RELINE Small Stature

Technique Guide

NUVASIVE

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Preface

Fellow Colleagues,

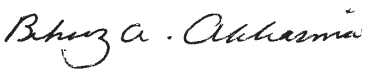
The foundation of our profession is built upon the principle and drive to help others. As pediatric surgeons, we are fortunate to be able to focus that drive on the pursuit of the best possible care for children and are particularly proud to have opportunities to partner with industry to advance spinal deformity treatment.

When our team of clinicians and NuVasive product development experts was initially assembled, our collective vision was clear: we committed to developing a world class small stature fixation system that would create an unparalleled experience in pediatric spinal care. Reline Small Stature was not only designed to stand on its own as a premium solution, but when packaged with the larger NuVasive pediatric portfolio, result in a best-in-class procedural offering.

Reline Small Stature is a system that leverages innovation, simple and elegant design, and our collective clinical experience to provide a superior solution that will elevate our ability to provide excellent patient care. We are confident that you will find value in Reline Small Stature and appreciate the dedication, diligence, and thoughtfulness that went into its design.

It is with great pleasure that we recommend Reline Small Stature as the premier fixation solution for your pediatric deformity patients.

Cordially,



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System Overview

Pedicle Screw Portfolio

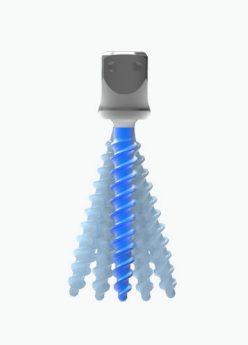
Reline Small Stature pedicle screws accept 4.5 or 5.0mm rods in titanium (Ti6Al4V) or cobalt chrome (CoCr).

The low-profile tulip design features Helical Flange Locking Technology designed to reduce head splay and minimize cross-threading.

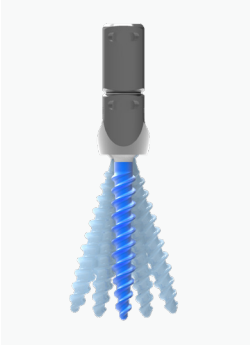
Screw shanks feature a double lead thread for efficient screw insertion and are available in a solid design. Screw shanks and load rings are color-coded to the shank diameter as outlined in Table 1 (e.g., a 6.5mm screw has a magenta shank and load ring).

Shank/load ring colors correspond to screw diameters

Bronze	Green	Light blue	Gold	Magenta	Dark blue	Purple
4.0mm	**4.5mm**	**5.0mm**	**5.5mm**	**6.5mm**	**7.5mm**	**8.5mm**



Polyaxial
Simplified rod seating in solid shanks



Polyaxial Reduction
Extended tulip for up to 15mm of instrument-free reduction

Monoaxial
Low-profile rigid fixation

Uniplanar
Angulation restricted to the sagittal plane for axial rotation correction while preserving sagittal alignment

Open Iliac
Simplified rod seating for iliac fixation

Lock Screw Compatibility

The Reline Small Stature portfolio includes two types of lock screws. Both can be used with 4.5 or 5.0mm rods.

Open lock screw: for open tulips and compatible with 4.5 and 5.0mm rod diameters. This lock screw will sit flush with the top of the tulip when final tightened on a 5.0mm rod and 0.5mm sub-flush when final tightened on a 4.5mm rod.

Closed lock screw: for closed Iliac Offset Connectors and closed Rod to Rod connectors. Compatible with 4.5 and 5.0mm rod diameters.

Open lock screw

Tulip: Open

Locking Mechanism: Helical Flange

Closed lock screw

Tulip: Closed

Locking Mechanism: Metric Thread

Rod Technology

Versatility in Construct Strength and Stiffness

The Reline Small Stature portfolio includes straight rods in two diameters (4.5 and 5.0mm) offered in titanium (Ti6Al4V) or cobalt chrome (CoCr), which enable surgeons to optimize the construct to the individual needs of the patient.

Titanium rods are color-coded by diameter and feature solid lines to help with proper sagittal orientation.

Cobalt chrome rods feature a textured surface for optimal grip strength with instruments and implants. All CoCr rods are marked with a dashed line to help with proper sagittal orientation.

Reline Small Stature 4.5mm and 5.0mm rods have differing end geometries to aid in rod rotation.

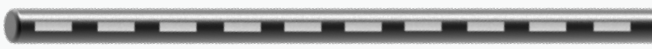
4.5mm Rods: Spline End

5.0mm Rods: Hex End

4.5mm Ti

5.0mm Ti

4.5mm CoCr



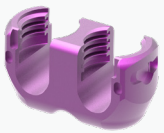
5.0mm CoCr

Rod-to-rod Connectors

Reline Small Stature rod-to-rod connectors feature rod slots designed to accommodate the range of rods typically seen in pedicle screw constructs:

- 4.5/5.0mm–4.5/5.0mm
- 4.5/5.0mm–5.0/6.0mm

With a variety of implant options, the Reline rod-to-rod connectors have the versatility to link onto existing constructs with minimal tissue disruption, and accommodate multiple surgical approaches to revision surgery.

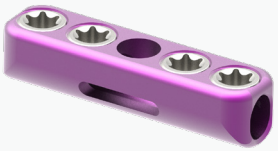


Open-Open Connector

Open-Closed Connector

Closed-Closed Connector

2H Inline Connector



4H Inline Connector

Traditional Growing Rods (TGR)

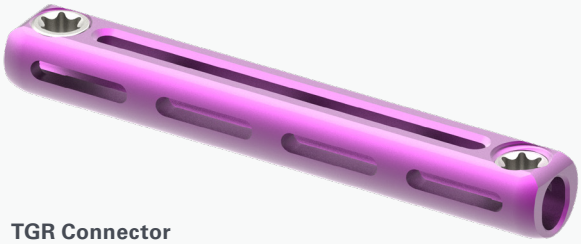
The Reline Small Stature Extended Inline Connectors (TGR Connectors) feature a slot that allows for distraction with a TGR distractor.

TGR Connectors are available in the following sizes:

- 50mm
- 70mm
- 90mm

These connectors do not have any limitations of a non-bending zone.

The 50mm connector can be used as the smallest alternative when the 70 and 90mm MAGEC actuators are too large for the patient.



TGR Connector

Cross Connector Portfolio

The low-profile cross connectors feature a T20 cam style locking mechanism designed for specific rod diameters: 4.5mm (gold) or 5.0mm (magenta).

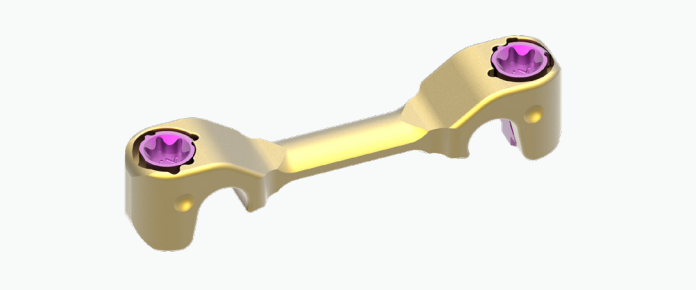
Fixed and adjustable cross connectors use the same inserters and drivers.

Low-profile fixed

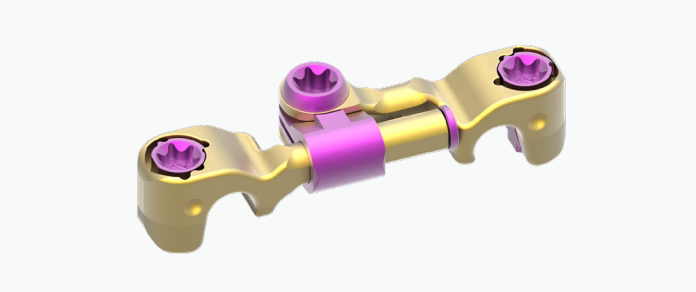
- **Size offering:** 11mm, 13mm, and 15-30mm in increments of 2.5mm
- **Rod compatibility:** 4.5mm, 5.0mm

Low-profile adjustable

- **Size offering:** ranges span from 22mm up to 60mm
- **Rod compatibility:** 4.5mm, 5.0mm



Low-profile fixed



Low-profile adjustable

Hook Portfolio for Variable Anatomy

The Reline hook portfolio offers a variety of anatomically designed blades in a range of throat diameters (color-coded to the right) to accommodate anatomic variability.

Multiple hook site preparation tools and inserter options enable surgeons to place hooks according to their preferred technique.

4.0mm

6.0mm

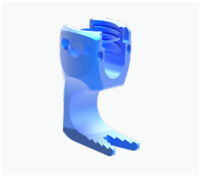
10.0mm

8.0mm

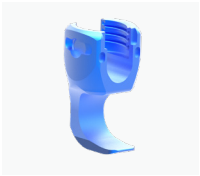
Standard hooks

Lamina narrow

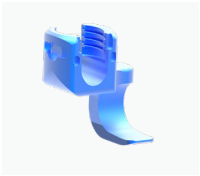
Lamina wide



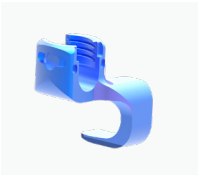
Pedicle



Transverse process



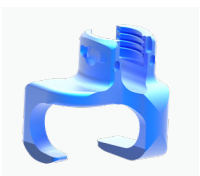
Offset left



Offset right

Alternative hooks

Hyperfit



Sidewinder left

Sidewinder right

Surgical Technique

Core Trays

- RELINE Small Stature Core Implant Tray (RSSCOREIMP)
- RELINE Small Stature Core Instrument Tray 1 (RSSCOREIN1)
- RELINE Small Stature Core Instrument Tray 2 (RSSCOREIN2)
- RELINE Small Stature Universal Rod Cutter Tray (RSSURODCUTIN)

Ancillary Trays

- RELINE Small Stature Alternative Hook Implant Tray (RSSALTHOOKIMP)
- RELINE Small Stature Reduction Screw Implant Tray (RSSREDIMP)
- RELINE Small Stature Uniplanar Screw Implant Tray (RSSUNIIMP)
- RELINE Small Stature Monoaxial Screw Implant Tray (RSSMONOIMP)
- RELINE Small Stature Iliac Screw Implant Tray (RSSILIACIMP)
- RELINE Small Stature 7.5mm Poly Screw Implant Tray (RSS75POLYIMP)
- RELINE Small Stature Extra Poly Screw Implant Tray (RSSEXTRAPOLYIMP)
- RELINE Small Stature Extra Core Instrument Tray (RSSEXTRACOREIN)
- RELINE Small Stature Saber Reducer Instrument Tray (RSSSABERIN)
- RELINE Small Stature Derotation Tray (RSSVBDIN)

Optional

- C-arm Fluoroscope
- Radiolucent Surgical Table
- NVM5 System

For a complete list of intended uses, indications, device description, contraindications, warnings, and precautions, please refer to the Instructions for Use (IFU) in the back of this technique guide.

Patient Positioning and O.R. Setup

Place the patient on the operating table in a prone position. Prepare and drape in a conventional manner. Ensure easy access to the surgical field to allow both A/P and lateral flouroscopic imaging. Uniplanar or biplanar fluoroscopy may be used. Fluoroscopic monitors and the NVM5 unit should be placed in clear view (Fig. 1).

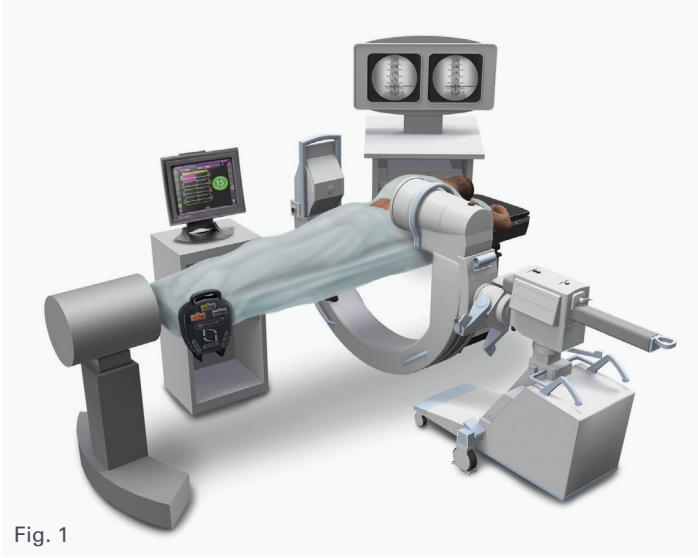


Fig. 1

It is preferable to place the NVM5 unit at the foot of the bed.

Place the EMG/MEP neuromonitoring electrodes on the patient. Additionally, SSEP electrodes may be used for SSEP monitoring.

Pedicle Preparation

Step 1

Locate the desired entry point into the pedicle, and perforate the cortex with a high-speed burr. Create a pilot hole by passing a Gearshift Probe through the pedicle and into the vertebral body (Fig. 2).

Tip: Gearshift Probes, Taps, and Pedicle Probes are marked with gold until 20mm, a thin black line at 25mm, a thick black band at 30mm, and thin black lines at 40 and 50mm.

Step 2

Inspect the pilot hole for perforations with the Dual-ended Ball Tip Pedicle Probe by palpating the pedicle wall on all sides (Fig. 3).

Step 3

Reline Small Stature screws are self-tapping and may be inserted at this point.

Step 4

If tapping is preferred, select the Fixed or Ratcheting Handle, and attach to an appropriately sized Tap. If using a ratcheting handle, set the ratchet to the preferred drive position and tap through the pedicle into the vertebral body, using the markings on the shaft and fluoroscopy to monitor depth (Fig. 4).

Note: The taps, fixed handles, and ratcheting handles have AO connections.

Tip: Taps are sized line-to-line as marked, and the threads are 20mm in length.

Step 5

Prior to screw insertion, inspect the pilot hole again for perforations, using the Dual-ended Ball Tip Pedicle Probe.

Fig. 2

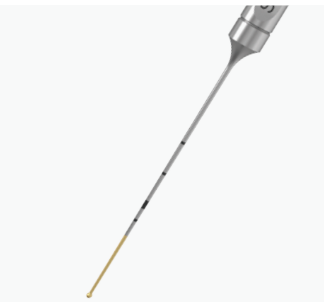


Fig. 3

Fig. 4

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.

Screw Insertion

Step 1

Once the pedicle has been prepared, select the preferred screw type and matching screwdriver (Fig. 5). Attach the fixed or ratcheting handle to the screwdriver.

Note: The screwdrivers, fixed handles, and ratcheting handles have AO connections.

Step 2

To load the screwdriver, insert the distal drive feature into the shank of the screw and attach by turning the silver knob clockwise. Verify that the screw and screwdriver interface is rigid and the shank is aligned straight.

Note: RSS Polyaxial Driver and Polyaxial Reduction Driver are two separate screwdrivers.

Step 3

Introduce the screw into the pilot hole and advance until the desired depth is reached. The screwdriver's sleeve is designed to rotate freely, allowing the instrument to be firmly grasped throughout insertion without unthreading from the screw.

Step 4

To release the screwdriver, turn the silver knob counterclockwise until the outer sleeve is fully unthreaded from the tulip, and remove from the screw.

Step 5

For polyaxial screws, ensure the tulip is free from tissue or bony impedance and retains its full polyaxial motion. If adjustment to screw depth is required, the Screw Adjuster may be used. The Head Adjuster may be used to adjust the cephalad/caudal or medial/lateral orientation of the tulip prior to rod insertion.

Step 6

Use NVM5 Stimulation Probe to test screws once inserted into bone (Fig. 6).

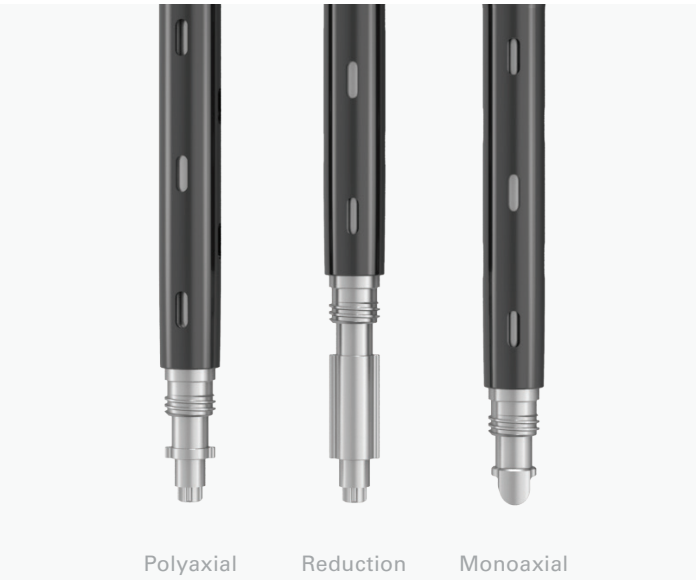


Fig. 5

Fig. 6

Rod Contouring

Once all screws are in position, measure the length of the construct, and bend the appropriately sized rod using the preferred technique.

Step 1

Use the French Bender to contour 4.5-5.0mm rods at multiple points, and adjust the dial to select the bend radii: small, medium, or large (Fig. 7).

Tip: Rods feature longitudinal lines along the sagittal plane to provide an alignment reference when contouring the rod.

Step 2

To achieve tight radii or larger radii bends, place the rod into the corresponding diameter hole of the Plate Bender and leverage the benders against each other to achieve the desired contour. For additional stability, one Plate Bender can be placed within slots adjacent to the Rod Cutter (Fig. 8).

Fig. 7

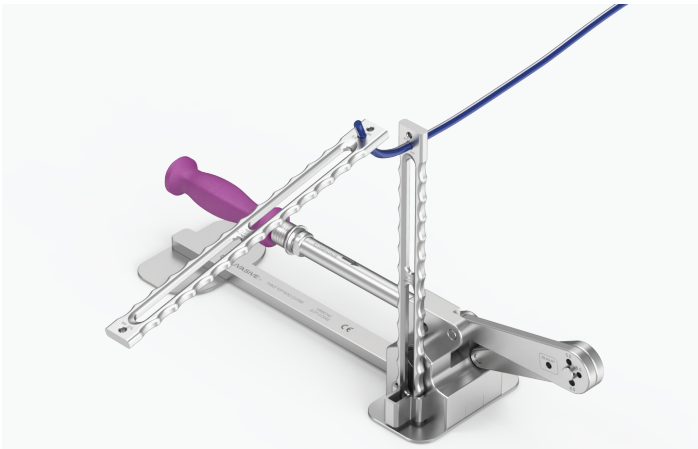


Fig. 8

Rod and Lock Screw Insertion

After cutting the rod to length and contouring, place the rod into the implants, and insert lock screws to provisionally secure the rod.

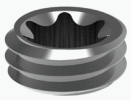
Step 1

The Rod Holder may be used to assist in placing the rod. Use the longitudinal lines to confirm the rod is placed in proper sagittal alignment. To release the rod, depress the button at the center of the proximal ratchet.

Step 2

Use the Lock Screw Starter to load a single lock screw and deliver down the reducer of choice, or place without a reducer if no reduction is required.

Tip: The Joystick Head Adjuster may be used to adjust the tulip if the rod is directly above the screw.

Lock screw		
Tulip	Open	Closed
Locking mechanism	Helical flange	Metric thread

Rod and Lock Screw Insertion (cont.)

The Rod Holder can be used for complex rod manipulation or rod rotation maneuvers.

Step 1

To attach the Rod Holders to a rod, confirm the tips of the Rod Holder are open by depressing the ratchet release trigger. Place the Rod Holder over the rod, and compress the handle until fixed to the rod.

Step 2

If a rod rotation maneuver is required, confirm the lock screws are loose within the tulips prior to attaching the Rod Holder. Two Rod Holders should be used to rotate the rod in multiple steps, alternating and releasing the Rod Holders one at a time, until the desired coronal and sagittal profile is achieved. After the rod has been rotated into its final position, tighten the lock screws using the Lock Screw Starter and release the Rod Holders from the rod. All rods also feature a hex end for attaching a Rod Rotation Wrench. All 4.5mm rods feature a spline end and all 5.0mm rods feature a hex end for attaching a Rod Rotation Wrench.

Rod Reduction

Saber Reducer

The Saber Reducer should be used when large amounts of reduction (up to 40mm) are required (Fig. 9).

Step 1

Confirm the threaded reduction sleeve is retracted by turning it counterclockwise until sufficient space is available within the rod slot.

Step 2

Capture the rod within the rod slot of the Saber Reducer and align the distal tip to the tulip. Push down on the reducer to engage the tulip and verify proper engagement by pulling up on the reducer. The Saber Reducer arms provide audible and tactile feedback when properly engaged to the tulip.

Fig. 9 Fig. 10 Fig. 11

Step 3

Place the Reduction Handle onto the threaded reduction sleeve, and turn clockwise (Fig. 10) until the black line overlaps the proximal end of the reducer. If reducing over multiple levels, use the Reduction Bell Attachment on a Straight Ratcheting Handle to minimize interference with adjacent reducers.

Step 4

Once reduction is achieved, insert the lock screw using the Lock Screw Starter (Fig. 11), and remove the reducer by depressing the medial/lateral silver buttons and pulling up on the instrument.

Tip: To ease removal of the reducer, turn the handle ¼ turn counterclockwise after fully reducing the rod and prior to lock screw delivery.

In Situ Rod Bending

In situ benders may be used for correction in the sagittal or coronal planes. Both Sagittal and Coronal Benders are modular, with tips offered in 4.5 (gold) and 5.0mm (silver). Sagittal Bender tips also come in a straight and angled version.

Step 1

For sagittal correction, connect the desired tips onto the handle. On each bender, attach the angled tip on one side, and the straight tip on the other side facing the opposite direction. Slide the ends of the In Situ Sagittal Benders around the rod so that the rod sits flush within the rod slot. Compress the sagittal benders toward each other to achieve lordosis, or bend away from each other to create kyphosis.

Step 2

For coronal correction, connect the desired tip onto the handle and place the right and left In Situ Coronal Benders over the rod until the slots sit flush. Align the ridges at the 90° bends, and compress the arms of the coronal benders toward each other.

Note: If bending over multiple levels, insert the pins of the Coronal Bender Extension Link into the benders, confirming the retention clips are fully engaged and the pins sit flush on the bender. Press the button and slide to change the distance between the benders.

Compression and Distraction

If compression or distraction is desired, provisionally tighten a lock screw on one side of the motion segment, leaving the adjacent lock screw loose to allow movement along the rod.

Step 1

Choose the Parallel Compressor or Distractor and place over the rod, against the tulip heads of the targeted screws. A Hinged Compressor and Distractor are also available.

Step 2

With the instrument properly engaged, deliver the desired level of compression or distraction. Provisionally tighten the loose lock screw to hold the construct in position prior to final tightening. Do not final tighten the lock screw while it is under the force of compression or distraction.

Final Tightening

All lock screws must be tightened to a torque of 70 in-lbs.

Attach the Torque Handle to the Final Lock Screw Driver. Slide the Counter-torque over the tulip until the instrument bottoms out. Insert the Final Lock Screw Driver through the Counter-torque, and seat into the lock screw. Turn the Torque Handle clockwise until the breakaway torque is reached. Repeat on each screw.

Cross Connectors

Two cross connector options are available in the Reline Small Stature portfolio. The low-profile adjustable cross connector and fixed cross connector both feature the same locking cam design instrument engagement features, and they use the same driver and Torque T-handle.

Prior to selecting the desired cross connector, measure the distance between the rods using the Cross Connector Measurement Guide to determine the correct length.

Low-profile Adjustable Cross Connector

Step 1

To prepare the Cross Connector Holder for engagement with the cross connector, rotate the top of the Holder counter-clockwise until the tapered inner portion emerges (Fig. 12).

Step 2

Place the distal end of the Cross Connector Holder over the end of the cross connector. Rotate the top of the holder clockwise to engage the cross connector.

Step 3

Place each end of the connector flush onto the rod.

Step 4

Attach the Cross Connector 30 in-lb Torque Handle to the Cross Connector Driver. Insert the driver into the Cross Connector Holder, ensuring that it seats properly within the cam drive.

Step 5

Verify the cam is locked by confirming the wide arc of the cam drive is as far counter-clockwise as possible (Fig. 13).

Step 6

Once both sides of the cross connector are tightened, place the low-profile Adjustable Cross-Connector Counter-torque over the center clamp, and proceed with final tightening the center lock nut until the breakaway torque is reached.

Fig. 12

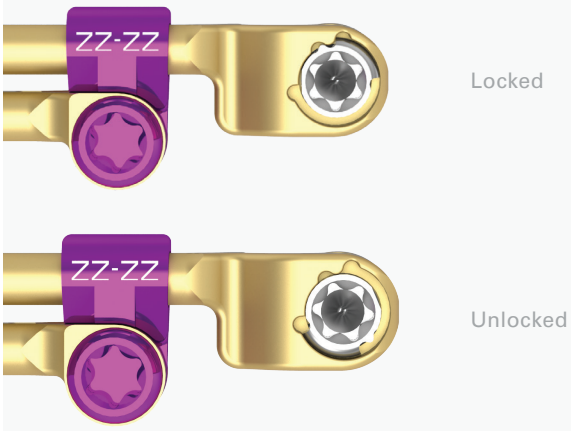


Fig. 13

Fixed Cross Connector

Step 1

When using fixed cross connectors, the Fixed Cross Connector Benders may be utilized to make fine adjustments to the length by changing the curvature or altering the orientation of the rod slots to accommodate nonparallel rods.

Step 2

After placing the fixed cross connector into the appropriate slot of the Fixed Cross Connector Benders, slide the thumb piece toward the connector to attach it. Compress the benders toward each other to achieve the desired bend.

Step 3

Prepare the Cross Connector Holder for engagement with the cross connector by rotating the top of the Holder counter-clockwise until the tapered inner portion emerges.

Step 4

Place the distal end of the Cross Connector Holder over the end of the cross connector. Rotate the top of the Holder clockwise to engage the cross connector.

Step 5

Place each end of the connector flush onto the rod.

Step 6

Attach the Cross Connector 30 in-lb Torque T-handle to the Cross Connector Driver. Insert the driver into the Cross Connector Holder, confirming that it seats properly within the cam drive.

Step 7

Verify the cam is locked by confirming the wide arc of the cam drive is as far counter-clockwise as possible.

Growing Rod Constructs

Magnetically Controlled Growing Rod Construct

If using MAGEC rods, refer to the MAGEC Technique Guide (9501489) for insertion and distraction of MAGEC growing rods.

Traditional Growing Rod (TGR) Construct

TGR Connectors can be used to create a traditional growing rod construct.

Insertion:

Step 1

Cut a long rod into 2 shorter lengths.

Step 2

Insert one end of the first rod into one side of the TGR Connector, and provisionally tighten the corresponding lock screw.

Step 3

Insert one end of the second rod into the other side of the TGR Connector, and provisionally tighten the second lock screw.

Note: Be sure to leave 5 mm of clearance between the rods to allow the tips of the TGR Distractor to fit.

Step 4

Bend rod to desired curvature.

Step 5

Make all desired adjustments to the rod lengths in the TGR Connector. When all adjustments have been made, final tighten the TGR Connector lock screws.

Step 6

Insert the rod into the proximal opening, and pass it subfascially, and in a caudal direction, to the distal opening.

Step 7

Rods with any sagittal bends should be rotated into the coronal plane when passed subfascially. Once the rod is visible within the proximal and distal exposures, rotate the rod back into the sagittal plane utilizing a rod gripper.

Tip: Typically, the TGR connector-portion is placed at the thoracolumbar junction of the spine, which anatomically accommodates the connector portion more optimally than other regions. TGR connector profiles should be parallel to help minimize the flat portion of the rod within the sagittal spine profile.

Step 8

Provisionally lock down the proximal and distal rods with lock screws.

Step 9

Repeat steps 6-8 if a second traditional growing rod is being implanted.

Step 10

If at any point a rod requires persuasion, use a Saber and Reduction Handle to capture the rod and reduce it into the appropriate screw tulip.

Step 11

Apply distraction to the construct if necessary.

Step 12

Utilize the Torque T-handle, Final Driver, and Counter-torque to final-tighten the lock screws and lock down the construct. Next, prepare the distal, or proximal and distal, instrumented vertebrae for fusions. Autograft may be used to promote fusion.

Step 13

Take a final fluoroscopy image to verify correct implantation of the rods prior to closing the incision.

Distraction

Step 1

Expose the anatomy for access to the TGR Connector.

Step 2

Loosen one lock screw on the TGR Connector.

Step 3

Place the tips of the TGR Distractor into the slot between the two rods within the TGR Connector.

Step 4

Compress the handles to distract (Fig. 14).

Step 5

Once distraction is achieved, final tighten the lock screw on the TGR Connector.

Fig. 14

Advanced Applications

Reduction Screws

Reduction screws provide an alternative, low-profile rod reduction method.

Reduction Screw Insertion

Step 1

Follow the Pedicle Preparation and Screw Insertion steps on pages 7–8 of the Reline Small Stature Technique Guide.

Note: The Reline Small Stature Polyaxial Driver and Polyaxial Reduction Driver are two separate drivers.

Step 2

With the reduction screws and rod in place, slide the Reduction Screw Counter-torque over the screw head until it seats flush on the rod.

Step 3

Using the Lock Screw Starter, reduce the rod by threading a lock screw down the extended tulip. Be sure to apply downward force on the Counter-torque so the slot remains fully seated on the rod during reduction. The rod is fully reduced when the top of the lock screw sits below the recessed ridge at the base of the extended tulip.

Tip: It is recommended to final tighten the lock screws prior to breaking off the Reduction Extensions to confirm that the lock screw is seated below the extended tulip.

Step 4

With the rod fully reduced and the Counter-torque seated flush on the rod, slide the Reduction Screw Break-off Tool over the extended tulip with the thumb piece facing inward toward the rod slot. Rock the Break-off Tool in a medial/lateral direction until it breaks free from the screw head (Fig. 15). Repeat this process on the opposite Reduction Extension.

Note: The Break-off Tool can hold up to four Reduction Extensions. To expel the Reduction Extensions from the Break-off Tool, slide the thumb piece distally.

Tip: The Reduction Screw Cap can be used on multiple screws as an alternative to the Counter-torque to restrict tulip splay during reduction (Fig. 16). After fully reducing the rod, remove the caps and use the Reduction Screw Counter-torque to secure the tulip while breaking off the extended tulip.

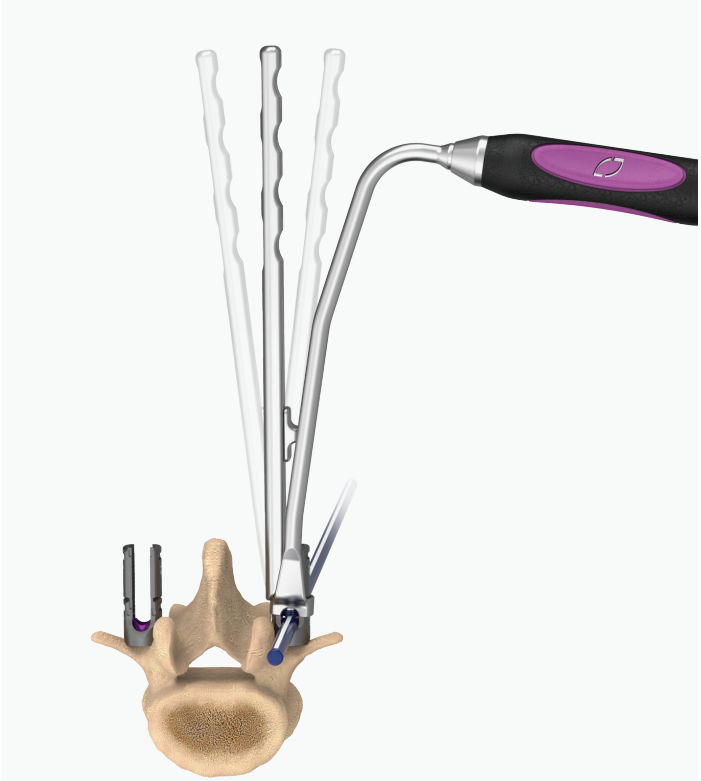


Fig. 15

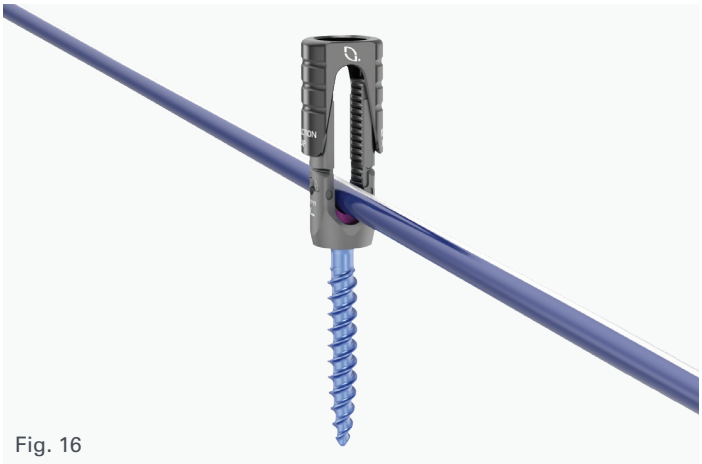


Fig. 16

Hooks

Hook Insertion

The Reline Small Stature system offers a variety of hooks with anatomically contoured blades in a range of sizes.

Step 1

The following instruments may be used to release the ligamentous attachment prior to hook insertion:

- Pedicle Elevator
- Lamina Elevator
- Transverse Process (TP) Elevator

Step 2

Once the hook site has been properly prepared, choose the preferred inserter to securely engage the hook for placement.

- Threaded Hook Inserter (Fig. 17)
- Bilateral Hook Inserter (Fig. 18)
- Unilateral Hook Inserter (Fig. 19)

Step 3

If impaction is desired, partially thread the Threaded Hook Inserter into the hook. Insert the Hook Pusher into the rod slot under the Threaded Hook Inserter, and tighten the Threaded Hook Inserter onto the Hook Pusher until the instruments are secure (Fig. 17).

Fig. 17

Fig. 18

Fig. 19

Iliac Screws

Iliac Screw Insertion

Step 1

If iliac screw fixation is desired, expose the posterior superior iliac spine, and decorticate the entry point using a burr or rongeur.

Step 2

Use the Iliac Gearshift Probe to create a pilot hole, aiming for the thick bone just above the greater sciatic notch. Inspect the pilot hole for cortical wall violations using the Dual-ended Ball Tip Pedicle Probe.

Step 3

Tap the pilot hole using the markings on the shaft and fluoroscopy to monitor depth. Re-inspect the pilot hole for perforations.

Step 4

With the ilium prepared, select the iliac screw in the appropriate size and insert into the Polyaxial Screwdriver.

Step 5

Insert the iliac screw into the pilot hole, and advance until the desired depth is reached. If screw adjustment is needed, use the Screw Adjuster to adjust screw depth.

Offset Iliac Connectors

An open or closed offset connector may be used to connect the iliac screw to the rod.

Step 1

Determine the offset length required and use the Rod Holder to insert the shaft of the preferred connector into the rod slot of the iliac screw.

The Unilateral Inserter can be used to place open offset iliac connectors.

Step 2

To hold the offset connector in position, insert the appropriate lock screw into the tulip of the iliac screw using the Lock Screw Starter, and provisionally tighten the lock screw. Use the Open Offset Connector Counter-torque to final tighten the lock screw.

Vertebral Body Derotation

Vertebral body derotation is performed by linking multiple screws together with instrumentation to drive axial correction of the spine. Derotation can be performed on a single vertebral body (segmental) or over multiple vertebrae (en bloc). Either technique can be performed by linking Sabers together.

Segmental Derotation

Use preoperative radiographs to select the most caudal-neutral vertebral body as the starting point for segmental derotation.

Step 1

On both the neutral vertebral body and the first superior rotated vertebral body, align the Saber Reducers with the tulips, and apply downward pressure to engage the screws.

Step 2

Connect the Coupled Segmental Derotation Link to the derotation towers across each vertebral body, and lock the set screws.

Step 3

Provisionally tighten the lock screws on the neutral vertebral body, leaving the lock screws loose on the rotated superior vertebral bodies.

Step 4

Using the neutral vertebral body as a reference, derotate the rotated vertebral body into a neutral position. Provisionally tighten the lock screws with the Long Lock Screw Driver to hold correction.

Step 5

The derotated vertebral body is now used as the neutral segment for the next rotated level. This process is repeated until all vertebral bodies have been derotated into neutral positions.

En Bloc Derotation

Use preoperative radiographs to identify the apex of the rotational deformity for the assembly of the en bloc construct.

Step 1

On the selected vertebral bodies, align the Saber Reducers with the tulips, and apply downward pressure to engage the screws.

Step 2

Connect the Coupled Segmental Derotation Link to the derotation towers across each vertebral body, and lock the set screws.

Step 3

Connect all the Coupled Segmental Derotation Links together with the Derotation Clamp, and squeeze to engage adjacent towers. Rotate the black locking lever into the locked position for a secure connection.

Note: If bilateral clamping is not achievable, unilateral clamping may provide adequate rigidity.

Step 4

Construct a segmental frame that is inferior or superior to the en bloc frame as a reference during the derotation.

Tip: Provisionally lock at least one lock screw at a neutral segment above and below the Derotation Towers to hold the rod in a fixed position.

Step 5

Rotate the en bloc construct around the rod until the rotated vertebral bodies are in a neutral position. Lock the correction by provisionally tightening the lock screws with a Ratcheting Handle attached to the Long Lock Screw Driver.

Tip: Having an assistant push on the rib hump during derotation can aid in the correction maneuver.

Implant Removal

Cross Connector Removal

Step 1

To remove the fixed or low-profile adjustable cross connector, attach the Cross Connector 30 in-lb Torque T-handle to the Cross Connector Driver (T20).

Step 2

If removing the low-profile adjustable cross connector, first loosen the center lock screw by turning the driver counterclockwise.

Step 3

Loosen the connection to the rod by inserting the driver into the cam above each rod and rotating counterclockwise 180°.

Step 4

Once both cams have been unlocked, grasp the cross connector with Cross Connector Holder and lift up to remove.

Lock Screw Removal (T27)

Step 1

Seat the Open Screw Counter-torque over the screw tulip. With a Ratcheting T-handle attached to a Lock Screw Driver, insert the instrument through the Counter-torque until it is securely seated in the lock screw. Turn the driver counterclockwise to loosen the lock screw. Repeat on the remaining screws.

Step 2

The lock screws in the rod-rod connectors are also T27 and may be removed using the same technique.

Rod and/or Rod-to-Rod Connector Removal

Once all the lock screws have been removed from the tulips, grasp the rod with a Rod Holder, and lift up to remove it from the screw heads.

Screw Removal (C-Star25 or T25)

Insert the tip of the appropriate screwdriver into the head of the screw, and secure into position by turning the silver knob clockwise to thread into the tulip. Remove the screw by rotating the screwdriver handle counterclockwise. If preferred, the Screw Adjuster may be used for removal. Insert the instrument into the shaft of the screw and turn counterclockwise to remove. To remove the provisional locking screw, insert the Fixed Screwdriver into the head of the screw and secure into position by threading the outer sleeve into the tulip. Rotate the Fixed Screwdriver counterclockwise in an orbital motion to remove.

Hook Removal

Grasp the hook with an Implant Holder, and slide in a cephalad or caudal direction to remove.

Instructions for Use

The NuVasive Reline System consists of variety of screws, hooks, rods, lock screws, transverse connectors, rod-to-rod connectors and iliac connectors manufactured from Ti-6Al-4V ELI per ASTM F136 and ISO 5832-3, Grade 4 CP Ti per ASTM F67, or cobalt chromium per ASTM F1537.

INDICATIONS FOR USE

When used as a pedicle screw fixation system, the NuVasive Reline System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the posterior thoracic, lumbar, and sacral spine:

1. Degenerative disc disease (as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies)
2. Degenerative spondylolisthesis with objective evidence of neurologic impairment
3. Fracture
4. Dislocation
5. Scoliosis
6. Kyphosis
7. Spinal tumor and/or
8. Failed previous fusion (pseudoarthrosis)

When used for posterior non-cervical screw fixation in pediatric patients, NuVasive Reline System is indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. Additionally the NuVasive Reline System is intended to treat pediatric patients diagnosed with the following conditions: spondylolisthesis / spondylolysis, and fracture caused by tumor and/or trauma. Pediatric pedicle screw fixation is limited to a posterior approach and is intended to be used with autograft and/or allograft. The NuVasive Reline System is also indicated for the treatment of severe spondylolisthesis (Grades 3 and 4) of the L5-S1 vertebral joint in skeletally mature patients receiving fusion by autogenous bone graft, having the device fixed or attached to the lumbar and sacral spine (L3 to sacrum), with removal of the implants after attainment of a solid fusion.

When used as an anterolateral non-pedicle screw system in the thoracic a nd lumbar spine, the NuVasive Reline System is also intended for the following indications:

1. Degenerative disc disease (as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies),
2. Spinal stenosis,
3. Spondylolisthesis,
4. Spinal deformities,
5. Fracture,
6. Pseudoarthrosis,
7. Tumor resection, and/or
8. Failed previous fusion.

In order to achieve additional levels of fixation, the Reline System rods may be connected to the Armada System.

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. Reusable 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 safety and effectiveness of pedicle screw spinal systems have been established only for spinal conditions with significant mechanical instability or deformity requiring fusion with instrumentation. These conditions are significant mechanical instability or deformity of the thoracic, lumbar, and sacral spine secondary to severe spondylolisthesis (grades 3 and 4) of the L5-S1 vertebra, degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudoarthrosis). The safety and effectiveness of these devices for any other conditions are unknown.

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

Benefit of spinal fusions utilizing any pedicle screw fixation system has not been adequately established in patients with stable spines.

Pivoting rod-rod connectors must be used in pairs (i.e., two per side). Ø4.75 mm rods are not intended for use as a main rod construct to be placed within a Reline pedicle screw tulip but exclusively as a supporting rod in multiple rod technique. The safety and effectiveness of this device has not been established for use as part of a growing rod construct. This device is only intended to be used when definitive fusion is being performed at all instrumented levels.

Correct selection of the implant is extremely important. The potential for success is increased by the selection of the proper size of the implant. While proper selection can minimize risks, the size and shape of human bones present limitations on the size and strength of implants. Metallic and 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.

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. Loads on the device produced by load bearing and by the patient's activity level will dictate the longevity of the implant.

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. 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.

The safety and effectiveness of this device has not been established when used in conjunction with bone cement or for use in patients with poor bone quality (e.g., osteoporosis, osteopenia). This device is intended only to be used with saline or radiopaque dye. 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: 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. Resterilization may result in damage or decreased performance.

Magnetic Resonance (MR) Safety: The Reline System has not been evaluated for safety and compatibility in the MR environment. The Reline System has not been tested for heating or migration in the MR environment. The safety of the Reline System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

Compatibility: Do not use Reline System with components of other systems than Armada System. Refer to the Armada System Instructions for Use for a list of the Armada System indications of use. 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). Iliac screws have a single lead thread on the shaft and must be used with single lead taps to ensure proper purchase in bone. Be careful when palpating the break point as the Tulip may be sharp. The Silencer and Gator Reducers are not compatible with Reduction Screws or Reduction Uni-planar Screws and may damage the implant if used. Only the Matador Reducer and Rocker may be used. K-wire should be removed when screw has reached the posterior wall of the pedicle to avoid kink in tip.

Ensure the K-wire is not advancing as the path is created over the K-wire. Use lateral fluoroscopy to properly manage the K-wire during pedicle preparation to confirm proper placement and avoid anterior advancement of the K-wire. All lock screws should be final-tightened with the Counter-torque and Torque T-handle. Do not final-tighten through compression instruments (e.g. C/D Rack and Figure 8 Compressor) in the set, as the rod may not be able to normalize to the tulip. Be cautious not to over compress or distract as you can loosen the screws in the spine and potentially pull out the screw.

The bulleted portion of the nose of the rod and the faceted portion of the rod (where the inserter locks down on the rod) must extend fully outside of the most inferior or most superior tulip on the construct. The set screw cannot be locked down on this unusable portion of the rod, as this may compromise the stability of the construct. Cross connectors are designed specific to the rod diameter and cannot be used on the tapered section of tapered rods. If using cross connectors on tapered rods, only attach them on constant diameter rod sections.

PREOPERATIVE WARNINGS

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 implants. The implants should not bescratched or damaged. Implants and instruments should be protected during storage and from corrosive environments.
4. All non-sterile parts should be cleaned and sterilized before use.
5. Devices should be inspected for damage prior to implantation.
6. 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 ensure the earliest possible detection of such catalysts of device dysfunction, the devices must be checked periodically postoperatively, using appropriate radiographic techniques.

Notes

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