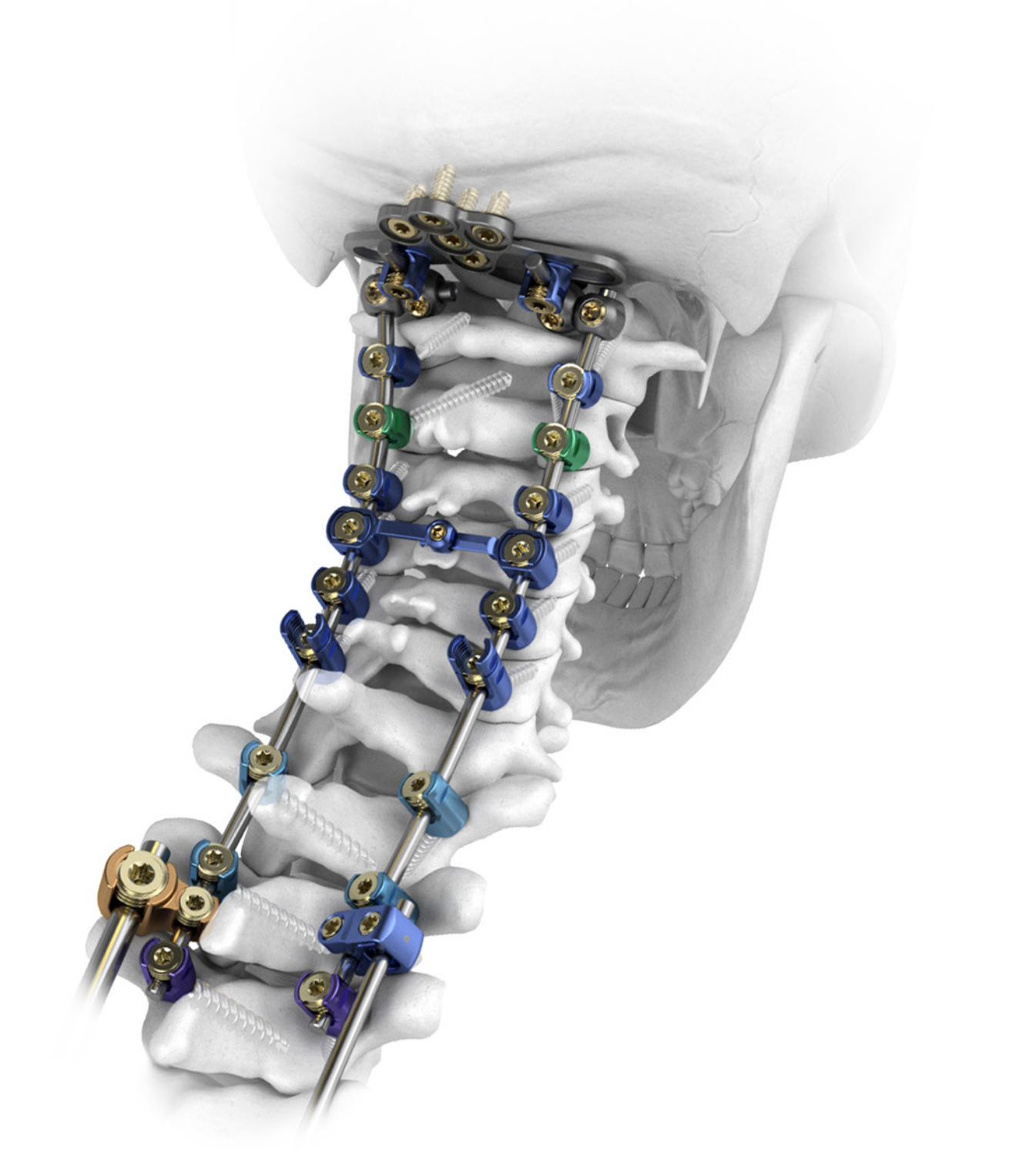
ORTHOFIX | SeaSpine



NORTHSTAR® OCT

POSTERIOR CERVICAL FUSION SYSTEM

SURGICAL TECHNIQUE

CONTENTS

NORTHSTAR® OCT

Note: This surgical technique is intended for the NorthStar OCT system, which includes posterior cervical fixation. This surgical technique guide does not review use of facet preparation and biologic delivery, i.e., NorthStar™ Facet Fusion. Refer to surgical technique guide D0006768.

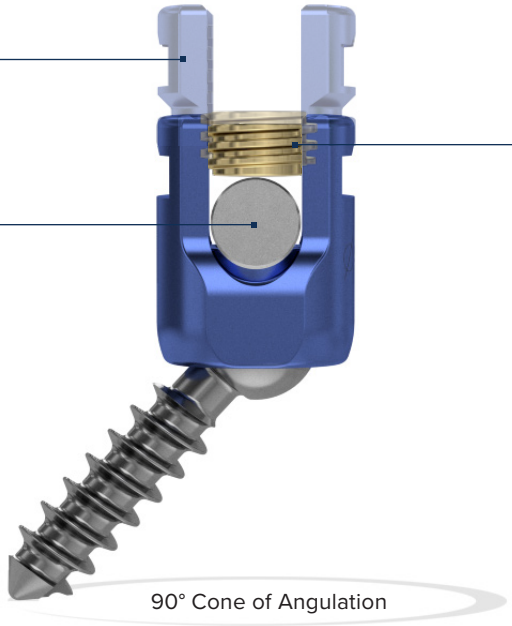
DESIGN RATIONALE

The SeaSpine® NorthStar® OCT System is a comprehensive posterior cervical fixation solution that features innovative implants combined with multi-functional instrumentation to provide surgeons with a safe and effective solution that can improve surgical flow and deliver value when navigating through complex procedures.

Enhanced Angulation Streamlining Implant Placement

Extended Tab Screw provides 5mm of reduction to aid in distributing the load sequentially over multiple screws

Polyaxial Screws accommodate 3.5 and 4.0mm rods for construct strength and versatility

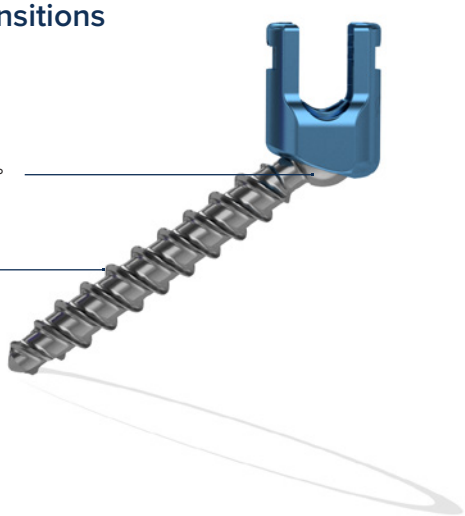


Set screw features enhanced timing for seamless engagement with screw tulip

Seamless Construct Transitions

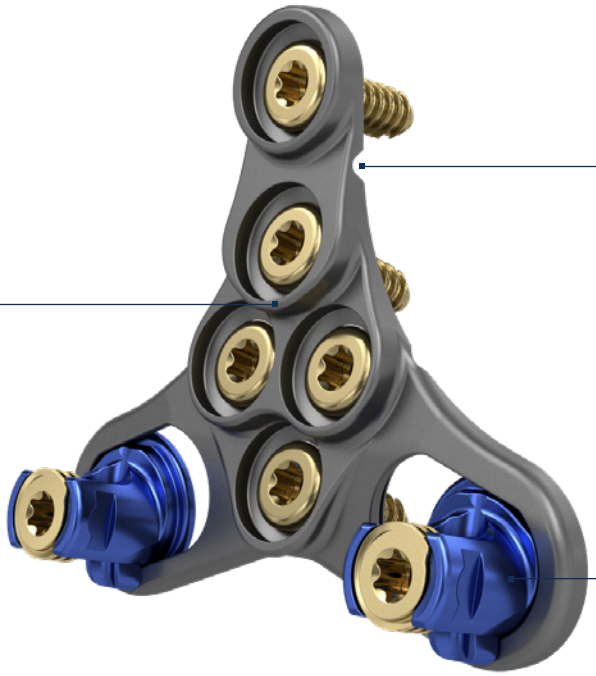
Favored angle screws provide 55°

Dual lead thread design

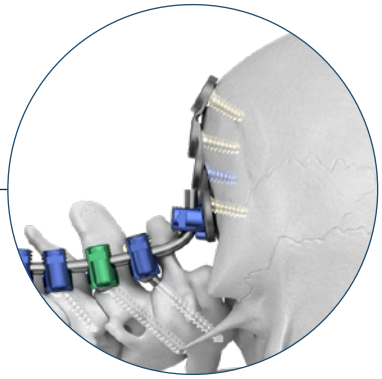


Variable transition implants provide 8° flexibility

Occipital Fusion Simplified



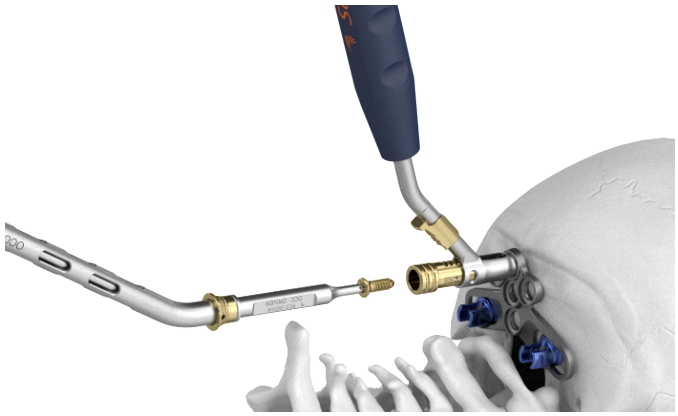
Occipital Plate angled approach screw holes provide 15° of variability in screw placement



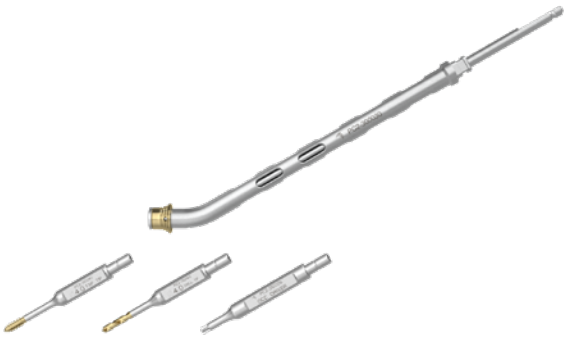
Three bend zones for easy plate contouring*

20° rotational adjustability

Maximized Functionality, Do More with Less Instruments



DTS Guide and Angled Driver provide efficiency in occipital fixation



Modular drill, tap, and driver tips

*For small and large occipital plate sizes.

PREOPERATIVE PLANNING

Ensure a thorough walkthrough and understanding of the NorthStar® OCT system.

STEP 1. SURGICAL APPROACH

With the patient placed in the prone position, identify the indicated surgical site with the use of imaging. An incision is made to effectively access the desired anatomical location (FIG. 01).

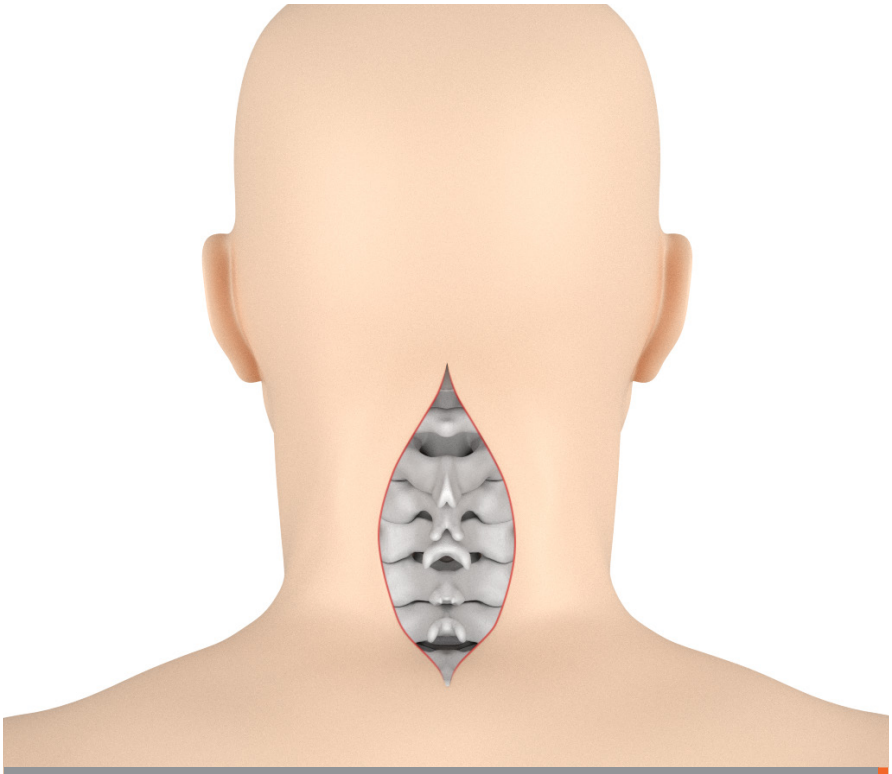


FIG. 01

STEP 2. SITE PREPARATION

A pilot hole can be prepared with an Awl. The tip of the Awl is 10mm with a depth stop (FIG. 02).

If a surgeon prefers, the path can be created with a Bone Probe.

NOTE
The Bone Probe has depth indicators every 5mm increments with a diameter of 2.3mm (FIG. 03).

FIG. 02

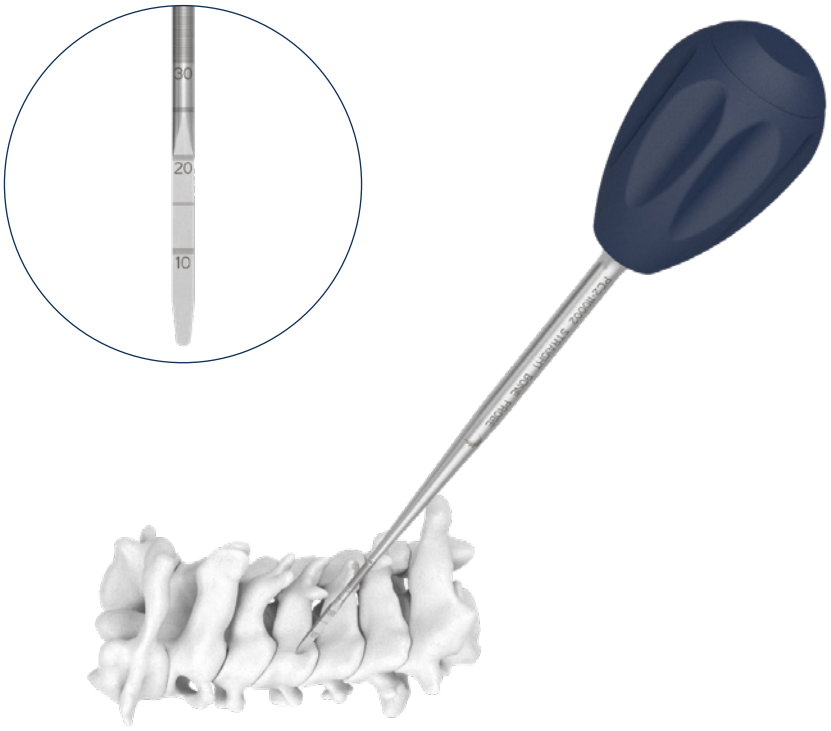


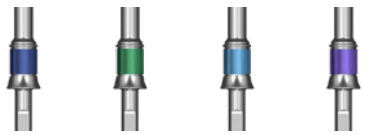
FIG. 03

STEP 2. SITE PREPARATION CONTINUED

Prepare pathway using the Drill and Adjustable Drill Guide. To set the Adjustable Drill Guide depth, pull the trigger toward the handle. Maneuver the gold sleeve to desired depth, indicated in the viewing window. Once depth is set, release the gold trigger and confirm the depth is set to the correct length. Attach the appropriate diameter Drill to the AO Handle and place into barrel and begin drilling (FIG. 04). Drills are provided for all screw diameters and are color-coded to match screw diameter. Two Adjustable Drill Guides are provided. PC2-110100 is to be used with 3.5 and 4.0mm Drills. PC2-110200 is to be used with 4.5 and 5.5mm Drills.

NorthStar® OCT Drill

Screw Diameter	Color
3.5mm	Dark Blue
4.0mm	Green
4.5mm	Light Blue
5.5mm	Purple



Once the pilot hole has been created, insert the Ball Tip Probe into the drill hole to verify the integrity of the pedicle or lateral mass wall (FIG. 05).

NOTE
Dual-ended Ball Tip Probe features a flexible and stiff end.

FIG. 04

FIG. 05

STEP 2. SITE PREPARATION CONTINUED

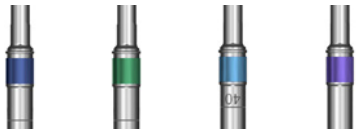
A Depth Gauge can be used to verify depth of the pathway by inserting the tip of the Depth Gauge into the drill hole until the tip contacts the bottom of the hole (FIG. 06).

Screws are self-tapping; however, if tapping is desired, the screw hole may be tapped.

Taps are provided for all screw diameters and are color-coded.

NorthStar® OCT Tap

Screw Diameter	Color
3.5mm	Dark Blue
4.0mm	Green
4.5mm	Light Blue
5.5mm	Purple



NOTE
The Tap flute length is 14mm. Tap diameters are 0.25mm undersized.

To tap the hole, select the appropriate Tap, attach to the AO Handle and apply downward pressure while turning the Tap clockwise. Advance the tap until desired depth is achieved (FIG. 07).

A Tap Sleeve is available if desired to indicate depth and for tissue protection (FIG. 08).

FIG. 06

FIG. 07

FIG. 08

STEP 3. IMPLANT PLACEMENT

Ensure the Polyaxial Screwdriver is in the unlocked position by moving the gold button to the indicated unlocked symbol. Select the appropriate diameter and length of screw, and load the screw onto the Polyaxial Screwdriver by placing the tip of the driver into the hexalobe cavity on the screw shank turning the knob clockwise until threads are fully seated (FIG. 09). Once threads are fully seated, move the gold button to the locked position.

If using extended tab screws, adjust the Polyaxial Screwdriver accordingly by pushing the small gold button, slide the inner shaft until the EXT window shows black (FIG. 10).

NOTE
For polyaxial screw insertion, redirection, or removal, the Polyaxial Screwdriver should always be utilized. If screw re-positioning is required, slide the Polyaxial Screwdriver's outer sleeve upward into extended tab mode to quickly engage the screw's hexalobe.

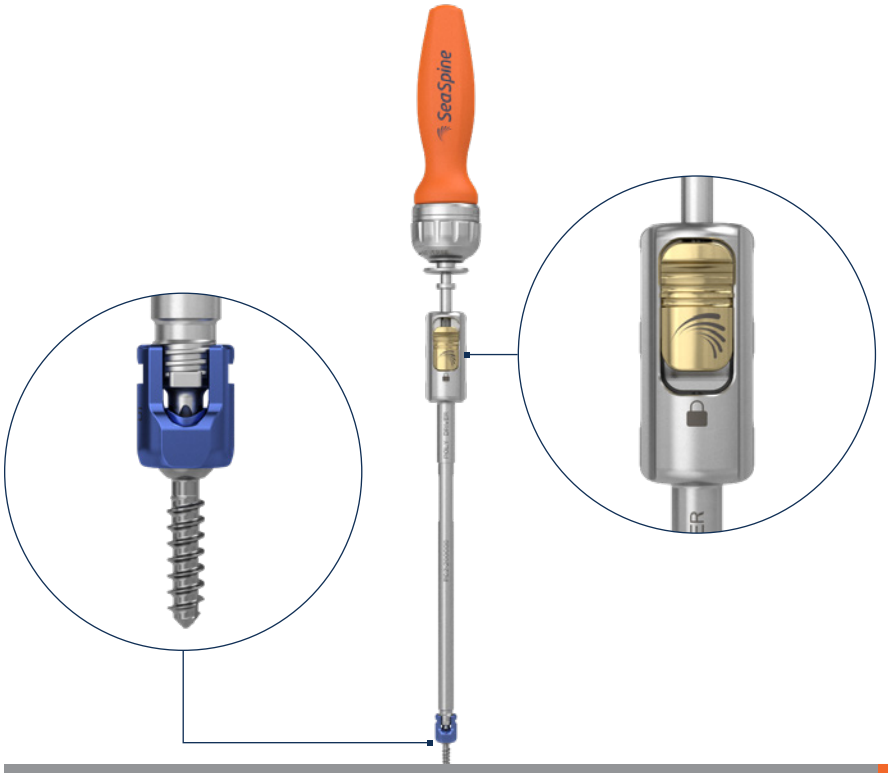


FIG. 09

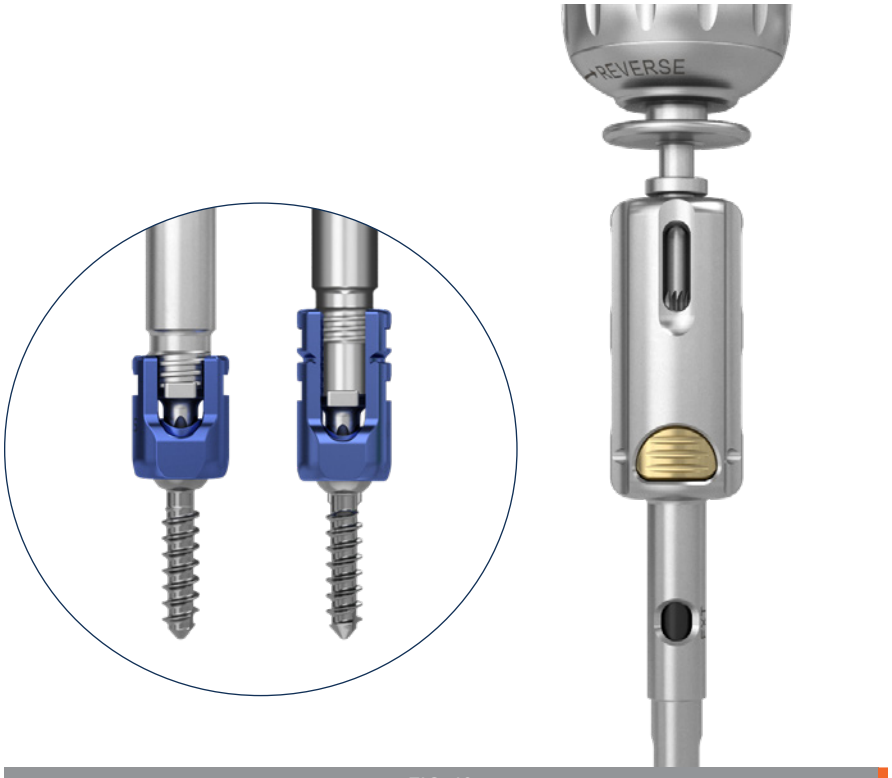


FIG. 10

STEP 3. IMPLANT PLACEMENT CONTINUED

Drive the screw to the desired depth, unlock the screw, and disengage the screw from the Polyaxial Screwdriver by rotating the knob counterclockwise (FIG. 11).

NOTE
Favored angle pedicle screws provide additional medial lateral angulation, allowing 55° in the favored direction and 30° in the unfavored position. Same insertion steps are used. The favored angle is laser marked on the top of the tulip (FIG. 12).

FIG. 11

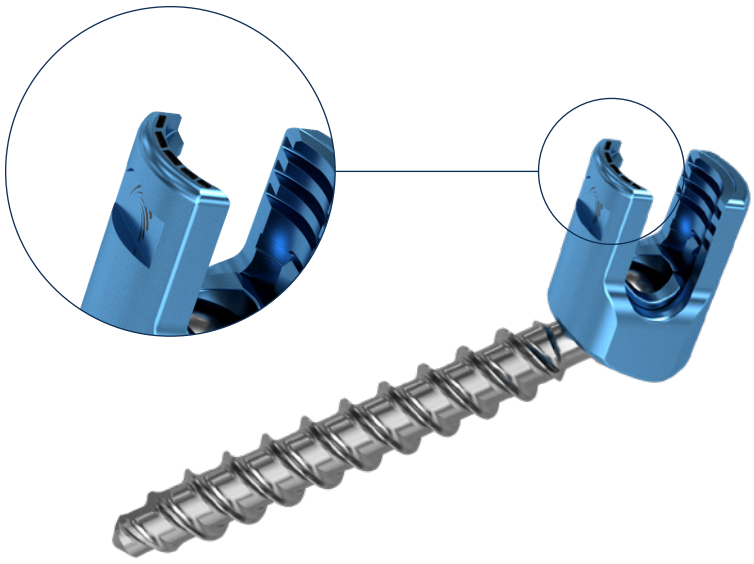


FIG. 12

To simplify rod placement, alignment of the tulips may be needed. Using the Head Adjuster, place the bulleted end of the Head Adjuster into the tulip of the screws and orient properly (FIG. 13).

If a tulip moves after rod has been placed at other levels and additional manipulation is needed, flip the Head Adjuster and use the hook end under the rod to align the tulip (FIG. 14).

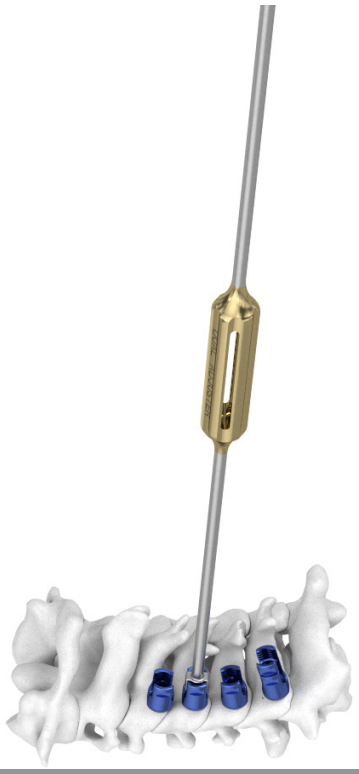


FIG. 13

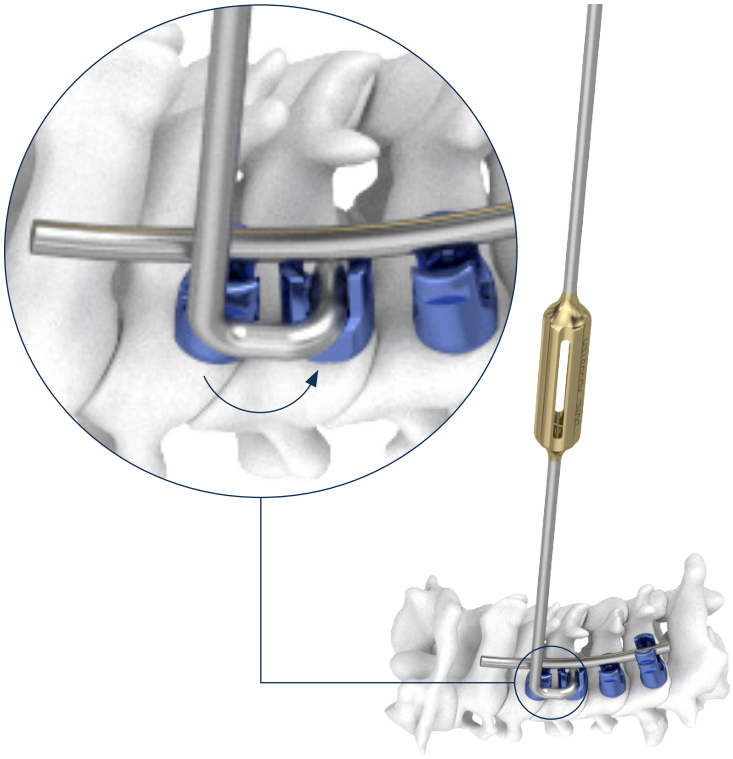


FIG. 14

STEP 4. ROD CUTTING

Place the Rod Template into the screw tulips and bend to the desired curvature. The length is noted on the Rod Template (FIG. 15).

Rod Cutting

The *In Situ* Rod Cutter is provided to cut both 3.5 and 4.0mm Ti and CoCr rods. To cut the rod, place the rod into the cutting jaws and forcefully grip the handles until the rod separates.

Straight rods can be cut using the shearing holes for the indicated size (FIG. 16).

NOTE
Secure the ends during cutting to prevent injury. Keep fingers away from the cutting jaws to avoid injury.

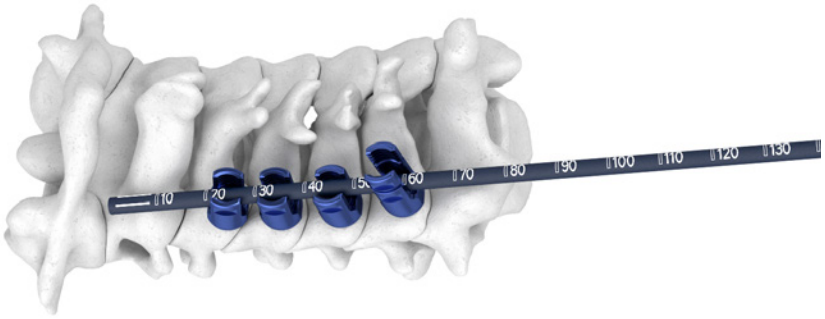


FIG. 15

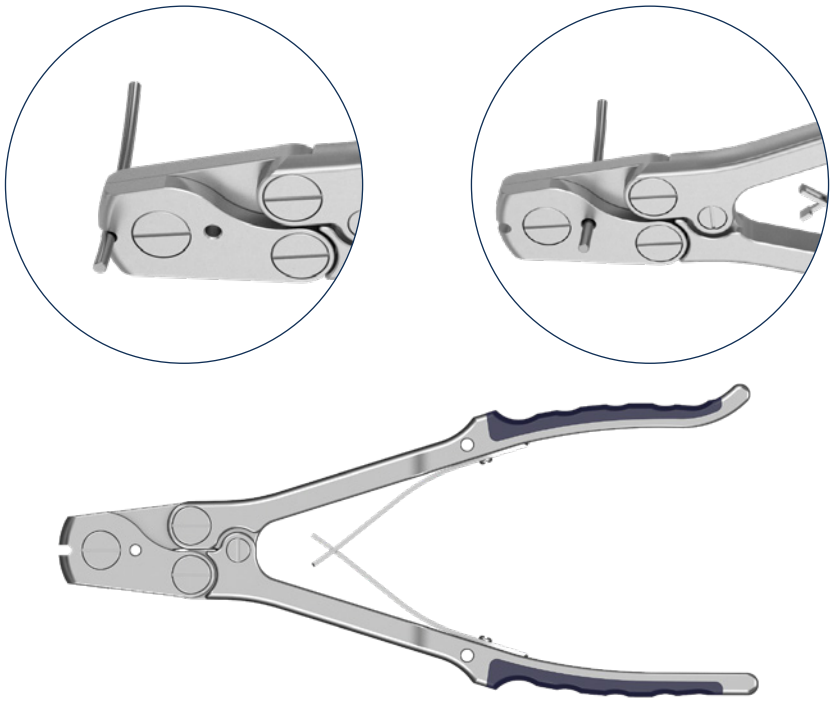


FIG. 16

STEP 5. ROD CONTOURING

Rod Contouring

Select rods are pre-contoured; however, if additional contouring is needed, feed the rod in the French Rod Bender (FIG. 17), grip the handles and manipulate to achieve desired bend.

> **NOTE**
> The center knob on the French Rod Bender can be adjusted to refine the bend desired by pulling up and rotating clockwise (FIG. 18).

In Situ Benders are provided if additional contouring is required after rod is secured in tulips (FIG. 19).

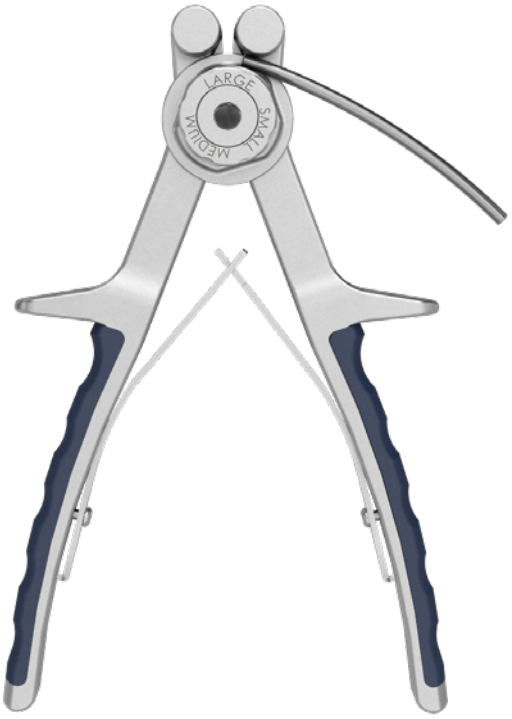


FIG. 17

FIG. 18

FIG. 19

STEP 6. ROD PLACEMENT

Rod Placement

To secure the rod for delivery, place the rod into the Rod Holder and turn the gold handle clockwise to secure it. Once the rod is delivered, turn the gold handle counterclockwise to release the Rod Holder from the rod.

FIG. 20

STEP 7. ROD REDUCTION

Multiple reduction techniques are offered.

Axial Reducer (20mm of reduction)

Ensure the Axial Reducer is ready for use by turning the gold knurled handle counterclockwise until the inner sleeve is no longer visible through the distal windows. To engage the Axial Reducer to the screw tulip, align the Axial Reducer over the screw, apply slight downward force until the Axial Reducer clicks into place on the tulip. Once secured, turn the gold knurled handle clockwise until the rod is fully seated (FIG. 21). Do not over tighten.

To lock the rod into position, attach the set screw to the self-retaining Set Screw Starter and place it through the Axial Reducer and provisionally tighten. To release the Axial Reducer simply press the gold tabs and lift (FIG. 22).

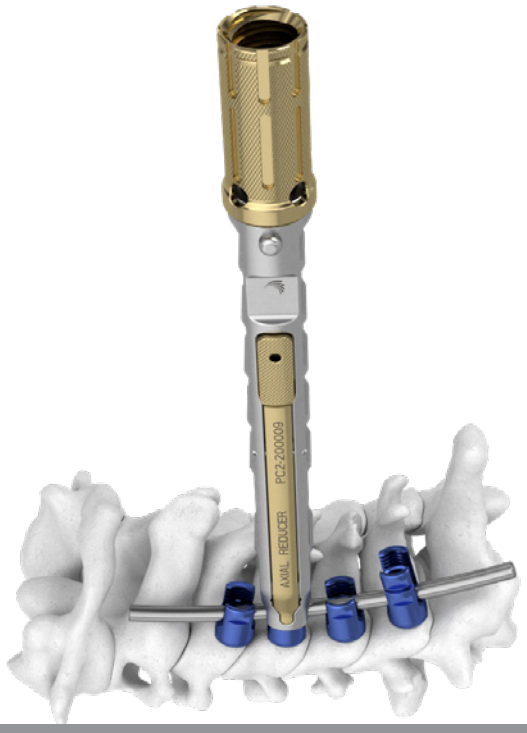


FIG. 21

FIG. 22

STEP 7. ROD REDUCTION CONTINUED

The Pumpkin Handle is available if additional grip or torque is desired to reduce the rod. Place the Pumpkin Handle with the text “EXTENDER” at base of the Axial Reducer's handle (FIG. 23).

Save a Step!

The Pumpkin Handle can also be used as a counter torque to final tighten. To do so, flip the Pumpkin Handle so the “COUNTER TQ” is displayed and slide over the gold handle to engage with silver pins. Once locked in place perform final tightening outlined in Step 10 (FIG. 24).

If additional height is needed on the Axial Reducer, place the Axial Reducer Extension over the gold handle (FIG. 25).

FIG. 23

FIG. 24

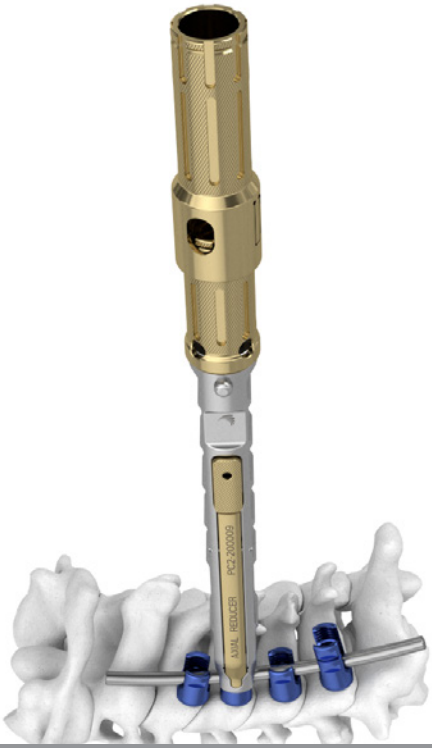


FIG. 25

Pistol Reducer (10mm of reduction)

To engage the Pistol Reducer, slide the distal tip over tulip and slowly squeeze handle to fully engage. Continue squeezing to reduce the rod until it is fully seated in tulip. The rack on the Pistol Reducer will maintain the reduction until the set screw is deployed.

When fully reduced, a lasermark line will appear in the proximal window. To provisionally tighten the rod, attach a set screw to the self-retaining Set Screw Starter and place it through the Pistol Reducer. Disengage the rack to release the Pistol Reducer from tulip (FIG. 26).

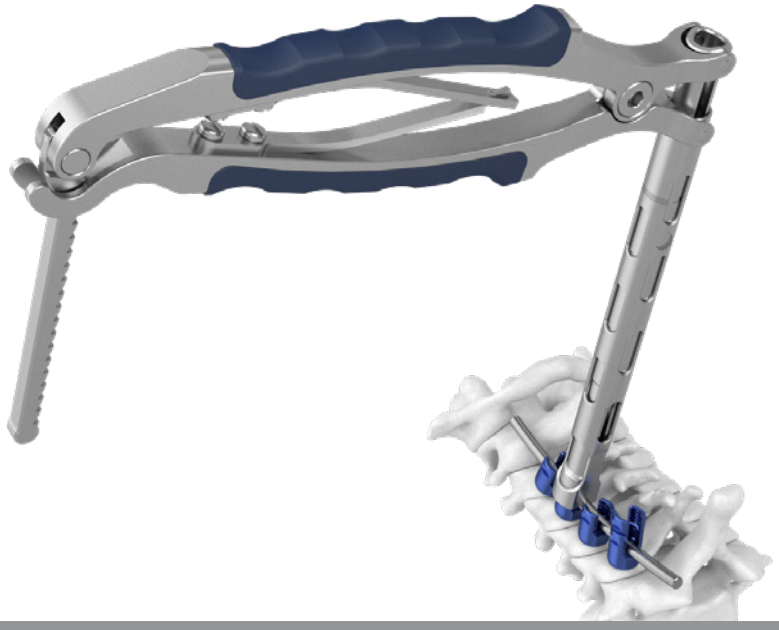


FIG. 26

STEP 7. ROD REDUCTION CONTINUED

Rod Rocker (5mm of reduction)

To attach the Rod Rocker, line up the engagement features on the side of the tulip and squeeze to fully engage. Gently move handle away from the tulip until rod is fully seated (FIG. 27). To provisionally tighten, attach the set screw to the self-retaining Set Screw Starter and place it through the Rod Rocker.

FIG. 27

STEP 8. SET SCREW INSERTION

Attach the set screw to the dual-ended Set Screw Starter and insert into the screw tulip to provisionally tighten (FIG. 28).

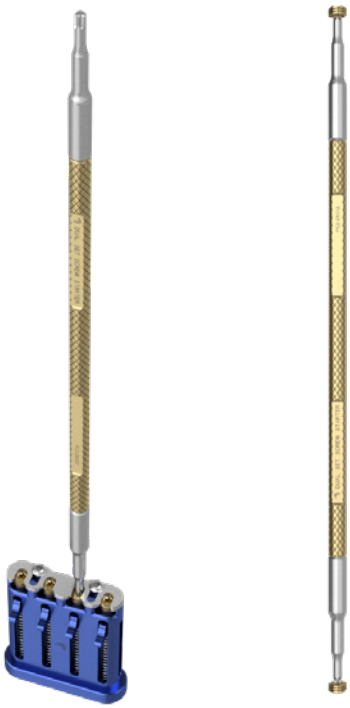


FIG. 28

STEP 9. ROD MODIFICATIONS

In situ rod bending may be performed prior to final tightening (FIG. 29).

If compression or distraction is desired, a Compressor and Distractor are available in the set (FIG. 30). To compress or distract, provisionally tighten one set screw which can be used as a fulcrum then gently squeeze the handles.

FIG. 29

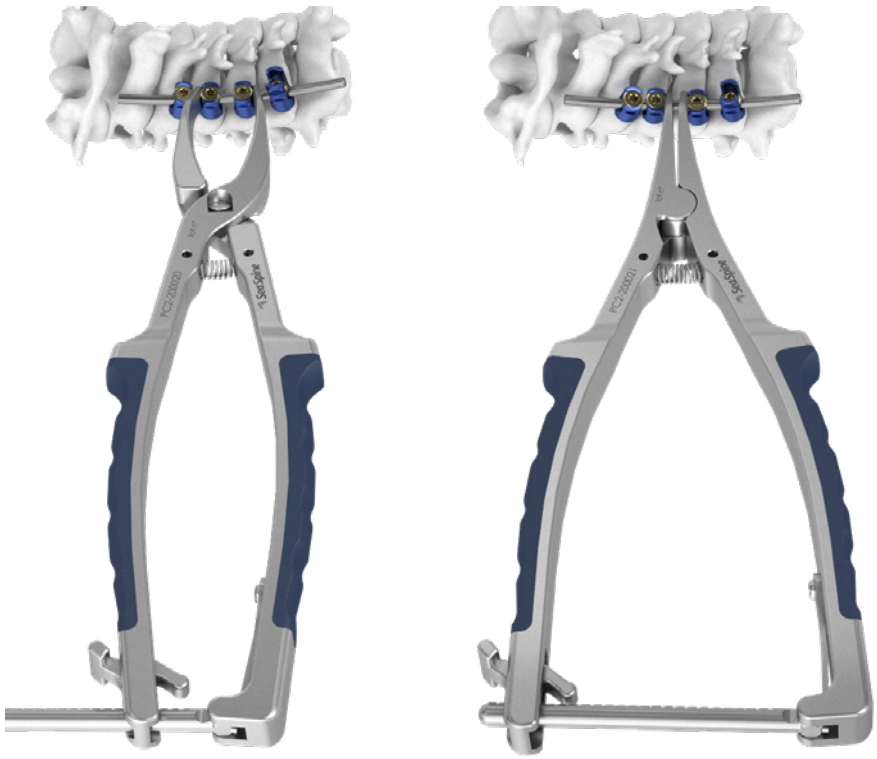


FIG. 30

STEP 10. FINAL TIGHTENING

Once all implants are securely in place, attach the Final Driver to the Torque-limiting Handle and insert the assembly into the Counter Torque. Place the Counter Torque over the tulip and turn the Torque-limiting Handle clockwise until it audibly clicks at 25 in-lb. Repeat steps for all the screws in the construct (FIG. 31).

FIG. 31

STEP 11. EXTENDED TABS

Once final tightening has been performed, the extended tabs can be removed. To remove the tabs, attach the Tab Breaker to the tulip and rock medial/lateral and tabs will snap off. Tabs will be retained in shaft until completed (FIG. 32).

FIG. 32

STEP 12. CROSS CONNECTORS

If additional stabilization is desired, there are three cross connector options available: rod-to-rod (R2R), screw-to-rod (S2R), and screw-to-screw (S2S) (FIG. 33). Choose the appropriate size cross connector:

Cross Connectors

Size	R2R & S2R Translation	S2S Translation
SM	21–26mm	21–25mm
MD	24–32mm	24–31mm
LG	30–44mm	29–41mm

Rod-to-Rod Cross Connector

Ensure the cross connector is ready for delivery by checking that the clamping screws at each end are in the open position. Place the clamp ends over each rod and tighten the clamping screws securely. Start by final tightening outer clamp set screws first then central set screw last. To final tighten set screws, utilize the Cross-Connector Set Screw Final Driver with the axial Cross-Connector Torque-limiting Handle until it torques off at 10 in-lb.

Screw-to-Screw Cross Connector

If rod space is a challenge, an S2S cross connector can be utilized. Place connector heads over exposed screw tulip heads. Place standard set screws in connector heads (FIG. 34). Assemble the S2S Counter Torque Adapter to the standard Counter Torque until it snaps into place (FIG. 35).

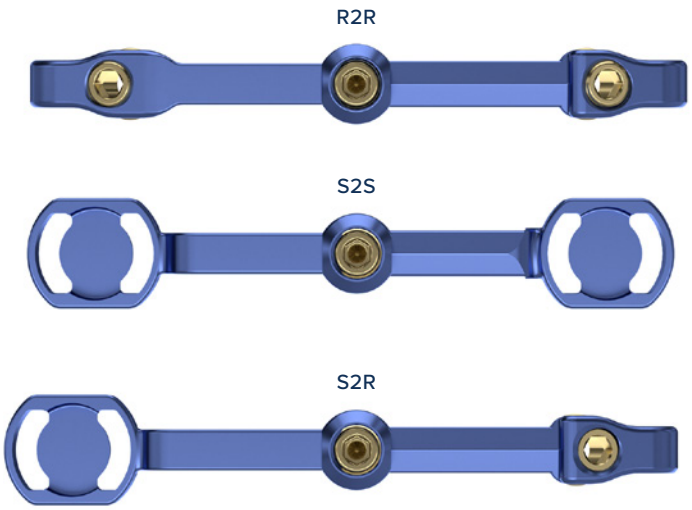


FIG. 33

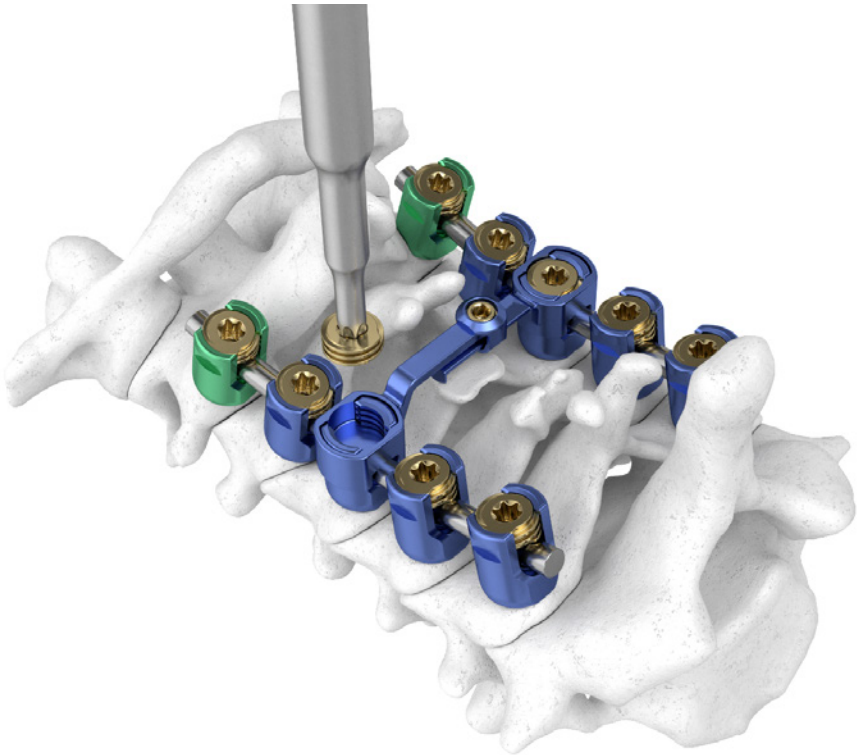


FIG. 34

Place assembled Counter Torque on connector heads (Fig. 35) and final tighten set screws with Final Driver and Torque-limiting T-handle, until it torques off at 25 in-lb.

Final tighten the central set screw with the Cross-Connector Set Screw Final Driver and axial Cross-Connector Torque-limiting Handle until it torques off at 10 in-lb.

Screw-to-Rod Cross Connector

If rod space is a challenge on one side, the S2R cross connector can be utilized. Place connector head over exposed screw tulip head, then place the clamp end over rod. Place standard set screw in connector head. Place assembled Counter Torque (Fig. 36) on connector head and final tighten set screw with Final Driver and Torque-limiting T-handle until it torques off at 25 in-lb.

Final tighten clamp end set screw with the Cross-Connector Set Screw Final Driver and Axial Cross-Connector Torque-limiting Handle until it torques off at 10 in-lb. Utilizing same instrument, final tighten central set screw last at 10 in-lb.

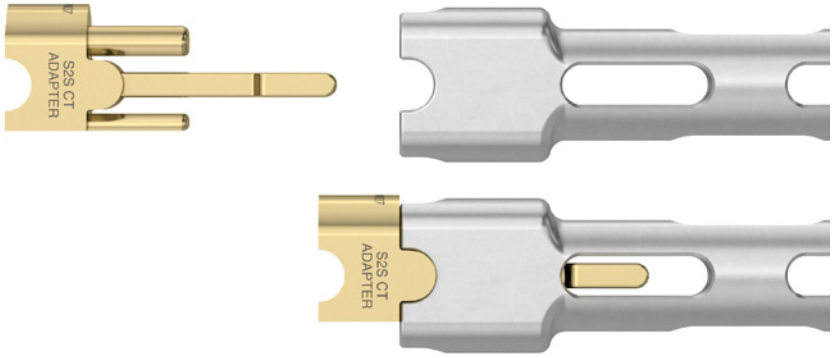


FIG. 35

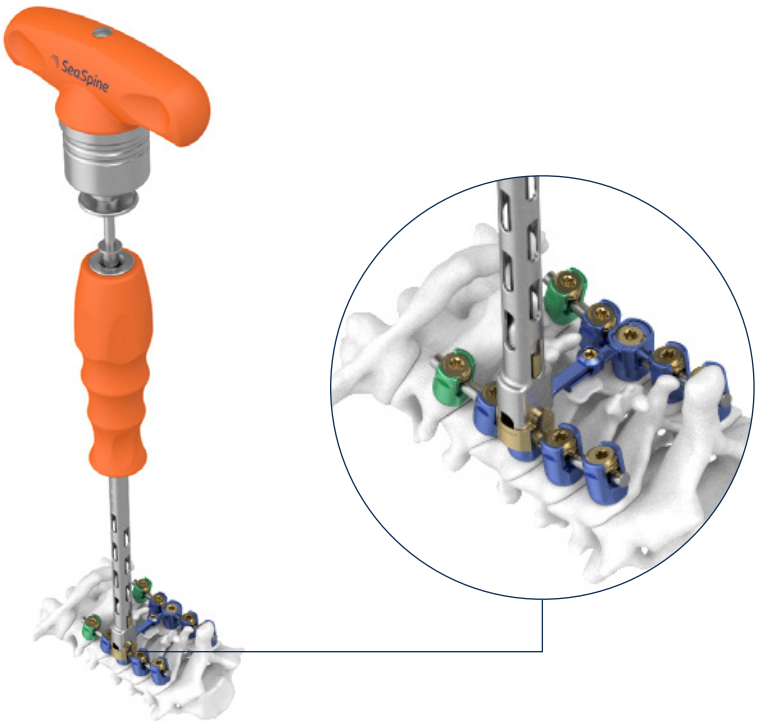


FIG. 36

STEP 13. TRANSITION IMPLANTS

Transition rods are available to link NorthStar® OCT with SeaSpine® thoracolumbar systems. Transition rods are offered in multiple variations:

- 3.5 to 5.5mm
- 3.5 to 6.0mm
- 4.0 to 5.5mm
- 4.0 to 6.0mm

Transition connectors are available for the coupling of two rods of same or larger diameters (FIG. 37).

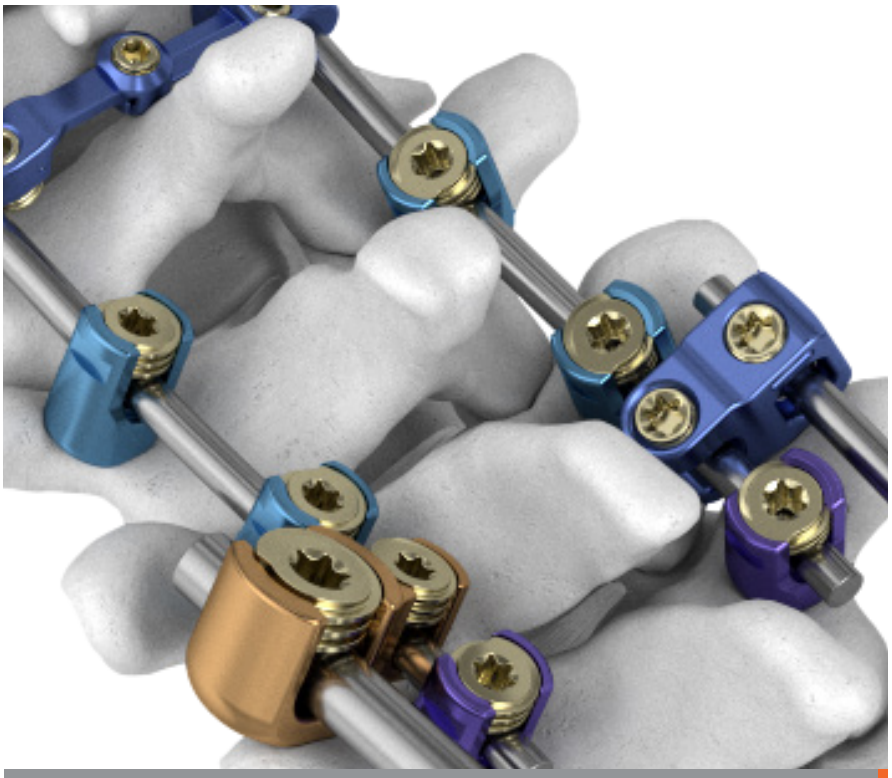


FIG. 37

STEP 14. FINAL TIGHTENING FOR TRANSITION IMPLANTS

Perform final tightening by attaching the designated Final Driver to the corresponding Torque-limiting Handle and rotate until an audible click is heard. See reference table for proper instruments.

IMPORTANT
Once a connector has been torqued down to the appropriate value, they cannot be tightened a second time and will need to be disposed.

NorthStar® OCT Final Tightening Instruments

Description	Image	Final Tightening Components
Top Loading, Lateral Offset PC1-020015		PC2-200011 – Set Screw Starter/Final Driver PC2-200014 – Torque-limiting Handle, 25 in-lb
Parallel, Top Loading PC1-023540		PC2-200011 – Set Screw Starter/Final Driver PC2-200014 – Torque-limiting Handle, 25 in-lb
Parallel, Top Loading to 5.5/6.0mm PC1-023560		**For 5.5/6.0mm side use:** 90-1701 – Final Driver Shaft, T-30 99-2085 – Torque-limiting Handle, 85 in-lb **For 3.5/4.0mm side use:** PC2-200011 – Set Screw Starter/Final Driver PC2-200014 – Torque-limiting Handle, 25 in-lb
Dual Parallel, Top Loading PC1-043540		PC2-200011 – Set Screw Starter/Final Driver PC2-200014 – Torque-limiting Handle, 25 in-lb
Dual Parallel, Top Loading to 5.5/6.0mm PC1-043560		**For 5.5/6.0mm side use:** 90-1701 – Final Driver Shaft, T-30 99-2085 – Torque-limiting Handle, 85 in–lb **For 3.5/4.0mm side use:** PC2-200011 – Set Screw Starter/Final Driver PC2-200014 – Torque-limiting Handle, 25 in-lb
Parallel, Side Loading/ Variable PC1-063535		PC2-200011 - Set Screw Starter/Final Driver PC2-200014 – Torque-limiting Handle, 25 in-lb
Parallel, 5.5/6.0mm Side Loading/ Variable PC1-063555		**For 5.5/6.0mm side use:** 99-0008 – T-25 Driver 99-2085 – Torque-limiting Handle, 85 in-lb **For 3.5/4.0mm side use:** PC2-200011 –Set Screw Starter/Final Driver PC2-200014 – Torque-limiting Handle, 25 in-lb

STEP 15. OCCIPITAL PLATE PLACEMENT

To bend the lateral wings of the occipital plate, place the right wing of the occipital plate into the right side of the OCC Plate Bending Wrench labeled “R”. Position the OCC Plate Bending Holder over the exposed screw holes of the bend zone and clamp down (FIG. 38). Apply downward pressure on both instruments to bend. Repeat for left wing.

For Small and Large Occipital Plates place the occipital plate into the lateral slit of the Plate Bending Wrench labeled “TOP”. Position the OCC Plate Bending Holder over the exposed screw holes of the bend zone and clamp down (FIG. 39). Apply downward pressure on both instruments to bend.

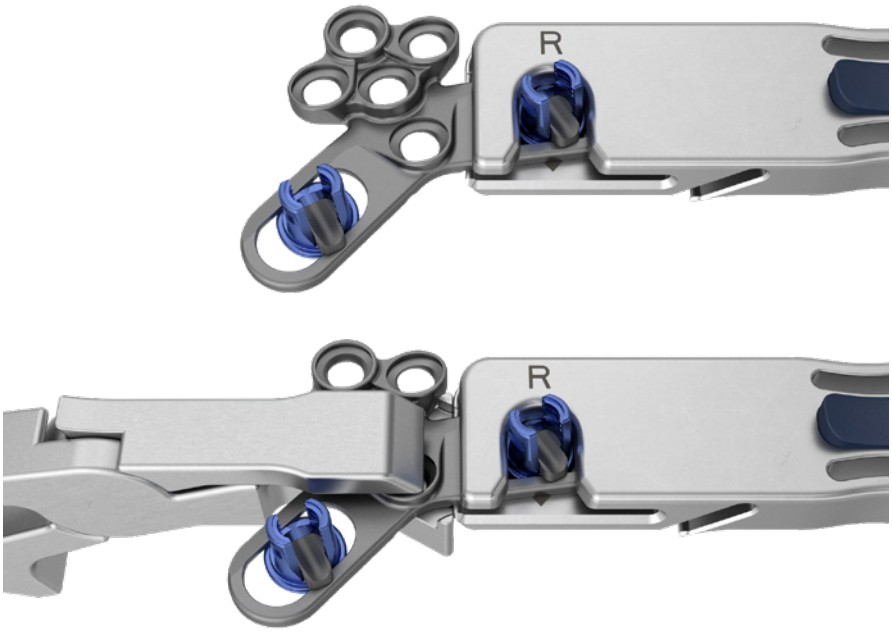
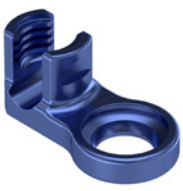


FIG. 38

NOTE
Too much downward pressure can compromise the integrity of the bend zone.

If anatomy does not allow for an occipital plate or if a quad-rod construct is desired, Occipital Eyelets can be used. The Occipital Eyelets can be implanted using standard NorthStar® instrumentation, occipital screws, and standard set screws.



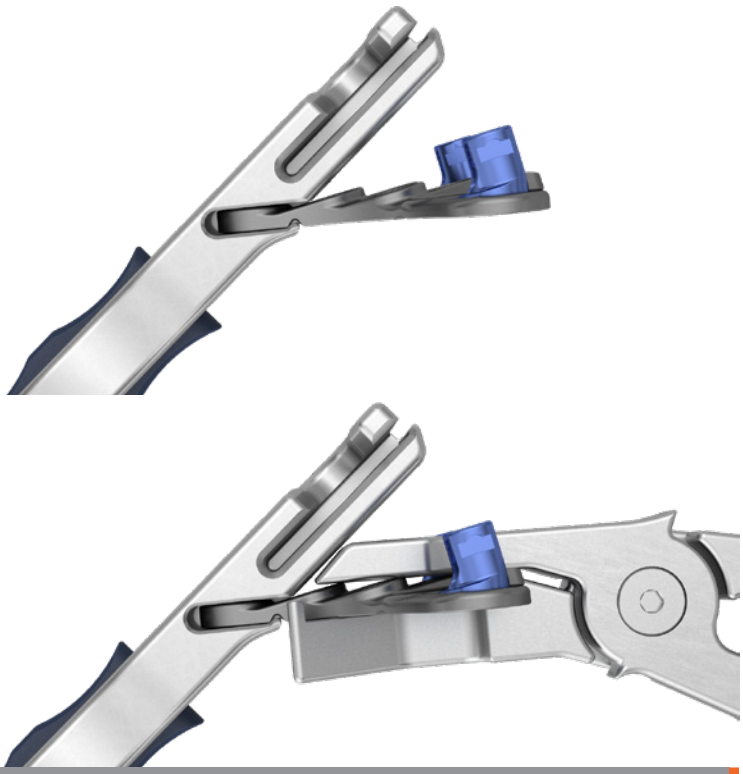


FIG. 39

STEP 16. OCCIPITAL SITE PREPARATION

Preset the desired depth on the OCC DTS Guide and Holder by pulling the gold trigger toward the handle and adjusting the gold sleeve until desired depth is indicated in the window. Once depth has been set, release the gold trigger and confirm the depth is locked at the correct length. Attach the OCC DTS Guide and Holder to the plate in any screw hole by applying slight downward pressure until the guide snaps into place. Once the occipital plate is securely in place with the OCC DTS Guide and Holder, center the plate on the midline between the external occipital protuberance and the posterior border of the foramen magnum (FIG. 40).

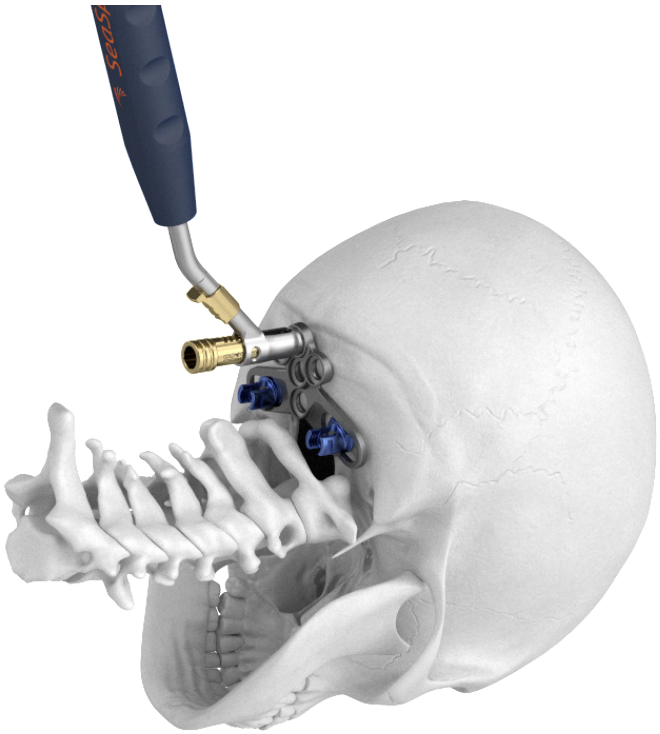


FIG. 40

With the occipital plate in place, attach the OCC AO Ratchet Handle to the OCC Angled DTS Driver. Select the desired size Modular Drill Tip, attach the Modular Drill Tip to the OCC Angled DTS Driver by pulling the gold collar proximally. Release collar to retain the Modular Drill Tip (FIG. 41). Check to confirm secure attachment.

Place the OCC Angled DTS Driver through the OCC DTS Guide and Holder and advance the Drill until the desired depth is reached.

Check the integrity of the hole with a Ball Tip Probe.

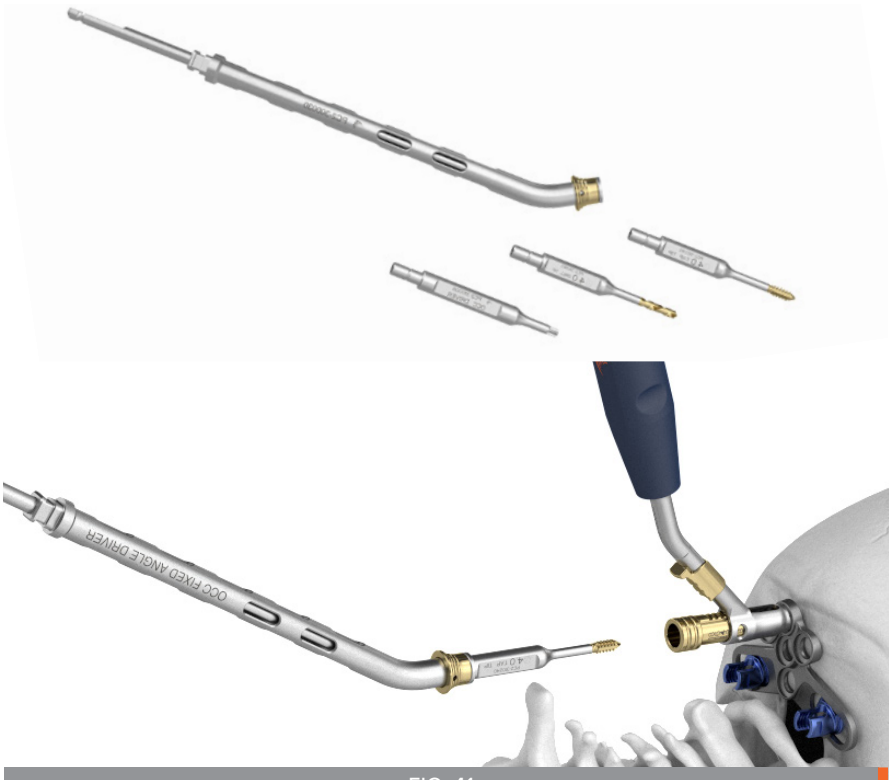


FIG. 41

STEP 16. OCCIPITAL SITE PREPARATION CONTINUED

Taps are available for each screw size.

NOTE
The OCC taps are undersized 0.5mm.

To tap, attach the Modular Tap Tip to the OCC Angled DTS Driver by pulling the gold collar proximally, then gently push the Modular Tap Tip until it snaps into place (FIG. 42). Place the OCC Angled DTS Driver through the OCC DTS Guide and Holder and advance the Tap until the desired depth is reached.

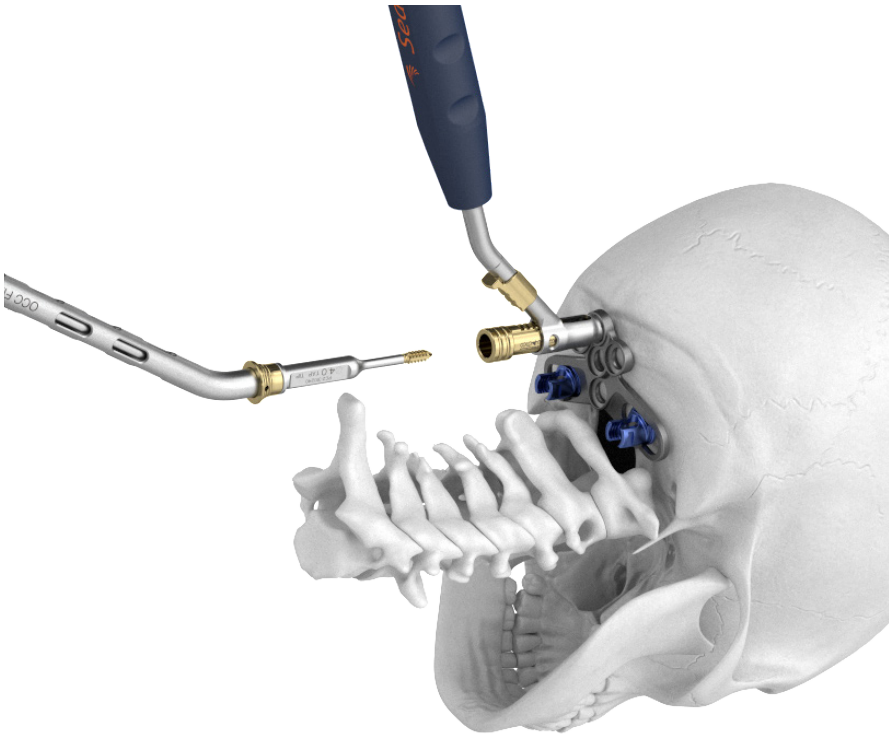


FIG. 42

STEP 17. OCCIPITAL SCREW PLACEMENT

Attach the Modular Driver Tip to the OCC Angled DTS Driver by pulling the gold collar proximally, then gently push the Modular Driver Tip until it snaps in place (FIG. 43). Stab-and-grab the desired screw. Place the OCC Angled DTS Driver through the OCC DTS Guide and Holder and advance the driver until the screw is fully seated in the screw hole.

NOTE
The occipital plate offers 15° of screw variability. For optimal visualization on the remaining screws, OCC DTS Guide and Holder is optional.

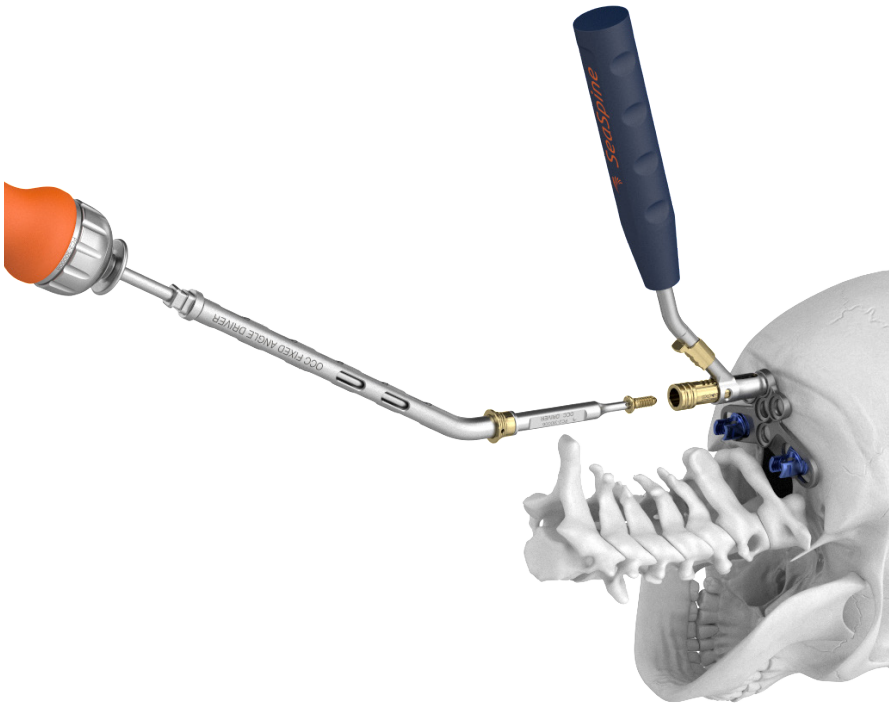


FIG. 43

STEP 18 OCCIPITAL ROD PLACEMENT

Once the occipital plate is secured, a contoured or hinged rod may be used in either 3.5 or 4.0mm diameters. The occipital plate tulips can rotate 20° for easy rod acceptance.

Hinged Rod Placement

Select either left or right hinged rod from caddy. Place desired 3.5 or 4.0mm sub-axial rod through the sub-axial joint and provisionally tighten the sub-axial joint set screw with Set Screw Starter. Provisionally tighten occipital joint set screw at desired rod angle (FIG. 44).

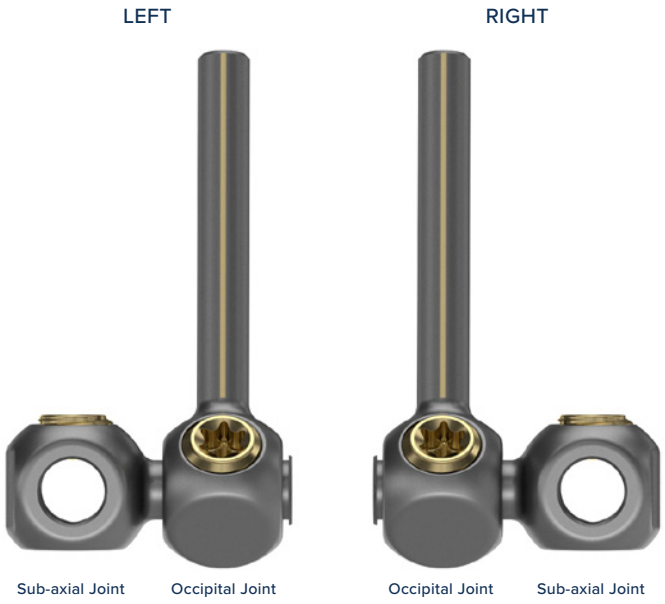


FIG. 44

STEP 18 OCCIPITAL ROD PLACEMENT CONTINUED

NOTE
The sub-axial rods will be lateral to the occipital rods.

NOTE
Prior to final tightening hinged rods, ensure occipital plate final tightening has occurred outlined in step 19.

NOTE
Hinged Rods allow for 1.7mm M/L translation.

Final tighten the hinged rods by placing the assembled Final Driver and Torque-limiting T-handle through the Hinged Rod Counter Torque on the sub-axial joint. Turn the handle clockwise until it audibly clicks at 25 in-lb (FIG. 45).

While keeping the Hinged Rod Counter Torque on the lateral sub-axial joint, remove the Final Driver and place Final Driver on the medial Occipital joint. Turn the handle clockwise until it audibly clicks at 25 in-lb (FIG. 46).

Contoured Rod Placement

Select desired rod, contour as needed, and place in occipital plate and sub-axial screw tulips (FIG. 47).

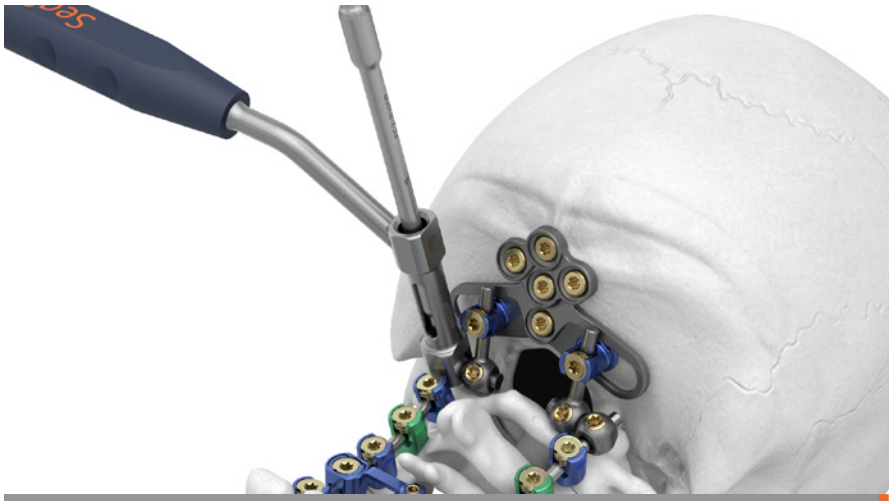


FIG. 45

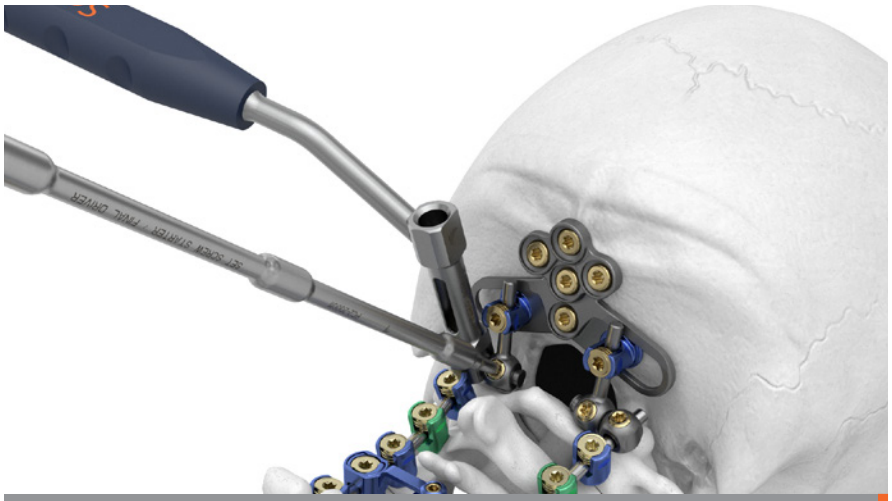


FIG. 46

FIG. 47

STEP 19. OCCIPITAL PLATE FINAL TIGHTENING

To final tighten the occipital plate tulips, place the Modular Driver Tip to the OCC Angled DTS Driver and attach the driver to the Torque-limiting T-handle and place the assembly through the OCC Counter Torque. Turn the handle until it audibly clicks at 25 in-lb (FIG. 47).

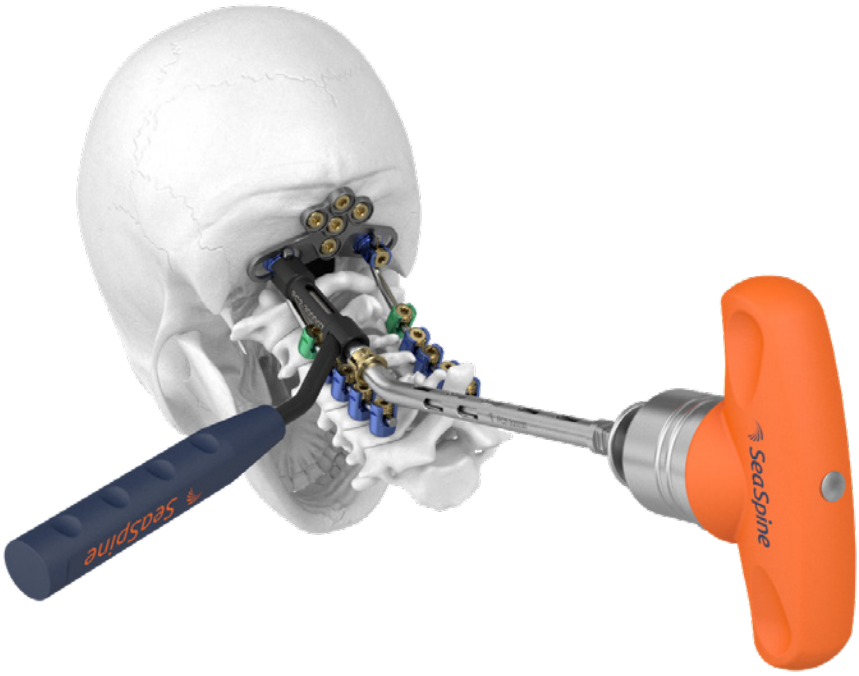


FIG. 48

IMPLANT REMOVAL

If it becomes necessary to remove implants, the following steps should be taken:

- Place the counter torque over the rod and implant head then remove the set screw with an AO Handle and the set screw starter/final driver. Repeat with all implants including the occipital plate set screws.
- Remove the rod with the rod holder. Remove any screws with the screwdriver or set screw starter/final driver.
- Remove crossbars with the cross connector final driver.
- Remove the occipital screws and set screws from the occipital plate with the OCC Angled DTS Driver.
- Remove transition implants with T25 driver and/or T30 driver, depending on the size of the transition implant and unthread all set screws.

ORDERING INFORMATION

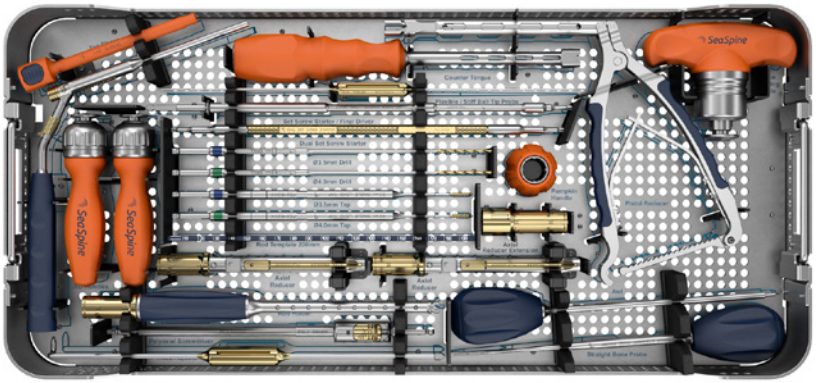
TRAY CONFIGURATION

NORTHSTARIMP

Implant Tray

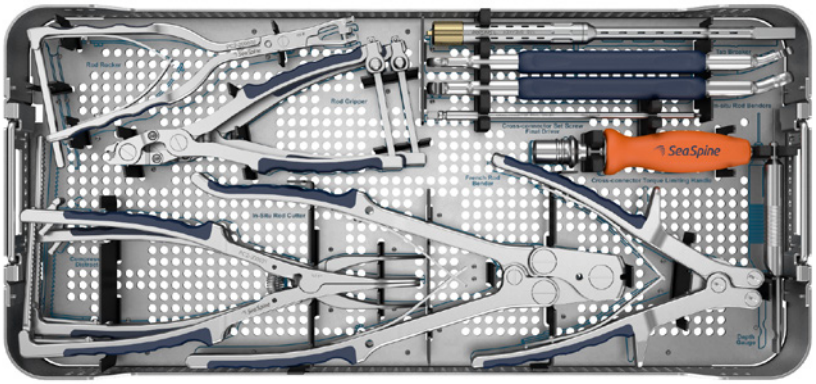
NORTHSTARINST

Instrument Tray–Top Level



NORTHSTARINST

Instrument Tray–Bottom Level

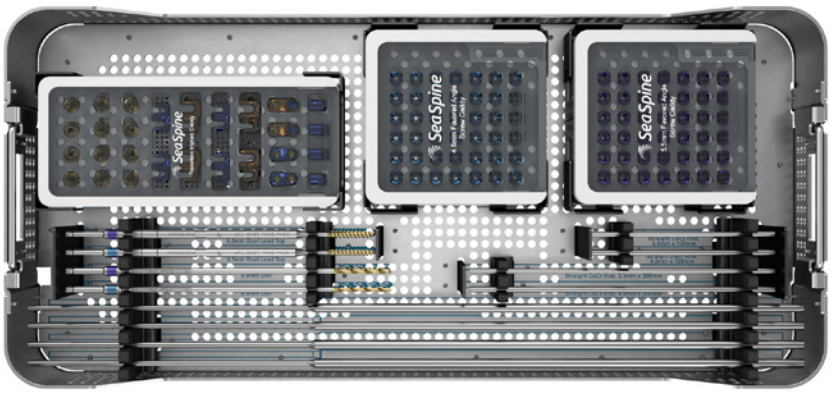


PRODUCTS SHOWN NOT TO SCALE

TRAY CONFIGURATION

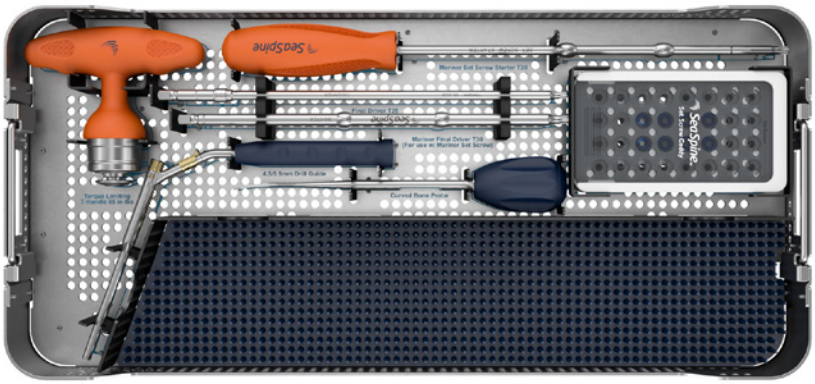
NORTHSTARTRANS

Transition Tray–Top Level



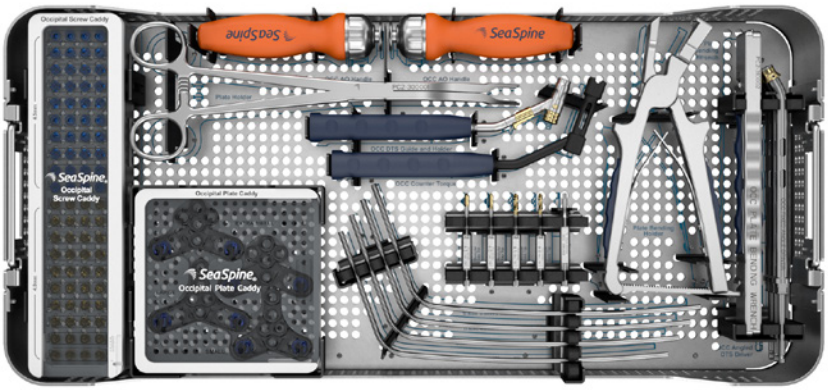
NORTHSTARTRANS

Transition Tray–Bottom Level



NORTHSTAROCC

Occipital Tray



PRODUCTS SHOWN NOT TO SCALE

INSTRUMENTATION NORTHSTARINST: NORTHSTAR OCT INSTRUMENTS

Awl

PN PC2-110001

Straight Bone Probe

PN PC2-110002

3.5mm Drill

PN PC2-110135

4.0mm Drill

PN PC2-110140

3.5mm Tap

PN PC2-110235

4.0mm Tap

PN PC2-110240

Tap Sleeve

PN PC2-103540

AO Handle

PN PC2-200001

3.5/4.0mm Adjustable Drill Guide

PN PC2-110100

PRODUCTS SHOWN NOT TO SCALE

INSTRUMENTATION NORTHSTARINST: NORTHSTAR OCT INSTRUMENTS

Flexible/Stiff Ball Tip Probe

PN PC2-110003

Dual Set Screw Starter

PN PC2-210012

Set Screw Starter/Final Driver

PN PC2-200011

Polyaxial Screwdriver

PN PC2-200000

Head Adjuster

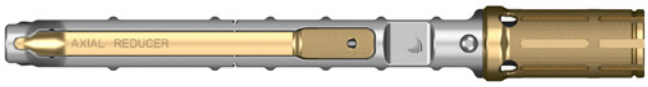
PN PC2-200002

Rod Rocker

PN PC2-200008

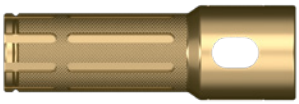
Axial Reducer

PN PC2-200009



Axial Reducer Extension

PN PC2-210009



Pumpkin Handle

PN PC2-200029

PRODUCTS SHOWN NOT TO SCALE

INSTRUMENTATION NORTHSTARINST: NORTHSTAR OCT INSTRUMENTS

Pistol Reducer

PN PC2-200010

Counter Torque

PN PC2-210013

Torque-limiting Handle

PN PC2-200014

Rod Template 200mm

PN PC2-200003

Rod Holder

PN PC2-200007

Rod Gripper

PN PC2-200006

Depth Gauge

PN PC2-200022

Tab Breaker

PN PC2-200024

Rod Cutter

PN PC2-210004

PRODUCTS SHOWN NOT TO SCALE

INSTRUMENTATION NORTHSTARINST: NORTHSTAR OCT INSTRUMENTS

French Rod Bender

PN PC2-200005

In Situ Rod Bender, Left

PN PC2-200025

In Situ Rod Bender, Right

PN PC2-200026

Compressor

PN PC2-200020

Distractor

PN PC2-200021

Cross-connector Set Screw Final Driver

PN PC2-200016

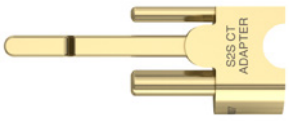
Cross-connector Torque-limiting Handle

PN PC2-200017

S2S Counter Toque Adapter*

PN PC2-010007

*Instrument found in NORTHSTARIMP



PRODUCTS SHOWN NOT TO SCALE

INSTRUMENTATION NORTHSTARTRANS: NORTHSTAR OCT TRANSITION

Curved Bone Probe

PN PC2-120002

4.5mm Drill

PN PC2-110145

5.5mm Drill

PN PC2-110155

4.5/5.5mm Adjustable Drill Guide

PN PC2-110200

4.5mm Dual Lead Tap

PN PC2-110345

5.5mm Dual Lead Tap

PN PC2-110355

PRODUCTS SHOWN NOT TO SCALE

Set Screw Starter, Axial

PN 90-1305

Final Driver Shaft, T30

PN 90-1701

T-25 Driver

PN 99-0008

Torque-limiting T-handle,
¼ in sq, 85 in-lb

PN 99-2085

PRODUCTS SHOWN NOT TO SCALE

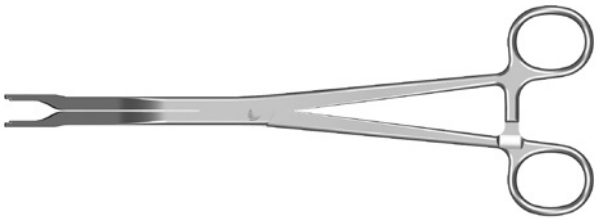
INSTRUMENTATION NORTHSTAROCC: NORTHSTAR OCT OCCIPITAL

OCC AO Handle

PN PC2-300008

OCC Plate Holder

PN PC2-300001

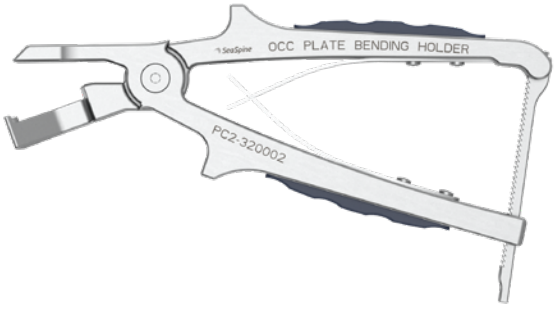


OCC Plate Bending Wrench

PN PC2-310002

OCC Plate Bending Holder

PN PC2-320002



OCC DTS Guide and Holder

PN PC2-310003

OCC Angled DTS Driver

PN PC2-300004

4.0mm Modular Drill Tip

PN PC2-310140

PRODUCTS SHOWN NOT TO SCALE

4.5mm Modular Drill Tip

PN PC2-310145

4.0mm Modular Tap Tip

PN PC2-310240

4.5mm Modular Tap Tip

PN PC2-310245

Modular Driver Tip

PN PC2-310006

OCC Counter Torque

PN PC2-300007

PRODUCTS SHOWN NOT TO SCALE

IMPLANTS

NORTHSTARIMP: 3.5mm Polyaxial Screws

Part Number	Part Description
PC1-400000	NorthStar OCT Set Screw
PC1-003508	Poly. Screw, 3.5 x 8mm
PC1-003510	Poly. Screw, 3.5 x 10mm
PC1-003512	Poly. Screw, 3.5 x 12mm
PC1-003514	Poly. Screw, 3.5 x 14mm
PC1-003516	Poly. Screw, 3.5 x 16mm
PC1-003518	Poly. Screw, 3.5 x 18mm
PC1-003520	Poly. Screw, 3.5 x 20mm
PC1-003522	Poly. Screw, 3.5 x 22mm
PC1-003524	Poly. Screw, 3.5 x 24mm
PC1-003526	Poly. Screw, 3.5 x 26mm
PC1-003528	Poly. Screw, 3.5 x 28mm
PC1-003530	Poly. Screw, 3.5 x 30mm
PC1-003532	Poly. Screw, 3.5 x 32mm
PC1-003534	Poly. Screw, 3.5 x 34mm

NORTHSTARIMP: 4.0mm Polyaxial Screws

Part Number	Part Description
PC1-004010	Poly. Screw, 4.0 x 10mm
PC1-004012	Poly. Screw, 4.0 x 12mm
PC1-004014	Poly. Screw, 4.0 x 14mm
PC1-004016	Poly. Screw, 4.0 x 16mm
PC1-004018	Poly. Screw, 4.0 x 18mm
PC1-004020	Poly. Screw, 4.0 x 20mm
PC1-004022	Poly. Screw, 4.0 x 22mm
PC1-004024	Poly. Screw, 4.0 x 24mm
PC1-004026	Poly. Screw, 4.0 x 26mm
PC1-004028	Poly. Screw, 4.0 x 28mm
PC1-004030	Poly. Screw, 4.0 x 30mm
PC1-004032	Poly. Screw, 4.0 x 32mm
PC1-004034	Poly. Screw, 4.0 x 34mm

NORTHSTARIMP: 3.5mm Rods

Part Number	Part Description
PC1-503530	Contoured Ti Rod, 3.5 x 30mm
PC1-503540	Contoured Ti Rod, 3.5 x 40mm
PC1-503550	Contoured Ti Rod, 3.5 x 50mm
PC1-503560	Contoured Ti Rod, 3.5 x 60mm
PC1-503570	Contoured Ti Rod, 3.5 x 70mm
PC1-503580	Contoured Ti Rod, 3.5 x 80mm
PC1-503590	Contoured Ti Rod, 3.5 x 90mm
PC1-503500	Contoured Ti Rod, 3.5 x 100mm
PC1-503502	Contoured Ti Rod, 3.5 x 120mm
PC1-503503	Straight Ti Rod, 3.5 x 200mm

NORTHSTARIMP: 4.0mm Rods

Part Number	Part Description
PC1-504030	Contoured Ti Rod, 4.0 x 30mm
PC1-504040	Contoured Ti Rod, 4.0 x 40mm
PC1-504050	Contoured Ti Rod, 4.0 x 50mm
PC1-504060	Contoured Ti Rod, 4.0 x 60mm
PC1-504070	Contoured Ti Rod, 4.0 x 70mm
PC1-504080	Contoured Ti Rod, 4.0 x 80mm
PC1-504090	Contoured Ti Rod, 4.0 x 90mm
PC1-504000	Contoured Ti Rod, 4.0 x 100mm
PC1-504002	Contoured Ti Rod, 4.0 x 120mm
PC1-504003	Straight Ti Rod, 4.0 x 200mm

For additional information or set configurations, please contact SeaSpine® customer service.

IMPLANTS

NORTHSTARIMP: 3.5mm Smooth Shank Screws

Part Number	Part Description
PC1-203520	Smooth Shank Poly. Screw, 3.5 x 20mm
PC1-203522	Smooth Shank Poly. Screw, 3.5 x 22mm
PC1-203524	Smooth Shank Poly. Screw, 3.5 x 24mm
PC1-203526	Smooth Shank Poly. Screw, 3.5 x 26mm
PC1-203528	Smooth Shank Poly. Screw, 3.5 x 28mm
PC1-203530	Smooth Shank Poly. Screw, 3.5 x 30mm
PC1-203532	Smooth Shank Poly. Screw, 3.5 x 32mm
PC1-203534	Smooth Shank Poly. Screw, 3.5 x 34mm
PC1-203536	Smooth Shank Poly. Screw, 3.5 x 36mm
PC1-203538	Smooth Shank Poly. Screw, 3.5 x 38mm
PC1-203540	Smooth Shank Poly. Screw, 3.5 x 40mm

NORTHSTARIMP: Rod-to-Rod Cross Connectors

Part Number	Part Description
PC1-013501	Rod-to-Rod Cross Connector, 3.5mm SM
PC1-013502	Rod-to-Rod Cross Connector, 3.5mm MD
PC1-013503	Rod-to-Rod Cross Connector, 3.5mm LG
PC1-014001	Rod-to-Rod Cross Connector, 4.0mm SM
PC1-014002	Rod-to-Rod Cross Connector, 4.0mm MD
PC1-014003	Rod-to-Rod Cross Connector, 4.0mm LG

NORTHSTARIMP: Screw-to-Screw Cross Connectors

Part Number	Part Description
PC1-010001	Screw-to-Screw Cross Connector, SM
PC1-010002	Screw-to-Screw Cross Connector, MD
PC1-010003	Screw-to-Screw Cross Connector, LG

NORTHSTARS2R: Screw-to-Rod Cross Connectors*

Part Number	Part Description
PC1-013511	Screw-to-Rod, 3.5mm Cross Connector, SM
PC1-013512	Screw-to-Rod, 3.5mm Cross Connector, MD
PC1-013513	Screw-to-Rod, 3.5mm Cross Connector, LG
PC1-014011	Screw-to-Rod, 4.0mm Cross Connector, SM
PC1-014012	Screw-to-Rod, 4.0mm Cross Connector, MD
PC1-014013	Screw-to-Rod, 4.0mm Cross Connector, LG

*Optional implants. Not standard in set.
For additional information or set configurations, please contact SeaSpine® customer service.

IMPLANTS

NORTHSTARTRANS: 4.5mm Favored Angle Screws

Part Number	Part Description
PC1-104524	Poly. Screw, Favored Angle, 4.5 x 24mm
PC1-104526	Poly. Screw, Favored Angle, 4.5 x 26mm
PC1-104528	Poly. Screw, Favored Angle, 4.5 x 28mm
PC1-104530	Poly. Screw, Favored Angle, 4.5 x 30mm
PC1-104532	Poly. Screw, Favored Angle, 4.5 x 32mm
PC1-104534	Poly. Screw, Favored Angle, 4.5 x 34mm

NORTHSTARTRANS: Transition Implants

Part Number	Part Description
PC1-014500	In-line Hook, 4.5mm
PC1-016000	In-line Hook, 6.0mm
PC1-024500	Angled Offset Hook, Right, 4.5mm
PC1-026000	Angled Offset Hook, Right, 6.0mm
PC1-034500	Angled Offset Hook, Left, 4.5mm
PC1-036000	Angled Offset Hook, Left, 6.0mm
PC1-020015	Top Loading Lateral Offset
PC1-023540	Parallel Top Loading
PC1-023560	Parallel Top Loading to 5.5/6.0mm
PC1-043540	Dual, Parallel, Top Loading
PC1-043560	Dual, Parallel, Top Loading to 5.5/6.0mm
PC1-063535	Parallel, Side Loading/Variable
PC1-063555	Parallel, 5.5/6.0mm Side Loading/Variable
MD1-100016	PointLock Set Screw

NORTHSTARTRANS: 5.5mm Favored Angle Screws

Part Number	Part Description
PC1-105524	Poly. Screw, Favored Angle, 5.5 x 24mm
PC1-105526	Poly. Screw, Favored Angle, 5.5 x 26mm
PC1-105528	Poly. Screw, Favored Angle, 5.5 x 28mm
PC1-105530	Poly. Screw, Favored Angle, 5.5 x 30mm
PC1-105532	Poly. Screw, Favored Angle, 5.5 x 32mm
PC1-105534	Poly. Screw, Favored Angle, 5.5 x 34mm

NORTHSTARTRANS: Rods

Part Number	Part Description
PC1-513512	Straight CoCr Rod, 3.5 x 120mm
PC1-513520	Straight CoCr Rod, 3.5 x 200mm
PC1-514012	Straight CoCr Rod, 4.0 x 120mm
PC1-514020	Straight CoCr Rod, 4.0 x 200mm
PC1-523555	Transition Ti Rod, 3.5mm to 5.5mm, 500mm
PC1-523560	Transition Ti Rod, 3.5mm to 6.0mm, 500mm
PC1-524055	Transition Ti Rod, 4.0mm to 5.5mm, 500mm
PC1-524060	Transition Ti Rod, 4.0mm to 6.0mm, 500mm

For additional information or set configurations, please contact SeaSpine® customer service.

IMPLANTS

NORTHSTAROCC: Occipital Screws

Part Number	Part Description
PC1-714007	OCC Screw, 4.0 x 7mm
PC1-714008	OCC Screw, 4.0 x 8mm
PC1-714009	OCC Screw, 4.0 x 9mm
PC1-714010	OCC Screw, 4.0 x 10mm
PC1-714011	OCC Screw, 4.0 x 11mm
PC1-714012	OCC Screw, 4.0 x 12mm
PC1-714013	OCC Screw, 4.0 x 13mm
PC1-714014	OCC Screw, 4.0 x 14mm
PC1-714015	OCC Screw, 4.0 x 15mm
PC1-714016	OCC Screw, 4.0 x 16mm
PC1-714507	OCC Screw, 4.5 x 7mm
PC1-714508	OCC Screw, 4.5 x 8mm
PC1-714509	OCC Screw, 4.5 x 9mm
PC1-714510	OCC Screw, 4.5 x 10mm
PC1-714511	OCC Screw, 4.5 x 11mm
PC1-714512	OCC Screw, 4.5 x 12mm
PC1-714513	OCC Screw, 4.5 x 13mm
PC1-714514	OCC Screw, 4.5 x 14mm
PC1-714515	OCC Screw, 4.5 x 15mm
PC1-714516	OCC Screw, 4.5 x 16mm

NORTHSTAROCC: Occipital Rods

Part Number	Part Description
PC1-503177	Contoured Ti OCC Rod, 3.5 x 170mm x 70°
PC1-504177	Contoured Ti OCC Rod, 4.0 x 170mm x 70°
PC1-513177	Contoured CoCr OCC Rod, 3.5 x 170mm x 70°
PC1-514177	Contoured CoCr OCC Rod, 4.0 x 170mm x 70°

NORTHSTAROCC: Occipital Plates

Part Number	Part Description
PC1-700000	El Capitan OCC Plate, Extra Small
PC1-700003	El Capitan OCC Plate, Small
PC1-700004	El Capitan OCC Plate, Large

NORTHSTARHINGE: Occipital Hinged Rods*

Part Number	Part Description
PC1-514101	Ti Hinged Rod, 3.5mm Right
PC1-514102	Ti Hinged Rod, 3.5mm Left
PC1-514111	Ti Hinged Rod, 4.0mm Right
PC1-514112	Ti Hinged Rod, 4.0mm Left

NORTHSTAREYELET: Occipital Eyelets*

Part Number	Part Description
PC1-714500	Occipital Eyelet

*Optional implants. Not standard in set.
For additional information or set configurations, please contact SeaSpine® customer service.

INSTRUCTIONS FOR USE

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Indications for Use

The NorthStar® OCT 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, cervical spine (C1–C7), and upper thoracic spine (T1–T3):

- Traumatic spinal fractures and/or traumatic dislocations
- Instability or deformity
- Failed previous fusion (e.g., pseudarthrosis)
- Tumors involving the cervical/thoracic spine
- 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 NorthStar OCT 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.

The NorthStar OCT System can also be linked to other FDA-cleared SeaSpine®/Orthofix® screw systems with the use of transitional rods and/or transitional rod connectors.

Contraindications

Any medical or surgical condition which would preclude the potential benefit of spinal implant surgery is a contraindication. The following conditions may reduce the chance of a successful outcome and should be taken into consideration by the surgeon. This list is not exhaustive:

Absolute contraindications:

- Infection in or around the operative site
- Allergy or sensitivity to implant materials
- Any case not described in the indications

Relative contraindications:

- Local inflammation
- Morbid obesity
- Pregnancy
- Fever or leukocytosis
- Prior fusion at the level(s) to be treated
- Grossly distorted anatomy due to congenital abnormalities
- Metabolic joint disease, bone absorption, osteopenia, and/or osteoporosis
- Elevation of sedimentation rate unexplained by other diseases, elevation of white blood count (WBC), or a marked left shift in the WBC differential count
- Any case not requiring bone graft and fusion
- Patients having inadequate tissue coverage over the operative site
- Unsuitable or insufficient bone support
- Skeletally immature patient
- A patient unwilling or unable to cooperate with postoperative instructions
- Any case where implant utilization would interfere with anatomical structures or expected physiological performance
- Use with other devices with incompatible materials

INSTRUCTIONS FOR USE

Cleaning and Sterilization

The implants and instrumentation in the NorthStar® OCT System are supplied “NON-STERILE” and must be decontaminated and sterilized before use. Please refer to the IFU for details.

CAUTION Federal law restricts this device to sale by or on the order of a physician or practitioner.

Please refer to the following website for other important labeling information:
www.seaspine.com/eIFU
QF-10-01-115-ENGL

SeaSpine® Orthopedics Corporation does not practice medicine and does not recommend this or any other surgical technique for use on a specific patient. The surgeon who performs any procedure is responsible for determining and using the appropriate technique in each patient.

NORTHSTAR® OCT

POSTERIOR CERVICAL FUSION SYSTEM

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