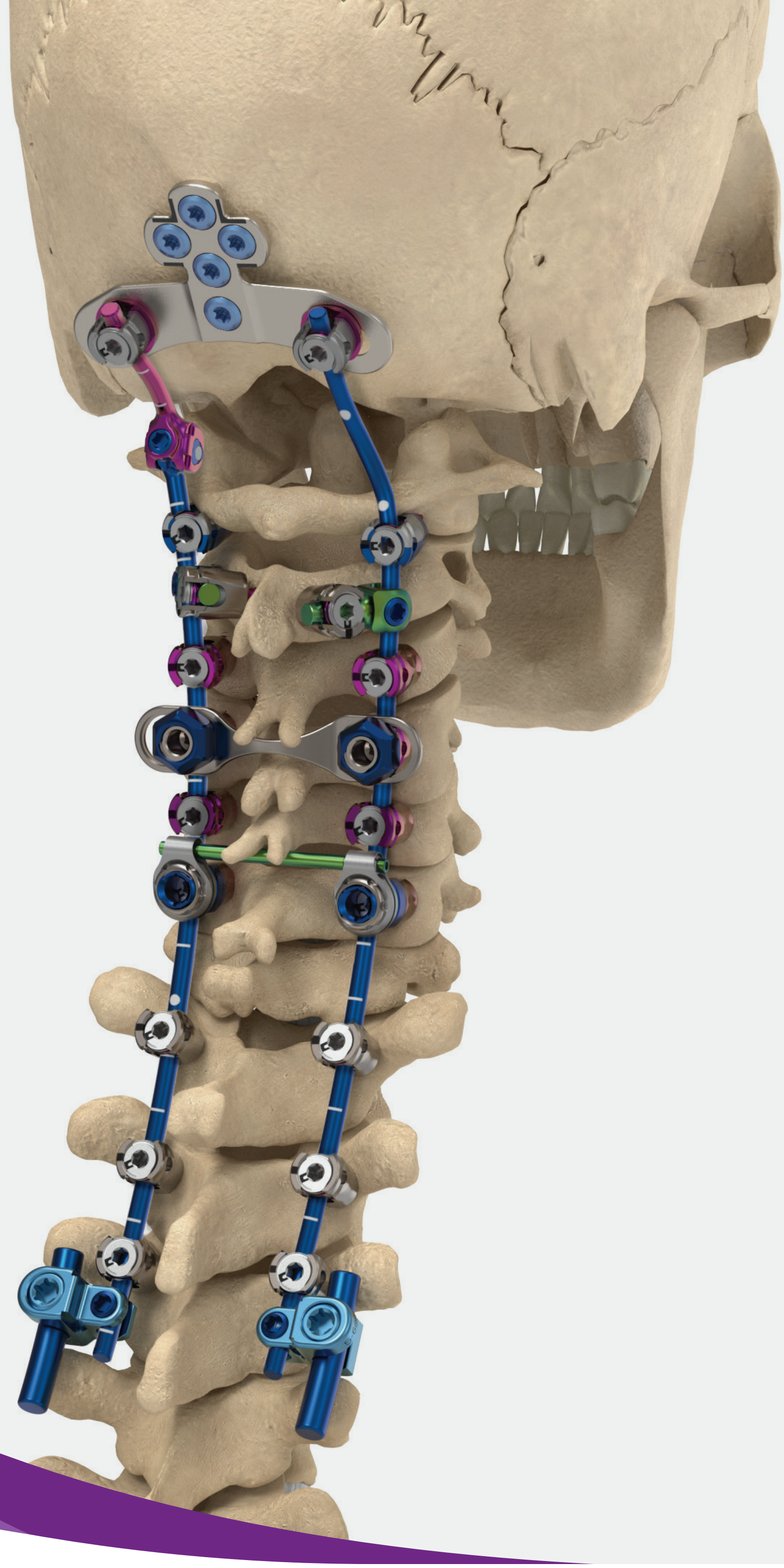

Reline Cervical

Technique guide

NuVasive

This document is intended exclusively for physicians.

This document contains general information on the products and/or procedures discussed herein and should not be considered as medical advice or recommendations regarding a specific patient or their medical condition.

This surgical technique guide offers guidance but is not a substitute for the comprehensive training surgeons have received. As with any such technique guide, each surgeon should use his or her own independent medical judgment to consider the particular needs of the patient and make appropriate clinical decisions as required. A successful result is not always achieved in every surgical case.

As with all surgical procedures and permanent implants, there are risks and considerations associated with surgery and the implant, including the use of the Reline Cervical system. It may not be appropriate for all patients and all patients may not benefit.

It is the surgeon's responsibility to discuss all relevant risks with the patient prior to surgery.

All non-sterile devices must be cleaned and sterilized before use. Multi-component instrument assemblies must be disassembled prior to cleaning.

This surgical technique guide provides information supplemental to information provided in the individual system instructions for use (IFU) regarding the products referenced herein.

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Introduction

The **Reline Cervical 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 (C1–C7), and the thoracic spine (T1–T3): traumatic spinal fractures and/or traumatic dislocations; instability or deformity; failed previous fusions (e.g., pseudoarthrosis); tumors involving the cervical 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 Reline Cervical 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 Reline Cervical system may be connected to the NuVasive Spherx spinal system, Precept spinal system, Armada spinal system, Reline system and Reline 4.5–5 system via the rod-to-rod connectors or transition rods.

Please refer to the corresponding individual system IFU for important product information, including but not limited to, indications, contraindications, warnings, precautions, and adverse effects, located at the back of this surgical technique guide, and which can also be found at **nuvasive.com/eIFU**

Reline Cervical standard technique

Step 1

Position, incision and exposure

While patient positioning is up to the discretion of the surgeon, care must be taken to position the patient's neck with the proper anatomic alignment prior to instrumentation *(Fig. 1)*. Place the patient in the prone position with the head in a Mayfield head-holder.

Perform a standard midline incision to expose the operative levels. Care should be taken to not expose any facet joint that is not in the planned construct, as exposure of any additional facet may contribute to facet disruption and instability.

Patient prep for cervical neuromonitoring with Pulse or NVM5

During patient positioning, place the appropriate electromyography (EMG), motor evoked potentials (MEP) and/or somatosensory evoked potentials (SSEP) neuromonitoring electrodes on the patient.

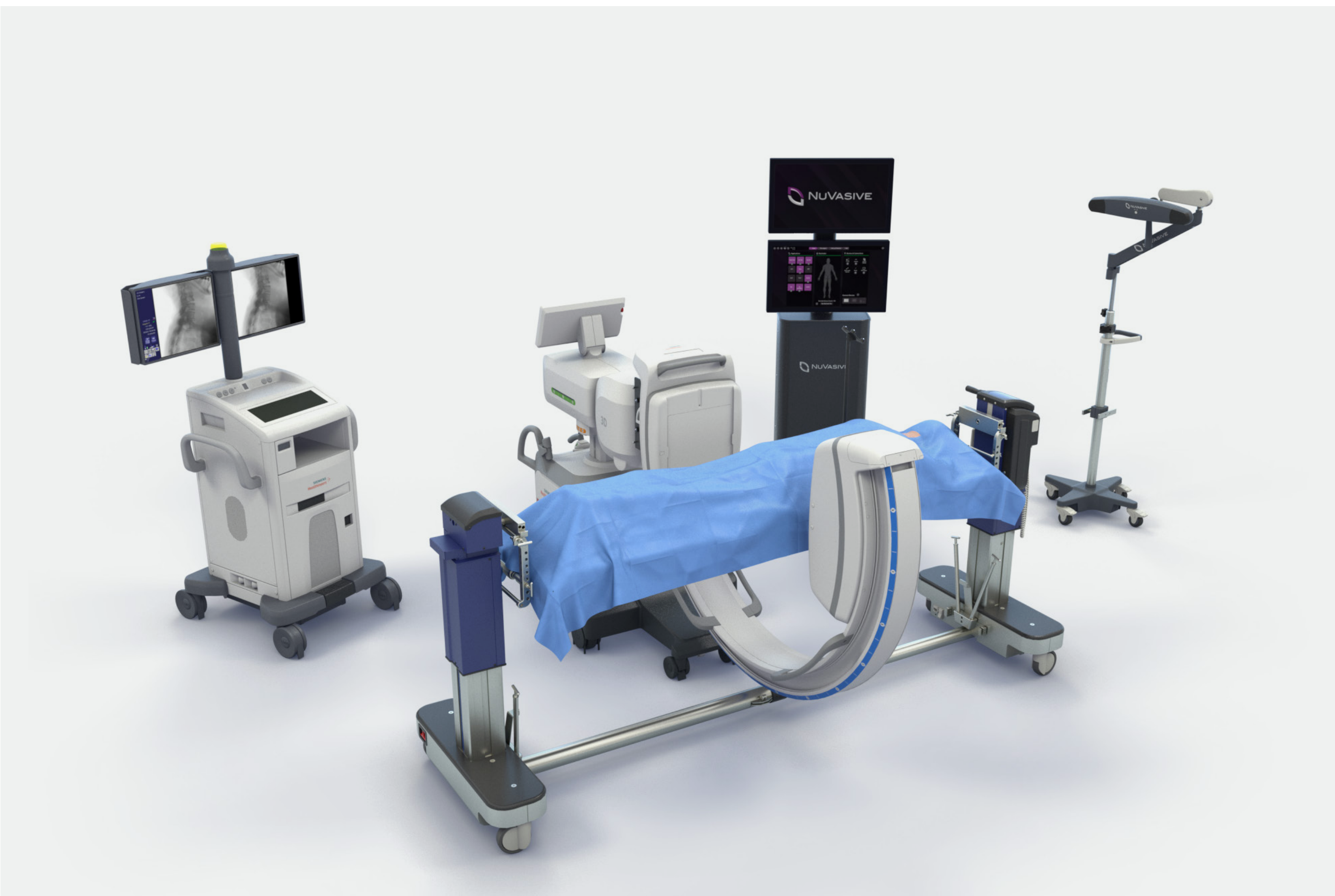


Fig. 1

Step 2

Screw preparation

To locate the desired entry point and perforate the outer cortex, an awl, high-speed burr or gearshift probe may be used.

Once the outer cortex is perforated, use a drill or probe to create a pilot hole.

Gearshift probes

The Reline Cervical system offers two types of probes: cervical and thoracic. Both types come in straight and curved configurations.

Cervical gearshift probes: The cervical gearshift probes are 1.6 mm wide at the distal tip and square in shape. When turned 90° in either direction they will produce a ø2.25 mm hole. The cervical probes are marked gold from the tip to 15 mm. Laser marked bands indicate 15, 20–30, 35, and 40 mm of depth with a silver band at 25 mm *(Fig. 2)*.

Thoracic gearshift probe: The thoracic gearshift probe is 2.1 mm wide at the distal tip and is square in shape. If turned more than 90° in either direction while making the hole, the instrument will produce a ø3 mm hole. The thoracic probes are marked gold from the tip to 15 mm. Laser marked bands indicate 15, 20–30, 35, 40–50, 55 and 60 mm of depth with silver bands at 25 and 45 mm *(Fig. 3)*.

Note: *The thoracic gearshift probe is recommended for use only with dual lead screws.*

Note: *The straight thoracic gearshift can be special ordered.*

Once the desired probe is selected, slowly twist and drive the gearshift to the desired depth.

NVM5 monitors pedicle integrity during pedicle preparation. Insulate a gearshift probe or tap from surrounding tissue with the insulating sheath. Attach the dynamic stimulation clip to the shaft of the instrument, and stimulate using the dynamic EMG modality.

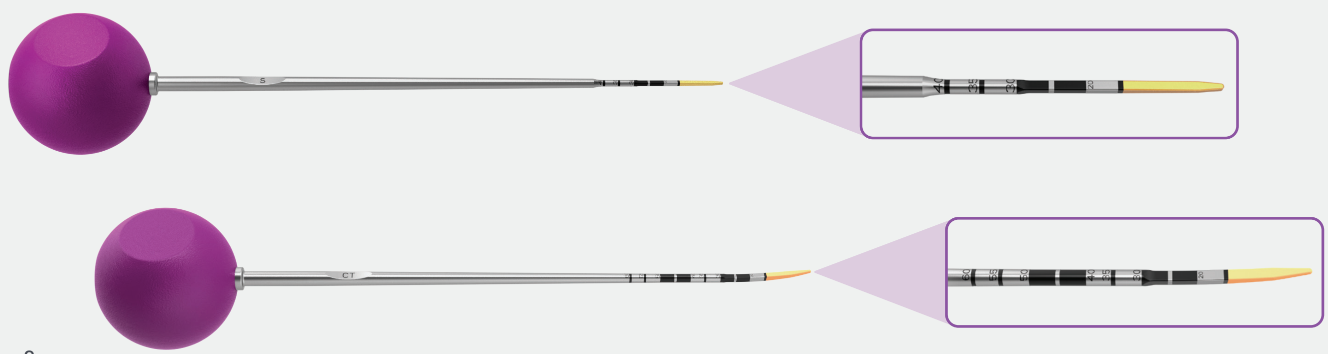


Fig. 2

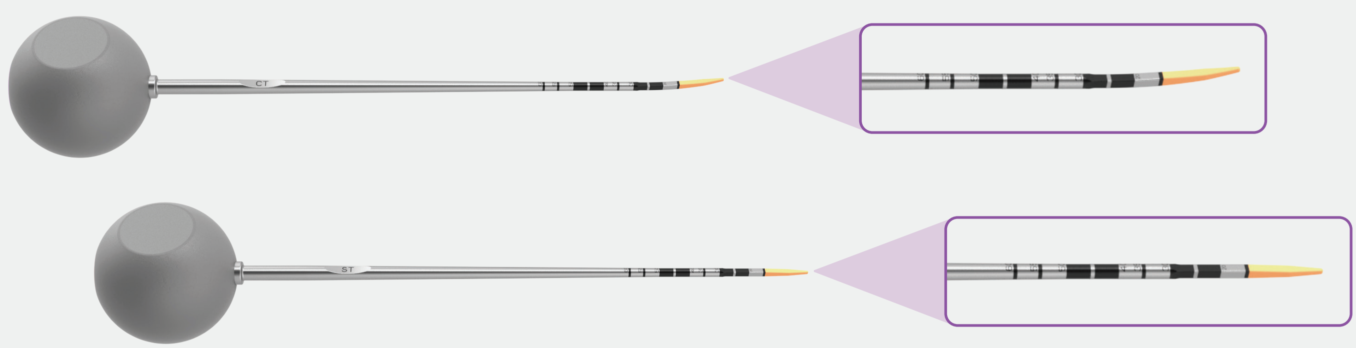


Fig. 3

Screw preparation (cont.)

Drill

Attach the drill bit to a fixed or ratcheting handle or to power. The drill must always be used with the drill guide.

Choose the appropriate drill guide for the determined screw depth. There are two types of drill guides in the system: fixed and adjustable.

Fixed: For added surgical efficiency, the fixed drill guide features pre-determined depths for the most common screw sizes: 12, 14 and 16 mm. The length of the fixed drill guide is marked on the proximal end of the instrument *(Fig. 4)*. Colored bands and handles are the same color as the tulip for screws of matching length *(Fig. 5)*.

Fig. 4

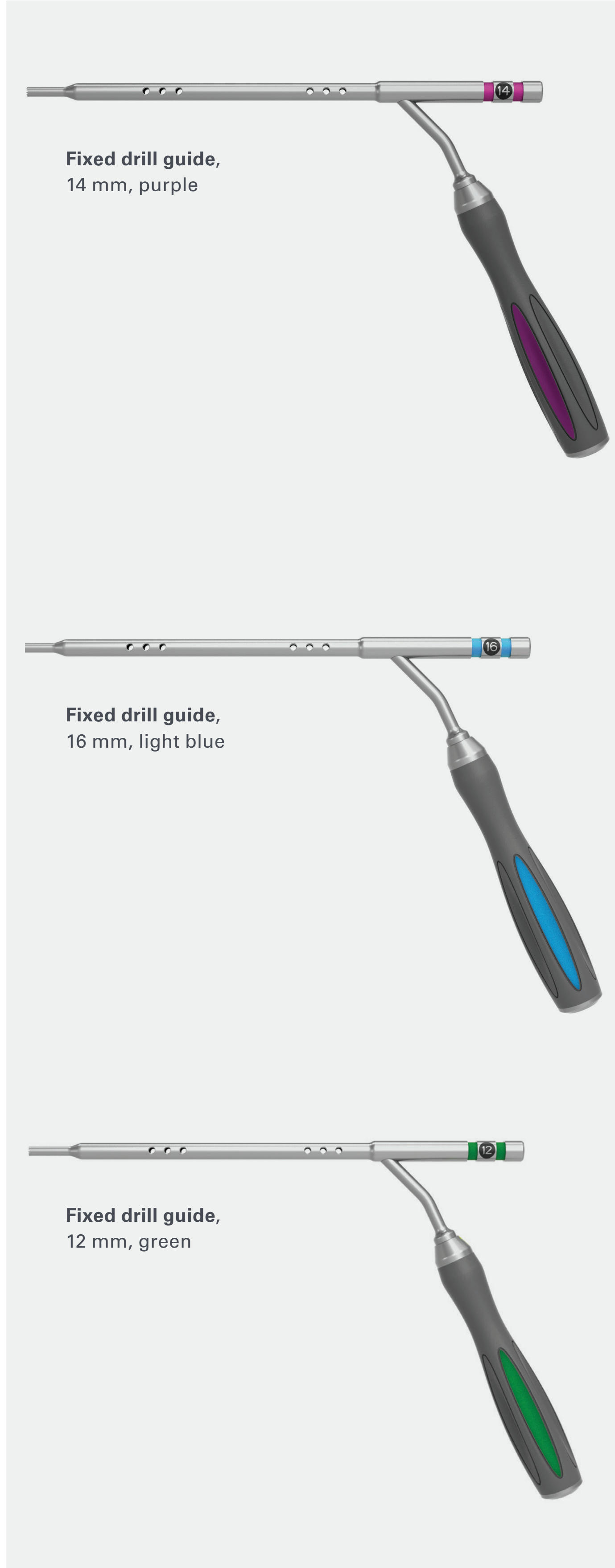


Fig. 5

Screw preparation (cont.)

Adjustable: The adjustable drill guide features a range of depths for sequential drilling. Depth is indicated by the laser marked numbered slots *(Fig. 6)*.

Select the desired depth by pulling back on the knurled segment and placing the metal slide into the numbered slot labeled with the appropriate depth *(Fig. 7)*.

Insert the drill bit assembly through the barrel of the drill guide and begin drilling until the desired depth is achieved. A designed safety feature of the Reline Cervical system is the positive stop on all drill guides, which can help prevent the drill from accidentally advancing deeper than intended *(Fig. 8)*.

Inspect the integrity of the pedicle walls by placing the ball-tip probe into the pilot hole and palpating the walls on all sides of the hole.

Note: *The drill bit is 2.25 mm in diameter.*

Note: *The adjustable drill guide ranges are 8–22, 24–40 and 42–50 mm. The 42–50 mm adjustable drill guide can be special ordered.*

Note: *A dual ended ball-tip probe can be special ordered. The dual ended ball-tip probe features a stiff and flexible end. This is denoted by the laser marked "S" and "F" on the shaft of the probe.*

Warning

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 confirm device placement, as necessary.

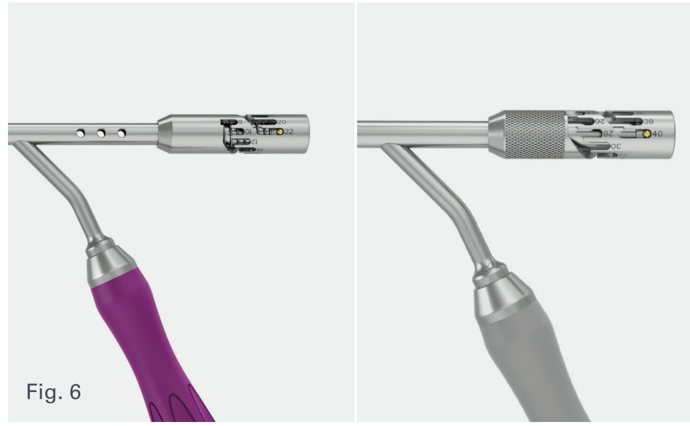


Fig. 6

Fig. 7

Fig. 8

Screw preparation (cont.)

Taps

All screws are self-tapping; however, if preliminary tapping is required, taps are available to prepare the threads for all screw types and diameters.

Attach the desired diameter tap to a fixed or ratcheting handle. Following the created pilot hole, tap to the desired depth. Continuously inspect the integrity of the pedicle walls by placing a ball-tip probe into the pilot hole and palpating on all sides.

Note: *Taps are line-to-line as marked.*

Note: *The threads on the taps are 15 mm in length.*

Note: *To help gauge depth, the taps are marked gold from tip to 15 mm and laser marked with solid black bands at 15, 20–30, 40–50, 55 and 60 mm, and silver bands at 25 and 45 mm where applicable (Fig. 10).*

Note: *Taps are color coded by diameter and match the shank of the same diameter screw. For under sizing a screw,* ***do not*** *match the colors. For example, if under sizing a 4 mm screw, use a 3.5 mm tap.*

Warning

To prevent stripping, stop tapping when the tap bottoms out on the tap guide.

Warning

To prevent stripping of the tap threads, **do not** attach the tap to power. Always hand-tap to depth.

Tap sizes and descriptions

Single lead taps (one colored band)

- 3 mm tap, orange
- 3.5 mm tap, purple
- 4 mm tap, bronze
- 4.5 mm tap, green

Dual lead thoracic taps (two colored bands)

- 4.5 mm dual lead tap, green
- 5 mm dual lead tap, light blue
- 5.5 mm dual lead tap, gold
- 6 mm dual lead tap, teal
- 6.5 mm dual lead tap, purple
- 7 mm dual lead tap, seafoam green
- 7.5 mm dual lead tap, blue

Note: *Dual lead taps are indicated with two proximal colored bands.*

Fig. 10

Step 3

Screw selection

Reline Cervical offers a variety of screw types to address the various challenges of the cervical spine. All screw types possess friction fit to provide superior alignment control as well as screw shanks and tulip heads that are color coded for ease of identifying diameter and length, respectively. All screw types accept a 3.5 and 4 mm rod diameter and possess a C-star 15 drive feature.

Once the bone is tapped to the desired depth, select the desired implant type and size.

Fig. 11

Multiaxial screw *(Fig. 11)*

45/45° of angulation

- Offers up to 90° conical sweep
- Offered in 3.5, 4 and 4.5 mm diameters
- Offered in 10–38 in 2 mm increments and 42, 46 mm lengths
- 3.5x8, 40, 44 and 48 mm available upon request

Fig. 12

Favored angle screw *(Fig. 12)*

65/25° of angulation

- Up to 65° of favored angulation
- Offers up to a 90° conical sweep
- The silver half of the bi-colored screw head provides a visual indication of the favored angle orientation
- Offered in 3.5 and 4 mm diameters
- Offered in 10–38 in 2 mm increments and 42, 46 mm lengths
- 3.5x8, 40, 44 and 48 mm available upon request

Fig. 13

Partially threaded favored angle screw *(Fig. 13)*

65/25° of angulation

- Smooth portion helps protect nerve roots and soft tissue if the tulip is left proud of the bone surface
- The last 10 mm of the proximal portion of the screw shaft is unthreaded
- The silver half of the bi-colored screw head provides a visual indication of the favored angle orientation.
- Offered in 3.5 and 4 mm diameter
- Offered in 22–46 mm lengths in 2 mm increments
- 3.5x48 and 50 mm available upon request

Screw selection (cont.)

Large diameter multiaxial screw *(Fig. 14)*

30/30° of angulation

- Offers up to a 60° conical sweep
- Offered in 4.5–7.5 mm diameters in 0.5 mm increments
- Offered in lengths of 20–40 mm in 5 mm increments

Medial lateral favored angle large diameter screw *(Fig. 15)*

40/20° of angulation

- Offers 60° conical sweep
- The silver half of the bi-colored screw head provides a visual indication of the favored angle orientation
- Offered in 4–5.5 mm diameters in 0.5 mm increments
- Offered in lengths of 20–40 mm in 5 mm increments

Cortical cancellous large diameter multiaxial screw *(Fig. 16)*

30/30° of angulation

- Offers 60° conical sweep
- Built in cortical cancellous shank threads
- Offered in 4–5.5 mm diameters in 0.5 mm increments
- Offered in lengths of 20–40 mm in 5 mm increments

Note: *All Reline Cervical screw shanks feature a C-star 15 drive feature*

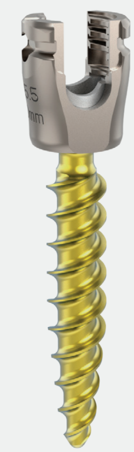


Fig. 14

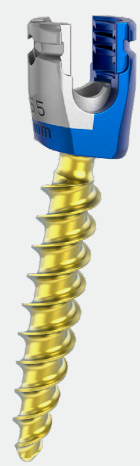


Fig. 15

Fig. 16

Screw selection (cont.)

Communicating through color

For surgical efficiency and ease of identification, Reline Cervical screws are color coded. Shank color indicates diameter *(Fig. 17)*. Tulip color indicates length *(Fig. 18)*.

Color indicating diameter									
Single lead			Dual lead						
3.5 mm	**4 mm**	**4.5 mm**	**4.5 mm**	**5 mm**	**5.5 mm**	**6 mm**	**6.5 mm**	**7 mm**	**7.5 mm**
Purple	Bronze	Green	Green	Light blue	Gold	Teal	Purple	Seafoam	Blue

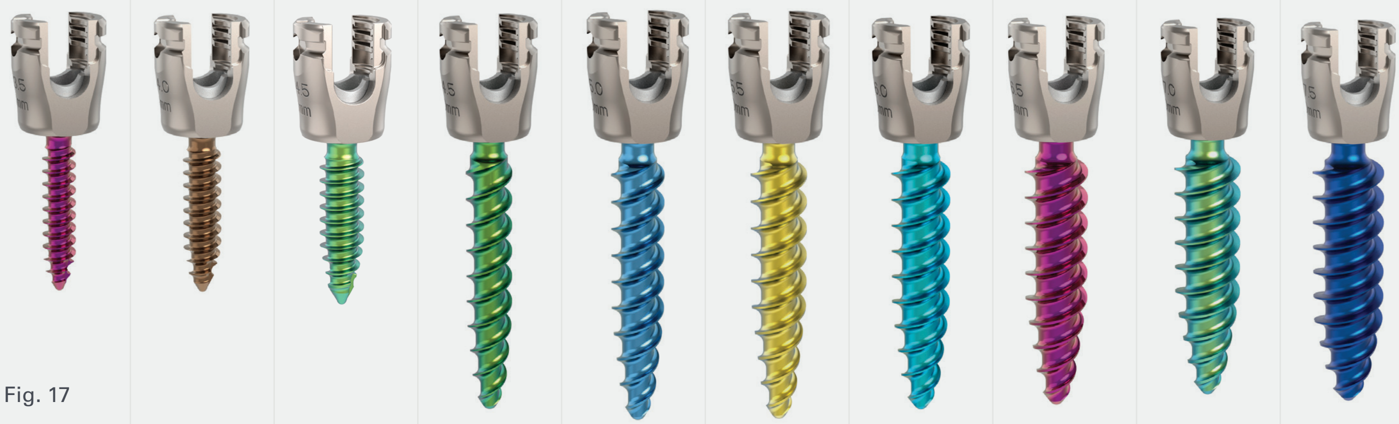


Fig. 17

Color indicating length			
12 mm	**14 mm**	**16 mm**	**All other lengths**
Green	Purple	Light blue	Grey

Favored angle screws will be indicated with dark blue.

Fig. 18

Laminar hooks

Laminar hooks are offered as an optional fixation method that may be useful in select situations such as a severely stripped screw hole. Hooks come in 6 mm (green) and 8 mm (purple) which refers to the length of the hook shelf *(Fig. 19)*.

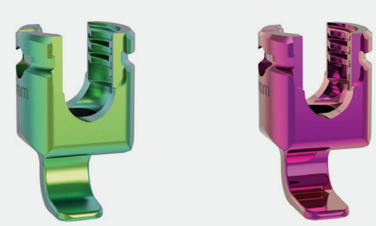


Fig. 19

Step 4

Driver selection, screw insertion, hook insertion and screw alignment

Driver selection

Reline Cervical offers three driver types with different attachment mechanisms to provide versatility in any scenario. The driver types are threaded, tapered and stab-n-grab *(Fig. 20).*

Threaded driver

The threaded driver attaches to the screw by threading into the tulip threads and offers a robust connection during insertion.

To engage: Attach the threaded driver to a fixed or ratcheting handle. Insert the distal drive feature into the hexalobe of the screw shank with the alignment pin seated in the rod slot *(Fig. 21).*

Attach the screw by turning the silver knob clockwise *(Fig. 22)*. The distal threads on the threaded driver will advance into the tulip threads. Continue turning the silver knob until snug.

Note: *To confirm proper engagement to the shank of the screw, attach the driver to the screw while the screw remains in its caddy.*

Fig. 20


Fig. 21


Fig. 22

Driver selection, screw insertion, hook insertion and screw alignment (cont.)

Confirm the screw and screwdriver interface is rigid and fully seated and the shank is aligned straight. If not, remove the screw from the driver and reload it paying close attention to the driver and screw interface *(Fig. 23)*.

The black rotation sleeve is designed to spin independent of the driver shaft and serve as a stabilization point during insertion. The sleeve is removable for a lower profile driver, if necessary (see steps below).

To disengage: Turn the silver knob counterclockwise while holding the handle still until the outer sleeve is fully unthreaded from the tulip and remove from the implant.

Repeat these steps for all implant placement sites.

Optional: To achieve a driver with a lower profile, the black rotation sleeve may be removed. To remove, depress the silver button on the black rotation sleeve and slide the sleeve off the distal end of the driver *(Fig. 24a–c)*.

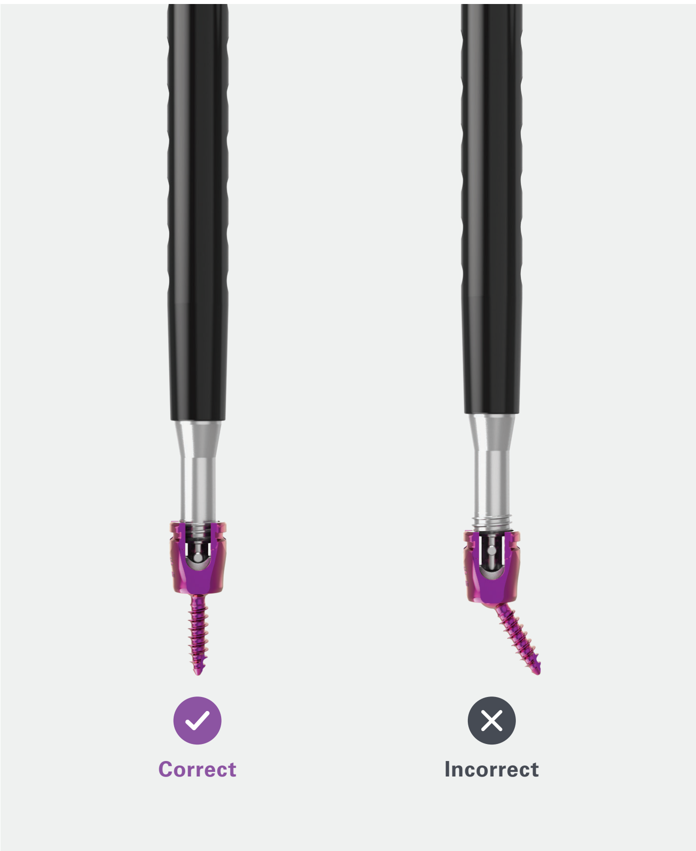


Fig. 23

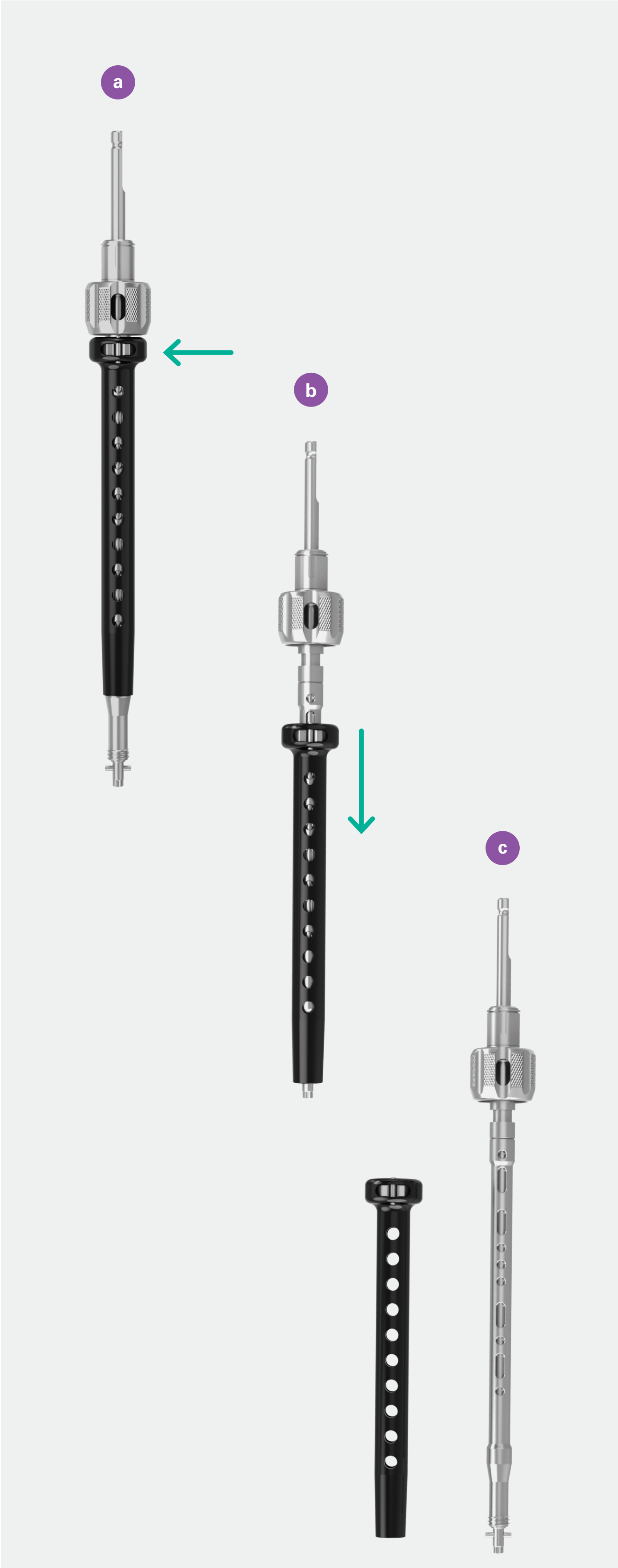


Fig. 24

Driver selection, screw insertion, hook insertion and screw alignment (cont.)

Tapered driver

The tapered driver attaches to the screw with a tapered fit and provides added efficiency for workflow due to the simplicity of the attachment.

To engage: Attach a tapered driver to a fixed or ratcheting handle. Insert the distal drive feature into the hexalobe of the screw shank. This driver will engage, pick up and hold a multiaxial screw using the tapered tip. Retention force of this driver is proportional to the axial force applied to the shaft when engaging the screw.

Confirm the screw and screwdriver interface is rigid and fully seated and the shank is aligned straight. If not, remove the screw from the driver and reload it paying close attention to the driver and screw interface *(Fig. 25)*.

To disengage: Place the implant in the desired location and gently pull the driver off the implant to disengage.

Repeat these steps for all implant placement sites.

Note: *The tapered driver is titanium nitride-coated gold on the proximal end of the instrument for ease of identification.*

Fig. 25

Driver selection, screw insertion, hook insertion and screw alignment (cont.)

Stab-n-grab driver

The stab-n-grab driver retains the screw with a spring clip and provides added efficiency for workflow due to the simplicity of the attachment.

To engage: Attach a stab-n-grab driver to a fixed or ratcheting handle. This driver will engage, pick up and hold a multiaxial screw, and retain the screw using a spring clip. Therefore, retention force between the driver and the screw remains consistent and independent from the amount of force that is applied to the driver when it engages the screw.

Confirm the screw and screwdriver interface is rigid and fully seated and the shank is aligned straight. If not, remove the screw from the driver and reload it paying close attention to the driver and screw interface *(Fig. 26)*.

To disengage: Once the screw is inserted, use a rolling or gentle rocking motion to disengage the screw from the driver.

Repeat these steps for all implant placement sites.

Note: Do not *insert the multiaxial screw to the point it is bottomed out against bone—the multiaxial feature will be lost.*

Note: *When using the stab-n-grab driver,* ***do not*** *bottom out the tulip on the bone, as the tulip will tilt, and the driver may jam or be more difficult to disengage from the screw.*

Note: *If the screw is bottomed out against bone and there is difficulty disengaging the driver, turn the screw back a quarter turn. This will allow the driver to disengage more easily.*

Note: *The drivers have a C-star 15 drive feature.*

Fig. 26

Driver selection, screw insertion, hook insertion and screw alignment (cont.)

Screw insertion

With the implant attached to the driver, follow the created pilot hole and insert the implant. Once the implant is at the desired depth, remove the driver using the disengagement steps detailed in the driver selection section on page 14. The tapered driver is recommended to make screw depth adjustments after driver disengagement. For a description of screw trajectories refer to the screw trajectories section on page 54.

Neuromonitoring with Pulse or NVM5

After screws are inserted, a subsequent MEP reading may be taken to confirm motor pathway integrity. If stimulating during pedicle screw insertion an insulator (catalog #8801205 or #10000413) must be used. These parts are not standard in the set and must be ordered separately.

Hook insertion

Threaded driver: Laminar hooks can be inserted using the threaded driver. Follow the same attachment steps as when attaching the multiaxial screw as detailed on page 14.

Implant holding forceps: Engage the distal end of the forceps on the cap so they encompass the head of the hook and engage the lateral engagement features. Close the forceps until a firm connection is felt *(Fig. 27)*. The implant should sit in the forceps with minimal toggle.

Screw head alignment

Use the alignment tool to align the screw heads and facilitate rod placement. Insert the distal end of the alignment tool so it sits in the rod opening and turn the heads of the screws so the rod slot is cranial-caudal *(Fig. 28)*. The screw heads will remain in position due to the friction fit head.

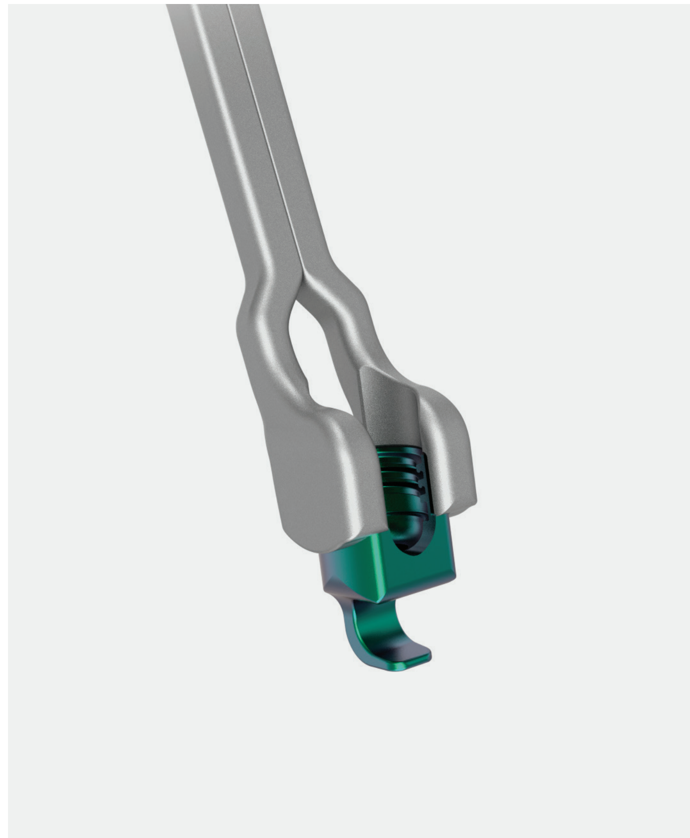


Fig. 27

Fig. 28

Step 5

Rod selection and measurement

Rod measurement

Seat the rod template into the tulip heads of the construct and use the reference lines to determine the length and shape of the rod. Once determined, the template can be used as a reference when bending the rod *(Fig. 29)*.

Note: *The rod template is 240 mm in length*

Fig. 29

Rod selection and measurement (cont.)

Rod selection

Reline Cervical features multiple rod types, diameters and materials to offer the correction desired. Select the size and type of rod using the measurement determined by the rod template.

3.5 mm diameter rods

- Straight titanium and cobalt chrome in 120 and 240 mm lengths
- Pre-bent titanium and cobalt chrome 25 mm, 30–120 mm lengths in 10 mm increments
- Transition titanium in ø3.5–ø5.5 220/265
  - ø3.5–4, ø3.5–ø4.5, and ø3.5–ø5 are available upon request (220 mm of small diameter and 265 mm of larger diameter)
- Transition cobalt chrome in ø3.5–ø5.5 220/265
  - ø3.5–ø4 in 485 mm length are available upon request (220 mm of small diameter and 265 mm of larger diameter)
  - ø3.5–ø4.5 and ø5 in 700 mm length are available upon request (200 mm of small diameter and 500 mm larger diameter)

4 mm diameter rods

- Straight titanium in 120 and 240 mm lengths
- Straight cobalt chrome in 240 and 500 mm lengths are available upon request
- Pre-bent titanium 25, and 30–120 mm lengths in 10 mm increments
- Transition titanium in ø4–ø5.5 mm (220 mm of small diameter and 265 mm of larger diameter)
  - ø4–ø4.5, ø4–ø5, and ø4–ø6 in 700 mm length are available upon request (200 mm of small diameter and 500 mm of larger diameter)
- Transition cobalt chrome in ø4–ø4.5, ø4–ø5, and ø4–ø6 in 700 mm length are available upon request (200 mm of small diameter and 500 mm of larger diameter)

Titanium rods are color coded to indicate diameter and material type for ease of identification. The Reline Cervical rods possess length markings and a longitudinal line to conveniently identify the proper cut location and bend orientation *(Fig. 30)*.

Note: *The length markings are indicated every 10 mm with vertical dashes. Every 50 mm are indicated with a circle. Cobalt chrome rods **do not** possess a longitudinal line.*

Note: *The large diameter of the Reline Cervical transition rods are color coded according to the diameter—4.5 mm (gold), 5 mm (purple), 5.5 mm (dark blue) and 6 mm (teal).*

Rod selection and markings		
3.5 mm, titanium	**4 mm, titanium**	**3.5 and 4, cobalt chrome**
Dark blue with silver markings	Teal with purple markings	No color, bare metal

Fig. 30

Step 6

Rod cutting, bending and placement

Rod cutting

The rod cutter can be used to cut the appropriate length of straight or curved ø3.5 and ø4 mm rods in titanium and cobalt chrome. The length markings on the rods can be used to conveniently identify the proper cut location.

The rod cutter offers two different cutting locations:

Scissor: The scissor portion of the cutter is recommended for primary cuts as well as to address in-situ cutting requirements *(Fig. 31)*.

To use the scissor portion, fully open the handle of the cutter and insert the rod so the desired cut location is in the center of scissor, where the two plates meet *(Fig. 32)*.

Holding both ends of the rod, compress the handle and cut the rod.

Side hole: The side hole of the cutter may be used for primary cuts *(Fig. 33)*. The cut is recessed 5 mm. To use the side hole of the cutter, fully open the handle of the cutter and insert the rod. Holding both ends of the rod, compress the handle and cut the rod.

Fig. 32

Fig. 31

Fig. 33

Rod cutting, bending and placement (cont.)

Rod bending

Reline Cervical offers two instruments for rod bending: the French bender and the pipe bender.

French bender

The French bender features three bending mandrills to aid in acute bends of both ø3.5 or ø4 mm rods *(Fig. 34)*. Primary contours are accomplished with the two central mandrills while the offset third mandrill allows for a more acute bend.

Use the rod bender to impart the desired sagittal and coronal contour. While bending, observe the longitudinal line and length markings on the rod to confirm the contour is congruent with the shape of the spine and/or rod template.

Pipe bender

A pipe bender may also be used to make acute bends to rods. The pipe benders offer two bending holes: parallel and perpendicular *(Fig. 35)*.

Coronal bender handles also have a rod cutout and can function as perpendicular pipe benders *(Fig. 36)*.

Warning

To maintain mechanical integrity of the rod, once the rod is bent in one direction, further bending only in that same direction should be attempted. Unbending the rod may cause mechanical compromise.

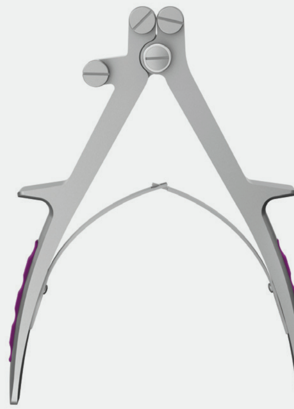


Fig. 34

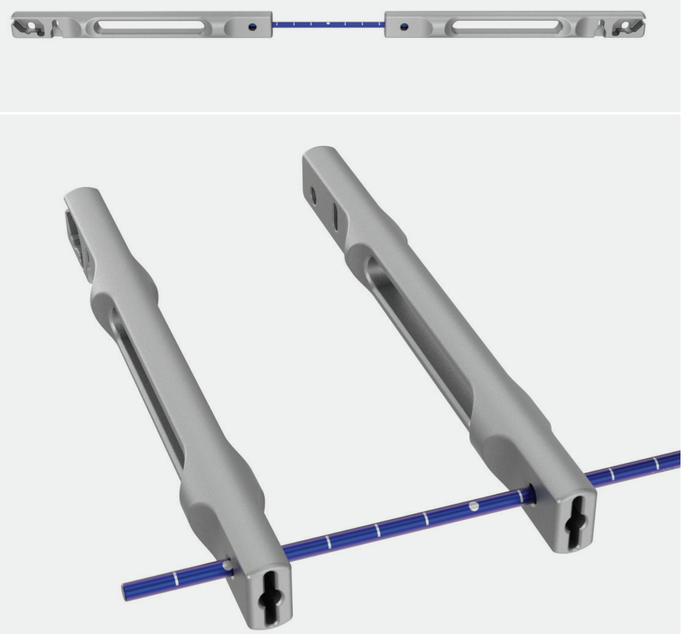


Fig. 35

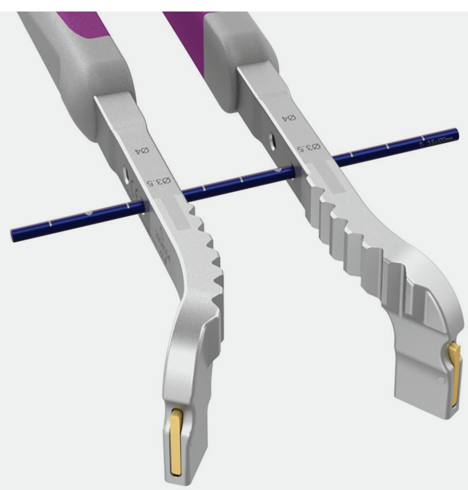


Fig. 36

Rod cutting, bending and placement (cont.)

Bendini with Pulse

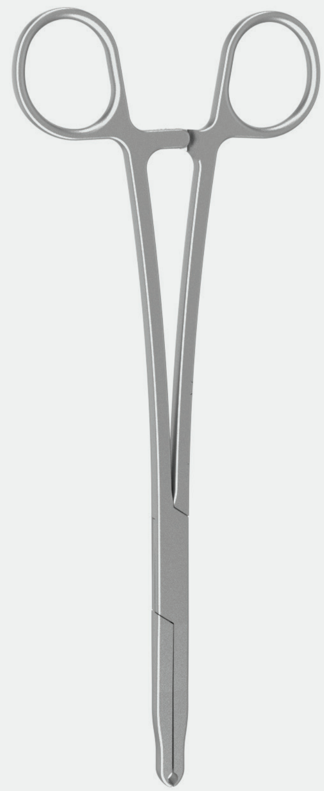
Bendini can also be used to bend a ø3.5 mm rod. For instructions, follow the Bendini surgical technique guide (document #9501356).

Rod placement

Insert the ø3.5 or ø4 mm rod into the tulip head of the desired implant using the rod holder or gripper *(Fig. 37)*. The rod gripper may be used if more control over the rod is desired.

> **Warning**
>
> Notching, striking and/or scratching of implants with any instrument should be avoided to reduce the risk of breakage.

Rod holder



Rod gripper

Fig. 37

Step 7

Rod reduction

Reline Cervical hosts a family of reduction instruments designed for different surgical goals including the reduction tower, Kerrison reducer, rocker and rod pusher.

Reduction tower

The reduction tower offers up to 15 mm of threaded reduction and provides a threaded method of reduction ideal for sequential reduction or rod capture. The reduction tower attaches to the tulip head of the screw by mating with the lateral engagement features of the tulip *(Fig. 38)*. To provide added ease of use, the reduction tower may be attached to the tulip in two ways, includes color indication for the reduction window and uses an automatic locking feature to maintain connection to the tulip head.

Attachment option 1: Position the reduction tower so the rod capture window is parallel with the rod *(Fig. 39)*. Push on the proximal end of the instrument to engage the lateral engagement features of the tulip head, a click can be felt when attached.

Attachment option 2: The reduction tower also attaches by depressing the arms on the sides of the tower. Once depressed, align the rod capture window so it is parallel with the rod *(Fig. 40)*. Capture the tulip head with the reduction tower and release the tower arms.

Reduction: The reduction tower features green and black markings on the internal shaft of the reducer. The reducer is unlocked and may be engaged or disengaged from the tulip when the black line is exposed. To begin reduction, bury the black line within the body of the reducer. When the black line is buried, it also indicates an automatic locking feature of the reducer to the tulip *(Fig. 41)*.

When the green line is buried within the reducer body, the rod is fully reduced within the tulip *(Fig. 42)*.

Fig. 38

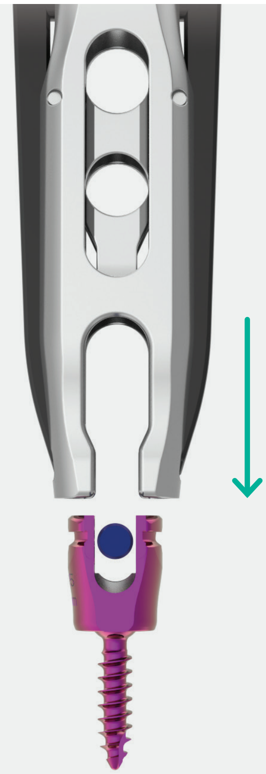


Fig. 39

Fig. 40

Fig. 41

Fig. 42

Rod reduction (cont.)

A lock screw can be passed through the cannulation of the reduction tower with the tapered driver. The tapered driver includes a centering guide that constrains the driver to keep the lock screw coaxial with the screw tulip *(Fig. 43)*.

To disengage: Fully unthread the reduction tower inner shaft so the black line is visible *(Fig. 44)*. Compress the tower arms to release the reducer from the lateral engagement features of the screw *(Fig. 45)*. Gently pull the tower off the tulip head to remove. The reducer should disengage from the tulip head with no resistance.

Note: *Prior to engaging, unthread the reducer knob so the black line is showing.*

Note: *The tower will not disengage from the screw unless the black line is showing.*

Reduction tower cap (optional)

The reduction tower cap may be used to provide improved grip and increased torque transfer during reduction.

Attachment: Once the tower reducer is attached to the tulip and prior to reduction, slide the cap on to the proximal knob of the reducer. The tower cap is fully seated when it bottoms out on the reduction knob *(Fig. 46)*. Perform reduction using the standard technique. A lock screw can be inserted with the cap on.

Removal: Remove the tower cap by sliding it off the proximal knob, then remove the reducer using the standard technique.

Fig. 44

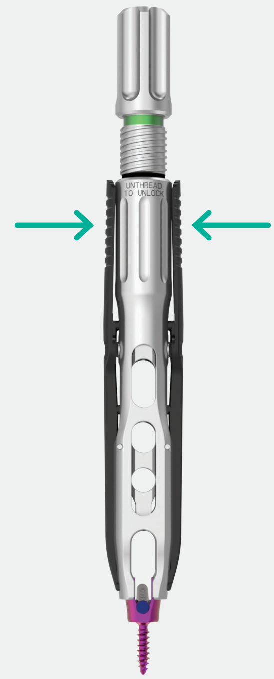


Fig. 45

Fig.46

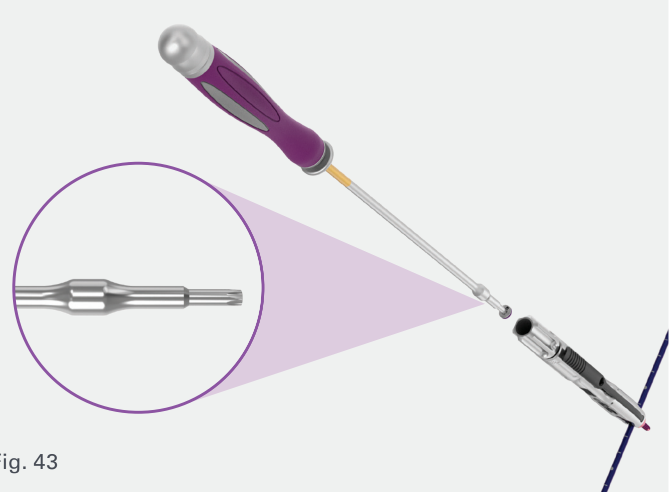


Fig. 43

Rod reduction (cont.)

Kerrison reducer

The Kerrison reducer offers up to 13 mm of reduction and provides tactile feedback during reduction. The reducer can be locked using the proximal locking rack.

Attachment: To attach the Kerrison, open the handle fully *(Fig. 47)*. While the handle is open, align the rod slot and apply gentle downward pressure to attach the Kerrison to the tulip head *(Fig. 48)*. The black arms will automatically connect with the lateral engagement features of the tulip. **Do not** squeeze the handle during attachment as this can cause the reducer to not properly engage to the tulip.

Squeeze the handle to lock the Kerrison onto the tulip *(Fig. 49)*. The sleeve will advance to capture the black arms in the locked position *(Fig. 50)*. Continue to squeeze the handle to reduce the rod.

While the handle is closed, insert the lock screw through the cannulation of the Kerrison using the tapered driver *(Fig. 51)*.

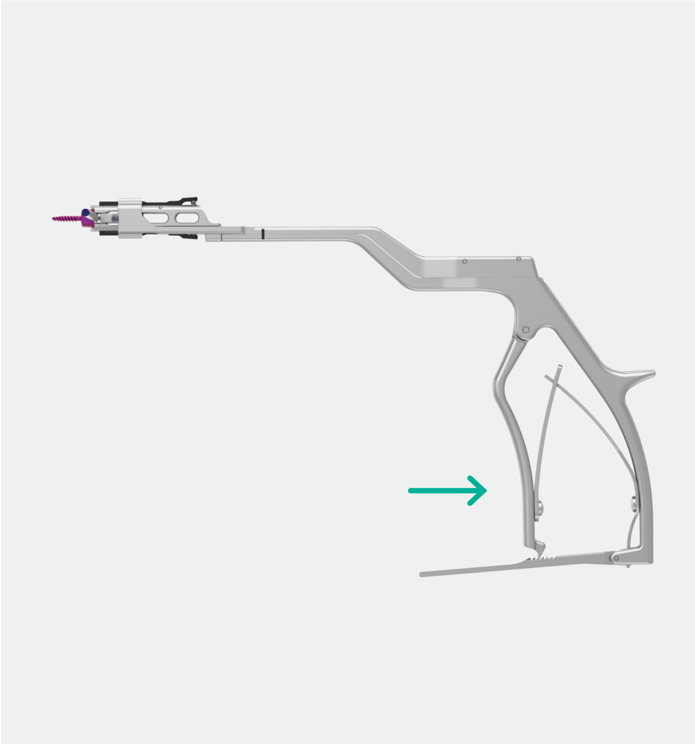


Fig. 49

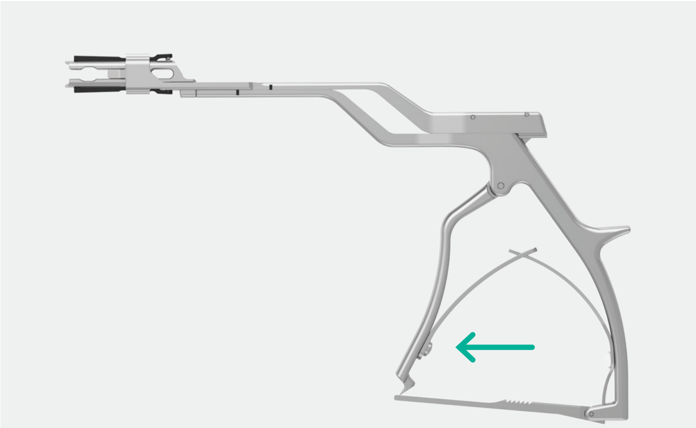


Fig. 47


Fig. 50

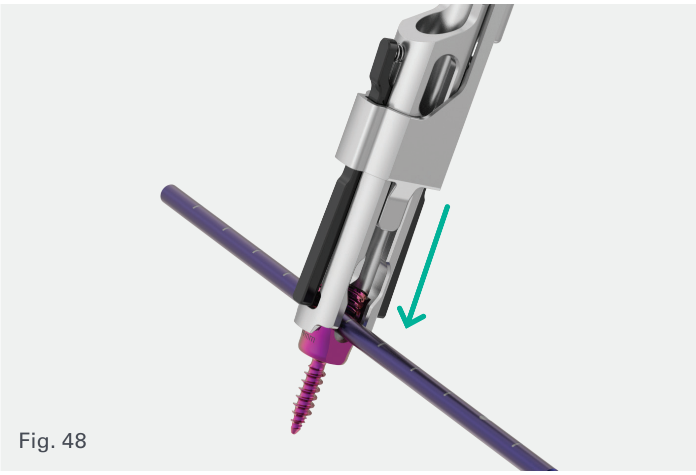


Fig. 48

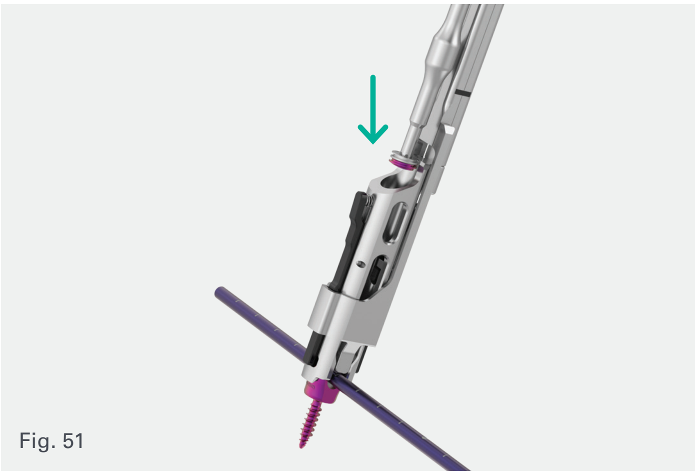


Fig. 51

Rod reduction (cont.)

Disengagement: Fully release the handle to unlock the Kerrison from the tulip *(Fig. 52)*. The sleeve will retract to release the black arms from the locked position *(Fig. 53)*. Gently pull the reducer off the tulip. The reducer should disengage from the tulip head with no resistance.

Note: *If the handle does not fully reopen, place one finger behind the handle arm and manually reopen. When the handle is fully open, the tulip should disengage by pulling off the instrument from the tulip.*

Note: *The Kerrison reducer may be manually engaged and disengaged by fully opening the handle and squeezing on the proximal end of the two black arms (Fig. 54).*

Locking rack (optional)

The Kerrison reducer features an optional locking rack. The locking rack can be engaged prior to reduction or once the amount of reduction desired has been achieved.

Engage: To engage the lock, flip the rack so it rests in the ratchet window *(Fig. 55a, b)*.

Disengage: To disengage the lock, flip the rack to the open position.

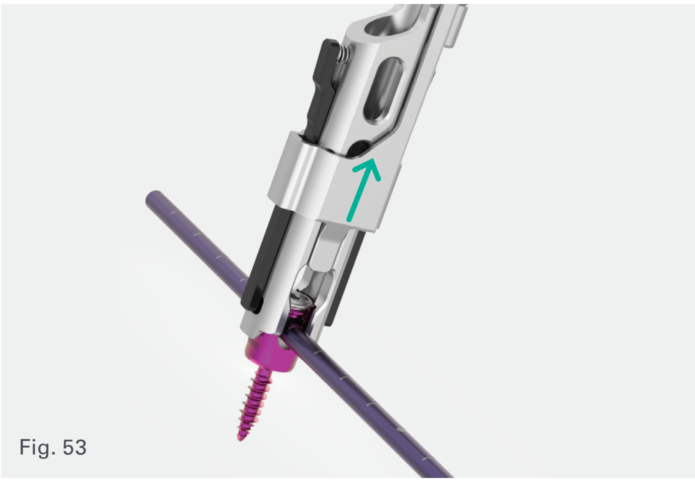


Fig. 53

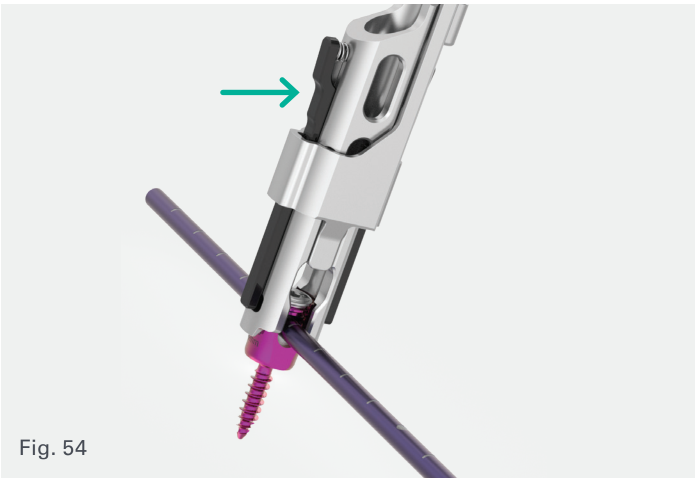


Fig. 54

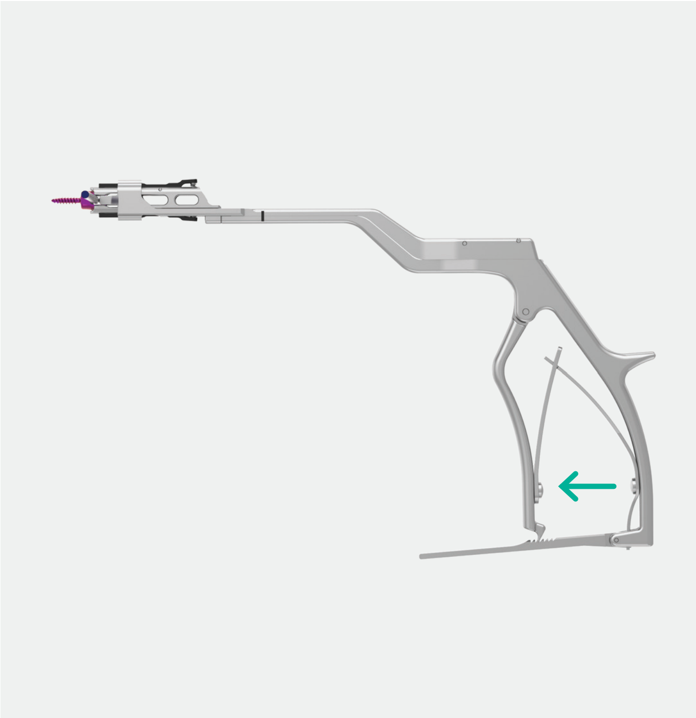


Fig. 52

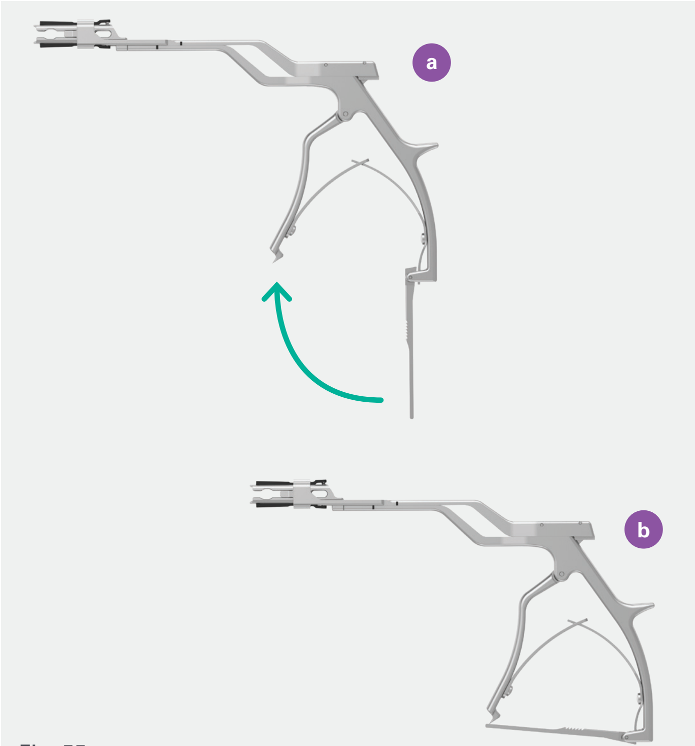


Fig. 55

Rod reduction (cont.)

Rocker

The rocker offers up to 8 mm of reduction. The rocker allows reduction to be performed even when the adjacent tulip head is close to the screw that needs to be reduced. The 15° bend designed into the rocker allows for reduction while approaching the occiput.

To engage: Confirm the rack of the instrument is fully open to allow the instrument to clear the tulip head *(Fig. 56)*.

Position the instrument so the engagement features are in line with the engagement features of the tulip head and the kickstand rests on the rod *(Fig. 57)*.

Squeeze the handle to attach the rocker to the tulip head. Slight clearance between the engagement arms and the tulip will remain after the first click of the rack; this helps to center the engagement tabs to the engagement features of the tulip head. The second click of the rack will lock the reducer on the tulip head. Squeeze the reducer to attach to the tulip head *(Fig. 58)*.

Once engaged tilt the kickstand down on the rod to reduce *(Fig. 59)*.

With the rocker engaged to the tulip and the rod reduced, use the tapered driver to insert the lock screw and capture the reduced rod.

To disengage: Open the proximal rack and remove the rocker from the tulip head.


Fig. 56

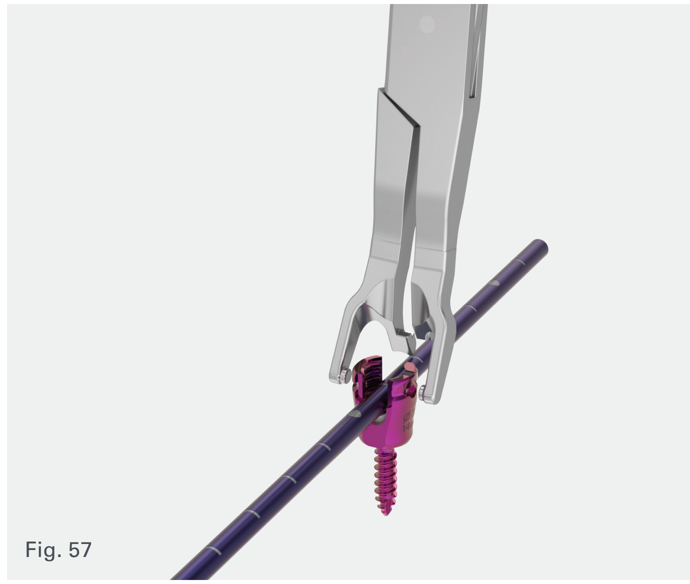


Fig. 57

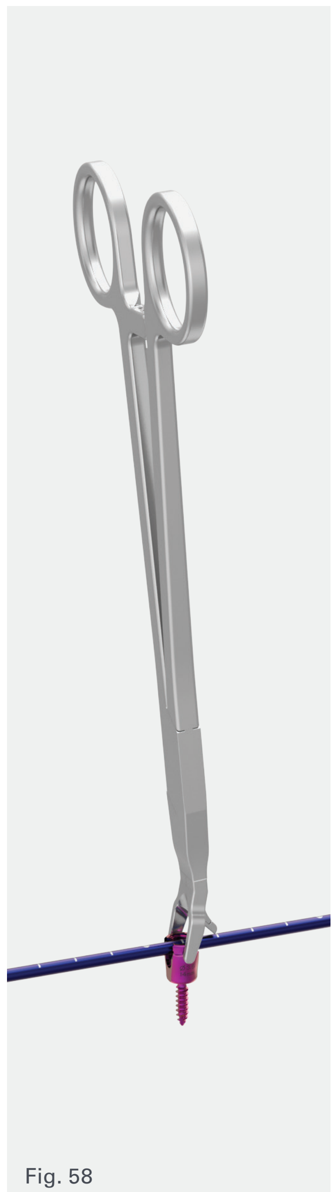


Fig. 58

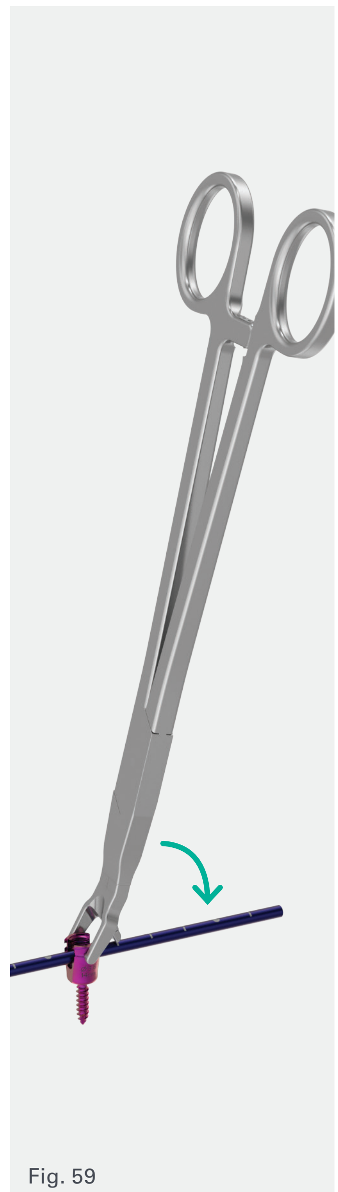


Fig. 59

Rod reduction (cont.)

Alignment tool (rod pusher)

The alignment tool can be used as a rod pusher by aligning the recessed U-shape on the rod and applying gentle downward pressure *(Fig. 60)*.

Caution: It is possible to pull out the screw if too much force is applied with a reducer.

Fig. 60

Step 8

Lock screw seating and provisional tightening

Lock screws feature a Helical Flange thread to minimize splay, reduce the likelihood cross-threading and simplify insertion *(Fig. 60)*. The coloring included on the lock screw indicates loading orientation: silver with laser markings should face up and purple should face down towards the rod *(Fig. 61)*.

Once the rod is positioned, the construct can be secured using lock screws with the tapered driver or the lock screw repeater.

Note: *The Reline Cervical lock screw features a C-star 15 drive feature.*

Tapered driver

While the lock screw is in the caddy, use the tapered driver attached to a handle to pick up the lock screw by centering the drive feature and pressing down. The taper of the driver will retain the lock screw for insertion.

Center the lock screw in the tulip head and provisionally tighten while maintaining axial alignment of the driver to the tulip. The Helical Flange does not require an excessive amount of downward pressure to engage the tulip head.

Note: *When loaded properly in the lock screw caddy, all lock screws should be silver side up.*

Note: *Align the black lock screw timing mark with the black timing mark on the tulip to confirm correct position to start the lock screw threads.*

Note: *Turning the lock screw quarter- to half-turn backward will help align the threads for ease of insertion. The lock screw may also give an audible click and drop into place. Turn the lock screw clockwise to drive into the tulip head.*

Note: *The tapered driver is indicated for ease of identification with a gold coating on the proximal end of the instrument (Fig. 62).*

Fig. 60

Fig. 61

Fig. 62

Step 9

In-situ rod bending

In-situ benders in sagittal and coronal configurations are offered to make adjustments to the rod with tips that balance size with strength.

Sagittal bender

Assembly: Choose the bender tip that corresponds to the rod size. Insert the sagittal bender tip to the end of the handle by pressing the tip into the handle until the engagement pin clicks into place *(Fig. 63a, b)*. Confirm the engagement by pulling the tip and handle away from one another while not pressing on the engagement pin. Repeat on both sides.

Note: *The sagittal bender tips come in straight and angled variations for both ø3.5 and ø4 mm rods (Fig. 64).*

Note: *When loading the angled bender tips confirm the concave side of the tip is on the same side of the bender handle as the pin.*

Note: *The bender tips are laser marked to match the diameter of the rod (Fig. 65). Additionally, the 3.5 mm bender tips have a blue circle, matching the 3.5 mm titanium rods.*

In-situ sagittal bending: Slide the in-situ sagittal bender tips underneath the rod in a way that provides proper leverage. Introduce the bend by tilting the handles toward or away from each other, depending on the desired bend *(Fig. 66)*.

Disassembly: While holding the sagittal bender tip and handle, depress the engagement pin and slide the tip out of the handle *(Fig. 67)*.

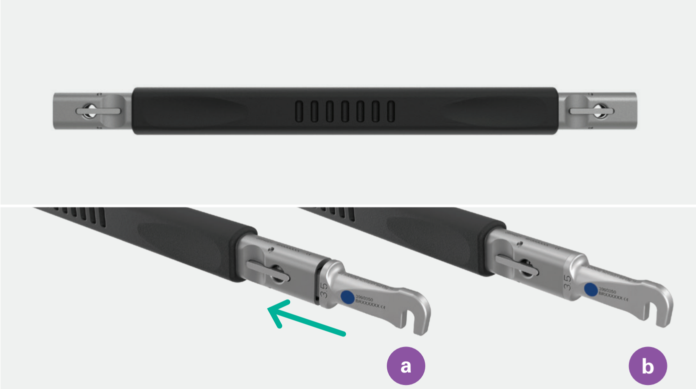


Fig. 63

Fig. 64

Fig. 65


Fig. 66

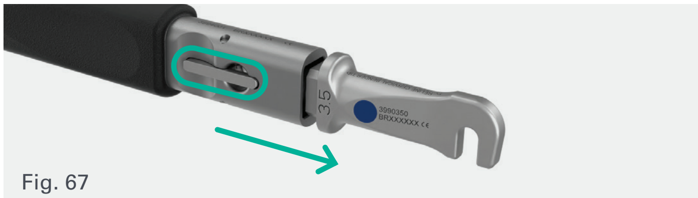


Fig. 67

Insitu rod bending (cont.)

Coronal bender

Assembly: Choose the bender tip that corresponds to the rod size. Assemble the tips to the coronal bender handles by depressing the gold button on the coronal bender handle. Insert coronal bender tip to the end of the handle until it sits flush with the handle and release the gold button *(Fig. 68)*. Confirm engagement by pulling the tip and handle away from one another while not pressing on the engagement button *(Fig. 69)*.

Note: *The coronal bender tips come in straight variations for both ø3.5 and ø4 mm rods.*

Note: *The bender tips are laser marked and color coded to match according to the diameter of the rod (Fig. 70). ø3.5mm bender tips have a blue circle, matching the ø3.5mm titanium rods.*

Insitu coronal bending: Place the right and left insitu coronal benders over the rod until the slots sit flush on the rod and the handles diverge *(Fig. 71)*. Introduce the bend by tilting the handles toward or away from each other, depending on the desired bend.

Disassembly: While maintaining control of the coronal bender tip and handle, depress the gold button and slide the tip out of the handle *(Fig. 72)*.

Fig. 69

Fig. 70

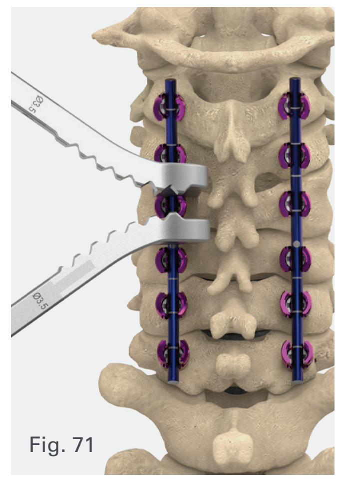


Fig. 71

Fig. 68

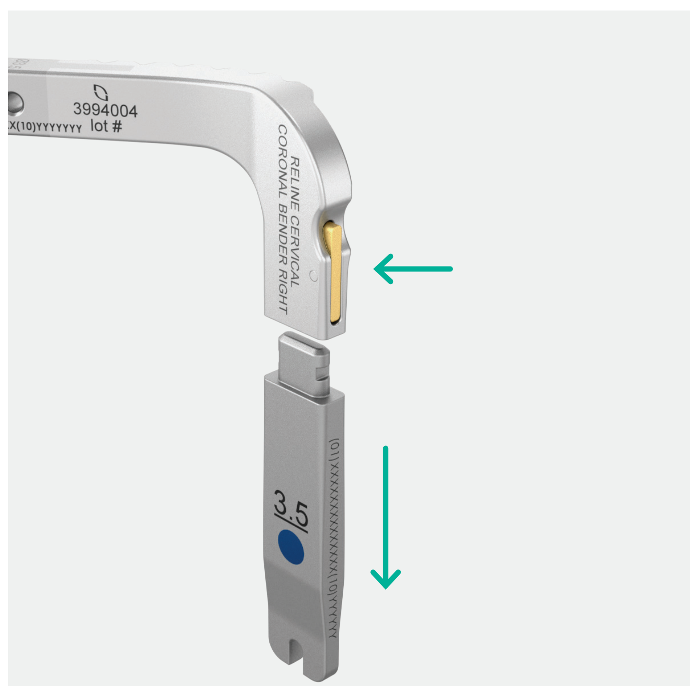


Fig. 72

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Step 10

Final tightening

To final tighten the construct, attach the final tightening driver to the black torque handle. The final tightening driver is indicated black on the proximal end. Seat the black counter-torque over the tulip head with the handle lateral and slide the final tightening driver assembly through the cannulation of the counter-torque *(Fig. 73)*. Engage the driver into the provisionally tightened lock screw and begin tightening the lock screw until the torque handle torques out. A tactile and audible click occurs when the lock screw is locked at the recommended 26 in-lbs (3 n-m).

Fig. 73

Step 11

Compression and distraction

Compression

If compression is required, provisionally tighten a lock screw on one side of the motion segment, leaving the other lock screw loose to allow movement along the rod. Place the compressor on the outermost part of both implants, relative to the construct. With the compressor properly engaged, deliver the appropriate amount of compression by squeezing the instrument handle and then provisionally tighten the loose lock screw to hold the construct in position prior to final tightening *(Fig. 74)*.

Note: *The compressor is indicated with a laser marked "C" at the joint of the instrument (Fig. 75).*

Note: *The compressor has a maximum travel distance of 48 mm.*

Distractor

If distraction is required, provisionally tighten the lock screw on one side of the motion segment, leaving the other lock screw loose to allow movement along the rod. Place the distractor on the innermost part of the multiaxial screws, relative to the construct. With the instrument properly engaged, deliver the appropriate amount of distraction by squeezing the instrument handle and then provisionally tighten the loose lock screw to hold the construct in position prior to final tightening *(Fig. 76)*.

Note: *The distractor is laser marked "D" at the joint of the instrument (Fig. 77).*

Note: *The distractor has a maximum travel distance of 48 mm.*

Note: *Continue to monitor for nerve root events (EMG) and shifts from motor (MEP) and sensory (SSEP) baselines during construct adjustments and alignments.*

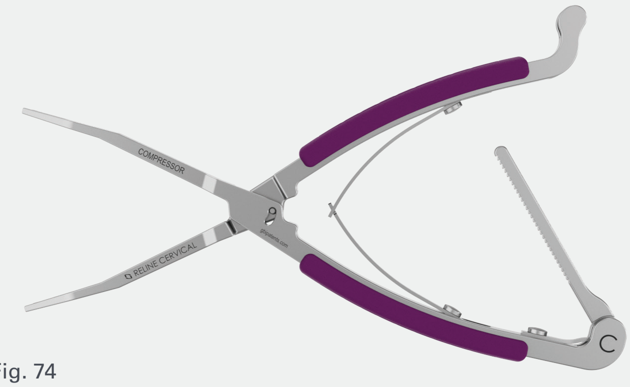

Fig. 74

Fig. 75

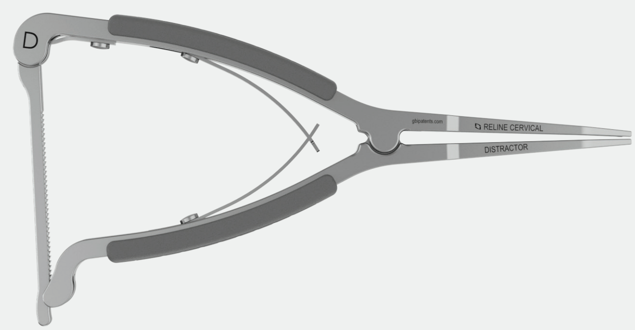

Fig. 76

Fig. 77

Step 12

Connector options

Reline Cervical provides a variety of connector options for difficult anatomy and a multitude of surgical goals with lateral offset connectors, cross connectors, extra rod connectors and adjacent segment fixation (ASF) connectors.

Lateral offset connector options

Lateral offset connectors allow for intraoperative flexibility of attaching to screws that are non-linear. Lateral offset connectors come in three configurations:

- open offset lateral connector *(Fig. 78)*,
- closed offset lateral connector *(Fig. 79)*, and
- acute-angle lateral offset connector *(Fig. 80)*.

Attaching an open lateral offset connector

Seat the rod of the connector in the tulip head *(Fig. 81)*. Use a standard lock screw to secure the rod of the connector in the tulip head by provisionally tightening the lock screw using the tapered driver. Connect the rod in the head of the connector and provisionally tighten the connector lock screw using the tapered driver *(Fig. 82)*.

Attaching a closed offset lateral connector

Slide the connector head onto the rod and place the rod. Seat the rod of the connector into the tulip head and secure the connector in the tulip head by provisionally tightening the lock screw using the tapered driver *(Fig. 83a, b)*. Provisionally tighten the connector lock screw using the tapered driver.

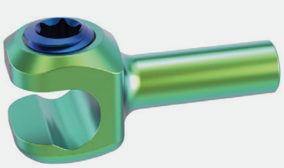

Fig. 78

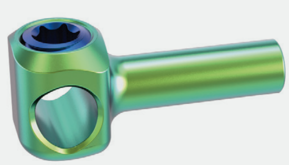

Fig. 79

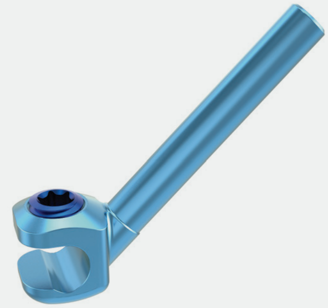

Fig. 80

Fig. 81

Fig. 82

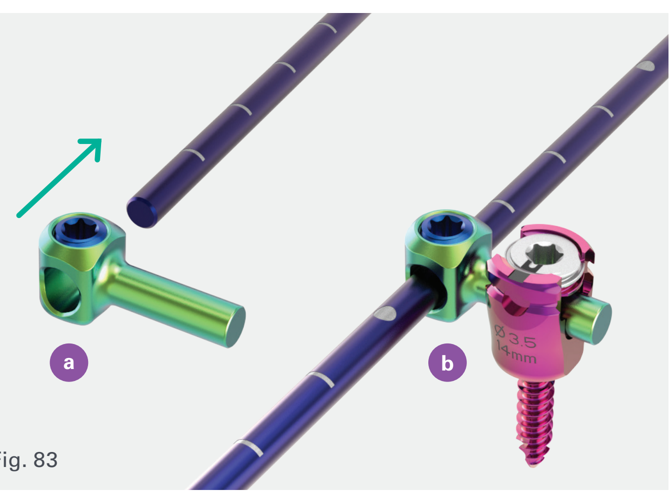

Fig. 83

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Connector options (cont.)

Final tightening offset lateral connectors

Final tighten the offset connector lock screw by engaging the black counter-torque over the offset connector with the handle lateral to the construct. The counter-torque has a medial cutout that engages the false rod of the offset connector *(Fig. 84)*. Place the final tightening shaft attached to the final tightening torque limiting handle assembly through the counter-torque. A tactile audible "click" signifies that the lock screw is locked at the recommended 26 in-lbs (3 n-m).

Note: *The open and closed lateral offset connectors come in lengths of 11, 18 and 25 mm, which are color-coded green, purple and light blue, respectively.*

Note: *The acute-angle lateral offset connector comes in a 25 mm length with a 45° angle from the tulip head. The offset connectors accept both a 3.5 and 4 mm rod.*

Note: *The rod end of the lateral offset connector can be cut using the scissor cutting mechanism of the rod cutter following the standard scissor cutting technique. The rod end of the lateral offset connector is 4 mm.*

Note: *The Reline Cervical lateral offset connector set screws feature a C-star 15 drive feature.*

Fig. 84

Connector options (cont.)

Cross connectors come in four configurations offering versatility in connecting to a construct. The configurations that are offered are:

- adjustable tulip-to-tulip cross connector *(Fig. 85)*,
- static rod-to-rod cross connector *(Fig. 86)*,
- tall lock screw cross connector *(Fig. 87)*, and
- adjustable rod-to-rod connector *(Fig. 88)*.

Fig. 85


Fig. 86


Fig. 87


Fig. 88

Adjustable tulip-to-tulip cross connector

The adjustable tulip-to-tulip cross connector offers an optimized connection option with two adjustable sizes for efficient sizing intraoperatively. The connector requires minimal run-on rod and offers translation, rotation and swing for ease of attachment.

Measuring the adjustable tulip-to-tulip cross connector

To determine the appropriate size adjustable tulip-to-tulip cross connector, use the cross connector caliper. Seat the calipers on both rods directly superior or inferior of the tulip heads that will be connected *(Fig. 89)*. The calipers will dictate the distance between the rods and indicate which size connector to use (small or medium).

Note: *The adjustable tulip-to-tulip connector comes in two sizes—small (25–35 mm) or medium (35–45 mm). The rod portion of the connectors are colored green and purple, respectively.*

Note: *The cross connect measurement tool measures off the rod, not the tulip.*

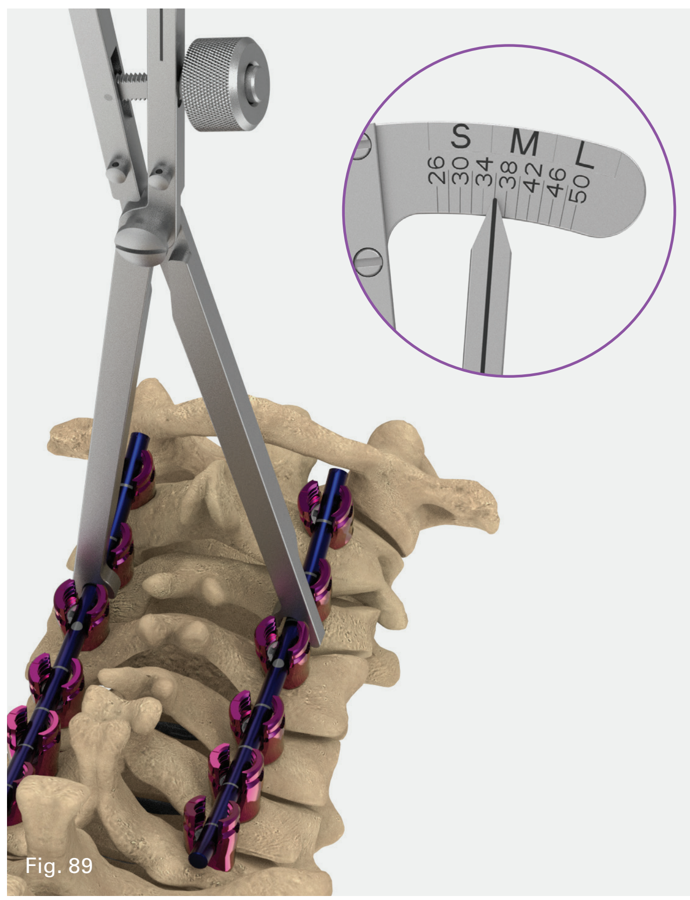


Fig. 89

Connector options (cont.)

Inserting the adjustable tulip-to-tulip connector

The spoke driver has a built in self-centering pin to aid in the insertion of the adjustable tulip-to-tulip connector to the tulip head *(Fig. 90)*.

Attach the spoke driver to a fixed or ratcheting handle. Position the spoke driver so the self-centering pin extends through the cannulation of the adjustable tulip-to-tulip connector. Engage the adjustable cross connector head by lining up the spokes with the drive features on the cross connector and pressing down firmly *(Fig. 91a, b)*. Repeat this on both sides of the connector.

To insert the adjustable tulip-to-tulip connector, position the spoke driver so the self-centering pin seats in the cannulation of the lock screw *(Fig. 92)*. Slowly press the adjustable tulip-to-tulip connector onto the screw. As force is applied, the self-centering pin will stay engaged in the lock screw to maintain proper engagement orientation and will retract to guide the connector onto the tulip head of the screw *(Fig. 93)*. There will be a tactile and audible "click" when the connector is attached.

Provisionally tighten the heads of the connector to the tulip head by turning the instrument clockwise.

Note: *The lock screw must be final tightened prior to attaching the adjustable tulip-to-tulip connector.*

Final tightening the adjustable tulip-to-tulip cross connector

Place the black counter-torque on the adjacent screw on the same side of the construct. Final tighten the adjustable cross connector at the recommended 26 in-lbs (3 n-m) using the break-off final tightening torque limiting handle connected to the spoke driver.

Repeat on the contralateral side.

Note: *When aligned, the load required to snap on the adjustable cross connector heads is minimal. If excessive force is required to load, reconsider the alignment. When the heads properly snap onto the tulips, there will be tactile feedback.*

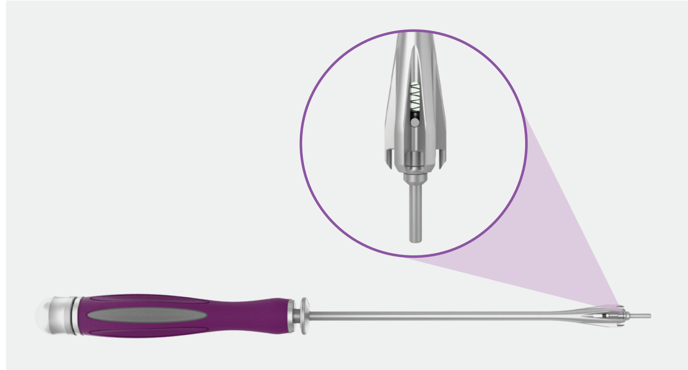


Fig. 90

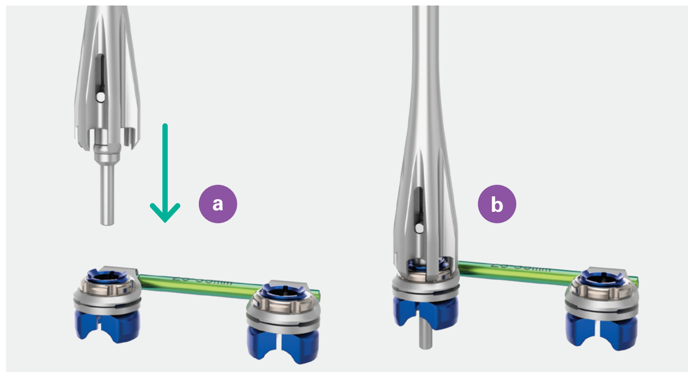


Fig. 91

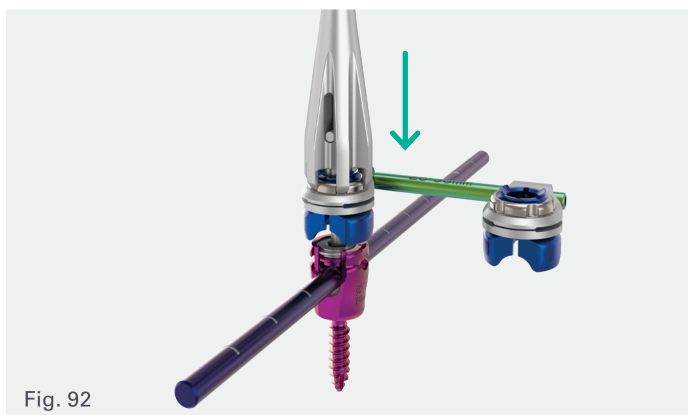


Fig. 92

Fig. 93

Connector options (cont.)

Static cross connector

The static cross connector offers a simplified rod-to-rod connection to the construct.

Measuring the static cross connector

To determine the appropriate size static cross connector, use the cross connector caliper. Seat the caliper on both rods where the connector will be attached *(Fig. 94)*. The caliper will dictate the distance between the rods and indicate which size connector to use.

Note: *The proximal rack of the caliper indicates length every 2 mm with every 4 mm labeled (Fig. 95).*

Note: *If between sizes, it is recommended to choose the larger of the sizes and contour the connector with a bend.*

Fig. 94

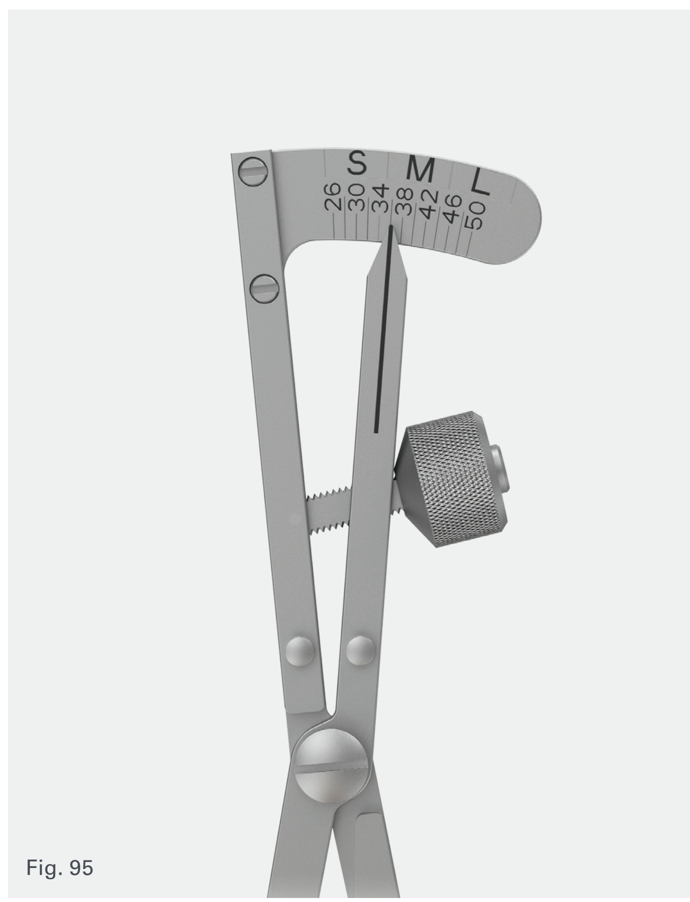


Fig. 95

Connector options (cont.)

Bending the static cross connector

The static cross connector can be bent in two planes using the cross connector benders.

Arch bend: When additional space between the spinal cord and the apex of the cross connector is required, an arch bend can be imparted on the connector. The arch bend is also useful in adjusting the size of the cross connector when the desired span is between offered sizes.

To place an arch bend, place the preselected cross connector in the bending slots and begin gently bending medially and downward until the desired bend is achieved *(Fig. 96)*.

Non-parallel bend: A non-parallel bend is useful if rods are not parallel in the coronal plane resulting in the inability to attach the rod capture window of the connector.

To place a non-parallel bend, place the preselected cross connector in the non-parallel bending slots and begin gently bending medially or laterally until the desired bend is achieved *(Fig. 97)*.

Warning

To maintain the mechanical integrity of the cross connector, once the connector is bent in one direction, further bending only in that same direction should be attempted. Unbending of the connector may cause mechanical compromise.

Fig. 97

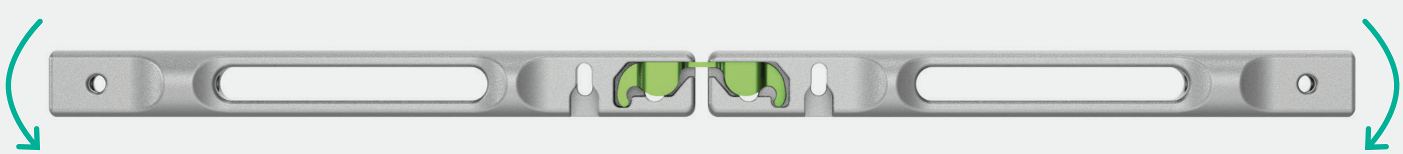


Fig. 96

Connector options (cont.)

Inserting the static cross connector

Place the cross connector over the rods at the desired level with the rod capture seated on the rod. Provisionally tighten the lock screw using the tapered driver *(Fig. 98)*.

Final tightening the static cross connector

Attach the black final tightening driver to the black torque handle. Seat the gray cross connector counter-torque over the cross connector so the handle is lateral to the rod with the fixed cross connector constraint medial and over the fixed cross connector lock screw *(Fig. 99)*.

Tilt the driver 35° from vertical, slide the driver through the medial constraint on the counter-torque and engage the driver into the provisionally tightened lock screw. Begin tightening the lock screw until the final tightening torque limiting handle torques out. A tactile and audible click will occur when the lock screw is locked at the recommended 26 in-lbs (3 n-m) *(Fig. 100)*.

Note: *The static cross connector attaches to a 3.5 and 4 mm diameter rod.*

Note: *Static cross connectors come in 28–46 mm widths in 2 mm increments.*

Note: *The lock screws of the Reline Cervical fixed cross connector feature a C-star 15 drive feature.*

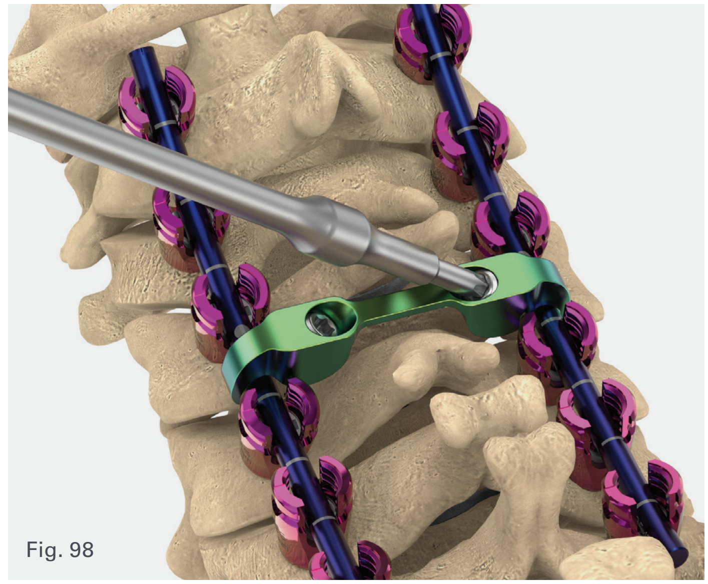


Fig. 98

Fig. 99

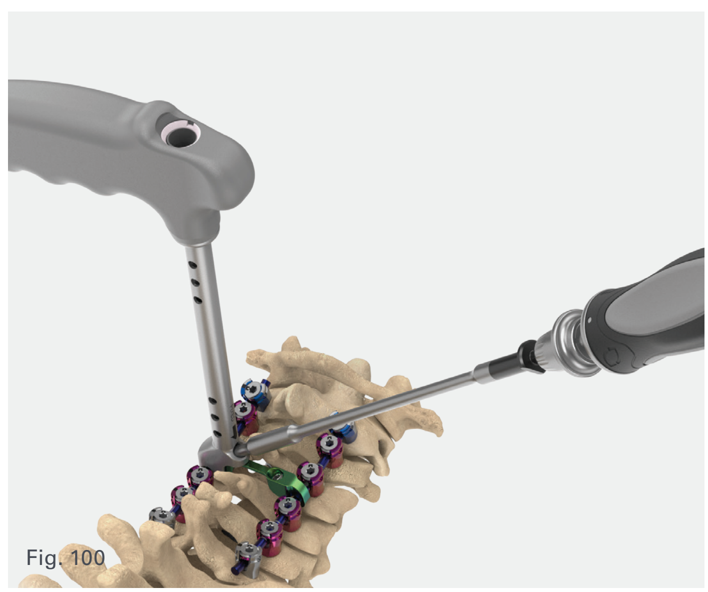


Fig. 100

Tall lock screw cross connector

The tall lock screw cross connector offers an alternate attachment mechanism using a lengthened lock screw to aid in the attachment of the connector to the construct. The connector has 10 mm of built-in translation and can rotate 360° around the tall lock screw connector for ease of placement.

Measuring the tall lock screw connector

To determine the appropriate tall lock screw cross connector size, use the cross connector caliper. Seat the measurement tool on both rods directly superior or inferior of the level that will be connected *(Fig. 101)*. The measurement tool will dictate the distance between the rods and indicate which size connector to use, small or medium.

When additional space between the spinal cord and the apex of the cross connector is required, an arch bend can be imparted on the connector. The arch bend is also useful in adjusting the size of the cross connector when the desired span is between offered sizes.

To impart an arch bend, place the preselected tall lock screw connector bar in the bending slots until the connector bottoms out and the washer is captured by the bending slot. Begin gently bending downward until the desired bend is achieved *(Fig. 102)*.

Warning

To maintain the mechanical integrity of the cross connector, once the connector is bent in one direction, further bending only in that same direction should be attempted. Unbending of the connector may cause mechanical compromise.

Fig. 101

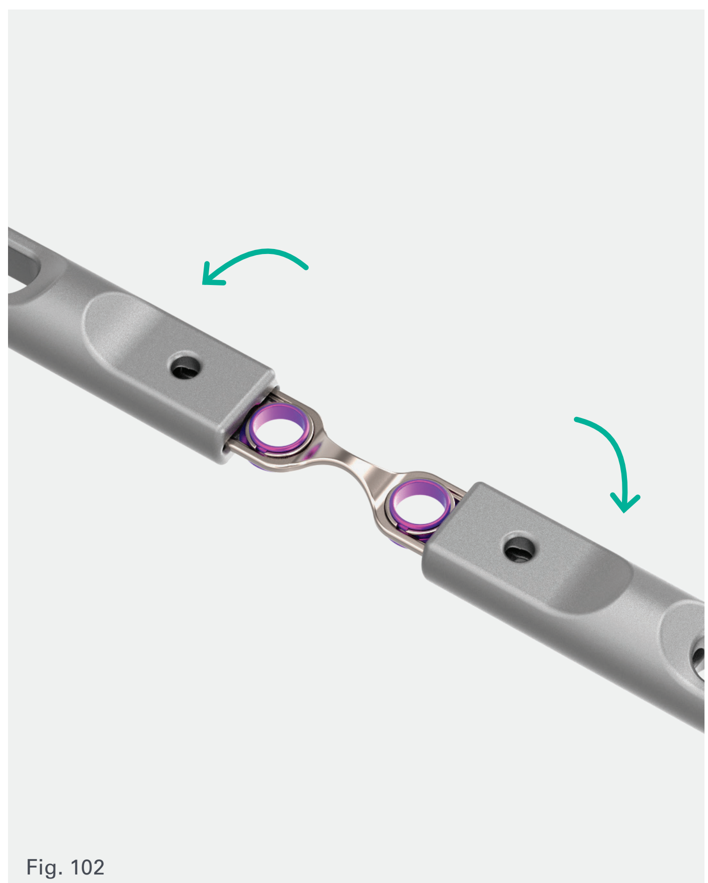


Fig. 102

Connector options (cont.)

Inserting the tall lock screw

Attach the tapered driver to a fixed or ratcheting handle and pick up a tall lock screw. Provisionally tighten the tall lock screw into the screw tulip head.

Note: *The tall lock screw connector relies on the tall lock screw and will not function with a standard lock screw (Fig. 103).*

Final tightening the tall lock screw

To final tighten the tall lock screw, place the black counter-torque on the adjacent screw on the same side of the construct. Engage the final tightening driver into the provisionally tightened tall lock screw and begin tightening the tall lock screw until the final tightening torque limit is reached. A tactile and audible click should occur when the lock screw is locked at the recommended 26 in-lbs (3 n-m). Repeat on the contralateral side.

Note: *The tall lock screw features a C-star 15 drive feature.*

Inserting the tall lock screw cross connector

Once the tall lock screw is final tightened, place the connector over the tall lock screw so the retention rings captures the tall lock screw *(Fig. 104)*. Attach the hex driver to a fixed or ratcheting handle. Load a hex cap, tapered side up, into the hex driver by applying downward pressure on the hex cap with the driver. The driver will retain the hex cap with force proportional to downward force applied. Thread the hex cap onto the tall lock screw to secure the connector *(Fig. 105)*.

Note: *The hex cap must be inserted in the proper orientation with the flat side down against the connector bar (Fig. 106).*

Fig. 103

Fig. 104

Fig. 105

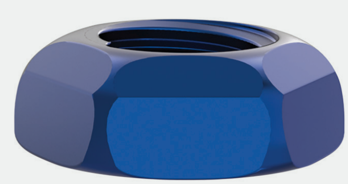


Fig. 106

Connector options (cont.)

Final tightening the tall lock screw cross connector

Place the black counter-torque on the adjacent screw on the same side of the construct. Attach the hex driver to the black final tightening handle and final tighten *(Fig. 107)*. A tactile and audible click should occur when the tall lock screw is locked at the recommended 26 in-lbs (3 n-m).

Note: *The tall lock screw connector comes in small (25–35 mm) and medium (35–45 mm).*

Fig. 107

Connector options (cont.)

Adjustable rod-to-rod connector

The adjustable rod-to-rod connector offers added versatility when connecting across a construct. The design features a contoured adjustable center span, rotational rod engagement and semi-constrained rod connection points for simplified single-level attachment, as well as unconstrained rod connection points for single and multi-level spanning. An optional central guide is provided to protect the spinal cord while provisionally and final tightening the central span.

Measuring the adjustable rod-to-rod connector

To determine the appropriate size adjustable rod-to-rod cross connector, use the cross connector caliper. Seat the measurement tool on both rods directly superior or inferior of the level that will be connected *(Fig. 108)*. The measurement tool will dictate the distance between the rods and indicate which size connector to use small, medium or large.

Inserting the adjustable rod-to-rod connector

The adjustable rod-to-rod connector is offered in two different configurations: single-pivot with single-level spanning and double-pivot with multi-level spanning.

Single-pivot with single-level spanning

The single-pivot with single-level spanning offers a simplified design for ease of attachment with a pivoting translating center joint, one pivoting rod connection point and one fixed rod connection point. To insert the single-pivot design, begin with loosening the lock screws of the central span and the pivoting connection with the tapered driver *(Fig. 109)*.

Introduce the static end to the rod at a 45° angle to clear the spinal anatomy. Rotate the connector downward until the adjustable end sits on the contralateral rod and provisionally tighten the central span and the rod connection pieces in place using the tapered driver *(Fig. 110a–d)*. See page 49 for optional central guide steps.

Note: *For ease of insertion, the central span lock screw and pivoting connection point lock screw can be provisionally tightened to add rigidity to the implant.*

Note: *The single-pivot design offers two sizes: small with 30–35 mm of translation and medium with 35–45 mm of translation.*

Note: *The pivoting rod connection point offers ±50° of rotation.*

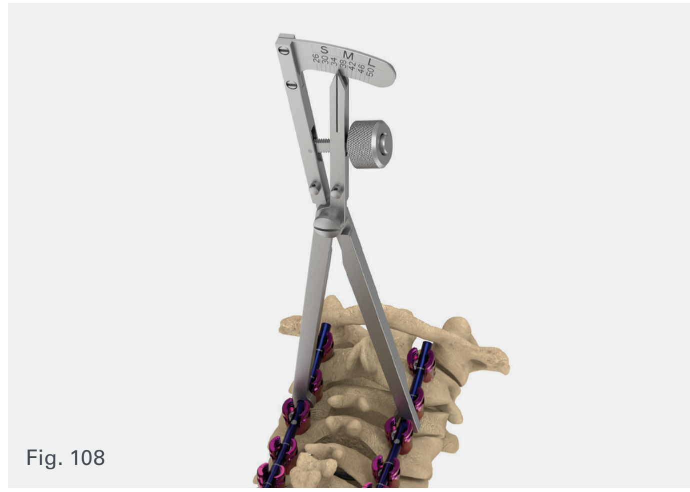


Fig. 108

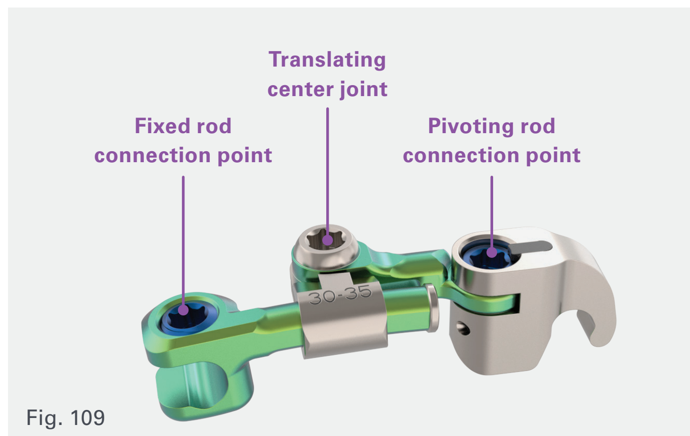


Fig. 109

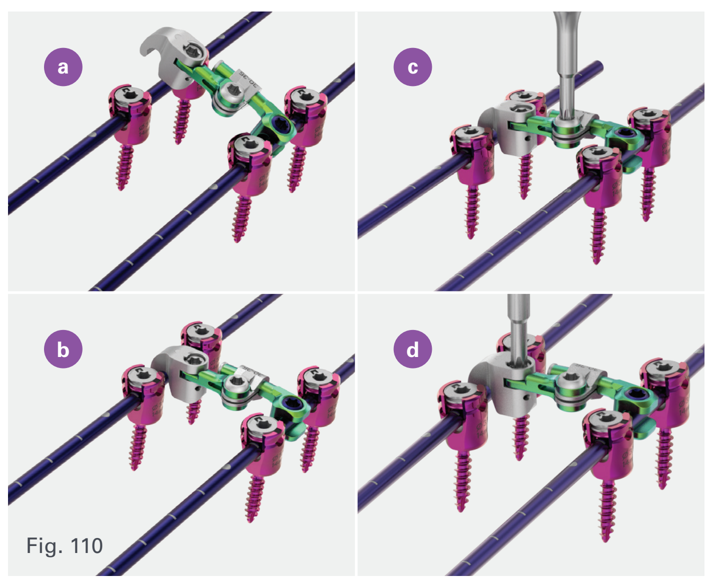


Fig. 110

Connector options (cont.)

Double pivot with single-level spanning

The double-pivot with single-level spanning offers complete attachment adjustability through the central span and rod connection points. To insert the double-pivot single-level design, begin with loosening the lock screws of the central span and pivoting rod connection points with the tapered driver *(Fig. 111)*.

Attach the connector to construct one side at a time and provisionally tighten the central span and rod connection pieces using the tapered driver *(Fig. 112)*. See page 49 for optional central guide steps.

Note: *For ease of insertion the central span lock screw and pivoting connection point lock screw can be provisionally tightened to add rigidity to the implant.*

Note: *Each side of the connector offers ±50° of rotation.*

Note: *The double-pivot design comes in size 'L' and offers 45–55 mm of translation.*

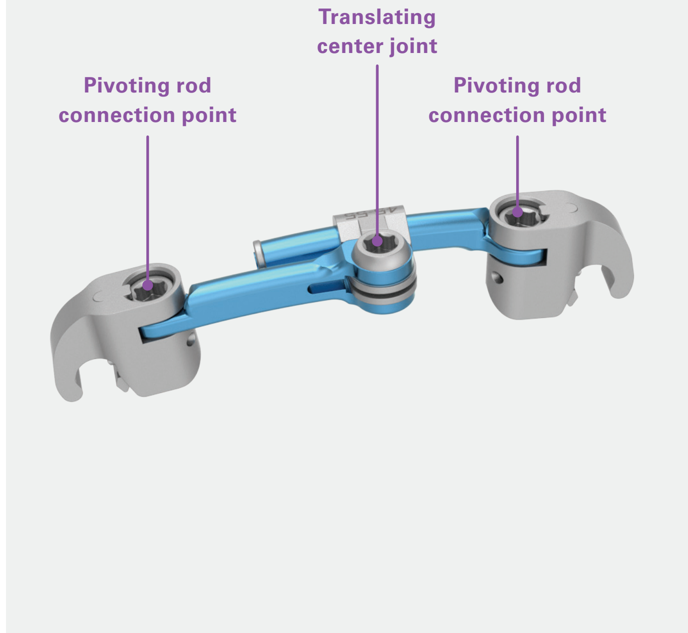


Fig. 111

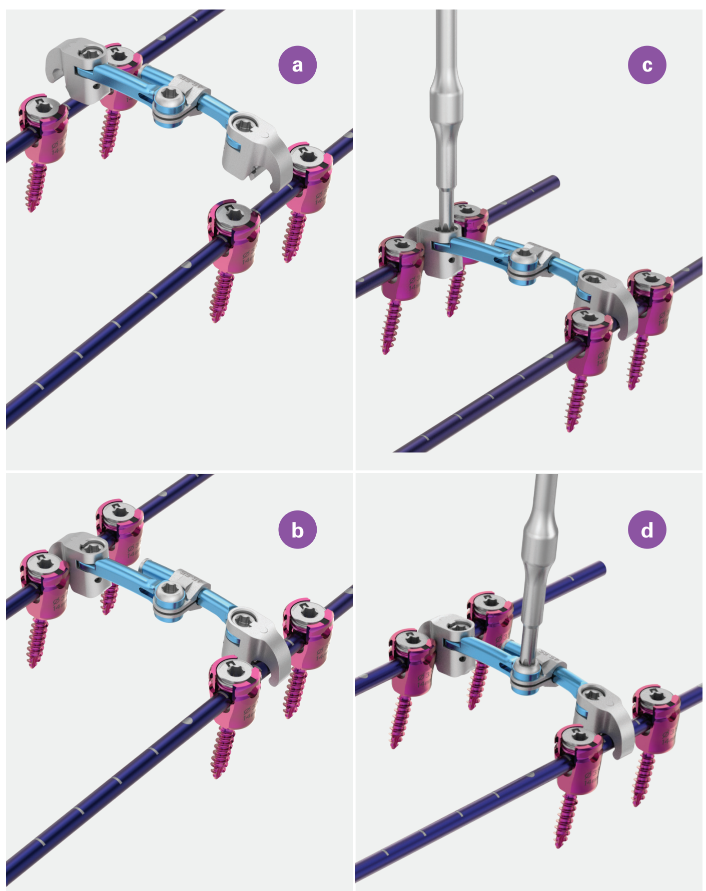


Fig. 112

Connector options (cont.)

Double pivot with multi-level spanning

The double-pivot with multi-level spanning offers up to two level spanning as anatomical challenges dictate. To insert the double-pivot design, begin with loosening the lock screws of the central span and rod connection points with the tapered driver *(Fig. 113)*. Manually manipulate the central span to mimic the necessary contour and then tighten the joints so the ability to adjust remains but is controlled with some friction *(Fig. 114)*. Use the rod holder to engage the central span of the connector.

Attach the connector to one side of the construct at a time and provisionally tighten the central span and rod connection points using the tapered driver. See page 49 for optional central guide steps.

Note: *For ease of insertion the central span lock screw and pivoting connection point lock screw can be provisionally tightened to add rigidity to the implant.*

Warning

Rod-to-rod connectors must be used when connecting two separate constructs. **Do not** use Reline Cervical extra rod connectors as the mechanical strength is not adequate for stable fixation of two separate constructs.

Fig. 113

Fig. 114

Connector options (cont.)

Final tightening

Single pivot with single-level spanning

To final tighten the single-pivot design, attach the standard black counter-torque over the fixed rod connection point with the handle of the counter-torque lateral to the construct. The counter-torque has a medial cutout that engages the central span *(Fig. 115)*. Place the final tightening shaft attached to the final tightening torque limiting handle assembly through the counter-torque *(Fig. 116)*. A tactile audible "click" signifies that the lock screw is locked at the recommended 26 in-lbs (3 n-m).

Next, place the gray cross connector counter-torque on the pivoting connection point with the handle of the counter-torque lateral to the construct. The counter-torque has a medial cutout that engages the central span of the offset connector *(Fig. 117)*. Place the final tightening shaft attached to the final tightening torque limiting handle assembly through the medial shaft of the counter-torque *(Fig. 118)*. A tactile audible "click" signifies that the Lock screw is locked at the recommended 26 in-lbs (3 n-m).

Lastly, final tighten the central span with the final tightening shaft attached to the final tightening torque limiting handle assembly. A tactile audible "click" signifies that the lock screw is locked at the recommended 26 in-lbs (3 n-m). The optional central guide can be used to protect the spinal cord during final tightening the central span. See page 49 for optional central guide instructions.


Fig. 115

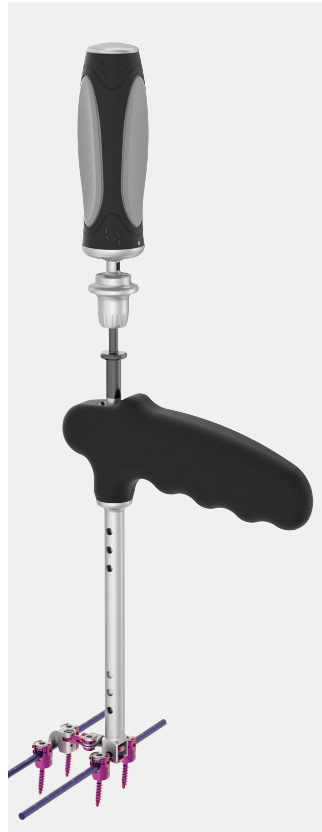


Fig. 116


Fig. 117


Fig. 118

Connector options (cont.)

Double pivot with multi-level spanning

To final tighten the double-pivot design, attach the gray cross connect counter-torque over one rotating rod engagement with the handle of the counter-torque lateral to the construct. The counter-torque has a medial cutout that engages the central span of the offset connector *(Fig. 119)*. Place the final tightening shaft attached to the final tightening torque limiting handle assembly through the counter-torque *(Fig. 120)*. A tactile audible "click" signifies that the lock screw is locked at the recommended 26 in-lbs (3 n-m). Repeat on both sides.

Note: *All adjustable rod to rod connector set screws feature a C-star 15 drive feature.*

Optional center guide

The center guide is used as an optional instrument during provisional or final tightening the central span. To attach the center guide, place the instrument onto the center connection with the cannulated shaft directly over the lock screw and the nose either cranial or caudal to fit onto the sliding collet *(Fig. 121)*. Insert the appropriate driver (tapered or final tightening) through the cannulation of the instrument to tighten the locking mechanism.

Fig. 119

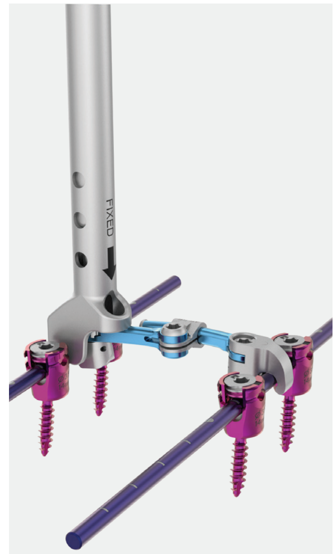


Fig. 120

Fig. 121

Connector options (cont.)

Extra rod connector

If a more robust construct is desired in the form of an extra rod, the extra rod connector can be used. The extra rod connector connects to the tulip head with a snap on mechanism similar to the adjustable cross connector caps and allows for placement of an additional rod medially or laterally from the main construct *(Fig. 122)*.

Inserting the extra rod connector

Attach the spoke driver to a fixed or ratcheting handle. Position the spoke driver so the self-centering pin extends through the cannulation of the extra rod connector *(Fig. 123)*. Engage the extra rod connector head using the spoke driver by lining up the spokes with the drive features on the connector and pressing down firmly *(Fig. 124)*.

To insert the extra rod connector, position the spoke driver so the self-centering pin seats in the cannulation of the lock screw *(Fig. 125)*. Slowly press the extra rod connector onto the screw. As force is applied, the self-centering pin will stay engaged in the lock screw to maintain proper engagement orientation and will retract to guide the connector onto the tulip head of the screw *(Fig. 126)*. There will be a tactile and audible "click" when the connector is attached.

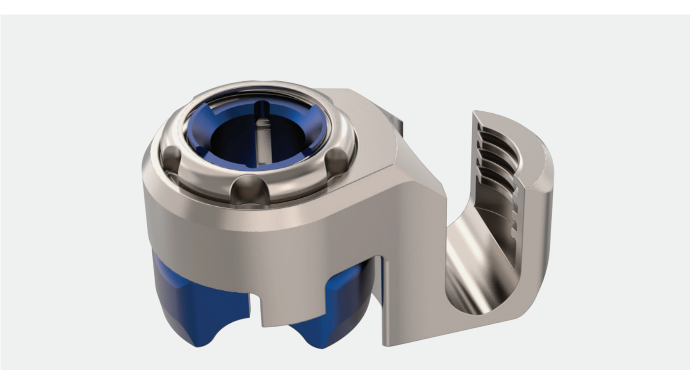


Fig. 122

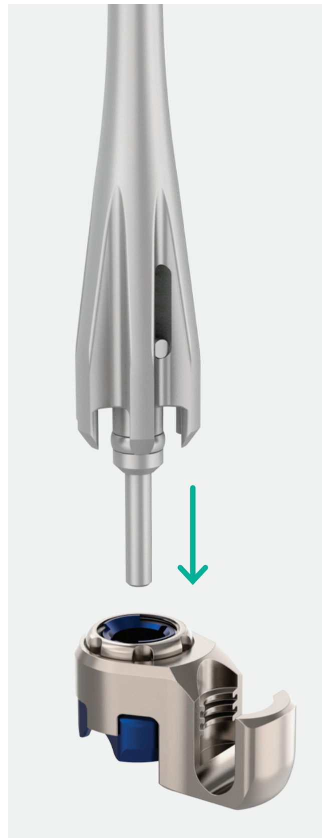


Fig. 123

Fig. 124

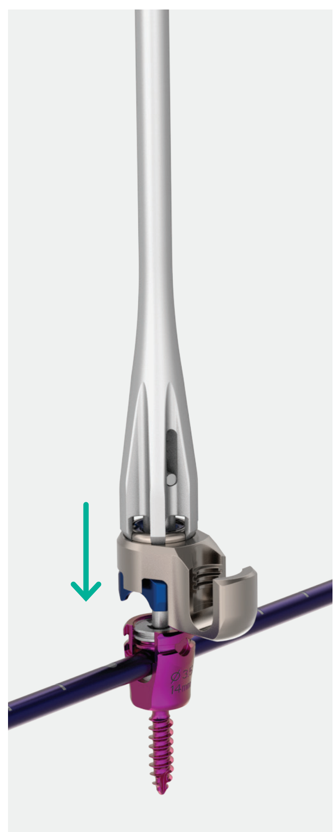


Fig. 125

Fig. 126

Connector options (cont.)

Inserting the extra rod

Insert the extra rod in the open tulip portion of the connector with the rod holder and provisionally tighten the lock screw with the tapered driver attached to a small or large ratcheting handle *(Fig. 127).*

Final tightening the extra rod connector

Place the black counter-torque on the adjacent screw on the same side of the construct. The snap-on portion of the extra rod connector is final tightened using the break-off final tightening torque limiting handle connected to the spoke driver *(Fig. 128)*. To final tighten the extra rod tulip, use the break-off final tightening torque limiting handle connected to the black final tightening driver *(Fig. 129)*. A tactile audible "click" signifies that the lock screw is locked at the recommended 26 in-lbs (3 n-m).

Note: *When properly aligned, the load required to snap on the adjustable cross connector heads is minimal. If excessive force is required to load, reconsider the alignment. When the heads properly snap onto the tulips, there will be tactile feedback.*

Fig. 128

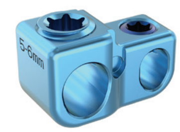
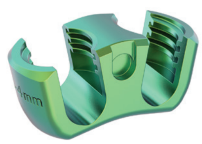
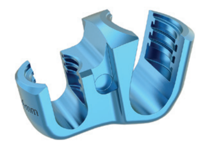
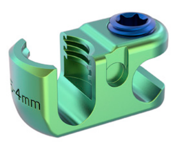
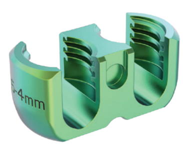
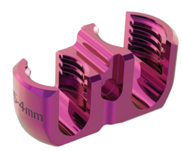
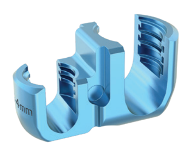
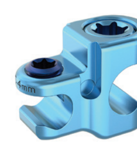
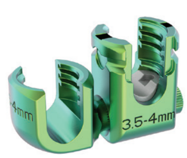
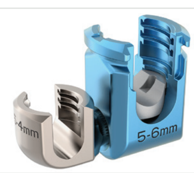
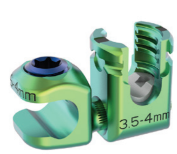
Fig. 127

Fig. 129

Connector options (cont.)

ASF connectors

ASF connectors are configured in a range of options for added versatility when joining two rods. Reline Cervical ASF connectors feature rod slots designed to accommodate a range of rods from 3.5–6 mm diameters. ASF connectors come in the following sizes and configurations:

ASF connector configuration	3.5/4–3.5/4 mm	3.5/4–4.5/5 mm	3.5/4–5/6 mm
Closed inline connector			
Closed parallel connector			
Offset angled top-top			
Offset open top-side			
Offset open top-top			
Offset open side-side			
Rotating open top-top			
Rotating open top-side			
Open top-bottom		-	-

Connector options (cont.)

Inserting the rod-to-rod connector

Attach the connector holders to the engagement features on the connector *(Fig. 130)*. Using the connector holders to maneuver the connector, capture one rod into the appropriately sized connector tulip and provisionally tighten the lock screw onto the rod using the appropriate lock screw driver *(Fig. 131)*. Next, insert the second rod into the empty tulip and provisionally tighten the lock screw down onto the rod using the appropriate lock screw driver.

Final tightening the rod-to-rod connector

Once both rods are in place and are provisionally tightened, use the black final tightening driver attached to the black final tightening handle to final tighten with the black handled counter-torque for the small diameter side *(Fig. 132)*. A tactile audible "click" signifies that the lock screw is locked at the recommended 26 in-lbs (3 n-m).

If using an offset ASF connector there may be a need to place the counter-torque on the small diameter while final tightening the larger diameter.

Note: *If an ASF connector was used for a rod larger than 4 mm, use the appropriate final tightening driver and handle according to the appropriate Reline Small Stature or Reline technique.*

Note: *Rod-to-rod connectors are color coded by the large diameter rod size with 3.5/4 to 3.5/4 being green, 3.5/4 to 4.5/5 being purple and 3.5/4 to 5/5.5/6 being light blue.*

Warning

Rod-to-rod connectors must be used when connecting two separate constructs. **Do not** use Reline Cervical extra rod connectors as the mechanical strength is not adequate for stable fixation of two separate constructs.

Caution: Pivoting rod-to-rod connectors should be used in pairs (i.e., two per side).

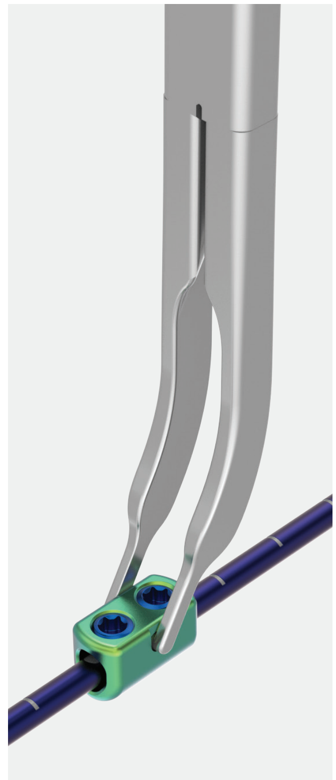


Fig. 130

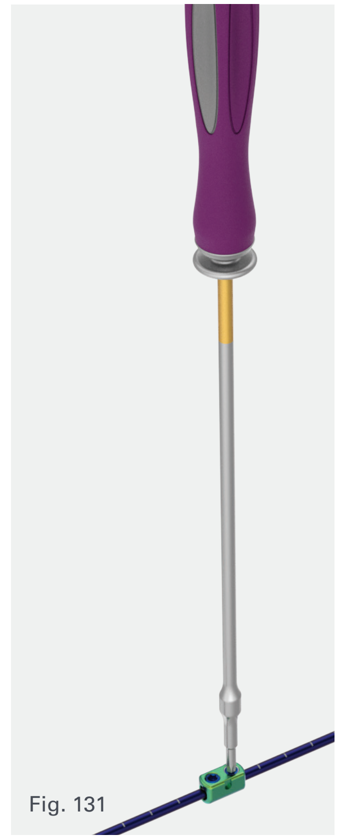


Fig. 131

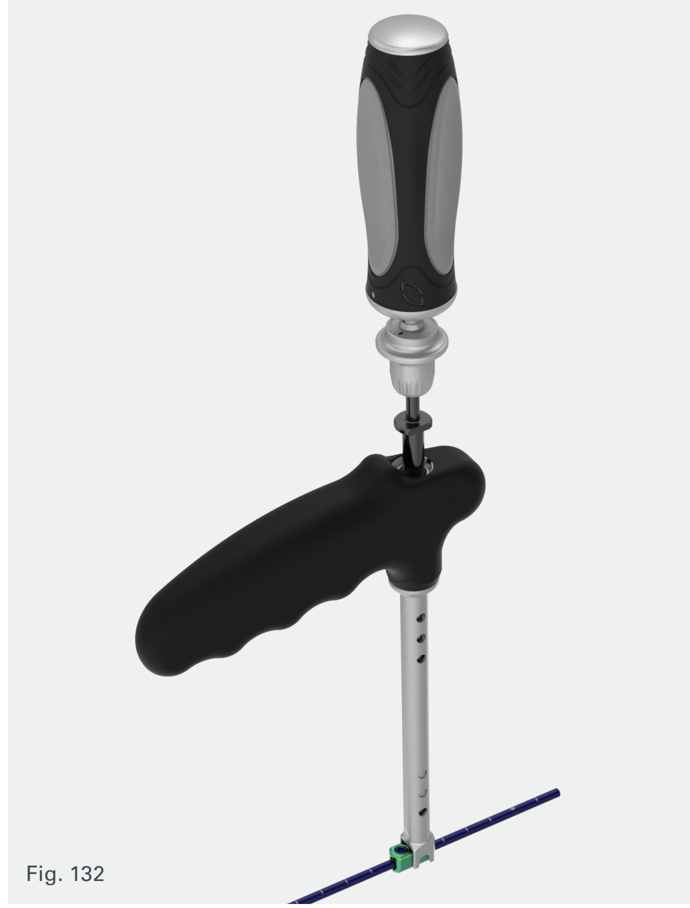


Fig. 132

Step 13

Screw trajectories

C1 lateral mass screw

Once access to the anatomy is gained, an entry point can be made at the center of the C1 lateral mass (using a high-speed drill). The screw trajectory should be parallel to the plane of the C1 posterior arch in the sagittal plane and slightly medial (~10º) in the axial plane.

C2 pedicle screw

The starting point for the C2 pedicle screw is in the rostral and medial quadrant of the exposed isthmus surface. The location of the vertebral artery's transverse foramina must be identified on preoperative imaging to determine appropriate screw length and trajectory. A pilot hole can be marked with an awl or high-speed burr at the desired entry point. A high-speed drill can be directed 20–30° in the lateral-to-medial trajectory and 20° cephalad to the appropriate premeasured depth.

C2 pars screw

After C2 exposure, the borders of the pars are identified. The C1–C2 joint is exposed for visualization of the screw trajectory, with the starting point 2–3 mm lateral to the medial border, and 2–3 mm superior to the inferior border of the pars C2–C3 facet joint. An awl or high-speed burr can be used to mark the entry location. The trajectory typically does not deviate in the sagittal plane, but is usually very steep (~40º). The target is the midpoint of the C1 anterior tubercle, as seen during lateral fluoroscopy. The location of the vertebral artery's transverse foramina must be identified on preoperative imaging to determine appropriate screw length and trajectory. Favored angle screws are useful at C2, due to the steep sagittal trajectory of the pars.

C2 translaminar screw

C2 translaminar screws begin on the top of the lamina. They transcend down the lamina in a crisscross fashion. The downward trajectory of the drill should be kept similar to that of the downslope of the lamina but slightly less increasing the likelihood that any breach goes dorsal and not ventral toward the spinal cord. The precise angle will vary according to patient anatomy and is most guided by the visualized laminar surface.

C3–C6 lateral mass screw

Lateral mass screw placement has been described by several techniques. One method is the Magerl's technique, which outlines the entrance point to be slightly medial and cranial to the midpoint of the lateral mass when divided by a horizontal and vertical line.

The screw trajectory is described as 20–30° lateral and parallel to the adjacent facet joint, aiming toward the anterolateral corner of the upper articular process.

Examples of screw fixation from C1–C7 are lateral mass screws at C1 and C3–C6, C2 pars screws and C7 pedicle screws.

C7 lateral mass screw

Screw placement in the lateral masses of the C7 is similar to that in the other subaxial cervical vertebrae. The insertion point is slightly medial to the midpoint of the lateral mass and a trajectory ~20° lateral and ~20° cephalad is employed. To accommodate the smaller size of the C7 lateral mass, the entry point may be made slightly more medial and the trajectory slightly more lateral.

C7 pedicle screw

In most cases, the entry to the C7 pedicle is found just slightly lateral to the midpoint between the medial and lateral margins of the lateral mass and ~2 mm caudal to the inferior margin of the superior articular facet. Once the entry point is established, the pedicle is probed at a lateral-to-medial trajectory of ~30° with a slight (<5°) superior-to-inferior tilt; the screw is then placed along this trajectory. Prior to placing a C7 pedicle screw, T2-weighted, axial MRI images (or a CT angiogram) should be obtained to confirm the transverse foramen at C7 is empty (does not contain the vertebral artery).

Screw trajectories (cont.)

Warning

Preoperative planning prior to implantation of posterior cervical lateral mass and pedicle screw spinal systems should include review of cross-sectional imaging studies (e.g., CT and/or MRI imaging) to evaluate the patient's cervical anatomy including the transverse foramen and the course of the vertebral arteries. If any findings would compromise the placement of lateral mass or pedicle screws, other surgical methods should be considered. In addition, use of intraoperative imaging should be considered to guide and/or confirm device placement, as necessary.

Warning

Use of posterior cervical pedicle screw fixation at the C3–C6 spinal levels requires careful consideration and planning beyond that required for lateral mass screws placed at these spinal levels, given the proximity of the vertebral arteries and neurologic structures in relation to the cervical pedicles at these levels.

Removal

If it becomes necessary to remove the Reline Cervical construct:

Remove cross connectors and extra rod connectors, if necessary.

- Fixed cross connectors and adjustable rod-to-rod cross connectors are typically removed by loosening the lock screws with the final tightening shaft on a large ratcheting handle. The center guide may be used to loosen the center connection if necessary to remove the adjustable rod-to-rod cross connectors.
- Adjustable tulip-to-tulip cross connectors and extra rod connectors are removed by first loosening the silver lock nuts using the spoke driver and then using the final tightening driver to unthread the purple lock screws from within multiaxial screws and laminar hooks. Lock screws need to be backed all the way out of the tulips and then threaded back in lightly (threading the lock screws back in is important to prevent the lock screws from potentially falling out when the tulip-to-tulip cross connector cap is removed). Unscrewing the lock screws should cause the tulip-to-tulip cross connector cap to pop up from the tulips, allowing them to be removed.
- Tall lock screw cross connectors are removed by loosening the hex cap with the hex cap driver, then removing it. Next, remove the tall lock screw cross connector from around the tall lock screw. Remove the tall lock screw with the final tightening driver and large ratcheting handle.
- Rod-to-rod connectors can be removed with the final tightening shaft and a large ratcheting handle for rod diameters 4 mm and under. For rod diameters over 4 mm use the appropriate final tightening driver and handle according to the appropriate Reline Small Stature or Reline technique.

Unthread lock screws from multiaxial screws, laminar hooks, keel plate or eyelet connectors with the final tightening shaft on a large ratcheting handle.

Remove rods using the rod holders or rod grippers.

Use the final tightening shaft on a large ratcheting handle to remove multiaxial screws and occipital bone screws, as well as keel plate or eyelet connectors. Laminar hooks may either be removed using the implant holder or re-engaged with a threaded driver.

It may be appropriate to use the alignment tool to reposition multiaxial screw tulips for driver re-engagement. If the multiaxial motion remains locked after lock screw removal in step 2, the alignment tool or counter-torque may be used to unthread tulip screws.

Reline Cervical reduction screw technique

Reduction screws provide an alternative zero run-on-rod reduction method. The tabs provide 12 mm of reduction.

Step 1

Screw preparation

Follow step 2, screw preparation on page 7.

Step 2

Screw selection

Reduction screws offer 12 mm of reduction built in to the tulip head. There are three types of reduction screws: multiaxial reduction screws, favored angle reduction screws, and large diameter multiaxial thoracic screws.

Multiaxial reduction screws *(Fig. 133)*

45/45° of angulation

- Offers up to 90° conical sweep
- Offered in 3.5 and 4 mm diameters
- Offered in 12–16 mm lengths in 2 mm increments

Favored angle reduction screws *(Fig. 134)*

65/25° of angulation

- Up to 65° of favored angulation
- Offers up to a 90° conical sweep
- The silver half of the bi-colored screw head provides a visual indication of the favored angle orientation.
- Offered in 3.5 and 4 mm diameters
- Offered in 20–38 mm lengths in 2 mm increments

Large diameter multiaxial reduction screws *(Fig. 135)*

30/30° of angulation

- Offers up to 60° conical sweep
- Offered in 4.5–5.5 and 6.5 mm diameters in 0.5 mm increments
- Offered in 12–16 mm and 20–38 mm lengths in 2 mm increments

Note: *All Reline Cervical reduction screws feature a C-star 15 drive feature.*

Fig. 133

Fig. 134

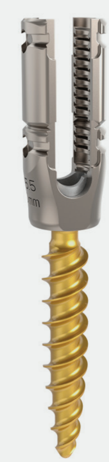


Fig. 135

Step 3

Screw insertion and screw alignment

The reduction screw driver features similar benefits to the standard threaded driver but also incorporates an anti-splay sleeve that, while engaged, prevents the tabs from splaying during insertion.

To engage: Attach the threaded driver to fixed or ratcheting handle. Insert the distal drive feature into the hexalobe of the screw shank with the alignment shelf seated in the rod slot *(Fig. 136)*. Take care to fully seat the driver, failure to do so may compromise the strength of the tabs. If the driver is not fully seated, remove the screw from the driver and reload it paying close attention to the driver and screw interface. While inserting the drive feature, align the anti-splay sleeve by hand so that it captures the top of the tabs and prevents them from splaying during screw engagement and insertion. The anti-splay sleeve is fully seated on the reduction screw tabs when the top of the reduction screw tabs can be seen through the window of the sleeve *(Fig. 137)*.

Turn the proximal knurled knob clockwise to attach the screw *(Fig. 138)*. Confirm the screw and screwdriver interface is rigid and the shank is aligned straight with the hexalobe of the driver buried in the screw shank of the screw.

To disengage: Turn the silver knob counterclockwise until the outer sleeve is fully unthreaded from the tulip and remove from the implant. There is no need to manually disengage the anti-splay sleeve from the tab as it will disengage as the driver is removed.

Repeat these steps for all implant placement sites.

Note: *The reduction screw threaded driver anti-splay sleeve possesses friction that keeps the sleeve in place during insertion.*

Note: *The reduction screw threaded driver anti-splay sleeve has built in visualization windows both medial/lateral and cranial/caudal. The reduction screw tabs should be visible through the medial/lateral visualization windows with no empty space when the sleeve is fully seated.*

Note: *The standard threaded driver is not compatible with the reduction screws.*

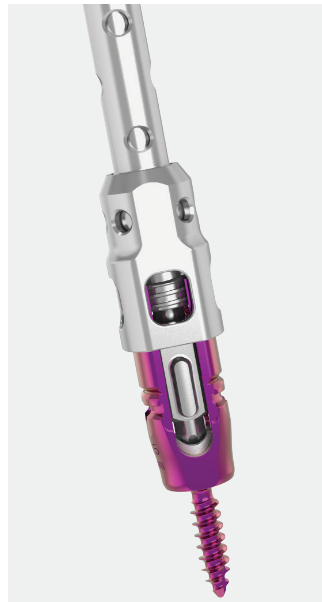


Fig. 136

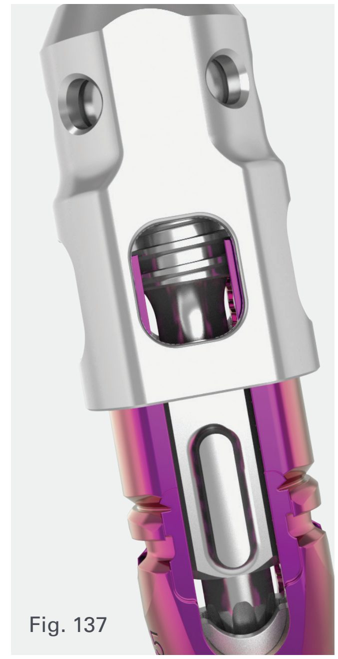


Fig. 137

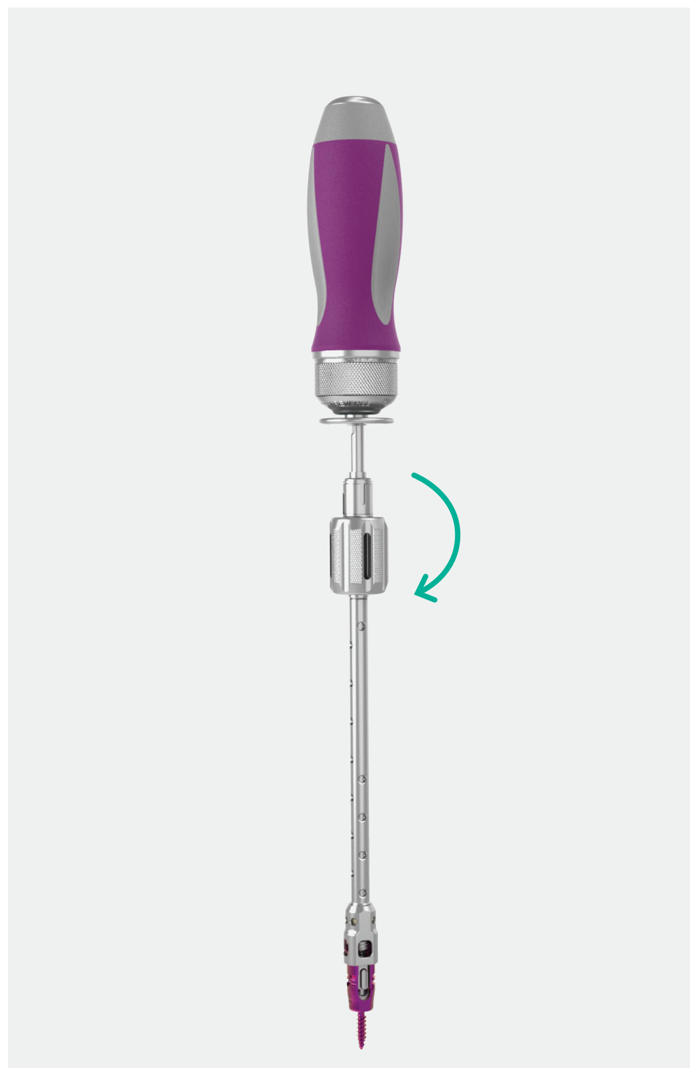


Fig. 138

Step 4

Rod preparation and insertion

Follow rod preparation and insertion instructions in step 6 on page 21.

Rod reduction

Reduce the rod by threading the lock screw down the reduction screw tabs. To insert a lock screw and reduce the rod, two methods may be used: reduction screw lock screw starter or standard tapered driver with reduction screw cap.

Reduction screw lock screw starter: The reduction screw lock screw starter uses a tapered attachment mechanism to retain the lock screws and is used to introduce lock screws to provisionally tighten the construct. The retention strength is proportional to the axial force applied during loading. While inserting the lock screw, align the lock screw starter anti-splay sleeve with the tabs of the reduction screw so the rod slots are parallel *(Fig. 139)*. As the lock screw is inserted, a spring will allow the inner shaft of the driver to insert the lock screw while the anti-splay sleeve remains in place *(Fig. 140)*.

Note: *The sheath of the lock screw starter can be adjusted proximally for better visualization upon attaching a lock screw or upon inserting the lock screw.*

Note: *The reduction screw lock screw starter will not function with the reduction screw cap in place.*

Tapered driver with reduction screw cap: The standard tapered driver is another option to introduce lock screws and provisionally tighten the construct. It is recommended that the reduction screw cap be inserted prior to introducing lock screws with this driver.

To attach the cap to the reduction screw tab, engage the distal end of the inserter on the cap with the inserter's cylindrical tips in the cap's lateral engagement features. When properly engaged, the top of the cap will line up with the laser marked lines on the inserter *(Fig. 141)*.

Fig. 139

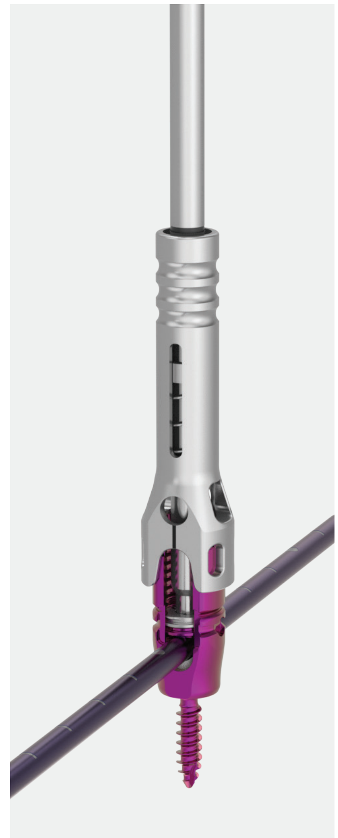


Fig. 140

Fig. 141

Rod preparation and insertion (cont.)

Place the cap onto the tulip with the rod slot of the cap, parallel to the rod slot in the tulip *(Fig. 142)*. The cap will cover the tab break-off grooves when fully seated on the tulip *(Fig. 143)*.

Once the cap is seated introduce the lock screw with the standard tapered driver.

Note: *There are a total of four reduction screw caps offered in the set.*

Note: *The lock screw repeater is not compatible with the reduction screws.*

Note: *If reduction is required after a tab has been removed, reducers may be attached directly to the tulip and used per the standard technique in step 7* *on page 24.*

Fig. 142

Fig. 143

Step 5

Final tightening

To final tighten, attach the black final tightening driver to the black torque handle. Slide the reduction screw counter-torque over the reduction tabs until the instrument encompasses the tulip head and is seated on the rod. The handle will sit lateral to the construct and the rod slot will be aligned *(Fig. 144)*.

Engage the driver into the provisionally tightened lock screw and begin tightening the lock screw until the torque handle torques out. A tactile and audible click occurs when the lock screw is locked at the recommended 26 in-lbs (3 n-m).

Note: *Improper seating of the counter-torque can cause premature break-off of the reduction screw tabs. To avoid this, properly seat the counter-torque so it encompasses the tulip and not the tabs (Fig. 145).*

Note: *The standard counter-torque is not compatible while the reduction screw tabs remain on the screw.*

Note: *The final tightening handle may also sit medial to the construct.*

Fig. 144

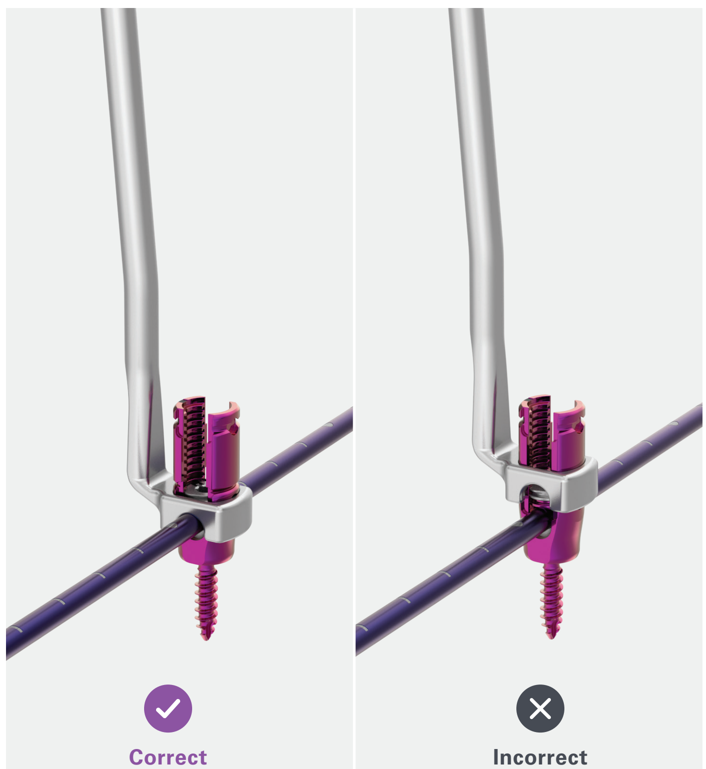


Fig. 145

Step 6

Reduction screw tab break-off

The reduction screw break-off tool is used to remove the reduction screw tabs. Position the break-off tool so the ejector thumb slide faces the screw rod slot. Slide the break-off tool over the tabs so that the tool captures the tabs *(Fig. 146)*. When fully seated, the distal end of the break-off tool will contact the tulip capture of the counter-torque *(Fig. 147)*.

Gently rock the handle of the break-off tool medially and laterally to remove the tab from the screw *(Fig. 148a)*. To break off the remaining tab, rotate the break-off tool 180° so the ejector thumb slide again faces the screw rod slot and repeat the break-off steps. The break-off tool will capture and constrain up to eight tabs within the tool. To eject the tabs, slide the ejector knob toward the distal end of the instrument *(Fig. 148b)*.

Fig. 147


Fig. 146

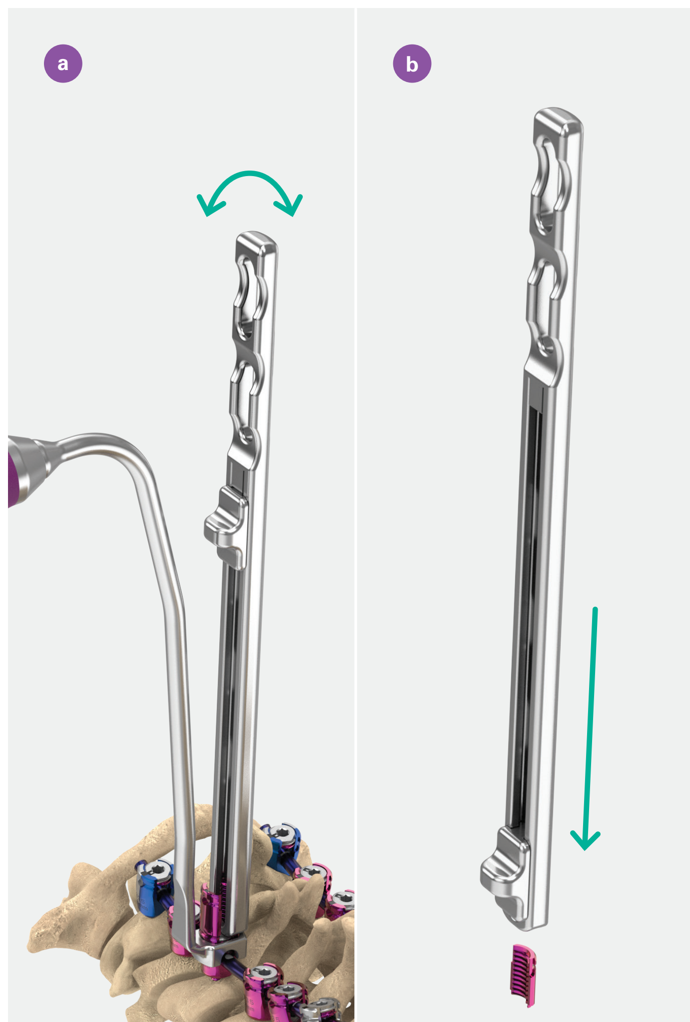


Fig. 148

Reline Cervical occipital technique

Step 1

Occipital fixation selection

There are three fixation options to fixate to the occiput each presenting varying levels of placement flexibility.

Occipital keel plate: The occipital keel plate offers five screw placement sites, three midline and two lateral *(Fig. 149)*. The medial screw holes are angled 10° caudally. The lateral screw holes are angled 5° medially and 8° caudally. The tulip heads offer 15° of rotation and 5 mm of translation on both sides for 10 mm of total translation.

Unilateral occipital plate: The unilateral occipital plates offer three midline screw placement sites with a 10° medial angle. The plate offers flexibility in placement as placement is independent of the contralateral plate *(Fig. 150)*.

Eyelets: The eyelets offer complete independent fixation placement and have options for single or dual screw placement sites *(Fig. 151)*. The screw holes are angled 10° medially.

Note: *The occipital keel plate, unilateral occipital plate, and eyelets accept 3.5 and 4 mm diameter rods.*

Note: *The occipital keel plate is offered in two sizes, small and medium. The sizes are color coded by the adjustable ring, green for small and purple for medium.*

Note: *The small occipital plate features tulip translation from 25–35 mm while the medium features tulip translation from 35–45 mm.*

Note: *The occipital keel plate and unilateral occipital plate thickness is 2.29 and 13.79 mm including the tulips.*

Note: *Eyelets come in single and dual screw designs as well as small and medium lengths. The colors of the small and medium lengths are green and purple, respectively.*

Note: *Reline Cervical occipital bone screws and eyelet lock screws feature a C-star 15 drive feature.*

Warning

When utilizing eyelets, a minimum of four eyelets should be used to allow for four fixation points.

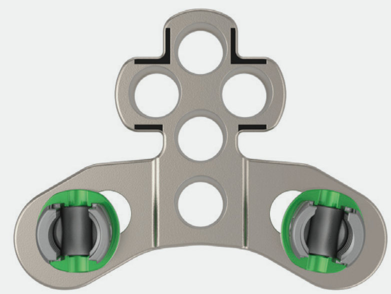


Fig. 149

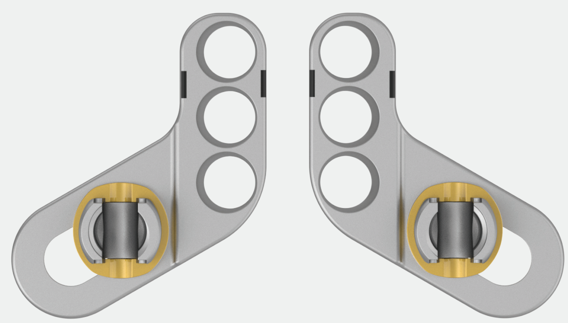


Fig. 150

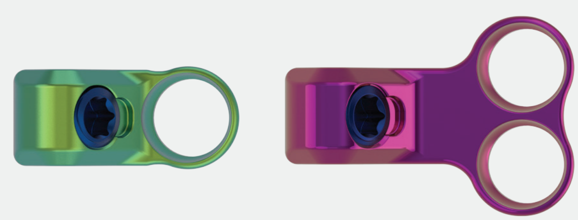


Fig. 151

Step 2

Occipital screw hole preparation

The Reline Cervical system offers both straight and angled occipital instrumentation to address the various anatomical challenges at the occipital-cervical junction.

Standard instrumentation should be used in the majority of cases when direct access and trajectories are not prohibitive and there are not anatomical obstacles that make accessing the occiput with straight instrumentation difficult.

Angled instrumentation should be used when necessary to help navigate cases with difficult occipital angles and challenging thoracic anatomy.

Both the straight and angled occipital drills and taps should be used through the occipital drill/tap guide to achieve proper depth *(Fig. 152)*.

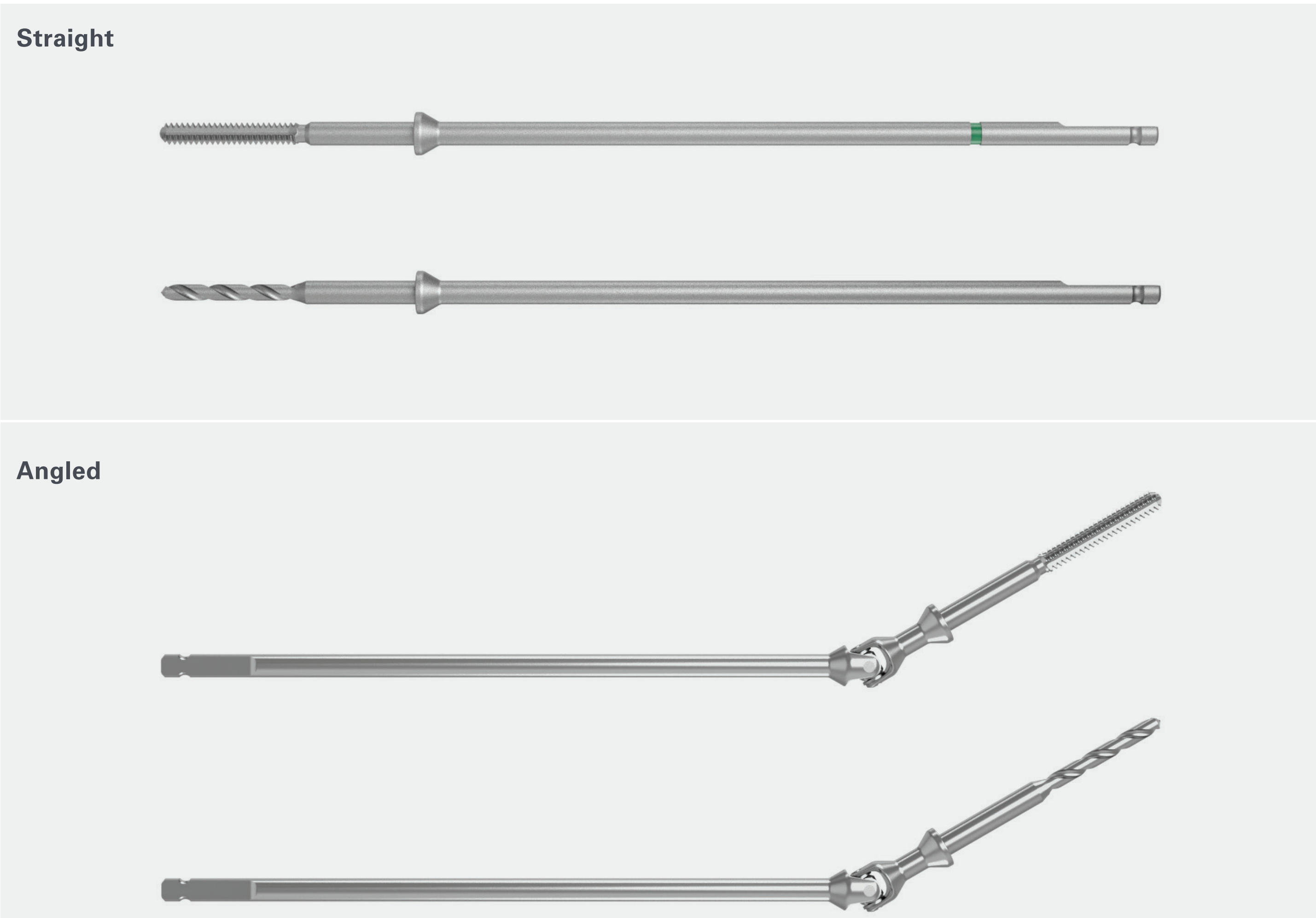


Fig. 152

Occipital screw hole preparation (cont.)

Drill

Select the drill/tap guide based on the desired drill depth. The lengths are laser marked on the back of the drill/tap guide and are offered in 6, 8, 10, 12 and 14 mm depths *(Fig. 153)*.

Place the straight/angled drill bit, through the drill/tap guide *(Fig. 154)*. Drill the screw holes starting with the shortest depth, probing and then drilling deeper if not bicortical. This sequence is repeated until the inner cortex is penetrated or depth is deemed sufficient. Drill depth has been reached when the positive stop on the drill meets the proximal end of the guide shaft *(Fig. 155)*.

Note: *The occipital drill guides are colored from small to large with 6/8 mm being green, 10/12 mm being purple and 14 mm being light blue.*

Tap

Occipital bone screws require hand-tapping to depth. Attach the straight/angled occipital tap to the fixed or ratcheting handle and place through the drill/tap guide. When the depth stop meets the top of the drill/tap guide, stop rotating the tap. Failure to do so may cause the threads of the tap to strip.

Note: *Reline Cervical occipital screws come in 4.5 and 5 mm diameter in 6–14 mm lengths in 2 mm increments. The screws are color coded green and light blue, respectively. Taps are 0.25 mm undersized from the diameter of the screw (4.25 and 4.75 mm).*

Caution: Avoid extreme trajectories for screw placement on the Reline Cervical occipital plate specifically where the drill/tap guide is pushed on the plate.

Warning

To prevent stripping, stop tapping when the tap bottoms out on the tap guide.

Warning

To prevent stripping of the tap threads, **do not** attach the tap to power. Always hand-tap to depth.

Fig. 153


Fig. 154


Fig. 155

Step 3

Plate bending and fixation placement

Plate bending

After burring down any bony protuberances (while still maintaining the integrity of the cortical bone), if necessary, the plate can be bent to the contour of the patient's anatomy.

To bend the occipital keel plate, hold the keel plate bender so the joint is facing up *(Fig. 156)*. Load the plate with the tulip facing up for a convex contour so the plate is centered and sits on the bottom shelf underneath the bend fulcrum. Compress the handles gently to impart the desired bend on the plate *(Fig. 157)*. The plate will bend around the bottom shelf.

Note: *The plate can be bent with a concave or convex contour. For a concave contour, flip the plate in the bender so the tulip heads of the plate face down.*

Caution: Care must be exercised not to over bend the occipital plate as it may cause interference with the occipital drill/tap guide.

Warning

To maintain the mechanical integrity of the plate, once the plate is bent in one direction, further bending only in that same direction should be attempted. Unbending of the plate may cause mechanical compromise.

Warning

Care must be exercised not to over bend the occipital plate. **Do not** unbend the plate once the plate is bent, as this may compromise the mechanical strength.

Warning

Care must be exercised not to over bend the occipital plate as it may cause interference with the occipital drill/tap guide.

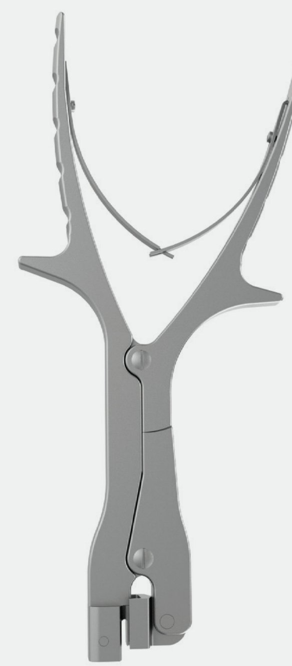


Fig. 156

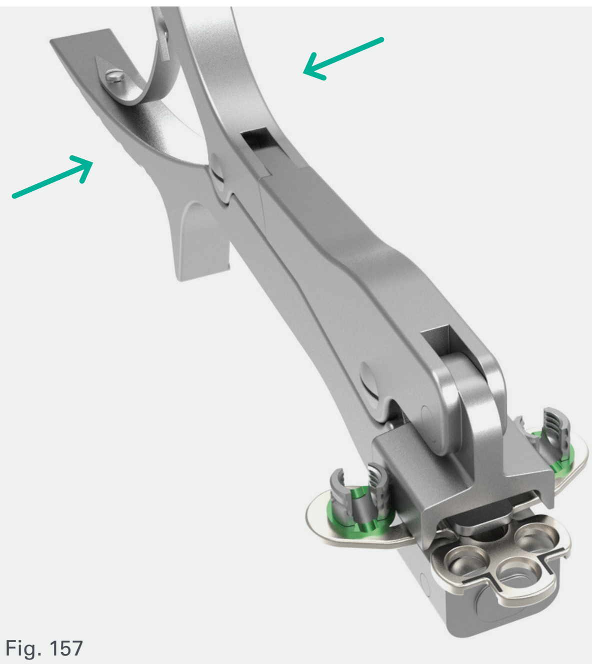


Fig. 157

Plate bending and fixation placement (cont.)

Fixation placement

Occipital keel plate

The plate holder may help in positioning the plate. To engage the occipital keel plate with the keel plate holder, confirm the rack of the instrument is fully open. Grab on to the plate using the distal features of the holder in one of three positions; cranial-caudal across either of the lateral screw holes or medial lateral over the cranial-most medial screw hole *(Fig. 158)*. The engagement sites are indicated with black laser marked lines *(Fig. 159)*. Release the teeth between the finger loops to release the plate.

Unilateral occipital plate

Follow the cranial caudal attachment steps as described in the keel plate section.

Eyelets

Preload the eyelet connectors to the rod once the rod bend is complete.

Note: *In lieu of the plate holder, the plate can be held with the drill/tap guide engaged in a screw hole to maintain orientation of the plate.*

Warning

When utilizing eyelets, a minimum of four (4) eyelets should be used to allow for four (4) fixation points.

Fig. 158

Fig. 159

Step 4

Occipital screw insertion

While holding the plate in place, select the appropriate screw length and diameter according to the pre-drilled depth. Pick up the screw with the tapered driver/angled occipital driver, attached to the fixed or ratcheting handle. Place the occipital bone screws through the midline holes. Repeat for lateral screw placements.

The angled ratcheting wrench may be used to insert the screws. Identify the drive direction on the shaft of the ratcheting wrench and insert the drive feature in the bone screw *(Fig. 160)*. Rotate the handle of the instrument to drive the screw in to bone.

Note: *The angled ratcheting wrench drives toward the large black marking on the side of the instrument, therefore when changing drive direction, flipping of the tool will be required.*

Note: *Reline Cervical occipital screws are available in 4.5 and 5 mm diameters in 6–14 mm lengths in 2 mm increments.*

Note: *When fully seated, the drill/tap guide allows only the full trajectory range within each screw hole on the plate/eyelet.*

Warning

Avoid extreme trajectories for screw placement on the Reline Cervical occipital plate specifically where the drill/tap guide is pushed on the plate.

Fig. 160

Step 5

Rod preparation and placement

A straight, pre-bent or hinged rod may be used when connecting to the occiput.

Hinged rod

The hinged rod may be used in occipital cases for ease of placement and may allow the surgeon to avoid weakening the rod with extreme bends that are often required to fixate in the desired position. The hinged rods have markings every 10 mm and may be cut with the standard rod cutter.

Start with the hinged rod in the unlocked state by backing out the lock screw in the hinge half a turn if necessary. Place the hinged rod in the sub-axial tulip heads from inferior to superior. Then seat the superior portion of the rod in the tulip heads of the keel plate. Provisionally tighten the hinge using the tapered driver *(Fig. 161)*.

To final tighten the hinge lock screw, use the black final tightening driver and handle with the standard counter-torque. Seat the counter-torque over the hinge so the handle is parallel with the rod. Insert the driver through the counter-torque cannulation and final tighten to the 26 in-lbs breakoff.

Note: *The hinged rod has 45–100° range of motion (Fig. 162).*

Note: *The hinged rod may be contoured like a standard rod. Care must be taken to not bend across the hinge as it could compromise strength.*

3.5 mm diameter rods

- Hinge rod titanium and cobalt chrome (90 mm occipital and 210 mm sub-axial with 45–100° angulation)

4 mm diameter rods

- Hinge rod titanium (90 mm occipital and 210 mm sub-axial with 45–100° angulation)
- Cobalt chrome is available upon request

Fig. 161

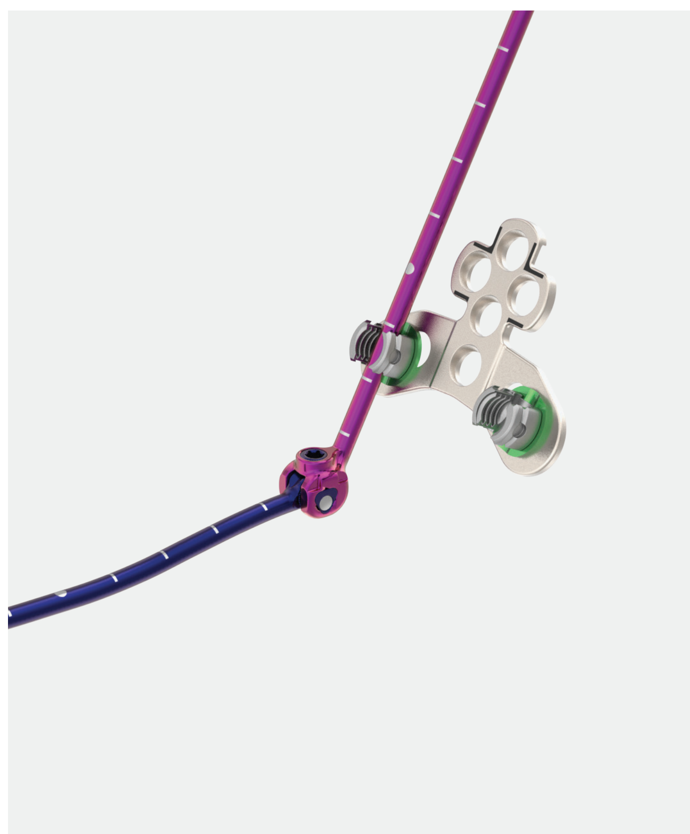


Fig. 162

Rod preparation and placement (cont.)

Straight and pre-bent rod

If not using a hinged rod, follow the rod bending instructions detailed on page 22. Pre-bent occipital rods come in the following sizes and configurations:

3.5 mm diameter rods

- Pre-bent occipital titanium and cobalt chrome (100 mm occipital and 250 mm subaxial)

4 mm diameter rods

- Pre-bent occipital titanium (100 mm occipital and 250 mm subaxial)

Bendini with Pulse

Bendini can also be used to bend a 3.5 mm rod. For instructions, follow the appropriate Bendini surgical technique (document #9501356).

Step 6

Final tightening

Once the rod is bent and seated within the tulip head, place the lock screws over the rod and provisionally tighten using the angled or tapered driver. Attach the final tightening shaft to the final tightening torque handle and insert the driver through the counter-torque to final tighten *(Fig. 163)*. A tactile and audible "click" indicates the lock screw is locked at the recommended 26 in-lbs (3 n-m) of torque.

Optional occipital tulip alignment guide: The occipital tulip alignment guide, on the back of the 14 mm occipital drill guide, can be used if additional assistance is required in maintaining axial alignment during occipital lock screw insertion.

First, pass the straight or angled occipital driver tip through the guide and engage a lock screw. Next seat the guide over the occipital tulip and provisionally tighten the lock screw.

Once the lock screw is provisionally tightened remove the assembly and replicate on the contra-lateral tulip.

Note: *The occipital tulip alignment guide is intended only for insertion and provisional tightening of the lock screw and is not intended as a counter-torque during final tightening.*

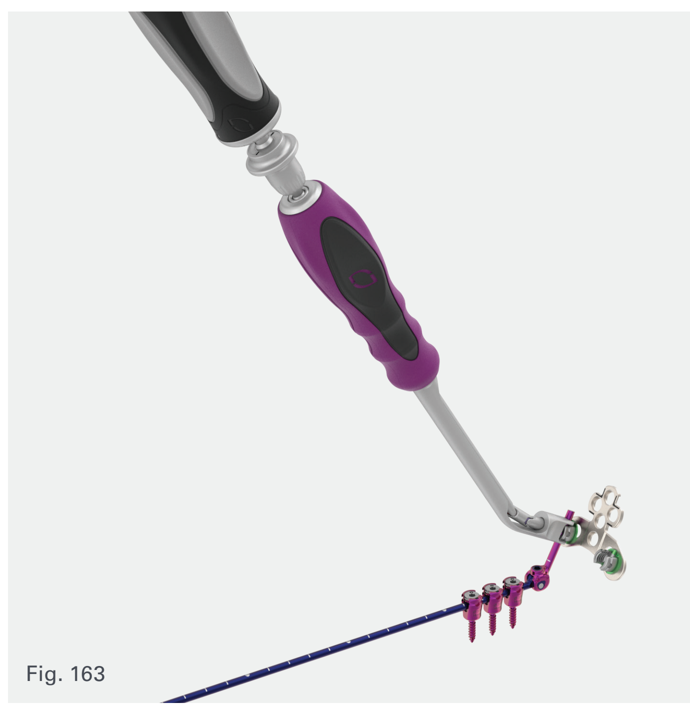


Fig. 163

Removal

Follow the below instructions if it becomes necessary to remove the Reline Cervical construct.

Remove cross connectors and extra rod connectors if necessary.

- Fixed cross connectors and adjustable rod-to-rod cross connectors are typically removed by loosening the lock screws with the final tightening shaft on a large ratcheting handle. The center guide may be used to loosen the center connection if necessary to remove the adjustable rod-to-rod cross connectors.
- Adjustable tulip-to-tulip cross connectors and extra rod connectors are removed by first loosening the silver lock nuts using the spoke driver and then using the final tightening driver to unthread the purple lock screws from within multiaxial screws and laminar hooks. Lock screws need to be backed all the way out of the tulips and then threaded back in lightly (threading the lock screws back in is important to prevent the lock screws from potentially falling out when the tulip-to-tulip cross connector cap is removed). Unscrewing the lock screws should cause the tulip-to-tulip cross connector cap to pop up from the tulips, allowing them to be removed.
- Tall lock screw cross connectors are removed by loosening the hex cap with the hex cap driver, then removing it. Next, remove the tall lock screw cross connector from around the tall lock screw. Remove the tall lock screw with the final tightening driver and large ratcheting handle.
- Rod-to-rod connectors can be removed with the final tightening shaft and a large ratcheting handle for rod diameters 4 mm and under. For rod diameters over 4 mm use the appropriate final tightening driver and handle according to the appropriate Reline Small Stature or Reline technique.

Unthread lock screws from multiaxial screws, laminar hooks, keel plate or eyelet connectors with the final tightening shaft on a large ratcheting handle.

Remove rods using the rod holders or rod grippers.

Use the final tightening shaft on a large ratcheting handle to remove multiaxial screws and occipital bone screws, as well as keel plate or eyelet connectors. Laminar hooks may either be removed using the implant holder or re-engaged with a threaded driver.

It may be appropriate to use the alignment tool to reposition multiaxial screw tulips for driver re-engagement. If the multiaxial motion remains locked after lock screw removal in step 2, the alignment tool or counter-torque may be used to unthread tulip screws.

Instructions for use

DESCRIPTION

The NuVasive Reline Cervical System consists of a series of polyaxial screws, collets, rods, offset connectors, inline connectors, lock screws, occipital plates, hooks and cross connectors manufactured from Ti-6Al-4V ELI per ASTM F136 and ISO 5832-3, and CoCr per ASTM F90 or ASTM F1537. The implants are available in a variety of different shapes and sizes to suit the individual pathology and anatomical conditions of the patient.

INDICATIONS FOR USE

The NuVasive Reline Cervical 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 (C1 to 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 Reline Cervical 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 Reline Cervical System may be connected to the NuVasive SpheRx Spinal System, Precept Spinal System, Armada Spinal System, Reline System, and Reline 4.5-5 System via the rod-to-rod connectors or transition rods.

CONTRAINDICATIONS

Contraindications include, but are not limited to:

1. Infection, local to the operative site.
2. Signs of local inflammation.
3. Patients with known sensitivity to the materials implanted.
4. Patients who are unwilling to restrict activities or follow medical advice.
5. Patients with inadequate bone stock or quality.
6. Patients with physical or medical conditions that would prohibit beneficial surgical outcome.
7. Use with components of other systems.
8. Reuse or multiple uses.

POTENTIAL ADVERSE EVENTS AND COMPLICATIONS

As with any major surgical procedures, there are risks involved in orthopedic surgery. Infrequent operative and postoperative complications that may result in the need for additional surgeries include: early or late infection; damage to blood vessels, spinal cord or peripheral nerves; pulmonary emboli; loss of sensory and/or motor function; impotence; and permanent pain and/or deformity. Rarely, some complications may be fatal.

Potential risks identified with the use of this system, which may require additional surgery, include:

- Bending, fracture or loosening of implant component(s)
- Loss of fixation
- Nonunion or delayed union
- Fracture of the vertebra
- Neurological, vascular or visceral injury
- Metal sensitivity or allergic reaction to a foreign body
- Infection
- Decrease in bone density due to stress shielding
- Pain, discomfort or abnormal sensations due to the presence of the device
- Nerve damage due to surgical trauma
- Bursitis
- Dural leak
- Paralysis
- Death

WARNINGS, CAUTIONS AND PRECAUTIONS

The subject device is intended for use only as indicated.

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

Correct selection of the implant is extremely important. The potential for success is increased by the selection of the proper size of the implant. The Reline Cervical System can also be linked to Ø3.5mm–Ø6.0mm rods of posterior pedicle screw and rod systems via the rod to rod connectors or transition rods.

While proper selection can minimize risks, the size and shape of human bones present limitations on the size and strength of the implants. Metallic internal fixation devices cannot withstand the activity levels and/or loads equal to those placed on normal, healthy bone. These devices are not designed to withstand the unsupported stress of full weight or load bearing alone.

Caution must be taken due to potential patient sensitivity to materials. Do not implant in patients with known or suspected sensitivity to the aforementioned materials.

These devices can break when subjected to the increased load associated with delayed union or nonunion. Internal fixation appliances are load-sharing devices that hold bony structures in alignment until healing occurs. If healing is delayed, or does not occur, the implant may eventually loosen, bend, or break. Implant breakage may lead to wear debris deposition into adjacent tissues, causing discoloration or immunological reaction. Loads on the device produced by load bearing and by the patient's activity level will dictate the longevity of the implant.

Corrosion of the implant can occur. Implanting metals and alloys in the human body subjects them to a constantly changing environment of salts, acids, and alkalis, which can cause corrosion. Placing dissimilar metals in contact with each other can accelerate the corrosion process, which in turn, can enhance fatigue fractures of implants. Consequently, every effort should be made to use compatible metals and alloys in conjunction with each other.

Notching, striking, and/or scratching of implants with any instrument should be avoided to reduce the risk of breakage.

Correct mating of system components should also be considered at each component interface, such as screwdriver-screw, rod-tulip rod slot, etc. Incorrect or inadequate mating of such components may result in further surgical delays or compromised construct integrity.

Based on the fatigue testing results, when using the NuVasive Reline Cervical System, the physician/surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc. which may impact on the performance of the system.

To maintain the mechanical integrity of the Cross Connector, once the Connector is bent in one direction, further bending only in that same direction should be attempted. Unbending of the Connector may cause mechanical compromise.

To maintain the mechanical integrity of the plate, once the plate is bent in one direction with either tool, further bending only in that same direction should be attempted. Unbending of the plate may cause mechanical compromise.

To prevent stripping, stop tapping when the tap bottoms out on the Tap Guide.

It is possible to pull out the screw if too much force is applied with the reducer.

Rod-to-Rod Connectors must be used when connecting two separate constructs. Do NOT use Reline Cervical Extra Rod Connectors as the mechanical strength is not adequate for stable fixation of two separate constructs.

Pivoting rod-rod connectors should be used in pairs (i.e., two per side).

Care must be exercised not to over bend the Occipital Plate. Do not unbend the plate once the plate is bent, as this may compromise the mechanical strength.

Care must be exercised not to over bend the Occipital Plate as it may cause interference with the Occipital Drill/Tap Guide.

To prevent stripping of the tap threads, do not attach the tap to power. Always hand-tap to depth.

Avoid extreme trajectories for screw placement on the Reline Cervical Occipital Plate specifically where the Drill/Tap Guide is pushed on the plate.

Exercise caution when using the Set Screw Repeater, as pulling up on the instrument may result in screw pullout or extreme forces on the spine.

When utilizing eyelets, a minimum of four (4) eyelets should be used to allow for four (4) fixation points.

Pre-operative planning prior to implantation of posterior cervical lateral mass and pedicle screw spinal systems should include review of cross-sectional imaging studies (e.g., CT and/or MRI imaging) to evaluate the patient's cervical anatomy including the transverse foramen and the course of the vertebral arteries. If any findings would compromise the placement of lateral mass or pedicle screws, other surgical methods should be considered. In addition, use of intraoperative imaging should be considered to guide and/or verify device placement, as necessary.

Use of posterior cervical pedicle screw fixation at the C3 through C6 spinal levels requires careful consideration and planning beyond that required for lateral mass screws placed at these spinal levels, given the proximity of the vertebral arteries and neurologic structures in relation to the cervical pedicles at these levels.

Care should be taken to insure that all components are ideally fixated prior to closure.

Patient Education: Preoperative instructions to the patient are essential. The patient should be made aware of the limitations of the implant and potential risks of the surgery. The patient should be instructed to limit postoperative activity, as this will reduce the risk of bent, broken or loose implant components. The patient must be made aware that implant components may bend, break or loosen even though restrictions in activity are followed.

Single Use/Do Not Re-Use: Reuse of a single use device that has come in contact with blood, bone, tissue or other body fluids may lead to patient or user injury. Possible risks associated with reuse of a single use device include, but are not limited to, mechanical failure, material degradation, potential leachables, and transmission of infectious agents.

MRI Safety Information: The Reline Cervical System has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of the Reline Cervical System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

Compatibility: Do not use Reline Cervical System with components of other systems. Unless stated otherwise, NuVasive devices are not to be combined with the components of another system.

All implants should be used only with the appropriately designated instrument (Reference Surgical Technique).

Instruments and implants are not interchangeable between systems.

PRE-OPERATIVE WARNINGS

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.

1. Only patients that meet the criteria described in the indications should be selected.
2. Patient condition and/or predispositions such as those addressed in the aforementioned contraindications should be avoided.
3. Care should be used in the handling and storage of the Reline Cervical implants. The implants should not be scratched or damaged. Implants and instruments should be protected during storage and from corrosive environments.

   For Sterile Implants: Assure highly aseptic surgical conditions, and use aseptic technique when removing the Reline Cervical implant from its packaging. Inspect the implant and packaging for signs of damage, including scratched or damaged devices or damage to the sterile barrier. Do not use the Reline Cervical implants if there is any evidence of damage.
4. Refer to Cleaning and Sterilization Instructions below for all non-sterile parts.
5. Care should be used during surgical procedures to prevent damage to the device(s) and injury to the patient.

POST-OPERATIVE WARNINGS

During the postoperative phase it is of particular importance that the physician keeps the patient well informed of all procedures and treatments.

Damage to the weight-bearing structures can give rise to loosening of the components, dislocation and migration, as well as to other complications. To confirm the earliest possible detection of such catalysts of device dysfunction, the devices must be checked periodically postoperatively, using appropriate radiographic techniques.

Please refer to the Reline Cervical System IFU found at **nuvasive.com/eIFU** for additional important labeling information.

Notes

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