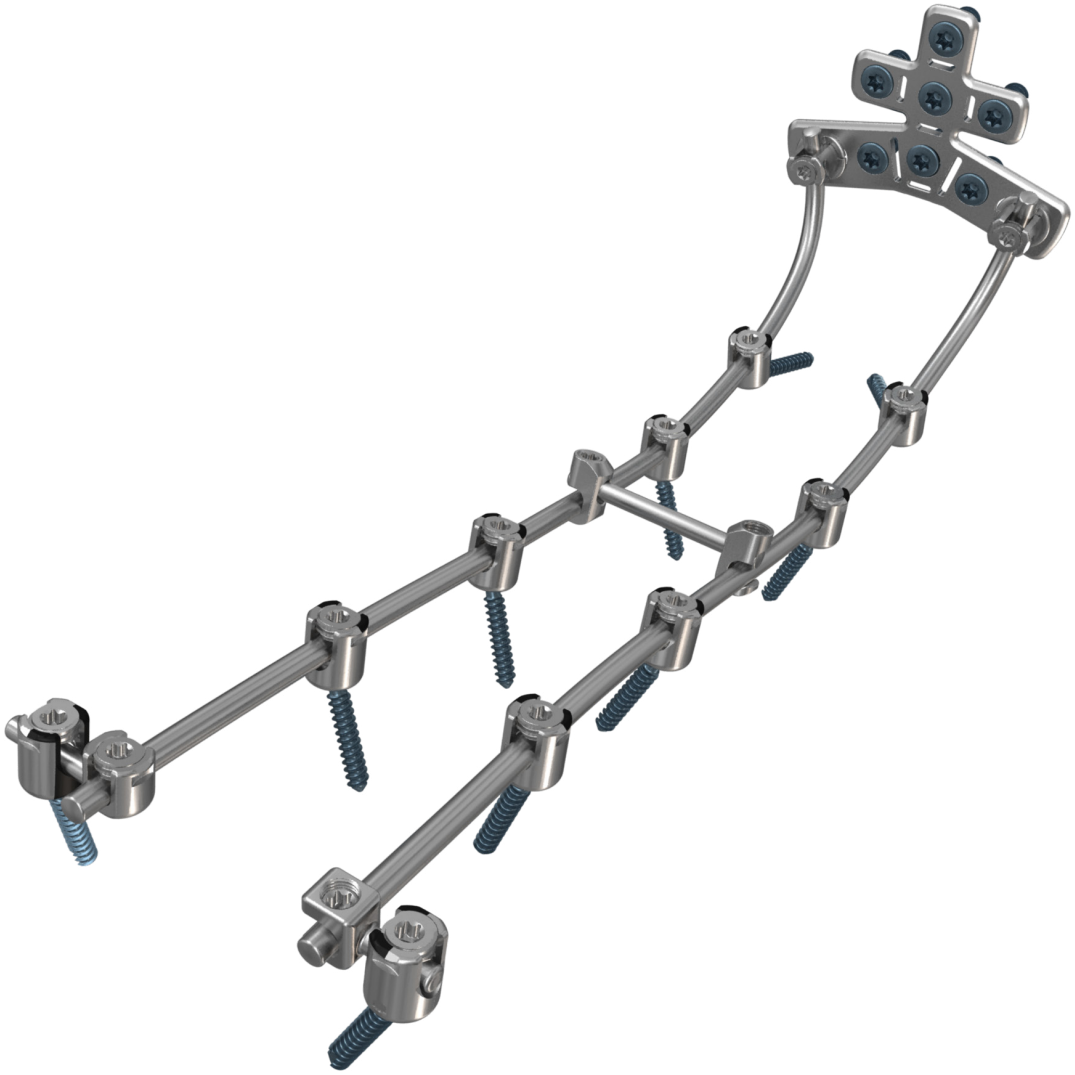
Surgical technique steps

Product catalog

This publication sets forth detailed recommended procedures for using the Yukon OCT Spinal System. It offers guidance that you should heed, but, as with any such technical guide, each surgeon must consider the particular needs of each patient and make adjustments when and as required.



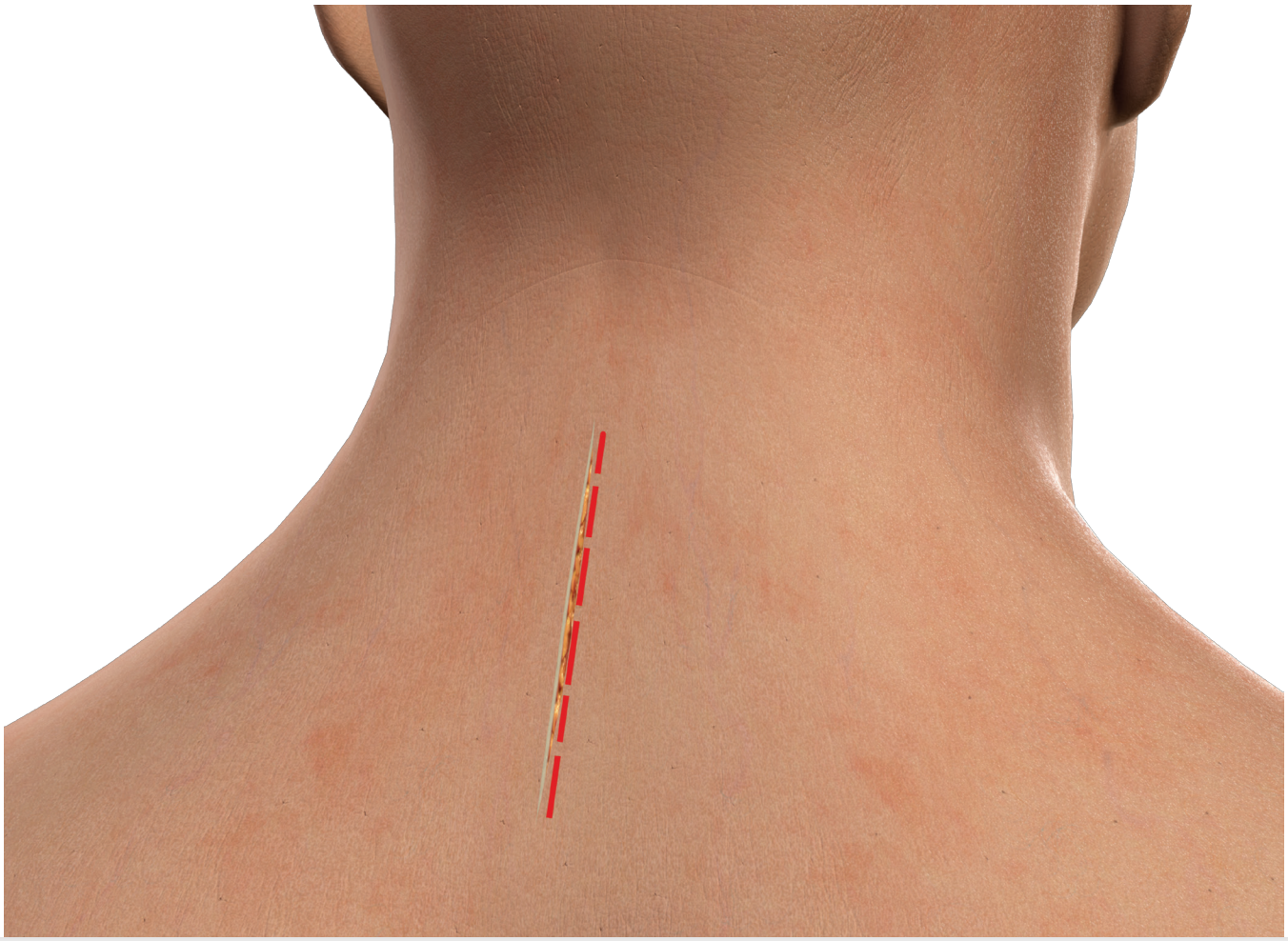
Surgical technique

Step 1

Patient positioning and exposure

The patient's position is always up to the discretion of the surgeon, but most commonly, patients will be positioned prone. The head and neck must be placed in proper alignment and held securely in position. Confirm proper alignment with necessary images prior to draping.

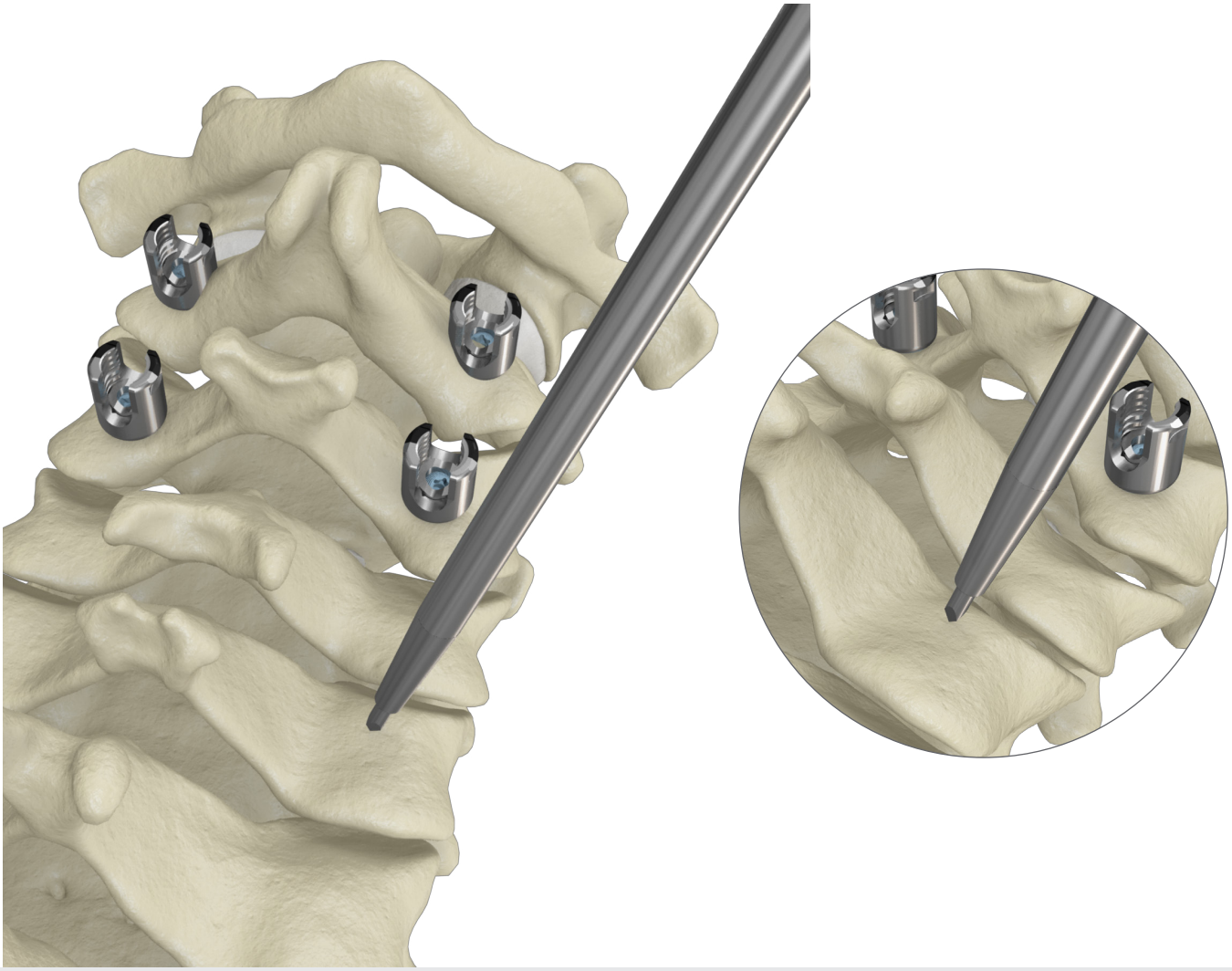
A standard midline exposure of the cervical and/or thoracic spine segments that are to be fused is performed. Retractors are then placed and used to extend the exposure laterally, to provide ample visualization.



Screw site preparation

The desired entry point of the lateral mass or pedicle is chosen and then perforated with an Awl to expose the underlying cancellous bone. The entry point is then cannulated with the Small Pedicle Probe. The Small Pedicle Probe is advanced to the appropriate depth, as determined by the surgeon. The correct insertion of the instrument will allow the tip of the Probe to follow a path of least resistance, reducing the potential of perforating the pedicle walls. The Small Pedicle Probe is laser etched at 10mm increments from 10–50mm, indicating the depth to which the Probe has been inserted. These markings also help the surgeon assess proper drill and screw length.

Note: Laser markings are for reference only.



Step 2

Screw site preparation (cont.)

An Adjustable Drill Guide is available to be used in conjunction with either a Ø2.3 or Ø2.8mm Adjustable Drill.

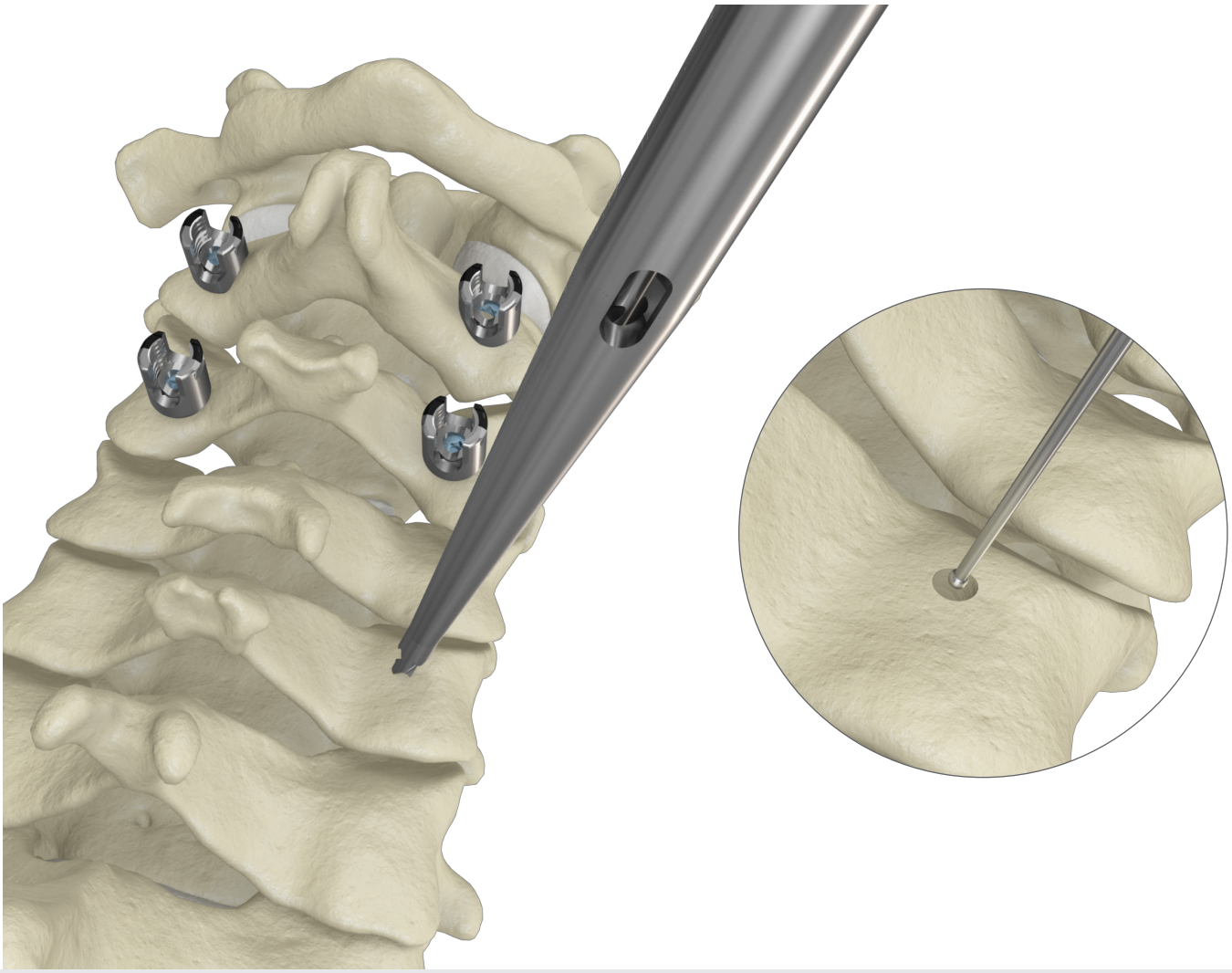
Ø2.3mm Adjustable Drill Bit

Ø2.8mm Adjustable Drill Bit

Adjustable Drill Guide

The Adjustable Drill Guide can vary the depth in which the drill penetrates from 6–50mm by pulling back on the lever above the Handle and then sliding out the adjustable shaft to the desired depth. Once the desired Drill Guide and depth is determined, attach the Drill to either the Ratcheting Axial Handle or Fixed Axial Handle and begin drilling. Check pedicle wall soundness with the Ball Tip Probe.

Note: All drill bits have an AO connection, which allows them to be used in conjunction with power drills, if preferred.



Ball Tip Probe

Ratcheting Axial Handle

Fixed Axial Handle

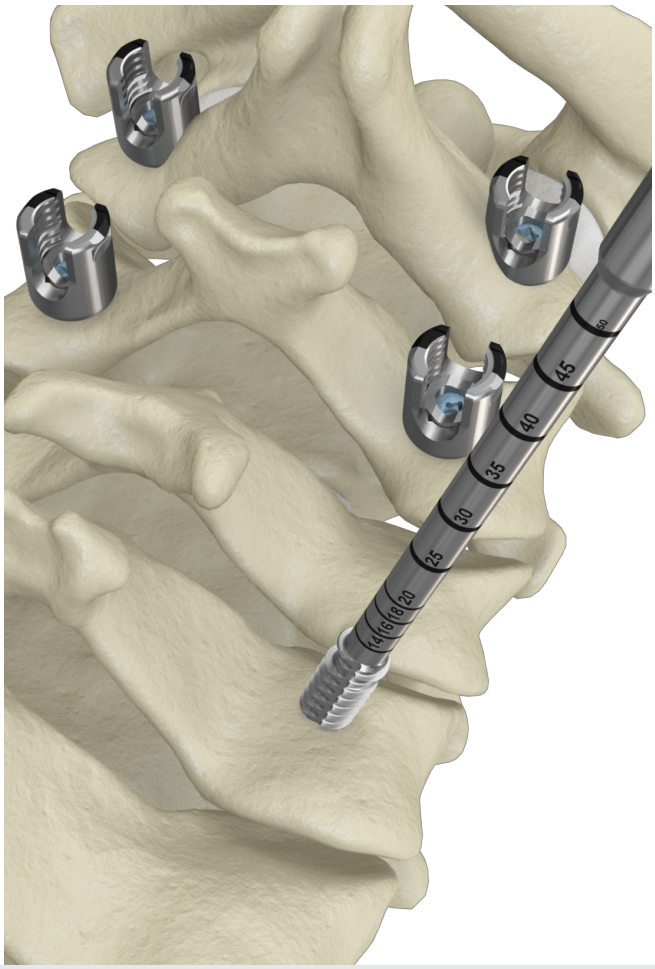
Screw site preparation (cont.)

The Yukon screws are self-tapping; however, Taps are provided for those preferring to do so. Taps are available in Ø3.0, Ø3.5, Ø4.0, Ø4.5, and Ø5.0mm. Slide the Tap Sleeve, slit side first, over the threaded portion until the distal end of the Tap Sleeve and the distal end of the Tap are flush.

As the Tap penetrates, the Tap Sleeve will begin to slide up the Tap. The Tap is etched with depth markings, and current depth is determined by the position of the top of the Tap Sleeve relative to the markings. These markings also help the surgeon assess proper screw length.*

Use the Depth Gauge to help determine pilot hole depth and correlating screw length.*

*All markings are for reference only



Taps
Ø3.0, Ø3.5, Ø4.0, Ø4.5, Ø5.0

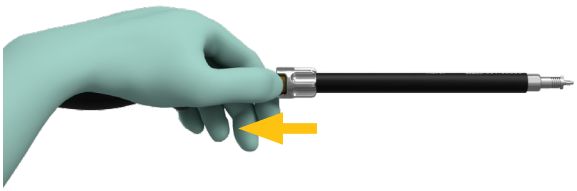
Tap Sleeve

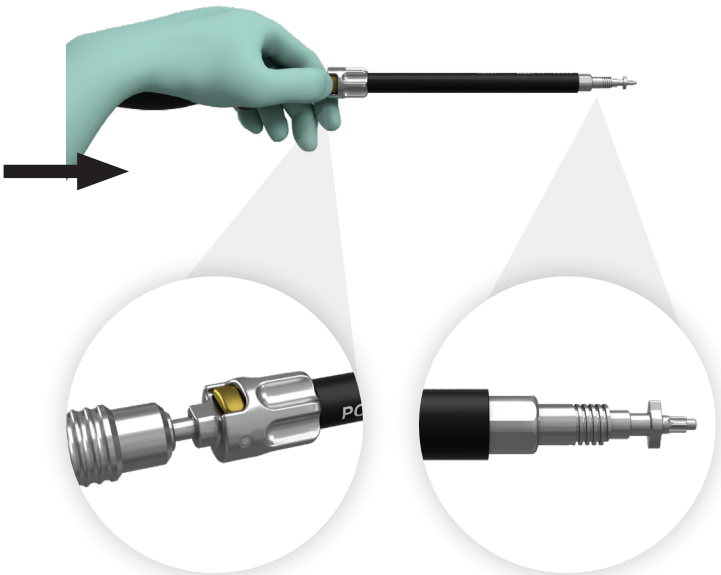
60mm Depth Gauge

Screw insertion

After the screw pathway has been prepared and proper screw size has been determined, the implant for screw insertion is ready to be loaded onto the Yukon Screw Inserter.

To load a screw onto the Yukon Screw Inserter, press the gold button located on the thumb knob and pull knob assembly proximally until the inner shaft tip is exposed distally.

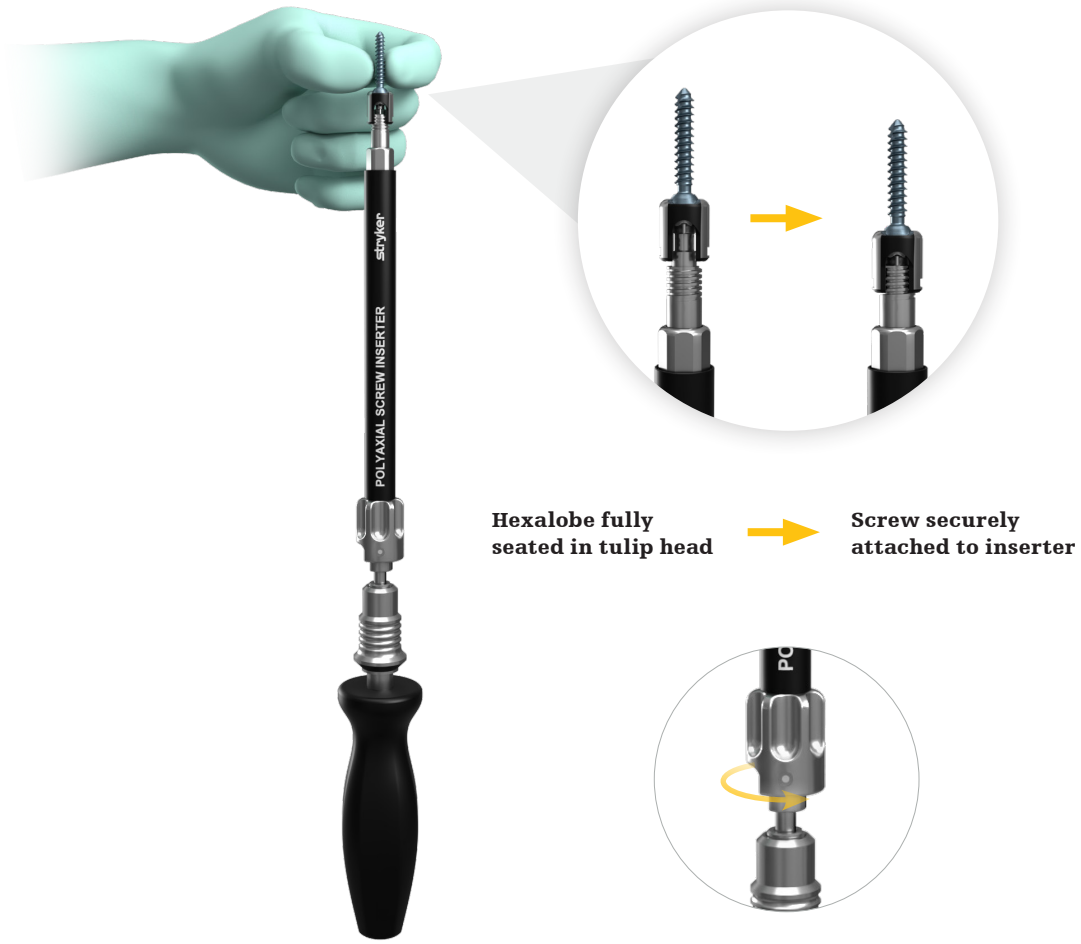




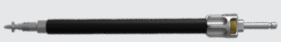
Step 3

Screw insertion (cont.)

When loading Yukon Screw Inserter, grasp the implant by the shaft of the screw and apply a downward force to engage the screw into the hexalobe fitting of the screwdriver shaft. Ensure the hexalobe portion of the tip of the inner shaft is fully seated in the screw head, shown below, and then push the outer shaft knob assembly distally to start the engagement of the threads on the outer shaft with the threads in the tulip head of the screw. Thread the thumb knob in a clockwise direction until the implant is securely attached to the inserter. The Yukon screw Inserter has a BLACK sleeve for ease of identification.



Yukon Screw Inserter



Ratcheting Axial Handle

Fixed Axial Handle

Once the screw has been loaded, insert it into the pilot hole until desired depth is reached. To disengage the Screw Inserter, gently turn the thumb knob in a counter-clockwise direction without engaging the gold button, and remove it from the surgical field. Repeat until all screws are placed.

Note: The Yukon Screw Inserter can be used with either the Ratcheting Axial Handle or the Fixed Axial Handle.

Note: See optional steps for additional Screw Insertion technique. Unique catalog revision numbers exist for each screw inserter.

Note: There is a laser marked line on the proximal end of the inner shaft that corresponds to the laser marked line on the outer shaft of the Yukon Screw Inserter (7601-90003) with the gold button on the thumb knob. There are no laser marked lines on the inner or outer shaft of the Yukon Screw Inserter (7601-90003) with no button on the thumb knob.

Yukon screws are available in the following options

Standard polyaxial screws	
Ø3.5	10–32mm, in 2mm increments
Ø4.0	10–34mm, in 2mm increments
Ø4.5	20–28mm, in 2mm increments
Ø5.0	20–30mm, in 2mm increments

Polyaxial ML screws	
Ø3.5	12–24mm, in 2mm increments
Ø4.0	12–26mm, in 2mm increments
Ø4.5	20, 24, 30, 34, 40, and 44mm

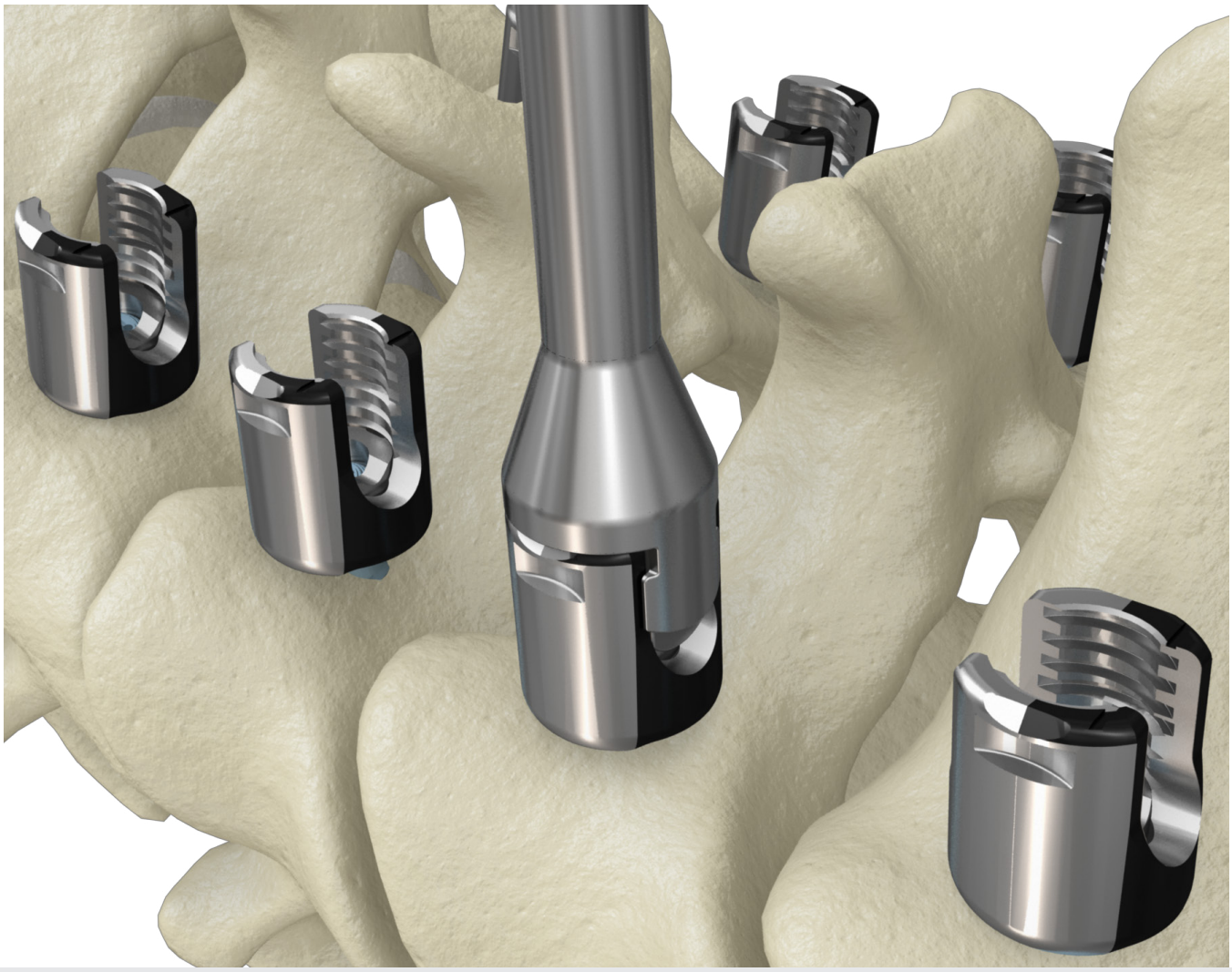
Polyaxial long shank screws	
Ø3.5	24–36mm, in 2mm increments

Step 3

Screw insertion(cont.)

Once the appropriate screw has been selected and inserted, the housing of the screw can be adjusted with the Yukon Head Adjuster. The Head Adjusters are system specific for proper instrument/implant connection.

The black laser marking indicates which side of the screw head allows for 60° of angulation for a 60° conical swing. Adjust the screw head so that the black laser mark is facing the desired direction, thus helping to maximize the higher angulation in that direction.



Yukon Head Adjuster

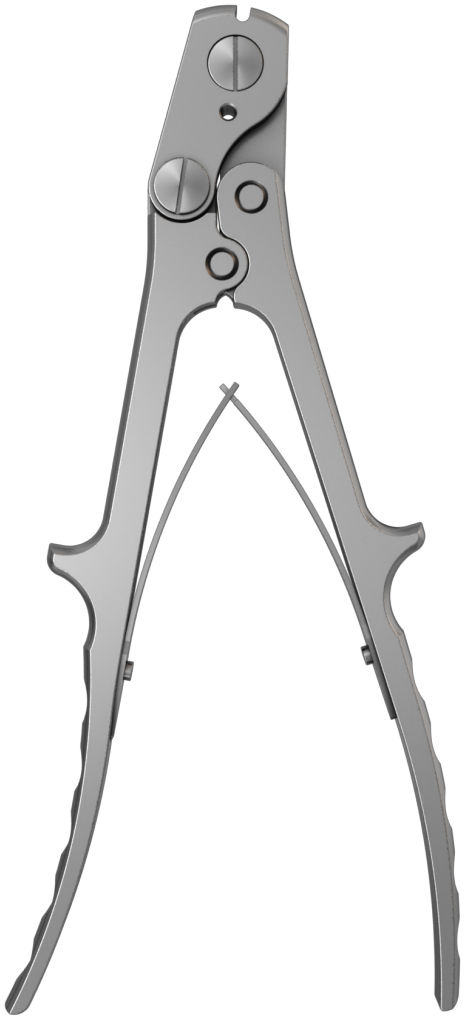
Rod cutting

Once all screws have been inserted, the rod is selected and cut to the appropriate length, if necessary. The rod can be cut by using the cutting portions of the Rod Cutter jaws at the tip or center. **Note**: Rod Templates*, available in 80 and 200mm lengths, may be used to help determine proper Rod length and contour.

*Single-use only

Note: Straight Rods are available in Ti and CoCr in Ø3.5 and Ø4.0mm. Transition Rods are available in Ti and CoCr in Ø3.5—Ø5.5mm and Ø4.0–Ø5.5mm. Contoured Rods are available in Ø3.5 and Ø4.0mm and in lengths from 25–75mm.

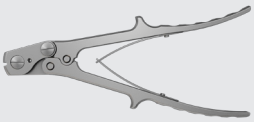
Note: Rods may be prebent to the degree of correction determined by preoperative testing, however reverse bends should be avoided.



Rod Template, 80mm

Rod Template, 200mm

Rod Cutter

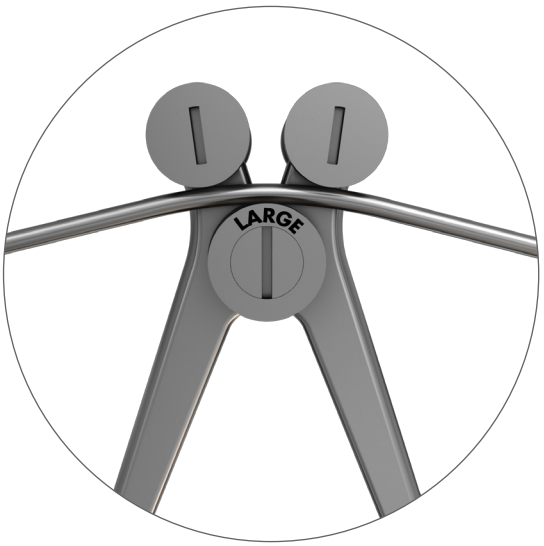


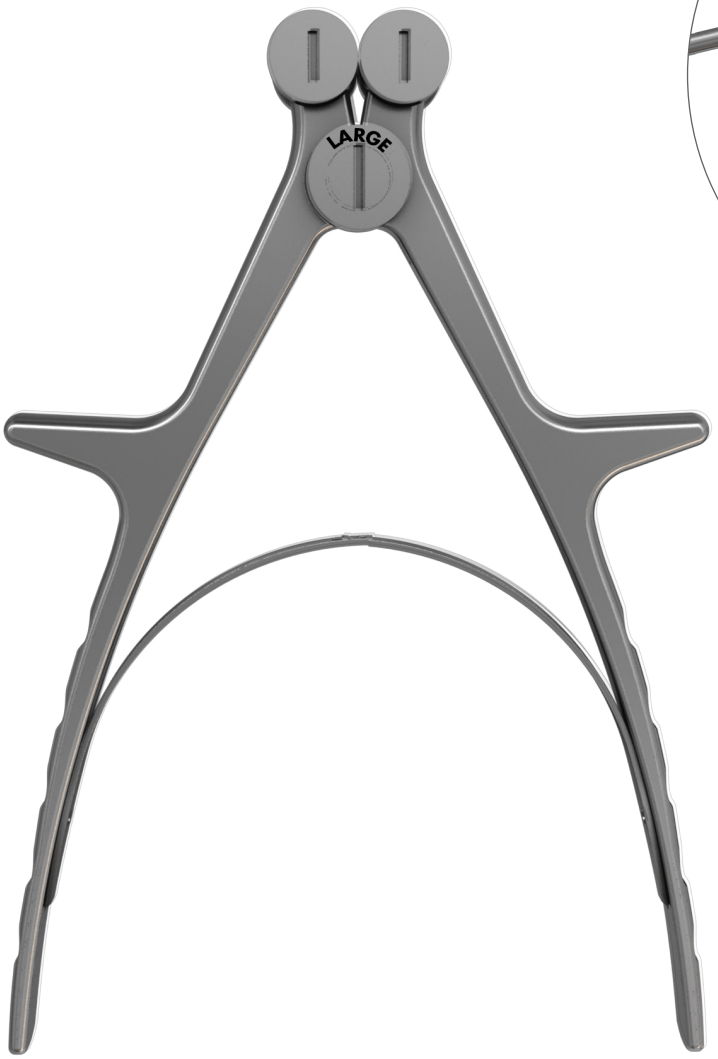
Step 5

Rod bending

The Rod Bender may be used to contour the rods to the desired amount of lordosis or kyphosis. There are two bending radius options, LARGE on one side and SMALL on the other.

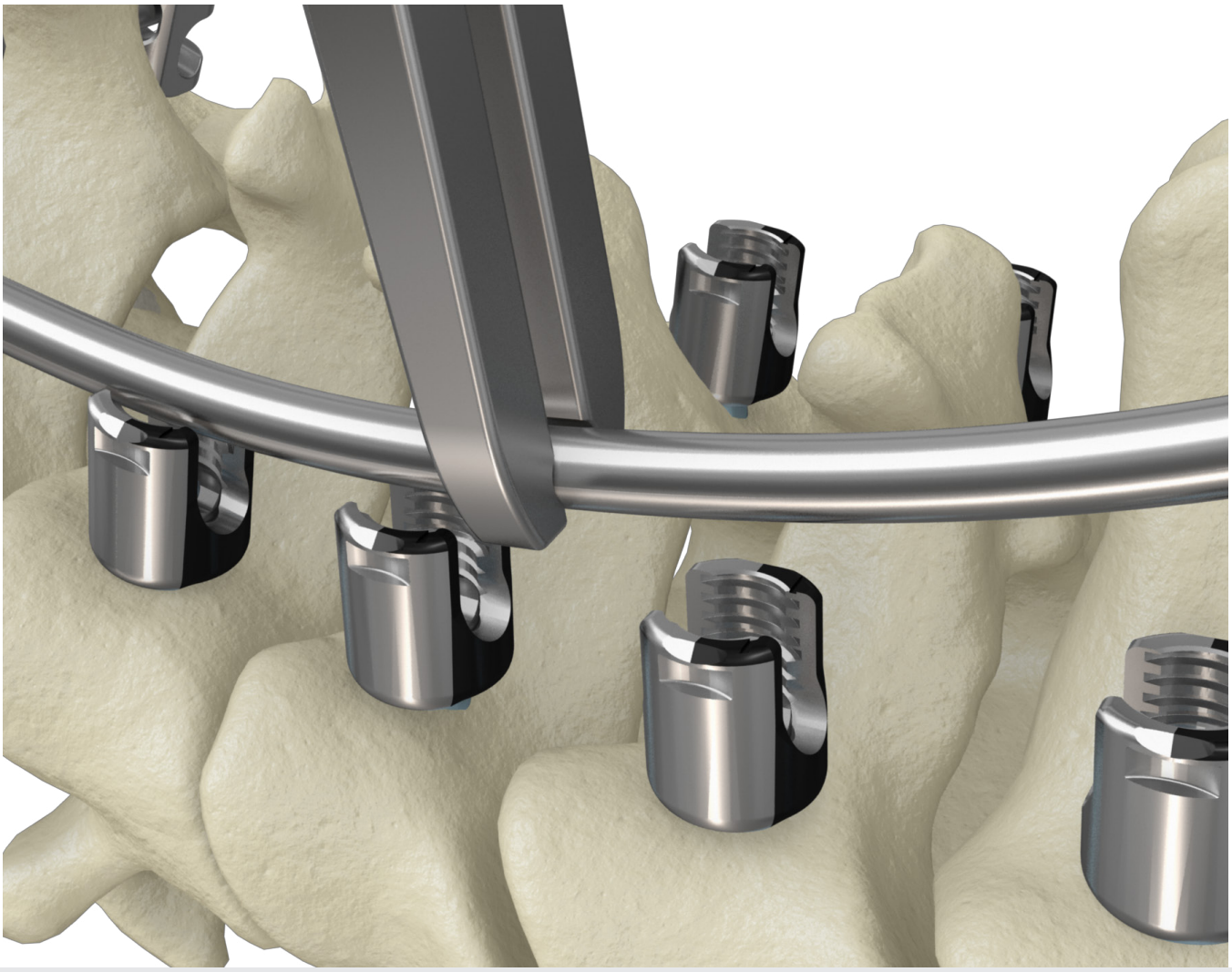
Note: Rods may be prebent to the degree of correction determined by preoperative testing, however reverse bends should be avoided.





Rod placement

Insert the Rod into the hooks or screw heads using the Rod Holding Forceps.



Rod Holding Forceps

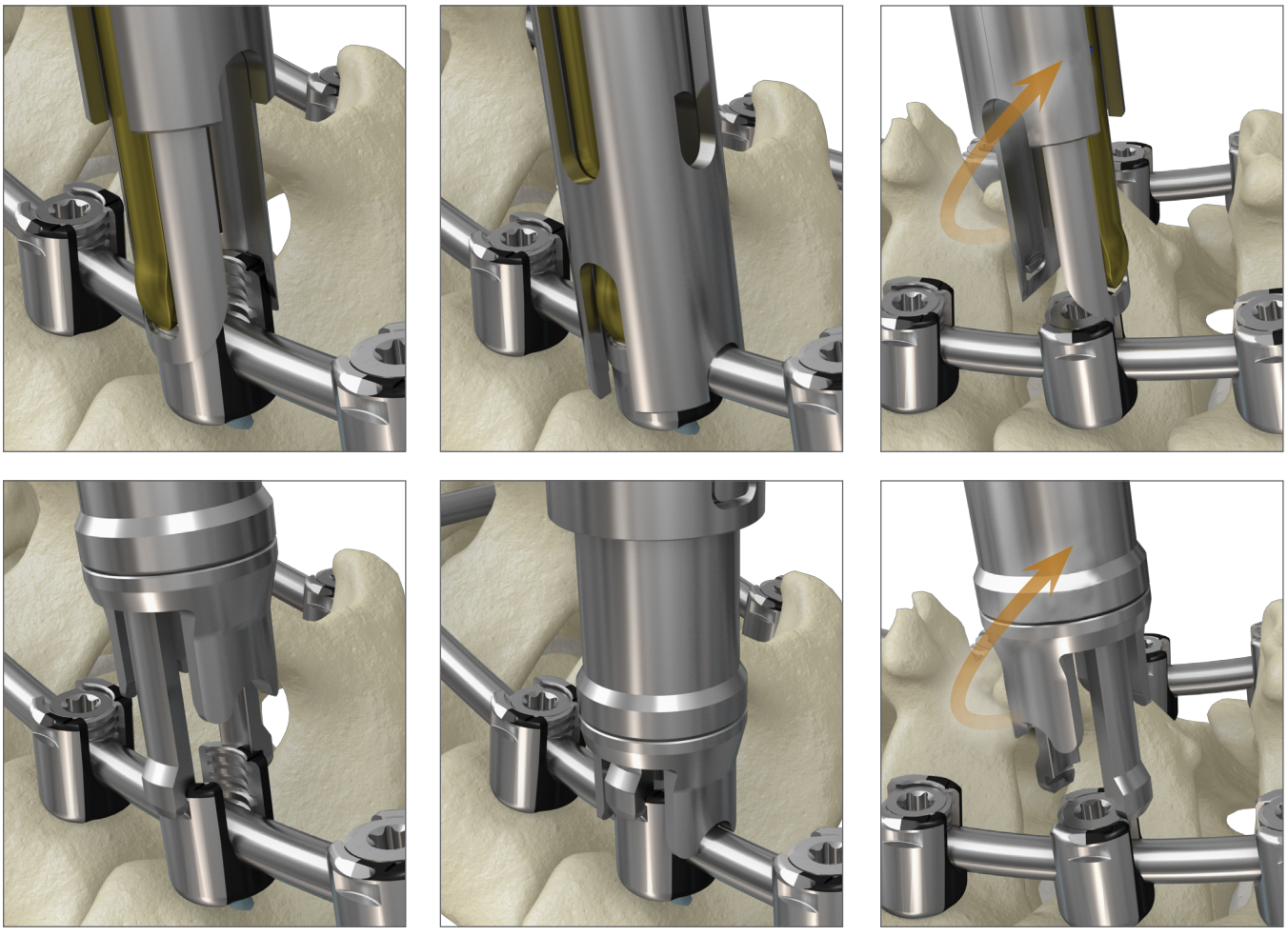
Step 7

Rod reduction and provisional tightening

For reductions up to 20mm into Yukon implants, the Pistol Grip Reducer may be used. When docking the Pistol Grip Reducer, slide the distal tip onto the Yukon screw head. Once the instrument is docked, squeeze the handle to reduce the Rod into the implant housing.

The Yukon Set Screw may be passed through the center of the Pistol Grip Reducer using the Provisional Screwdriver and threaded into the implant housing. When fully reduced, the Pistol Grip Reducer may also act as a counter torque when final tightening as described in Step 10. To disengage the instrument, release the handle or spin the knob counter-clockwise and turn the reducer 90°.

The Sequential Reducer may also be used for more controlled reduction up to 15mm. The Sequential Reducer is designed to engage with the head of the screw and can be reduced by hand or with the Reducer Tube and Tube Chuck, which extend the length of the Reducer. The Yukon Set Screw may be passed through the center of the Sequential Reducer using the Provisional Screwdriver and threaded into the implant housing.



Pistol Grip Reducer

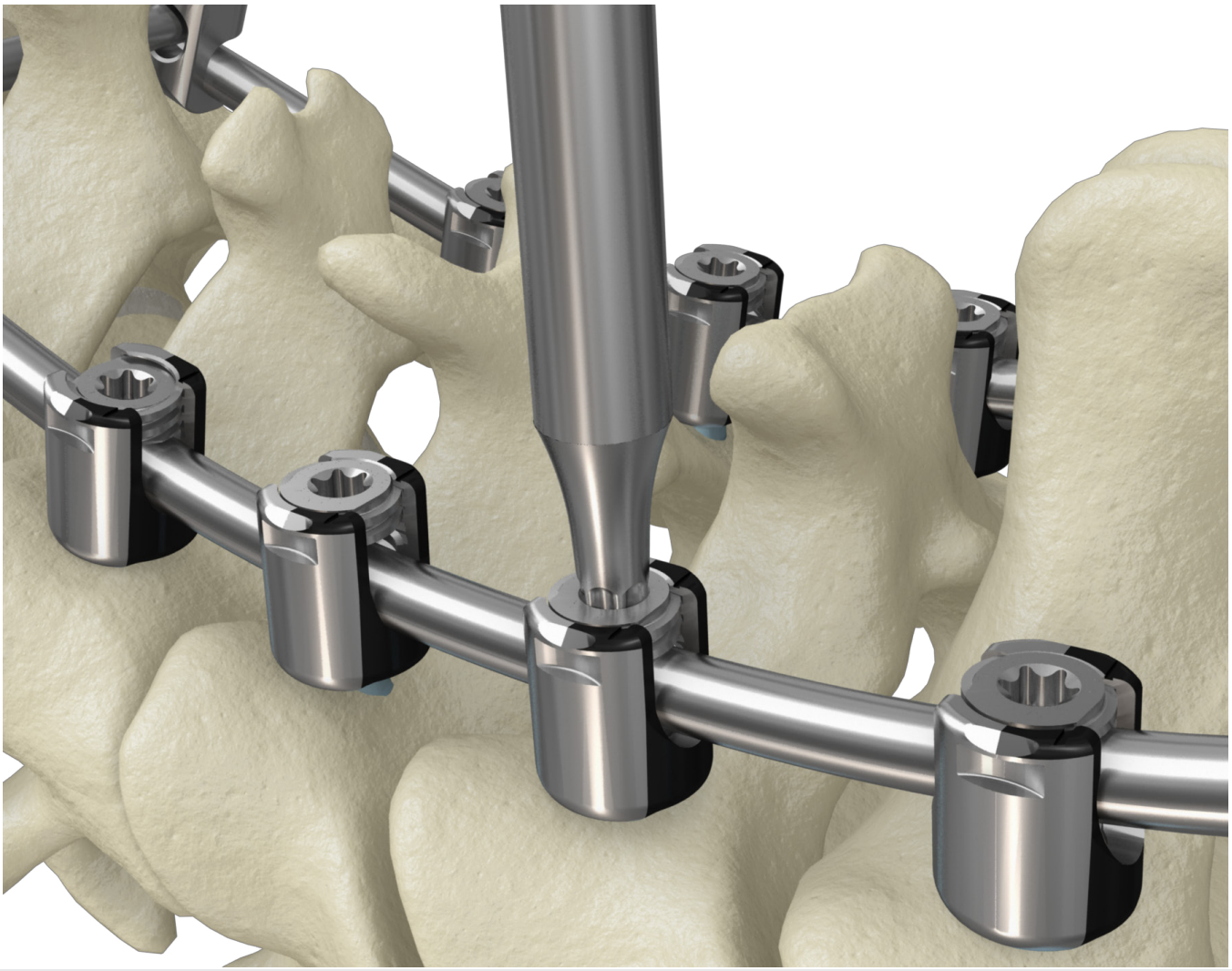
Sequential Reducer

Reducer Tube

Tube Chuck

For minimal reductions, the Rod Fork may be used. Engage the Yukon screw head or hook by placing the Rod Fork over the lateral part of the implant and squeeze the handles. The Rod Fork will engage into the small indents on the implant head. Once engaged, tilt the Rod Fork to reduce the Rod into the implant housing and then insert a Yukon Set Screw.

The Yukon Set Screw can be inserted into implants using the Provisional Screwdriver. It is essential that the Yukon Set Screw is oriented with the hexalobe/laser-marked surface facing up prior to "stab-and-grab" attachment. Do not attach the Yukon Set Screw to the instrument using any surface other than the Yukon Set Screw Caddy. Ensure the instrument is perpendicular to the caddy when engaging the hexalobe tip.



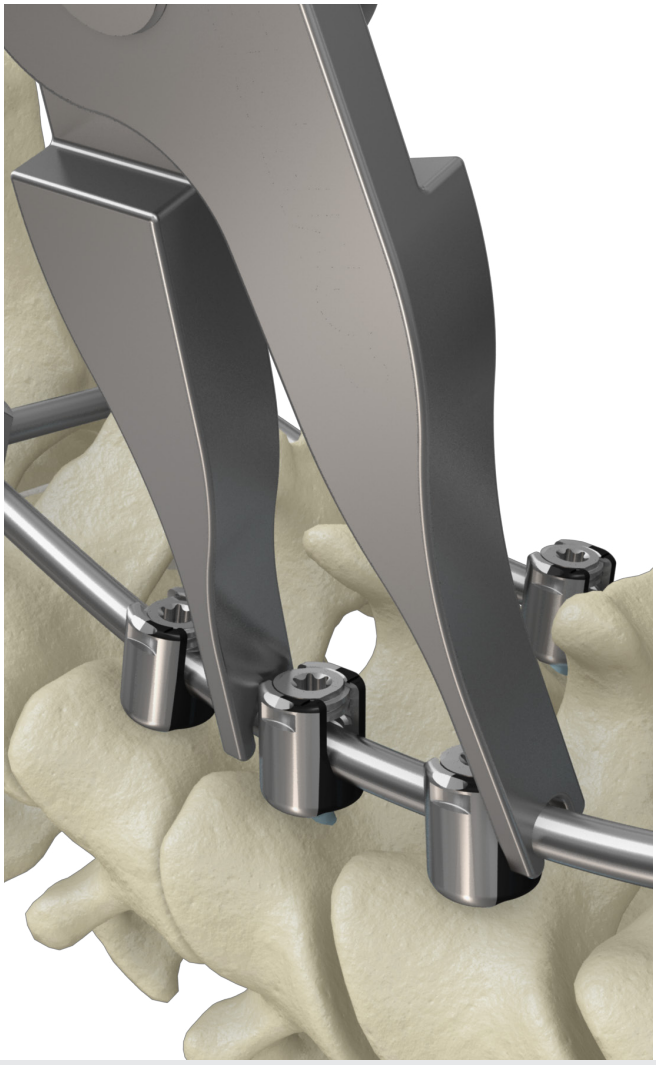
Rod Fork

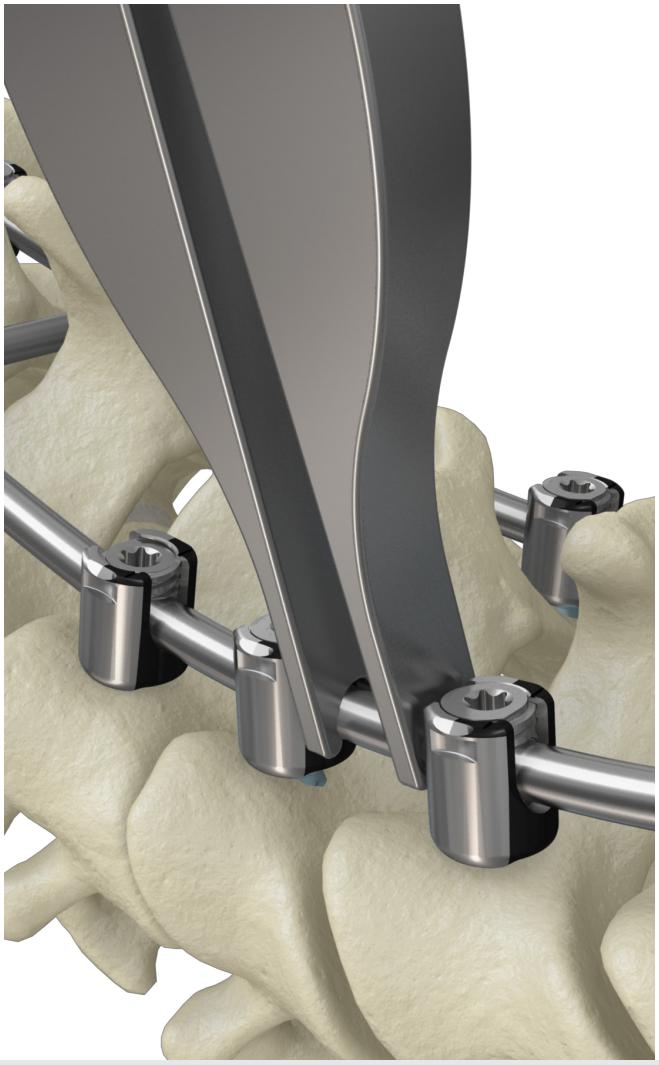
Provisional Screwdriver

Step 8

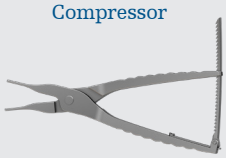
Compression and distraction

Compression and distraction may be performed with the Yukon implants while the Yukon Set Screws are provisionally tightened. Once the desired amount of compression and distraction has been achieved, it is necessary to tighten the Yukon Set Screws sufficiently to hold the implant in position.

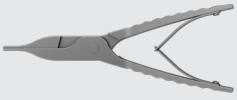




Compressor

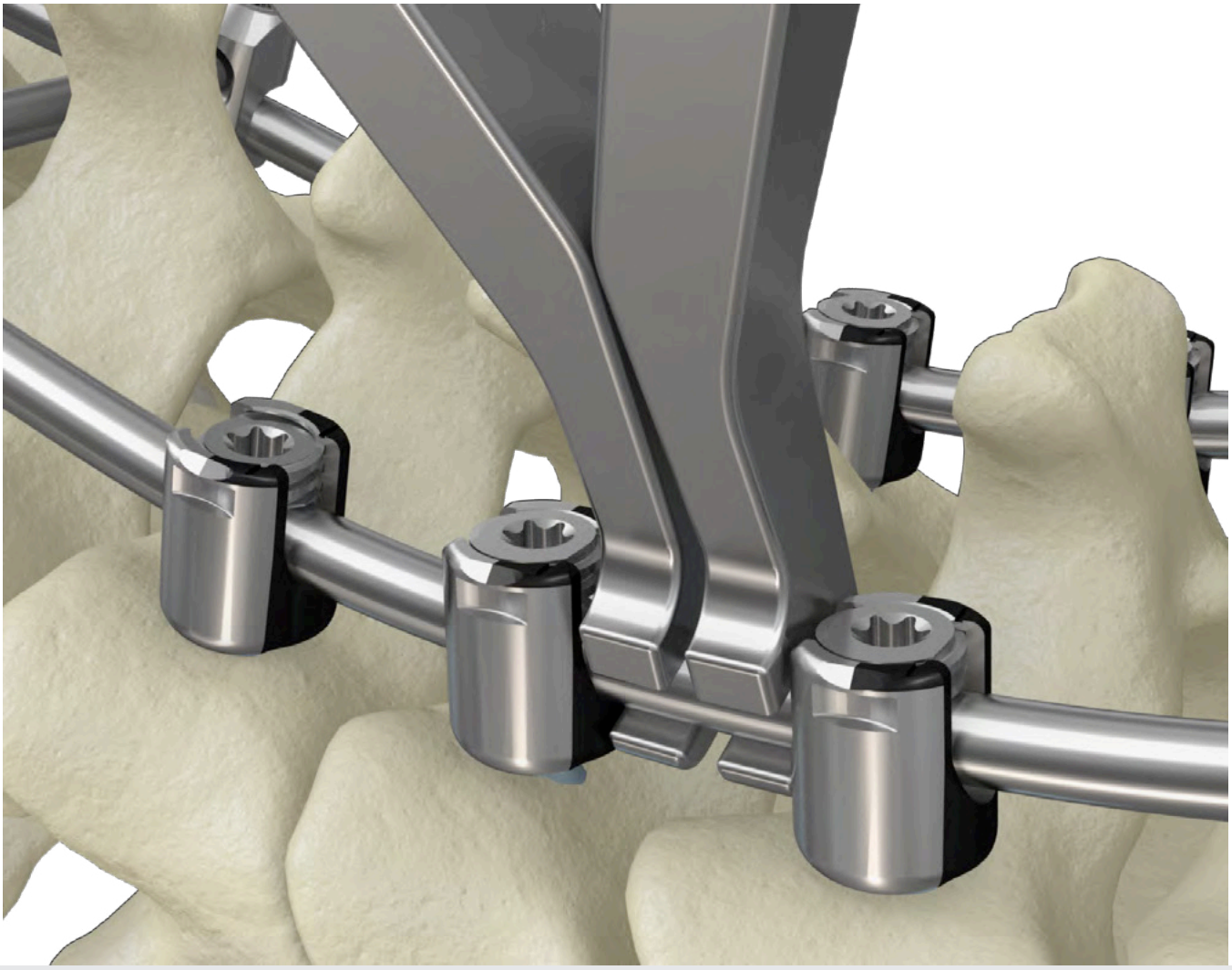


Distractor



In-situ bending

Once the rods have been placed in the implants and provisionally tightened, they may be contoured in-situ. To achieve additional correction in the sagittal plane, use the In-Situ Benders (Right and Left).



In-Situ Bender, Left

In-Situ Bender, Right

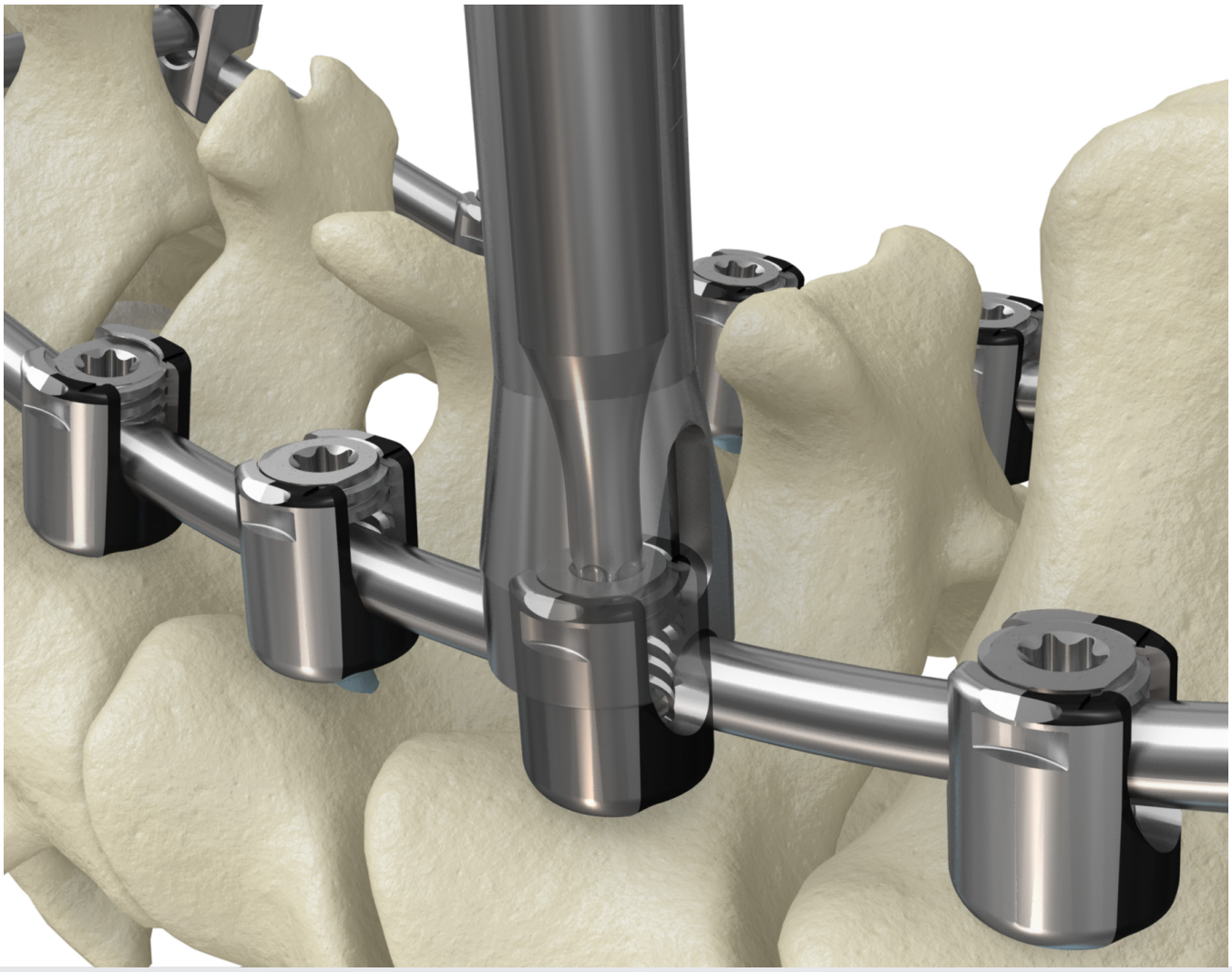
Step 10

Final locking

Final tightening of the Yukon implants is achieved utilizing the Anti-Torque Alignment Tube in conjunction with the Torque Limiting Shaft, Size 15, attached to the Torque Limiting Handle. Attach the Anti-Torque Alignment Tube onto the Yukon screw head and then slide the Torque Limiting Shaft assembly down. Final tightening may now be completed.

The Torque Limiting Handle is designed to achieve 2.2 N-m (19.5 in-lbs) of torque for final tightening. The Handle is designed to emit an audible "click" once the necessary torque is achieved.

Note: Do not exceed recommended torque or damage to the instrument may result.



Anti-Torque Alignment Tube

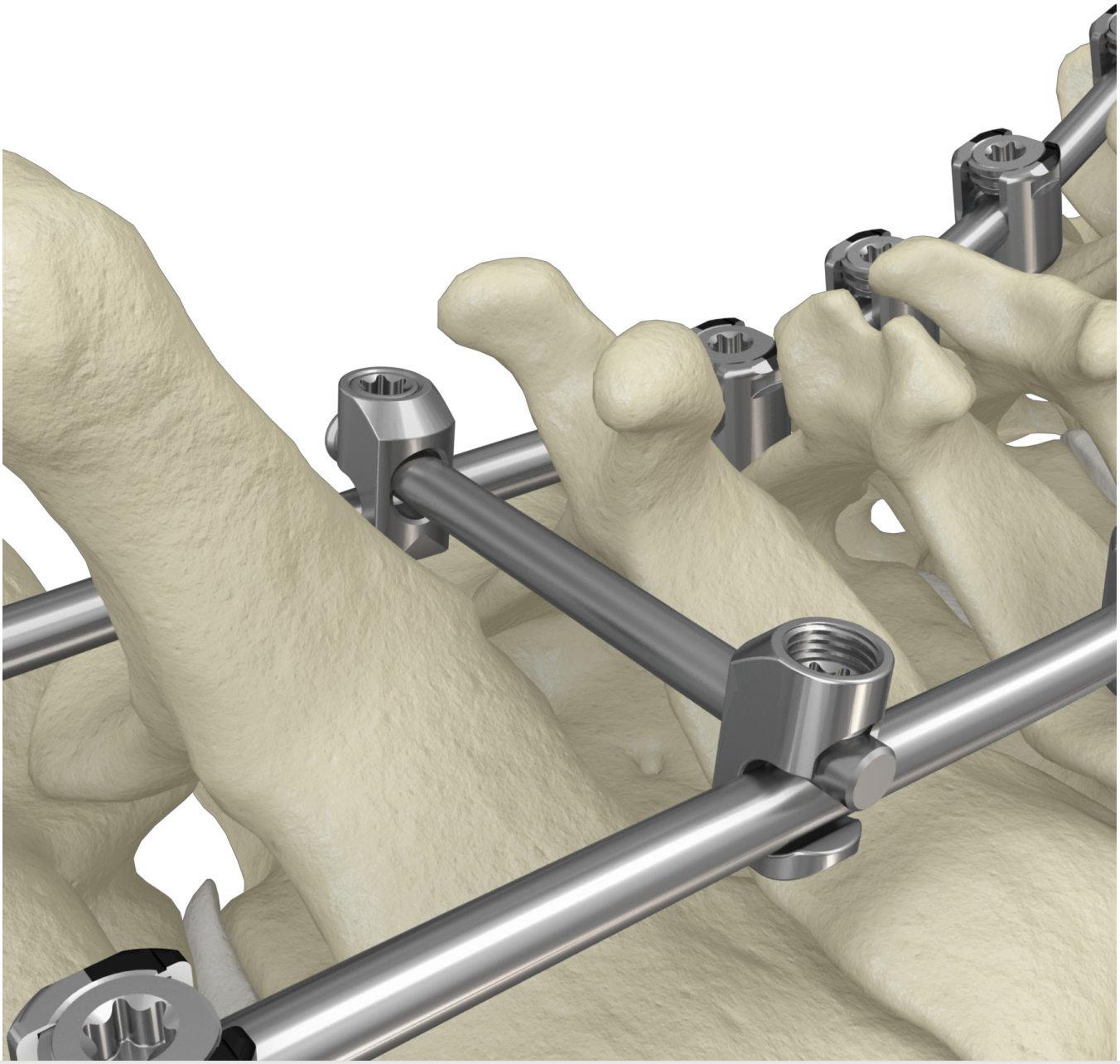
Torque Limiting Shaft, Size 15

Torque Limiting Handle, 2.2 Nm

Transverse Connectors

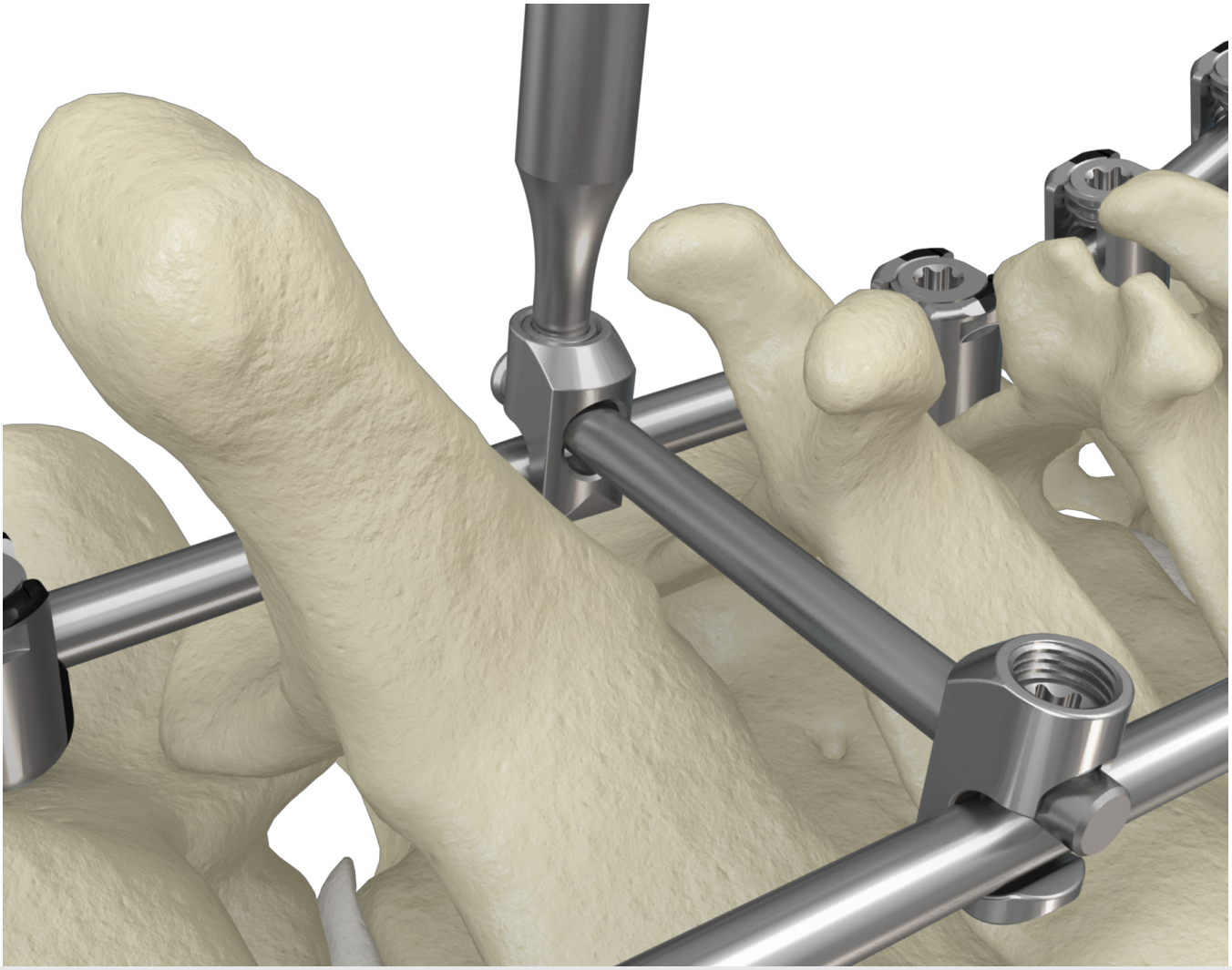
At the surgeon's discretion, a Transverse Connector may be used. Place the Transverse Connector Adjustable Hook over the longitudinal Rod. Insert the Ø3.5mm T-Bar through the head of the Transverse Connector Adjustable Hook. Provisionally tighten the set screw over the T-Bar. Repeat on the contralateral side.

Note: Do not exceed recommended torque or damage to the instrument may result.



Transverse Connectors (cont.)

Utilize the Torque Limiting Handle and Torque Limiting Shaft to final tighten both heads.



Torque Limiting Shaft, Size 15

Torque Limiting Handle, 2.2 Nm

Rod connection

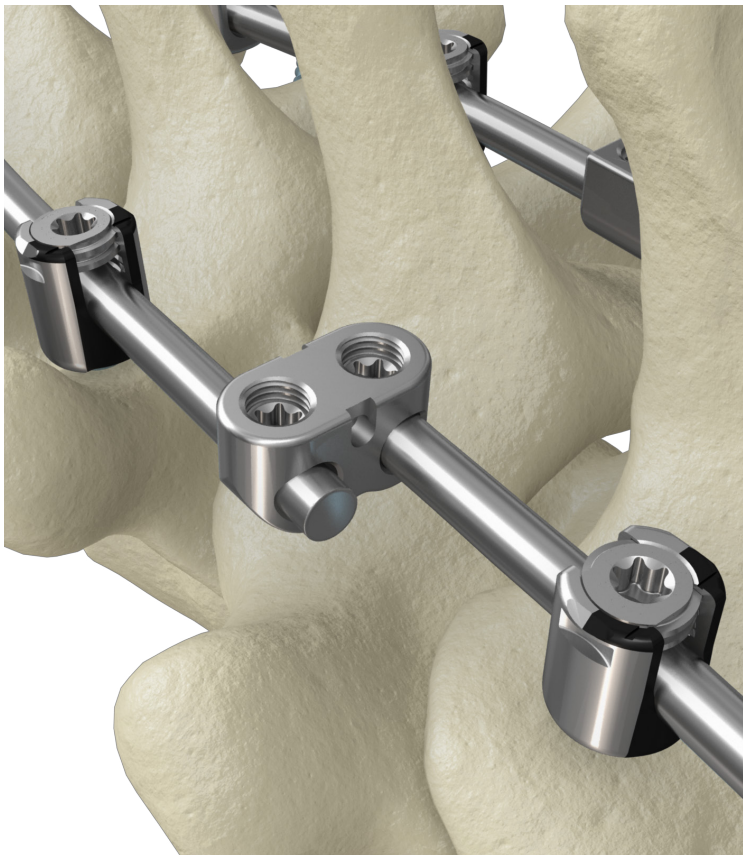
The Axial Connectors may be used to join two rods that are end-to-end. The implant is final tightened using the Torque Limiting Shaft attached to the Torque Limiting Handle.

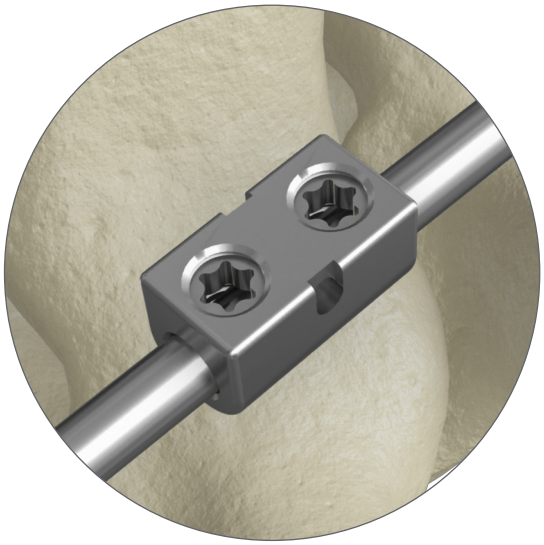
The Parallel Connectors may be used to join two rods that are parallel to one another. The implants are final tightened using the Torque Limiting Shaft attached to the Torque Limiting Handle.

Available in:

Parallel	**Axial**
Ø3.5/4.0mm Side/Closed	Ø3.5/4.0mm
Ø3.5/4.0mm Side/Side	Ø3.5/4.5–5.5/6.0mm
Ø3.5/4.0–5.5/6.0mm Closed	

Note: Do not exceed recommended torque or damage to the instrument may result.





Step 13

Optional step: hook placement

Hooks are typically placed caudal; however, in some instances they may be placed cranial. A division or removal of the ligamentum flavum and/or laminotomies is performed with Curettes and Kerrisons on the superior lamina to prepare the hook site.

The implant may be inserted with the Hook Holder by squeezing the Holder on the Hook head and then placing it onto the lamina. Once the Hooks are in place, seat the rod. For additional information on rod insertion, review Steps 4–6. Insert the Set Screw and turn a quarter turn to the left to seat the thread before provisionally tightening. Repeat these steps for further Hook placements.

Hook Holder

Optional step: screw insertion

After the screw pathway has been prepared and proper screw size has been determined, load the implant for screw insertion using a Yukon Screw Inserter. When loading the Yukon screws, grasp the implant by the screw shaft and give a slight rotation, while simultaneously applying a downward force to properly engage the screw. Once loaded, spin the knob located above the sleeve clockwise to secure the screw in place. The Yukon Screw Inserter has a BLACK sleeve for ease of identification.

Once the screw has been loaded, insert it into the pilot hole until desired depth is reached. Disengage the Screw Inserter by turning the knob above the sleeve counter-clockwise. Repeat until all screws are placed.

Note: The Yukon Screw Inserter can be used with either the Ratcheting Axial Handle or the Fixed Axial Handle.

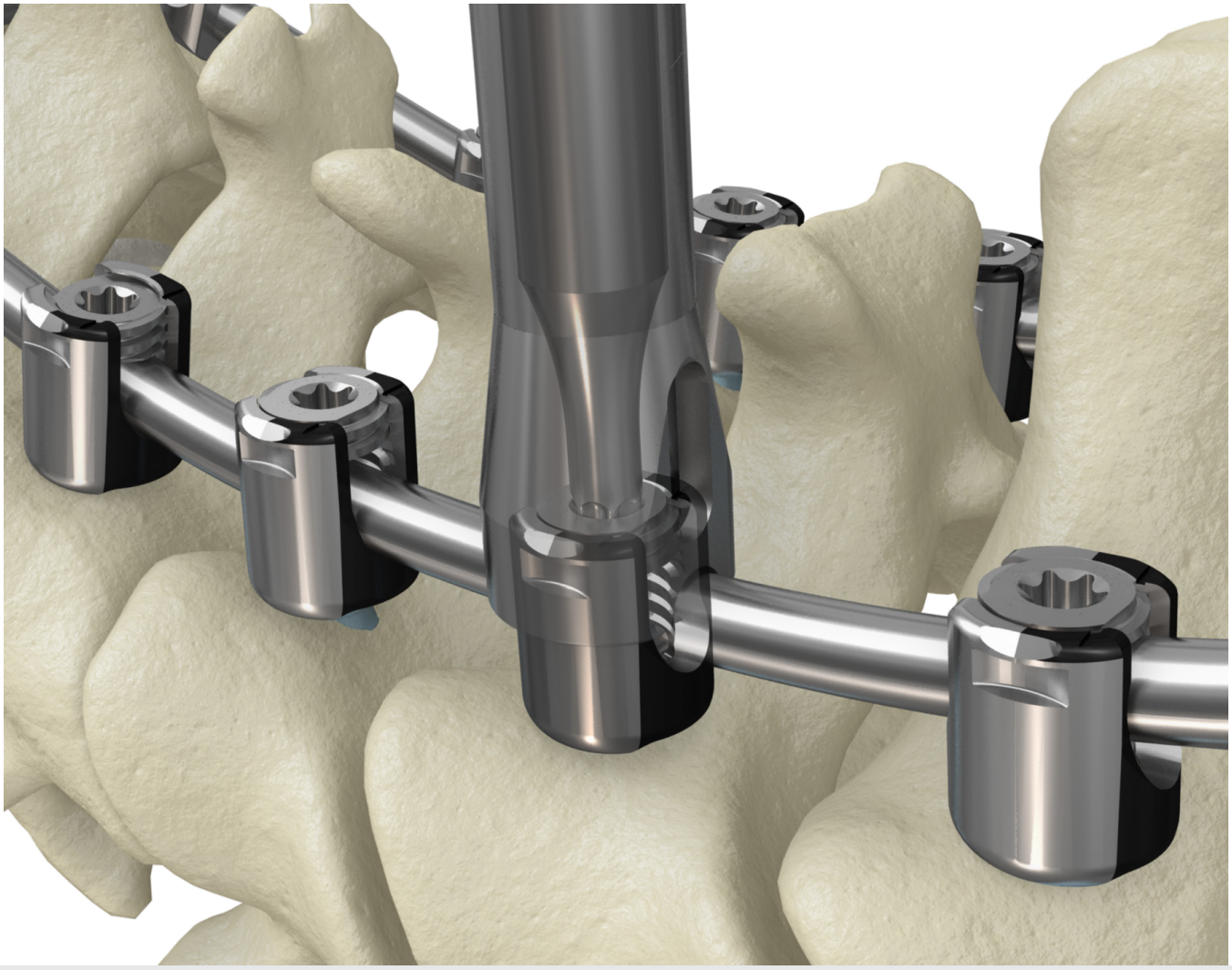
Note: Unique catalog revision numbers exist for each screw inserter.

Note: There is a laser marked line on the proximal end of the inner shaft that corresponds to the laser marked line on the outer shaft of the Yukon Screw Inserter (7601-90003) with the gold button on the thumb knob. There are no laser marked lines on the inner or outer shaft of the Yukon Screw Inserter (7601-90003) with no button on the thumb knob.

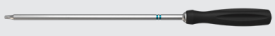
Step 15

Unlocking and removal instruments

Once the Yukon Set Screw has been final tightened, it may be loosened using the Provisional Screwdriver, Size 15 in conjunction with the Anti-Torque Alignment Tube.

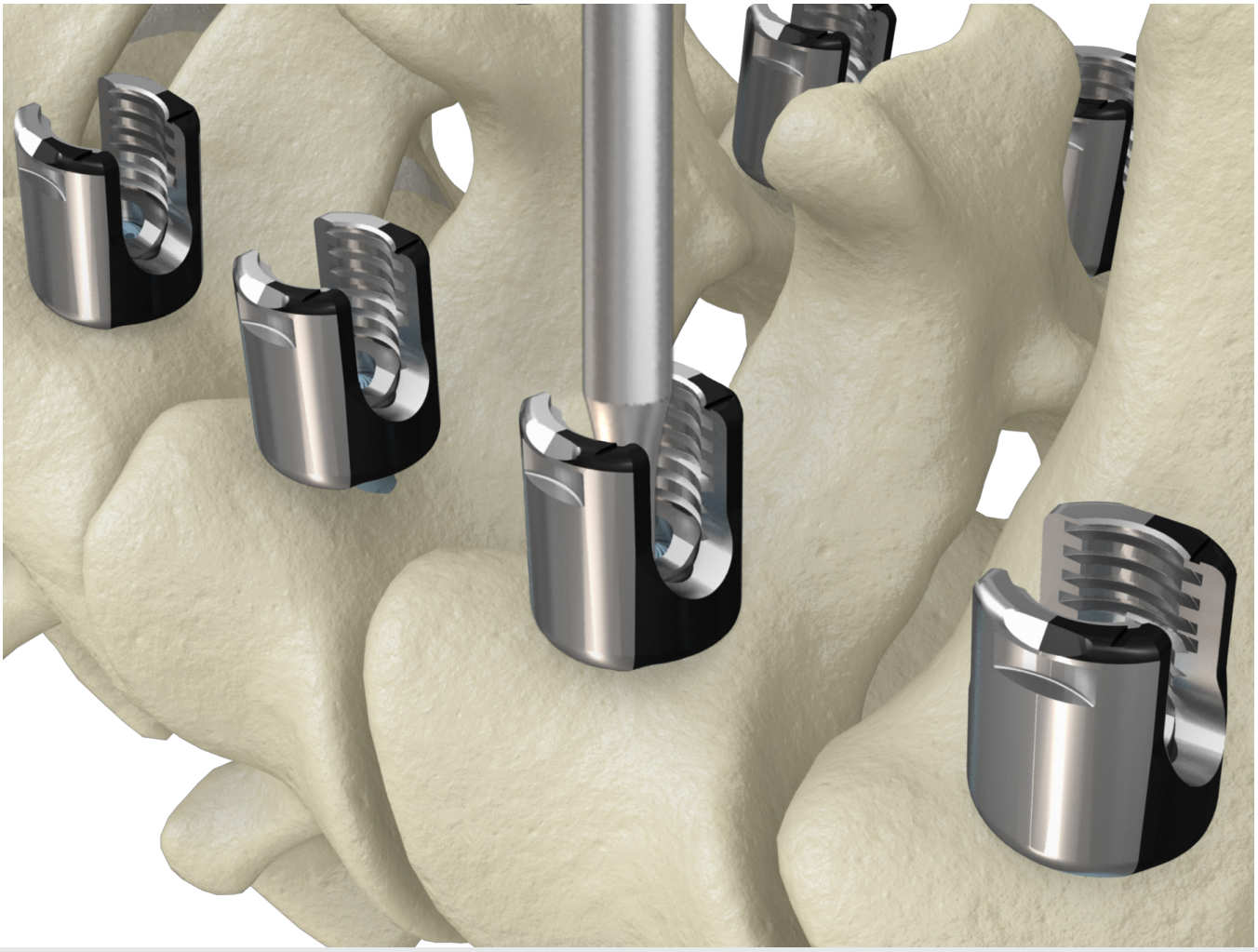


Provisional Screwdriver



Anti-Torque Alignment Tube

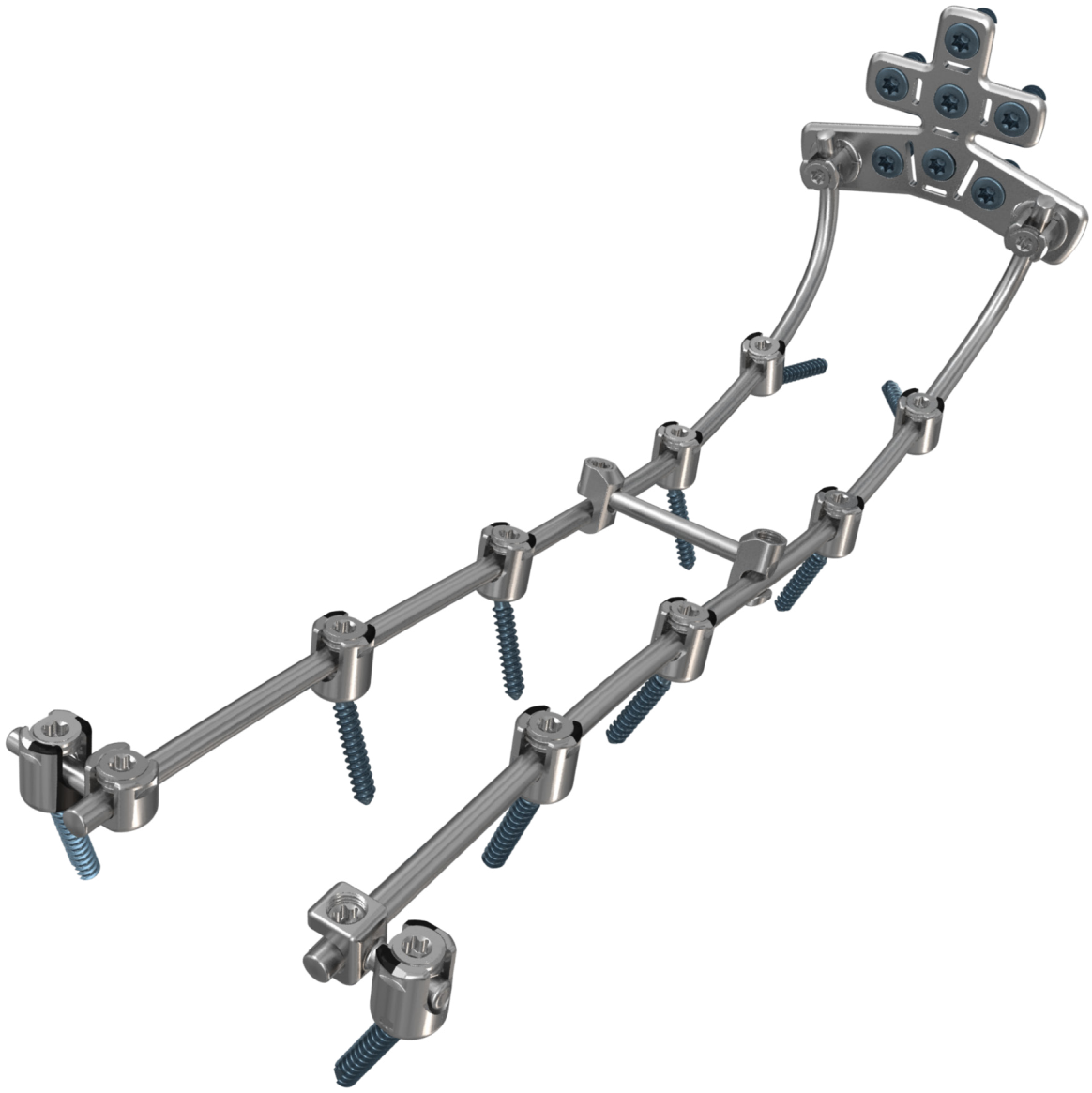
The screw height of the Yukon implants may be adjusted using the Screw Height Adjuster, Size 10 attached to either the Fixed Axial Handle or the Ratcheting Axial Handle. Insert the Screw Height Adjuster into the driving feature (hexalobe). Rotate counter-clockwise to remove.



Screw Height Adjuster

Fixed Axial Handle

Ratcheting Axial Handle



Product catalog

Catalog #	Description
7601-90054	Small Pedicle Probe
7601-90168	Mini Thoracic Probe
7601-90055	Awl
1101-90002	Ball Tip Probe
1101-90016	60mm Depth Gauge
1101-90017	Reamer
7601-90010	Ø2.8mm Adjustable Drill Bit

Catalog #	Description
7601-90009	Ø2.3mm Adjustable Drill Bit
7601-90004	Ø3.0mm Tap
7601-90005	Ø3.5mm Tap
7601-90006	Ø4.0mm Tap
7601-90007	Ø4.5mm Tap
7601-90008	Ø5.0mm Tap

Small Pedicle Probe

Mini Thoracic Probe

Awl

Ball Tip Probe

60mm Depth Gauge

Reamer

Ø2.8mm Adjustable Drill Bit

Ø2.3mm Adjustable Drill Bit

Ø3.0mm Tap

Ø3.5mm Tap

Ø4.0mm Tap

Ø4.5mm Tap

Ø5.0mm Tap

Instruments

Catalog #	Description
7601-90169	Ratcheting Axial Handle
7601-90170	Fixed Axial Handle
7601-90085	Tap Sleeve
7601-90171	Adjustable Drill Guide

Catalog #	Description
1101-90020	Screw Height Adjuster, Size 10
7601-90003	Screw Inserter*
7601-90000	Head Adjuster
7601-90092	Provisional Screwdriver, Size 15, Tapered

*Unique catalog revision numbers exist for each screw inserter. Please contact your local sales consultant with any questions you may have about ordering the Yukon Instruments.

Ratcheting Axial Handle

Fixed Axial Handle

Tap Sleeve

Adjustable Drill Guide

Screw Height Adjuster, Size 10

Screw Inserter*

Head Adjuster

Provisional Screwdriver, Size 15, Tapered

Catalog #	Description
7601-90103	Torque Limiting Shaft, Size 15
7601-90138	Torque Limiting Handle, 2.2 N-m
7601-90001	Anti-Torque Alignment Tube

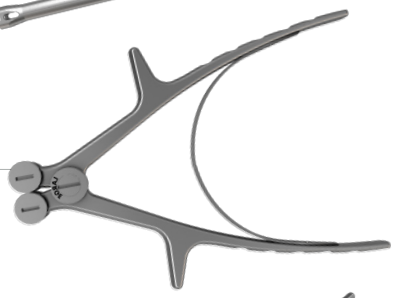
Catalog #	Description
7601-90134	Ø3.5/4.0mm Rod Bender
7601-90075	In-Situ Ø3.5/4.0 Rod Cutter
1101-90025	Rod Holding Forceps

Torque Limiting Shaft, Size 15

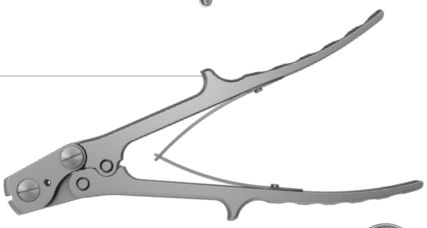
Torque Limiting Handle, 2.2 N-m

Anti-Torque Alignment Tube

Ø3.5/4.0mm Rod Bender



In-Situ Ø3.5/4.0 Rod Cutter



Rod Holding Forceps

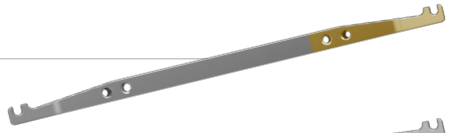
Instruments

Catalog #	Description
7601-90056	Rod Vise Grips, Ø3.5/4.0mm
7601-90051	In-Situ Bender, Right
7601-90052	In-Situ Bender, Left
7601-90077	Distractor

Catalog #	Description
1101-90022	Rod Template, 80mm
1101-90068	Rod Template, 200mm
7601-90049	Compressor
7601-90002	Rod Fork

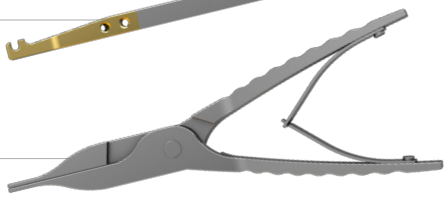
Rod Vise Grips, Ø3.5/4.0mm

In-Situ Bender, Right



In-Situ Bender, Left

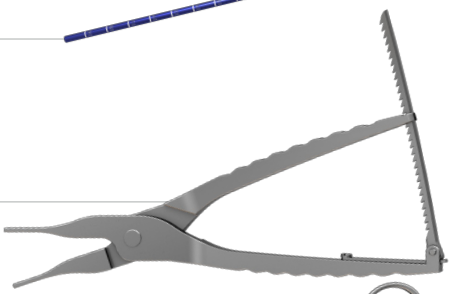
Distractor



Rod Template, 80mm

Rod Template, 200mm

Compressor



Rod Fork

Catalog #	Description
7601-90053	Pistol Grip Rod Reducer
7601-90088	Sequential Reducer
7601-90089	Reducer Tube
7601-90090	Tube Chuck
7601-90050	Offset Hook Holder

Catalog #	Description
7601-90018	Hook Holder
101-90220	Connector Holder
7601-90070	Hook Pusher
7601-90059	Hook Trial, 3.5 x 6.0mm

Pistol Grip Rod Reducer

Sequential Reducer

Reducer Tube

Tube Chuck

Offset Hook Holder

Hook Holder

Connector Holder

Hook Pusher

Hook Trial, 3.5 x 6.0mm

Instruments

Catalog #	Description
*See Note	Polyaxial Screw
*See Note	Polyaxial Screw, ML
*See Note	Polyaxial Screw, LS

*Unique catalog numbers exist for each screw length in each diameter. Please contact your local sales representative with any questions you may have about ordering the Yukon OCT Spinal System implants.

**There are sterile versions available for some Yukon implants. Please contact your local sales consultant about any questions you may have about ordering these sterile implants.

Polyaxial Screw

Diameter	Length
Ø3.5	10–50mm, in 2mm increments
Ø4.0	10–50mm, in 2mm increments
Ø4.5	20–50mm, in 2mm increments
Ø5.0	20–50mm, in 2mm increments

Polyaxial Screw, ML

Diameter	Length
Ø3.5	12–24mm, in 2mm increments
Ø4.0	12–26mm, in 2mm increments
Ø4.5	20, 24, 30, 34, 40, and 44mm
Ø5.0	24, 28, 30, and 34mm

Polyaxial Screw, LS

Diameter	Length
Ø3.5	16–40mm, in 2mm increments
Ø4.0	16–40mm, in 2mm increments

Catalog #	Description
7601-10001	Set Screw
*See Note	Ø3.5 and Ø4.0mm Straight Rods
*See Note	Ø3.5 and Ø4.0mm Contoured Rods

*Unique catalog numbers exist for each rod length in each diameter. Please contact your local sales representative with any questions you may have about ordering the Yukon OCT Spinal System implants.

**There are sterile versions available for some Yukon implants. Please contact your local sales consultant about any questions you may have about ordering these sterile implants.

Catalog #	Description
1101-535300-55	Ø3.5–Ø5.5mm Transitional Rod x 300mm
1101-535500-55	Ø3.5–Ø5.5mm Transitional Rod x 500mm
7601-540300-55	Ø4.0–Ø5.5mm Transitional Rod x 300mm
7601-540500-55	Ø4.0–Ø5.5mm Transitional Rod x 500mm
7601-540500-60	Ø4.0–Ø6.0mm Transitional Rod x 500mm
1111-B35500	Straight Rod, Dual Hex, Ø3.5 x 500, CoCr
7611-B40500	Straight Rod, Dual Hex, Ø4.0 x 500, CoCr
7611-540500-55	Ø4.0–Ø5.5mm Transitional Rod x 500mm

Set Screw

Straight Rod

Contoured Rod

Transition Rod, Ø3.5-Ø5.5

Transition Rod, Ø4.0-Ø5.5

Straight Rod, Dual Hex, Ø3.5mm CoCr

Straight Rod, Dual Hex, Ø4.0mm CoCr

Implants

Catalog #	Description
7601-70000	Transverse Connector – Adjustable Hook
7601-70001	Transverse Connector – T-Bar, 30mm
7601-70004	Transverse Connector – T-Bar, 60mm
7601-72131H	Head to head Connector Plate (S)
7601-72939H	Head to head Connector Plate (M)
7601-73510	Lateral Offset Connector, Open, Ø3.5/4.0mm 10mm

Catalog #	Description
7601-73515S	Lateral Offset Connector Slide, 15mm
7601-73520A	Lateral Offset Connector, Side Loading Angled, 20mm
7601-73747H	Head to head Connector Plate (L)
7601-74555H	Head to head Connector Plate (XL)

**There are sterile versions available for some Yukon implants. Please contact your local sales consultant about any questions you may have about ordering these sterile implants.

Transverse Connector – Adjustable Hook

Transverse Connector – T-Bar, 30mm

Transverse Connector – T-Bar, 60mm

Catalog #	Description
7601-83535D	Axial Connector, Ø3.5/4.0mm
1101-83560D	Axial Connector, Ø3.5/4.0–Ø5.5/6.0mm
7601-83535E	Parallel Connector, Ø3.5/4.0mm Side/Closed
7601-83535F	Parallel Connector, Ø3.5/4.0mm Side/Side
1101-83560A	Parallel Connector, Ø3.5/4.0–Ø5.5/6.0mm Closed/Closed

Catalog #	Description
7601-83535A	Parallel Connector, Closed, Ø3.5/4.0mm, 4 Screw
7601-83535B	Parallel Connector, Closed, Ø3.5/4.0mm
7601-83535C	Parallel Connector, Open/Closed, Ø3.5/4.0mm
7601-83535W	Parallel Connector, Open, Ø3.5/4.0mm

**There are sterile versions available for some Yukon implants. Please contact your local sales consultant about any questions you may have about ordering these sterile implants.

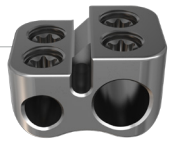
Axial Connector, Ø3.5/4.0mm

Axial Connector, Ø3.5/4.0–Ø5.5/6.0mm

Parallel Connector, Ø3.5/4.0mm Side/Closed

Parallel Connector, Ø3.5/4.0mm Side/Side

Parallel Connector, Ø3.5/4.0–Ø5.5/6.0mm Closed/Closed



Implants

Catalog #	Description
7601-73510S	Lateral Offset Connector, 10mm, Side
7601-73530	Lateral Offset Connector, 30mm, Open
7601-80002	Posterior Cervical Hook, 3.5 x 6.0mm, Laminar
7601-80001	Posterior Cervical Hook, 3.5 x 4.5mm, Laminar
7601-80003	Posterior Cervical Hook, Laminar, 3.5 x 8.0mm
7601-80019	Posterior Cervical Hook, 3.5 x 4.5mm TP
7601-80020	Posterior Cervical Hook, 3.5 x 6.0mm TP

Catalog #	Description
7601-80021	Posterior Cervical Hook, 3.5 x 8.0mm TP
7601-80023	Posterior Cervical Hook, 5.0 x 4.5mm, TP
7601-80024	Posterior Cervical Hook, 5.0 x 6.0mm, TP
7601-80027	Posterior Cervical Hook, 3.5 x 4.5mm, ML Laminar
7601-80028	Posterior Cervical Hook, 3.5 x 6.0mm, ML Laminar
7601-80029	Posterior Cervical Hook, Laminar, 3.5 x 8.0mm ML

**There are sterile versions available for some Yukon implants. Please contact your local sales consultant about any questions you may have about ordering these sterile implants.

Lateral Offset Connector, 10mm, Side

Lateral Offset Connector, 30mm, Open

Posterior Cervical Hook, 3.5 x 6.0mm, Laminar

Posterior Cervical Hook, 3.5 x 6.0mm, ML Laminar

Posterior Cervical Hook, 3.5 x 4.5mm, Laminar

Posterior Cervical Hook, 5.0 x 4.5mm, TP

Posterior Cervical Hook, 5.0 x 6.0mm, TP

Posterior Cervical Hook, 3.5 x 4.5mm, ML Laminar

Posterior Cervical Hook, 5.0 x 4.5mm, ML TP

Catalog #	Description
7601-80033	Posterior Cervical Hook, Laminar, 5.0 x 8.0mm ML
7601-80034	Posterior Cervical Hook, 3.5 x 3.5mm ML TP
7601-80035	Posterior Cervical Hook, 3.5 x 4.5mm ML TP
7601-80036	Posterior Cervical Hook, 3.5 x 6.0mm ML TP
7601-80037	Posterior Cervical Hook, 3.5 x 8.0mm ML TP
7601-80038	Posterior Cervical Hook, 5.0 x 3.5mm ML TP
7601-80039	Posterior Cervical Hook, 5.0 x 4.5mm, ML TP
7601-80008	Mini Deformity Hook Angled Right, Ø3.5/4.0
7601-80009	Mini Deformity Hook Angled Left, Ø3.5/4.0
7601-80010	Mini Deformity Hook Pedicle, 3.5 x 3.5mm

Catalog #	Description
7601-80011	Mini Deformity Hook Pedicle, 3.5 x 4.5mm
7601-80012	Mini Deformity Hook Pedicle, 3.5 x 6.0mm
7601-80014	Mini Deformity Hook, 5.0 x 3.5mm, Pedicle
7601-80043	Mini Deformity Hook Infralaminar, 3.5 x 4.5mm
7601-80045	Mini Deformity Hook Infralaminar, 3.5 x 8.0mm
7601-80047	Mini Deformity Hook Infralaminar, 5.0 x 4.5mm
7601-80049	Mini Deformity Hook Infralaminar, 5.0 x 8.0mm

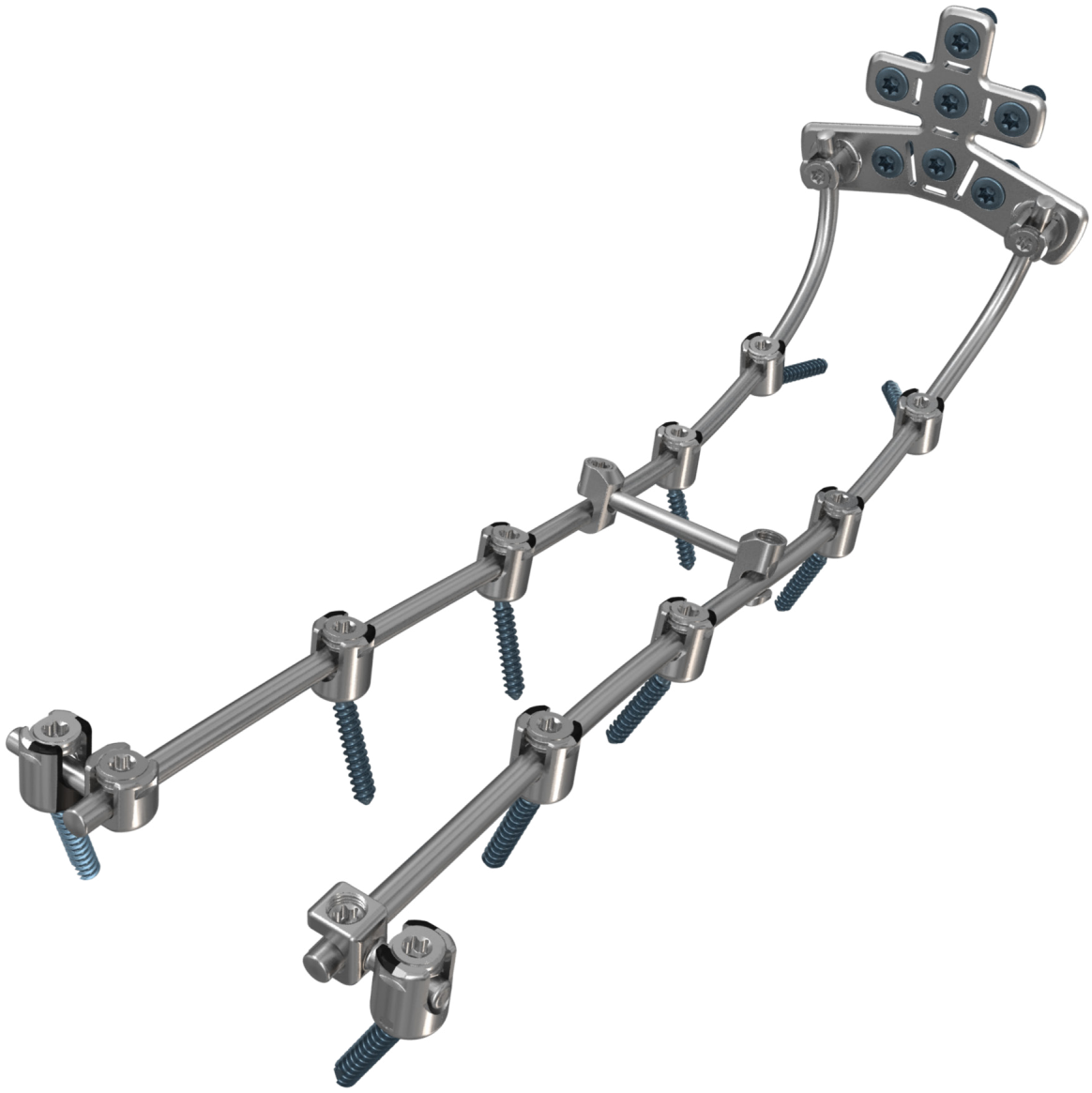
**There are sterile versions available for some Yukon implants. Please contact your local sales consultant about any questions you may have about ordering these sterile implants.

Posterior Cervical Hook, 5.0 x 4.5mm, ML TP

Mini Deformity Hook, 5.0 x 3.5mm, Pedicle

Torque specification

Catalog #	Description	Torque values and accuracy
7601-90138	Torque Limiting Handle, 2.2N-m	2.25 ± 0.225 Nm (10%)



Instructions for use

ENGLISH

YUKON OCT SPINAL SYSTEM

STERILE/NON-STERILE

IFU Reference Number: **PI060-2EN-02 Rev 0**

K2M, Inc.
600 Hope Parkway SE
Leesburg, VA 20175
USA
Toll Free: 1-866-526-4171
Fax: 1-703-777-4338

BEFORE USING PRODUCT, READ THE FOLLOWING INFORMATION

IMPORTANT

This booklet is designed to assist in using the YUKON OCT Spinal System. It is not a reference for surgical techniques.

CAUTION: Federal law (USA) restricts this device to sale and use by, or on the order of, a physician.

DESCRIPTION

The Yukon Spinal System is a top-loading, multiple component, posterior (cervical/ thoracic) spinal fixation system which consists of pedicle screws, rods, hooks, rod connectors and occipital fixation components.

INDICATIONS

The YUKON OCT Spinal System is 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 (C1to 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 spine; and degenerative disease, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies, and degenerative disease of the facets with instability.

The YUKON OCT Spinal System is also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion.

In order to achieve additional levels of fixation, the YUKON OCT Spinal System may be connected to Everest, Mesa and Denali Spinal System components via the rod to rod connectors or transition rods.

MATERIALS

All implant components are manufactured from Titanium and Cobalt Chrome per ASTM and ISO standards.

CLEANING/ REPROCESSING

K2M reusable devices are supplied non-sterile must be thoroughly cleaned prior to sterilization. The following instructions are recommended for Manual or Automated cleaning. Thermal disinfection may be also be performed to render the devices safe for handling however sterilization must be performed as a final step in reprocessing.

Point of Use

Contaminated instruments should be wiped clean of visible soil at the point of use, to prevent drying of soil and contaminants in and on the device. Flush cannulated devices with sterile or purified water to prevent the drying of soil and/or debris on the inside.

Manual Cleaning Steps

1. PREPARE low foaming pH neutral enzymatic detergent per manufacturer's recommendation. Presoak the instruments for the specified time or a minimum of 5 minutes, whichever is longer.
2. MANUALLY clean instruments using a soft-bristled brush and/or soft lint-free cloth.
3. PAY ATTENTION to instruments with crevices, interfaces, cannulations and moving parts. Actuate device (if applicable) and use an appropriately sized lumen brush to clean all cannulas.
4. RINSE parts under warm running tap water for 1 minute.
5. REPEAT the process until no visible debris remains.
6. PREPARE pH neutral detergent for ultrasonic cleaning per manufacturer's recommendations. Immerse the articles into the prepared detergent solution and allow the articles to sonicate for 10 minutes.
7. REMOVE the instruments from the sonicator and rinse under warm tap water for a minimum of 1 minute.
8. RINSE the instruments under running reverse osmosis/deionized (RO/DI) water for a minimum of 1 minute.
9. VISUALLY inspect each instruments for visible soil. If visible soil is noticed contact the sponsor.
10. DRY using a clean, soft, lint-free single use cloth.

Automated Cleaning Steps

PERFORM steps 1-5 of Manual Cleaning steps.

6. PROCESS in washer-disinfector using the following cycle parameters.

PHASE	RECIRCULATION TIME (min)	TEMPERATURE	DETERGENT TYPE
Pre-Wash	2 minutes	cold tap water	N/A
Enzyme Wash	4 minutes	hot tap water	neutral pH
Detergent Wash	2 minutes	65.5°C	neutral pH
Rinse	15 seconds	hot tap water	N/A
Drying	6 minutes	98.8°C	N/A
Thermal Disinfection* (optional)	2 minutes 30 seconds	93°C	N/A

7. VISUALLY inspect each test article for visible soil. If visible soil is noticed contact your local K2M sales representative.
8. DRY using a clean, soft, lint-free single use cloth.

**Note: Sterilization must also be performed following thermal disinfection.*

STERILIZATION

Non-Sterile Devices

Packaged components are packaged individually in sealed poly bags. **Unless specifically labeled sterile, the implants and instruments are supplied NONSTERILE and MUST be sterilized prior to use.** Recommended sterilization methods include steam autoclaving after removal of all protective packaging and labeling. The following steam autoclave cycles were validated to an SAL of 10^{-6} using the biological indicator (BI) overkill method however sterilization should be in accordance with the sterilizer manufacturer's instructions and the institution's procedures for assuring sterility.

	Autoclave Cycle	Temperature	Time	Drying Time
USA	Prevacuum	270°F (132°C)	4 minutes	30 minutes

Usage of an FDA cleared wrap to ensure that the device is actually sterile prior to implantation is recommended.

Use caution during sterilization and storage. Do not allow contact with metal or other hard objects that could damage the finish or prevent proper use. (See Preoperative Warnings and Precautions).

Sterile Devices

Components labeled as STERILE were sterilized by gamma irradiation.

CAUTION: Do not use if package is damaged. If the tamper proof seals or sterile packaging appear to be compromised or damaged, return the package and its contents to K2M.

CAUTION: The implants are intended for single use only. Do not attempt to clean or resterilize the implants. Reprocessing of single use devices may introduce risks associated with guaranteeing sterility assurance.

STORAGE

Store sterile packages in a well-ventilated area that provides protection from dust, insects, moisture, and vermin. Store at ambient temperature.

INSTRUCTIONS FOR USE

(For complete instructions refer to the appropriate surgical technique provided by your local K2M sales representative.)

CONTRAINDICATIONS

1. The YUKON OCT Spinal System is contraindicated in the presence of infection, pregnancy, metabolic disorders of calcified tissues, grossly distorted anatomy, inadequate tissue coverage, drug/ alcohol abuse, mental illness, general neurological conditions, immunosuppressive disorders, patients with known sensitivity to materials in the device, obesity, patients who are unwilling to restrict activities or follow medical advice, and any condition where the implants interfere with anatomical structures or precludes the benefit of spinal surgery.
2. Biological factors such as smoking, use of nonsteroidal anti-inflammatory agents, the use of anticoagulants, etc. all have a negative effect on bony union. Contraindications may be relative or absolute and must be carefully weighed against the patient's entire evaluation.
3. This device is not intended for use except as indicated.

POTENTIAL ADVERSE EVENTS

1. Potential adverse events include, but are not limited to pseudoarthrosis; loosening, bending, cracking or fracture of components, or loss of fixation in the bone with possible neurologic damage, usually attributable to pseudoarthrosis, insufficient bone stock, excessive activity or lifting, or one or more of the factors listed in Contraindications, or Warnings and Precautions; infections possibly requiring removal of devices; palpable components, painful bursa, and/or pressure necrosis; and allergies, and other reactions to device materials which, although infrequent, should be considered, tested for (if appropriate), and ruled out preoperatively.
2. Potential risks also include those associated with any spinal surgery resulting in neurological, cardiovascular, respiratory, gastrointestinal or reproductive compromise, or death.

WARNINGS AND PRECAUTIONS

Pedicle Screw Spinal Systems

WARNING: 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.

The safety and effectiveness of these devices for any other conditions are unknown.

The implants are for single use only and are not designed to be combined with devices from other manufacturers.

PRECAUTION: 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 implant diameter and length.

The surgeon should refer to the product labeling for details on use of this spinal system and the associated instrumentation to facilitate correct selection and placement of the implants. The size and shape of bones and soft tissue place limitations on the size and strength of the implants and proper selection will reduce the risk of neurological injury during implantation as well as metal fatigue leading to bending or breakage of the device.

Temporary Metallic Internal Fixation Devices

1. Patient selection and compliance is extremely important. Spinal implant surgery on patients with conditions listed under Contraindications may not be candidates for this procedure. The patient must be made aware of the limitations of the implant and that physical activity and load bearing have been implicated in premature loosening, bending or fracture of internal fixation devices. The patient should understand that a metallic implant is not as strong as a normal, healthy bone and will fracture under normal load bearing in the absence of complete bone healing. An active, debilitated or uncooperative patient who cannot properly restrict activities may be at particular risk during postoperative rehabilitation.
2. Potential risks identified with the use of this device system which may require additional surgery include device component failure, loss of fixation, non-union, fracture of the vertebra, and neurological, vascular or visceral injury.
3. Cutting, bending, or scratching the surface of metal components can significantly reduce the strength and fatigue resistance of the implant system and should be avoided where possible. These, in turn may cause cracks and/or internal stresses that are not obvious to the eye and may lead to fracture of the components. Especially avoid sharp or reverse bends and notches.
4. Special protection of implants and instruments during storage is recommended when exposed to corrosive environments such as moisture, salt, air, etc.
5. Implanting metals and alloys in the human body subjects them to a constantly changing environment of salts, acids and alkalis which can cause corrosion. Putting dissimilar metals in contact with each other can accelerate the corrosion process which in turn may enhance fatigue fractures of implants. Thus every effort should be made to use compatible metals and alloys. Fretting or wear at the interface between components of a device may also accelerate the corrosion process and may lead to the generation of wear debris which has been associated with localized inflammatory response.
6. The K2M spinal implants are intended to provide temporary stabilization. If an implant remains implanted after complete healing it can actually increase the risk of refracture in an active individual. The surgeon should weigh the risks versus the benefits when deciding whether to remove the implant.
7. Surgical implants must never be reused. An explanted metal implant should never be reimplanted.

   Even though the device appears undamaged, it may have small defects and internal stress patterns which may lead to early breakage.

MRI SAFETY INFORMATION

Non-clinical testing and in-vivo electromagnetic simulations demonstrated that the K2M Pedicle Screw System is MR Conditional. A patient with this device can be scanned safely in an MR system immediately after placement under the following conditions:

- Static magnetic field of 1.5-Tesla and 3-Tesla, only
- Maximum spatial gradient magnetic field of 3000 Gauss/cm or less
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 1-W/kg for 15 minutes of scanning in the Normal Operating Mode of operation for the MR system
- Under the scan conditions defined, the K2M Pedicle Screw System is expected to produce a maximum temperature rise of 3.92 ˚C after 15-minutes of continuous scanning.

Artifact Information

In non-clinical testing, the image artifact caused by the K2M Pedicle Screw System extends approximately 40 mm from this implant when imaged using a gradient echo pulse sequence and a 3-Tesla MR system.

PREOPERATIVE

1. Patient conditions and/or predispositions such as those previously addressed in Contraindications and Warnings and Precautions should be avoided.
2. Preoperative testing (simple bend and where necessary, stretch testing) should identify degree of correction possible without neurological damage and levels to be spanned using techniques similar to other spinal fusion procedures.
3. Use care in handling and storage of the implants. Prior to surgery components should be inspected for any evidence of damage or corrosion.
4. An adequate inventory of implant sizes should be available at the time of the surgery.
5. All components should be cleaned and sterilized before use.
6. Before the initial experience we recommend that the surgeon critically review all available information and consult with other surgeons having experience with the device.
7. Pre-Operative: Use of cross sectional imaging (i.e., CT and/or MRI) for posterior cervical screw placement is recommended due to the unique risks in the cervical spine. The use of planar radiographs alone may not provide the necessary imaging to mitigate the risk of improper screw placement. In addition, use of intraoperative imaging should be considered to guide and/or verify device placement, as necessary.

OPERATIVE

1. The primary goal of this surgery is to arthrodese selected vertebrae. Adequate exposure, bony preparation and grafting are essential to achieving this result.
2. Rods and plates may be prebent to the degree of correction determined by preoperative testing however reverse bends should be avoided.
3. The use of two rods and crosslinking the rods will provide a more rigid construct.
4. The placement of screws should be checked radiographically prior to assembly of the rod construct.
5. Care should be taken when positioning the implants to avoid neurological damage.

POSTOPERATIVE

1. Adequately instruct the patient. Postoperative care and the patient's ability and willingness to follow instructions are two of the most important aspects of successful healing.
2. Internal fixation devices are load sharing devices which maintain alignment until healing occurs. If healing is delayed or does not occur the implant could eventually break, bend or loosen. Loads produced by load bearing and activity levels will impact the longevity of the implant.
3. Metallic implants can loosen, fracture, corrode, migrate, cause pain, or stress shield bone even after a bone has healed. If an implant remains implanted after complete healing, it can actually increase the risk of refracture in an active individual. The surgeon should weigh the risks versus benefits when deciding whether to remove the implant. Implant removal should be followed by adequate postoperative management to avoid refracture.

4. Periodic X-rays for at least the first year postoperatively are recommended for close comparison with postoperative conditions to detect any evidence of changes in position, nonunion, loosening, and bending or cracking of components. With evidence of these conditions, patients should be closely observed, the possibilities of further deterioration evaluated, and the benefits of reduced activity and/or early revision considered.
5. Surgical implants must never be reused. An explanted metal implant should never be reimplanted. Even though the device appears undamaged, it may have small imperfections and internal stress patterns which may lead to early breakage.

SYMBOL KEY

This key contains all symbols used by K2M. Only symbols within the IFU text and on device label apply to the system listed in "IMPORTANT" section of the IFU.

	Manufacturer		Consult Instructions For Use
			Caution: Consult Accompanying Documentation
	Lot Number		Non-sterile
	Catalog Number		Do Not Reuse
	Use-by Date		
	Sterile		Sterilized Using Irradiation
	Sterilized Using Ethylene Oxide		Do Not Resterilize
	Do Not Use If Package Is Damaged		Temperature Limit

PI060-2EN-02 Rev 0
Stryker Spine
600 Hope Parkway SE
Leesburg, VA 20175
t: 571.919.2000
http://www.stryker.com

Notes

stryker

Spine division

A surgeon must always rely on his or her own professional clinical judgment when deciding whether to use a particular product when treating a particular patient. Stryker does not dispense medical advice and recommends that surgeons be trained in the use of specific products before using them in surgery.

The information presented is intended to demonstrate the breadth of Stryker product offerings. A surgeon must always refer to the package insert, product label and/or instructions for use before using any Stryker product. Products may not be available in all markets because product availability is subject to the regulatory and/or medical practices in individual markets. Please contact your Stryker representative if you have questions about the availability of Stryker products in your area.

YUKON-ST-4_Rev-2_34801

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