ApiFix System Surgical Technique Guide

ApiFix

OrthoPediatrics®
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INDICATIONS FOR USE

The MID-C System (ApiFix® System) is indicated for treatment of adolescent idiopathic scoliosis (AIS) for treatment of single curves classified as Lenke 1 (thoracic major curve) or Lenke 5 (thoracolumbar/lumbar major curve), having a Cobb angle of 35-60 degrees which reduces to less than or equal to 30 degrees on lateral side-bending radiographs, and thoracic kyphosis less than 55 degrees as measured from T5 to T12.

Use of the ApiFix System in patients with curves of lower magnitudes (i.e., less than 40 degrees) is based on the risk for curve progression.

Humanitarian Use Device. Authorized by Federal law for use in the treatment of adolescent idiopathic scoliosis (AIS). The effectiveness of this device for this use has not been demonstrated.

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CONTRAINDICATIONS

The ApiFix System should not be implanted in patients meeting any of the following conditions:

- Any type of non-idiopathic scoliosis[1]
- Thoracic kyphosis in excess of 55 degrees measured between T5-T12
- Any main thoracic deformity that includes vertebral levels including cranial to T2
- Known history of existing malignancy, or any systemic infection, local infection, or skin compromise at the surgical site
- Spinal cord abnormalities that require treatment
- Presence of neurological deficit (defined as a motor grade of less than 5 out of 5)
- Known poor bone quality defined as a T-score -1.5 or less

Warnings

- Metallic implants can loosen, fracture, corrode, migrate, or cause pain

Precautions

- Safety and probable benefit of the ApiFix System in skeletally immature patients with a Risser Grade status less than or equal to 1 have not been established
- The ApiFix System implants are supplied sterile and are for single use only and cannot be reused or re-sterilized
- Do not use if the sterile package has been damaged or is open
- Examine implant carefully prior to use to assure proper working condition. If you suspect a component to be faulty or damaged, do not use
- Do not use this device without proper training
- Patients implanted with the ApiFix System should not participate in contact or high demand sports such as weightlifting, tumbling, gymnastics, rowing, or other high-risk activities
- Do not attempt to re-sterilize the ApiFix System implantable components
- Do not use if package is damaged or sterile barrier is broken
- The surgeon should weigh the risks and benefits of using the ApiFix System in patients with the following conditions:
  - Insulin-dependent diabetes
  - Cardiopulmonary or other systemic disease
  - Bleeding disorder(s)
  - Ataxia
  - Documented HIV or hepatitis infection
  - Family history of neurofibromatosis or Marfan's syndrome
  - Medical contraindications to anesthesia
  - Patients who have major psychiatric disorders, or a history of substance abuse. These conditions should be defined per standard criteria, such as the Diagnostic and Statistical Manual of Mental Disorders (DSM-V).

MRI Safety Information

The ApiFix 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 is unknown. The safety of the ApiFix System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

Summary of Clinical Experience

For a summary of clinical experience, please see the ApiFix System's Instructions for Use.

[1] *idiopathic scoliosis defined as a lateral spine curve of more than 10 degrees of unknown cause.*

ApiFix SYSTEM SURGICAL INSTRUMENTS

SCREW DRIVER WITH TORQUE INDICATION
Holds the ApiFix screw and drives it into the pedicle. Measures the torque force of screw insertion.

NUT HOLDER
Holds the nut of the ApiFix screw.

CONTROL PIN DRIVER
Switches the Rod Control Pin between ratchet, idle, and locked positons.

SIZE SELECTION GAUGE
Measures the distance between the Extender Trial and the ApiFix screw to select the appropriate Rod.

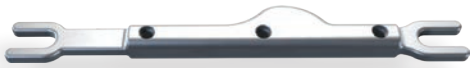
EXTENDER TRIAL
Used for initial measurements and Implant Trial.

IMPLANT TRIALS
Used to verify the implant is not pushing against soft or hard tissue while in place.

85 mm

105 mm

125 mm



TRIAL HANDLE
To be connected to any of the Implant Trials.

LP NUT LEADER
Used to lead the ApiFix screw nut onto the screw's threads and serves as an adaptor for the Counter Torque Handle.

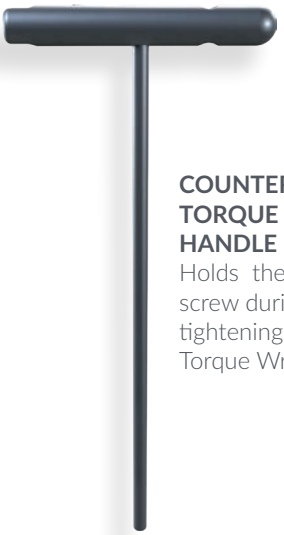
EXTENDER SCREW INSERTION ADAPTOR
Used to insert and torque the Extender screw.

EXTENDER

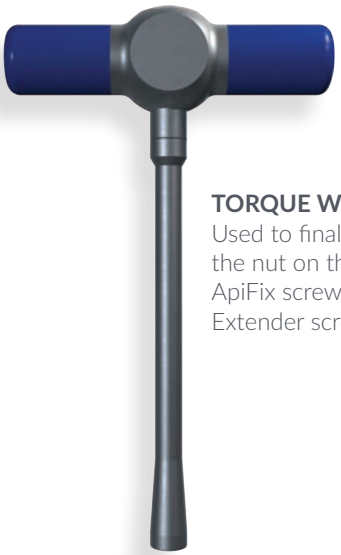
Extender diameter [mm]	Pre-shaped kyphosis	Classification
5.5	15°	Lenke Type 1
5.5	15°	Lenke Type 1 Left
5.5	0°	Lenke Type 5

MID-C

Rod length [mm]	85	95	105	115	125
Maximum Elongation [mm]	30	30	40	40	50



COUNTER TORQUE HANDLE
Holds the ApiFix screw during final tightening with the Torque Wrench.



TORQUE WRENCH
Used to final torque the nut on the ApiFix screw and the Extender screw.

DISTRACTOR WITH FORCE INDICATOR
Used by the surgeon to distract the Rod and presents the distraction force.

EXTENDER ANGLE MEASUREMENT TOOL.
Presents the angle of the Extender compared to the Rod.

UNIT 1
To be attached to the Extender.

UNIT 2
To be attached to the Rod.

LP NUT LEADER HOLDER
Used to insert the LP Nut Leader into the ApiFix screw.

Refer to the ApiFix System Surgical Instruments - Instructions for Use (Doc No. DMS-769).

APIFIX SCREW

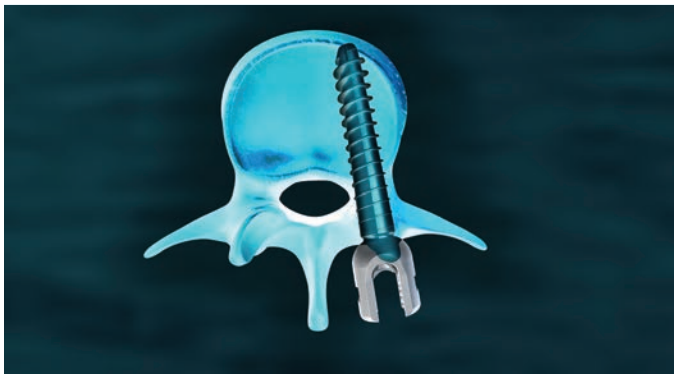
Screw diameter [mm]	5.0	5.0	5.5	5.5	5.5	5.5	6.0	6.0	6.0	6.5	6.5	6.5	6.5	7.0	7.0	7.0
Screw length [mm]	30	35	30	35	40	45	35	40	45	35	40	45	50	40	45	50

BEFORE YOU BEGIN

To ensure the optimal performance and correct functioning of the ApiFix System, the surgeon must select the appropriate instrumented levels, rod length and pedicle screw sizes.

Pre-Operative Planning

Pre-operative planning using x-ray films is important for determining the location, diameter and length of the pedicle screws.



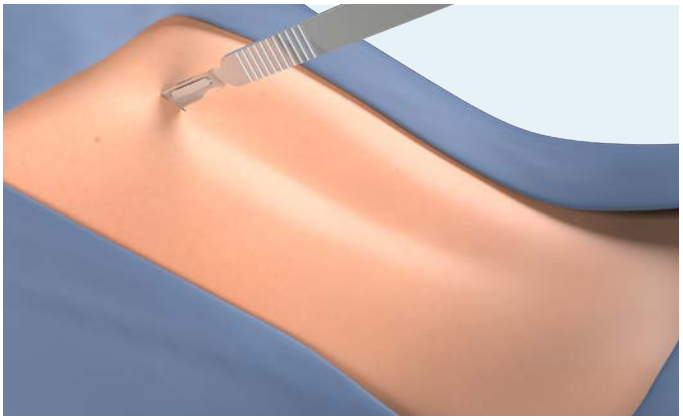
Patient Positioning

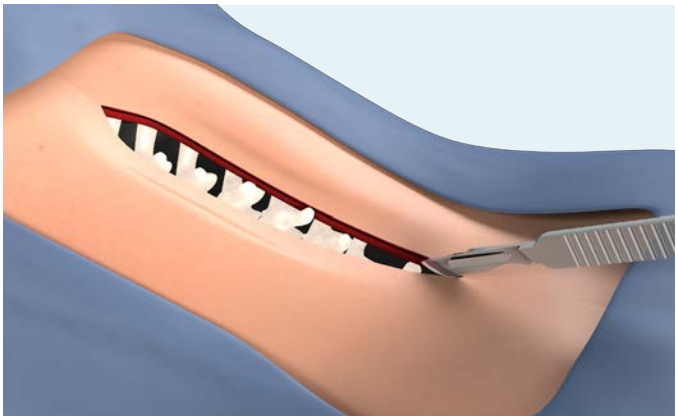
Patient must be prone on a radiolucent table suitable for AP and lateral fluoroscopy which are utilized during the ApiFix procedure.

SURGICAL EXPOSURE

Implantation of the ApiFix System is via an open posterior subperiosteal approach utilizing a standard vertical, unilateral midline incision. The ApiFix procedure requires visualization of the facet joints and medial aspects of the transverse processes continuously from the upper instrumented vertebra to the lower instrumented vertebra.

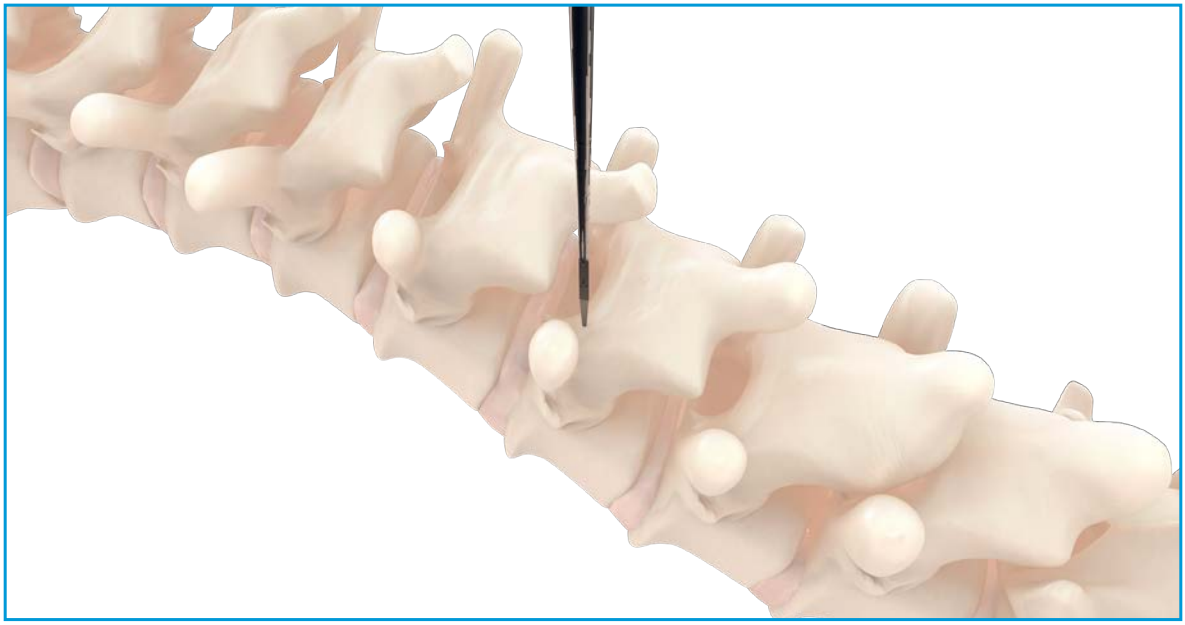
As with all surgical procedures, minimize damage to surrounding soft tissues. Use standard monopolar and bipolar cautery to control bleeding during muscle and soft tissue dissection.





Screw Preparation and Insertion

Use standard instruments to locate the selected vertebrae and prepare them for screw insertion.



APIFIX PROCEDURE

STEP 1

Once the ApiFix screw is taken out of the sterile packaging, use the Nut Holder to unscrew the nut from the screw.

STEP 2

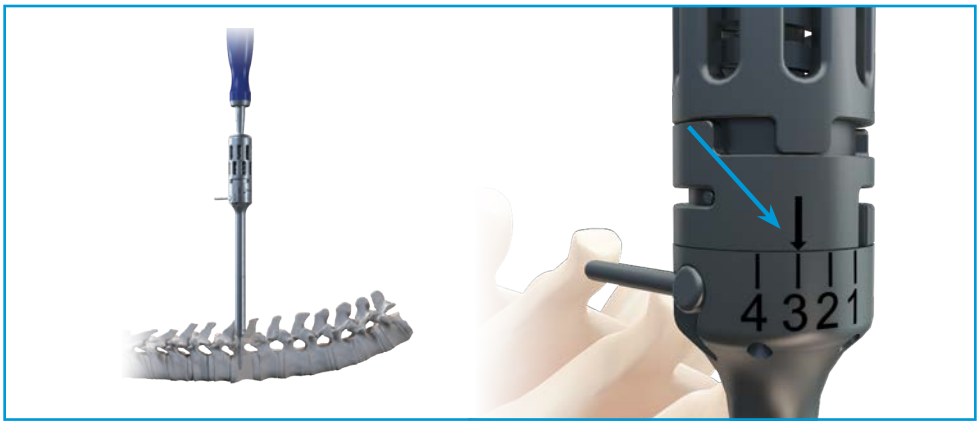
Use the Screw Driver with Torque Indication to insert the ApiFix screw into the lower instrumented vertebra. Use lateral X-ray to verify an angle of 90º to 105º between the screw and rod.

STEP 2 (cont.)

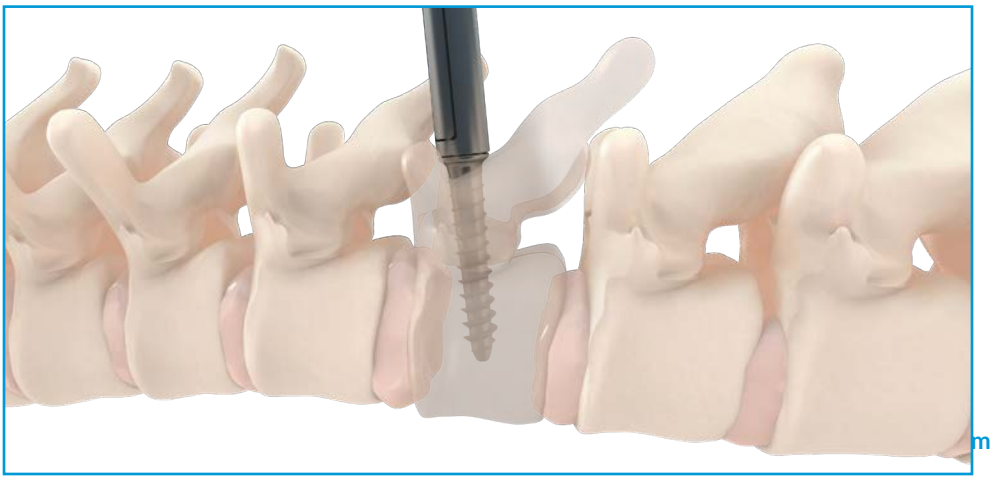
3-4mm before fully seating the ApiFix distal screw into the vertebra, rotate the small handle from the vertical to the horizontal position.

NOTE: Prior to using the Screw Driver with Torque Indication, ensure the arrow is in the initial position.

Apply torque on the Screw Driver and record the reading on the scale.

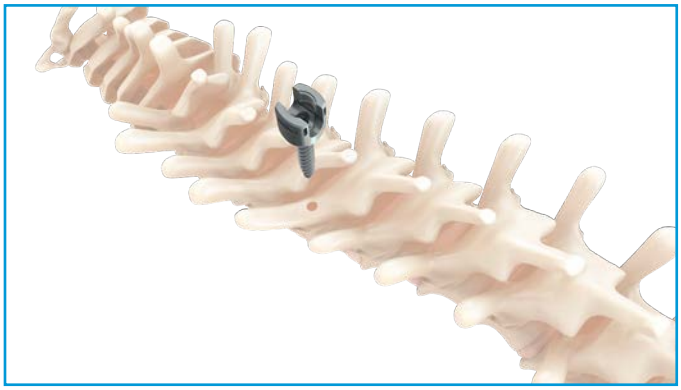


Use lateral X-ray to verify an angle of 90º to 105º between the screw and rod.



STEP 3*

Per the pre-operative plan, first insert the inferior of the two polyaxial screws.



NOTE: Do not drive the screws too low, and be sure to clean the area around the heads of the polyaxial screw in order to allow full polyaxial motion.

NOTE: Make sure to perform AP and lateral imaging to verify proper screw placement.

STEP 4

Temporarily hold the Extender Trial in the proper orientation (as shown) in the polyaxial screw using its dedicated set screw.

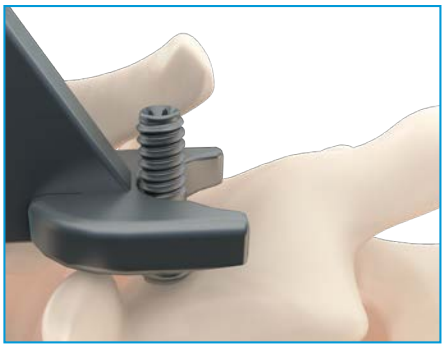
NOTE: The head of the Extender Trial should be placed within 2-3mm of the polyaxial screw head.

*For procedure steps without the Extender, refer to page 28.

STEP 5

Use the Size Selection Gauge to measure the distance between the post of the ApiFix screw and the Extender Trial. The markings on the Size Selection Gauge should be used to determine the appropriate Rod size. Always consider “rounding up” measurements in between sizes to utilize the longest implant possible.

The interface between the ApiFix screw, the Extender Trial and the Size Selection Gauge should be per the pictures below:



NOTE: If the measured distance is less than 135mm, place the second polyaxial screw superior as planned. If the measured distance is > 135mm, place the second polyaxial screw inferior to the first one to ensure enough distraction potential. If the second polyaxial screw was placed inferior to the first one, repeat step 5 for proper measurement of the Rod.

STEP 6

Insert the second polyaxial screw.

NOTE: Do not drive the screws too low, and be sure to clean the area around the heads of the polyaxial screw in order to allow full polyaxial motion.

NOTE: Make sure to perform AP and lateral imaging to verify proper screw placement.

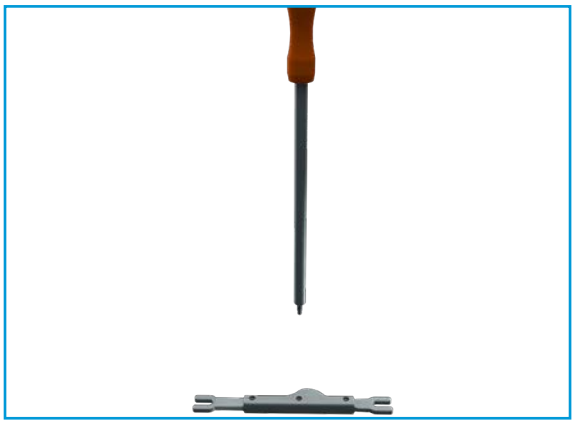
STEP 7

Temporarily hold the Extender Trial in the polyaxial screws using their dedicated set screws.

NOTE: The head of the Extender Trial should be placed within 2-3mm of the lower polyaxial screw head (as shown).

STEP 8

Connect the selected Implant Trial to the Trial Handle in the desired orientation.

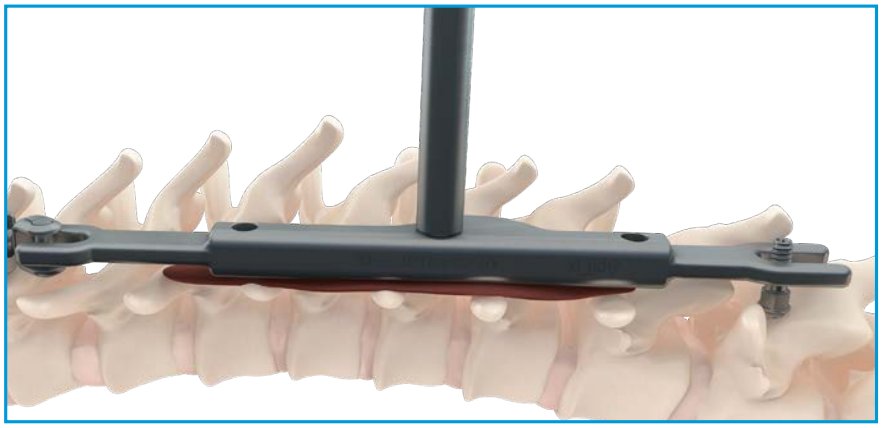


STEP 9

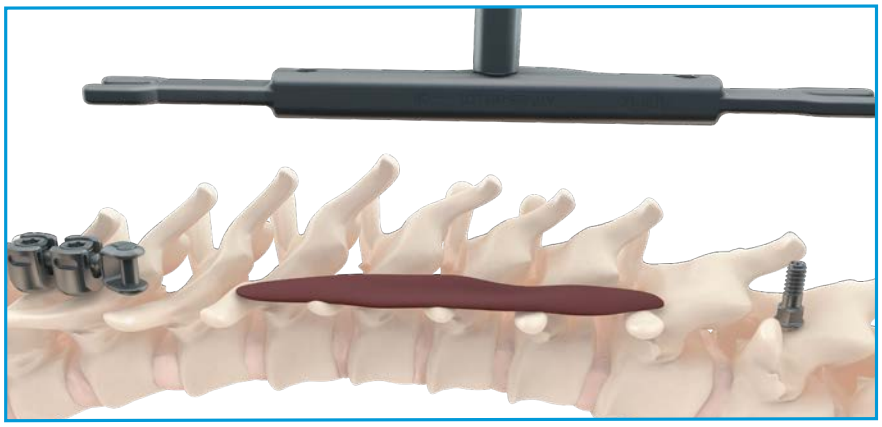
Use the Implant Trial to select the orientation of the Rod for clearance of the spinous and transverse processes. **NOTE:** the implant will be drawn centrally when distracting (after implantation).

Also, use the Implant Trial to verify a clean space below the Rod.

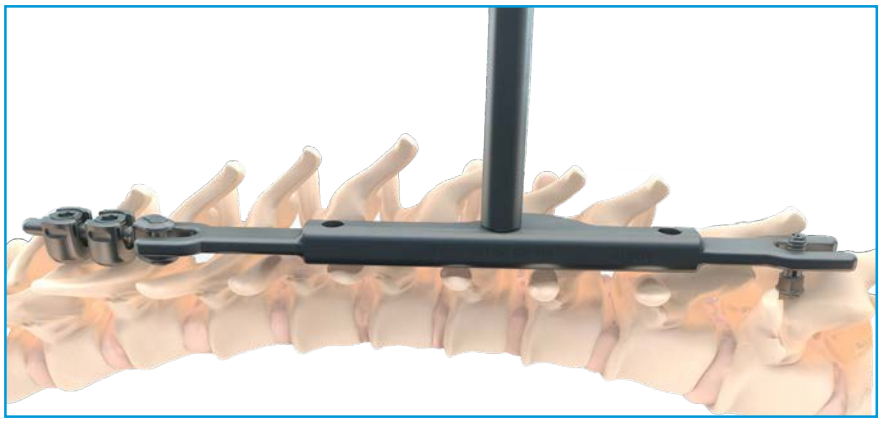
Place the Implant Trial from the post of the ApiFix screw to the Extender Trial to ensure no fulcrum motion underneath the Implant Trial.



If any fulcrum effect is present, remove the Implant Trial and clean the area below it.



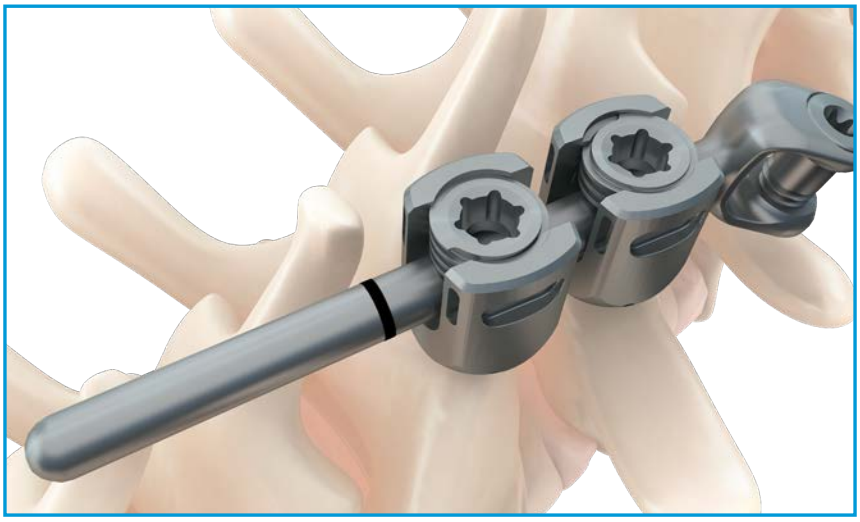
Use the Implant Trial again and verify that no tissue is pushing it from below.



STEP 10

Remove the Extender Trial. Place the Extender and mark the desired length.

NOTE: The head of the Extender should be placed within 2-3mm of the lower polyaxial screw head (as shown). Leave a tail of 5 mm between the lower polyaxial screw and the end of the Extender

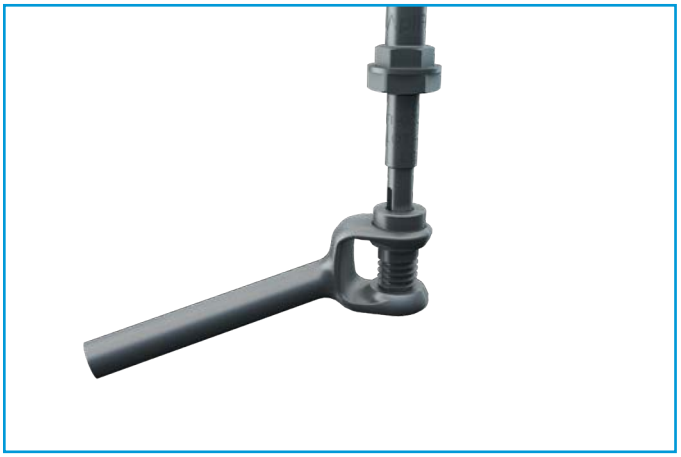


STEP 11

On a sterile table, cut the Extender shaft as marked, using a standard 5.5mm rod cutter.

STEP 12

Using the slotted (self-retaining) end of the Extender Screw Insertion Adaptor, remove the Extender Locking Screw and attach the Extender to the Rod.



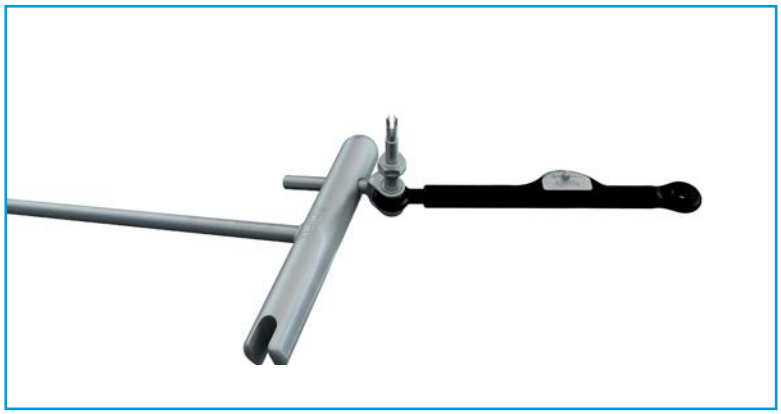
NOTE: You can place the Rod in four orientations as seen below:

STEP 13

Turn the Extender Screw Insertion Adaptor to the solid side and place it in the Extender locking screw.

STEP 14

Insert the Extender shaft into the hole of the Counter Torque Handle.

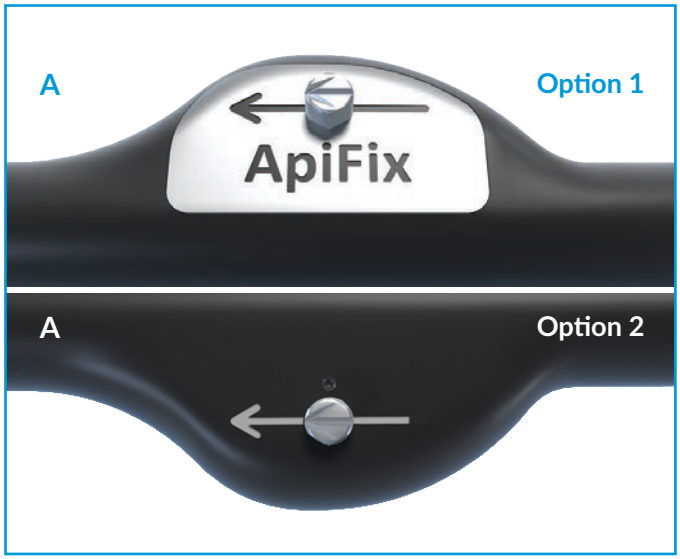


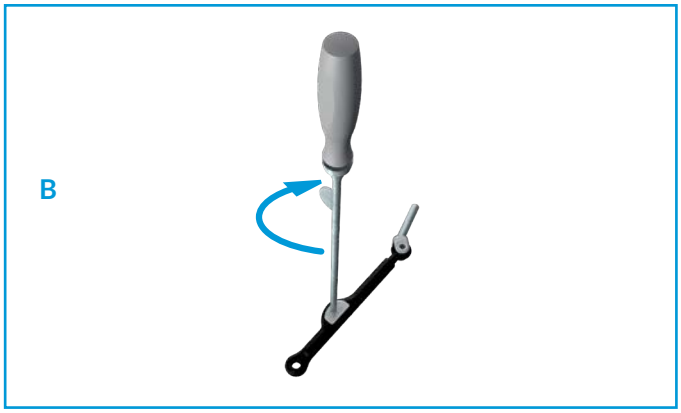
STEP 15

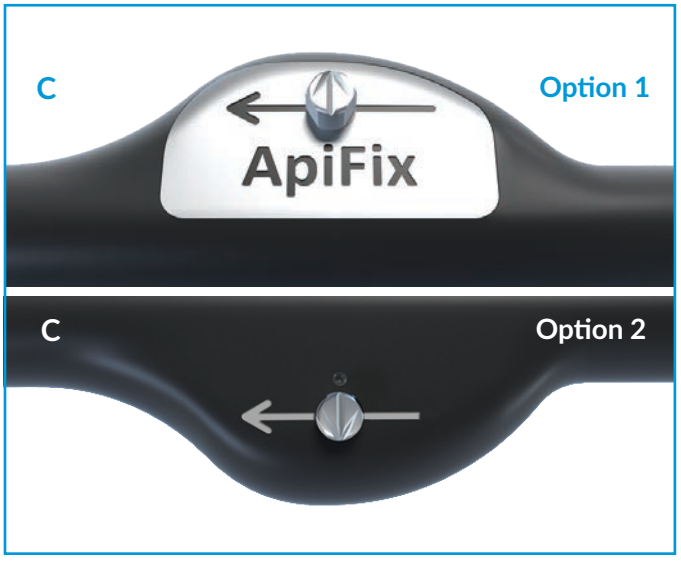
Place the Torque Wrench on the Extender Screw Insertion Adaptor. Hold firmly the Counter Torque Handle and torque the Torque Wrench until you achieve one click.

STEP 16.1

Use the Control Pin Driver to switch the control pin from ratchet position (Fig. A) to idle position (Fig. C).

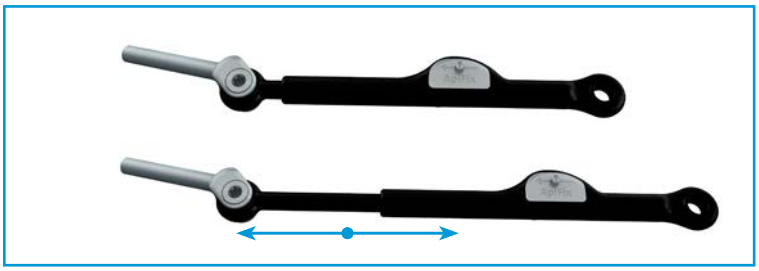






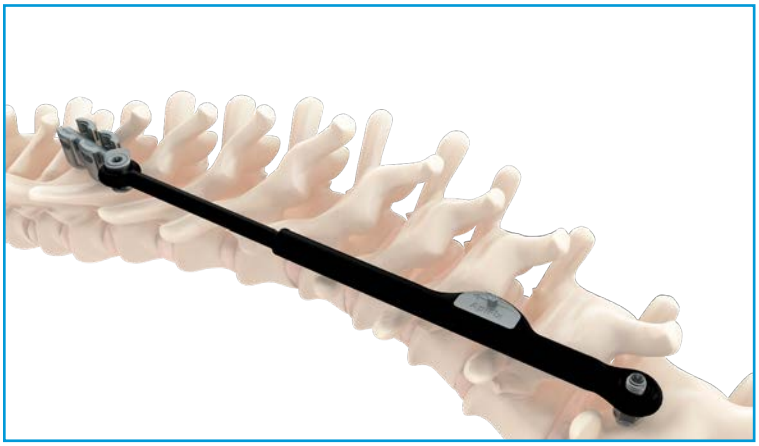
STEP 16.2

Make sure that the Rod can elongate freely.



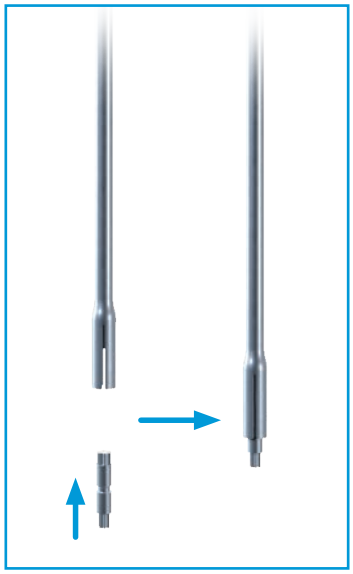
STEP 17

Insert the Rod and the Extender into place.



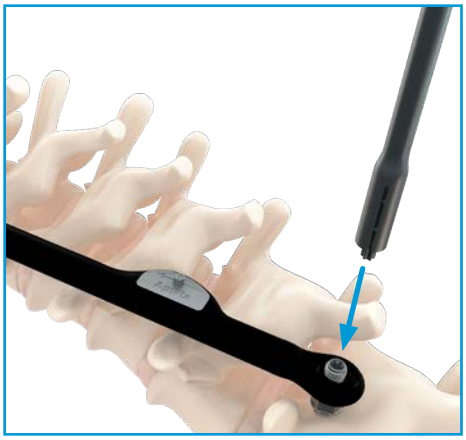
STEP 18

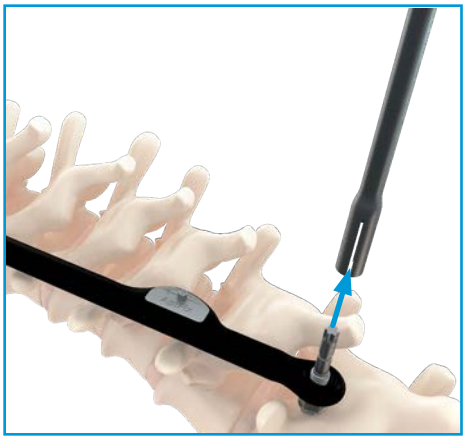
Insert the larger diameter end of the LP Nut Leader into the LP Nut Leader Holder.



STEP 19

Insert the LP Nut Leader into the ApiFix screw and press the ball end of device to leave the LP Nut Leader in the ApiFix screw.

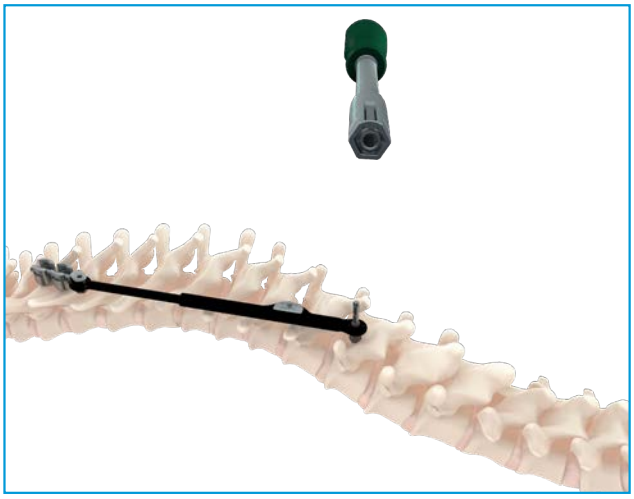


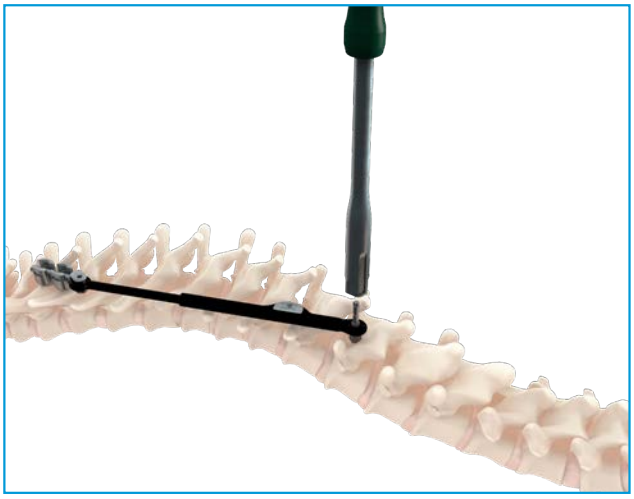


STEP 20

Use the LP Nut Leader Holder to place the nut gently on the ApiFix screw, passing over the LP Nut Leader, and provisionally tighten the nut.

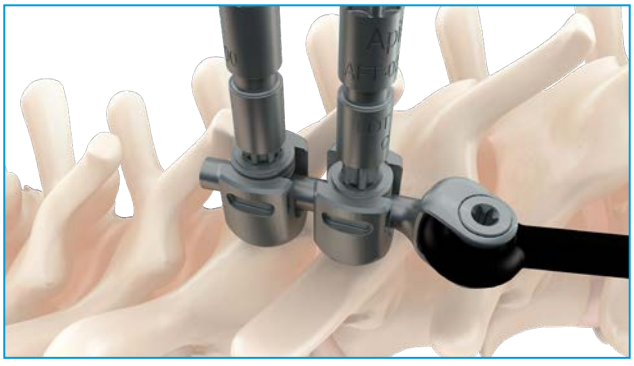
NOTE: Don't use excessive force. The nut should be threaded with two fingers only.





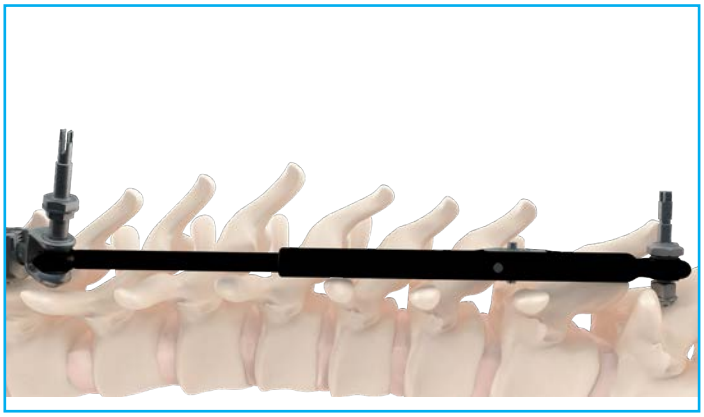
STEP 21

Provisionally tighten set screws without torqueing them.



STEP 22

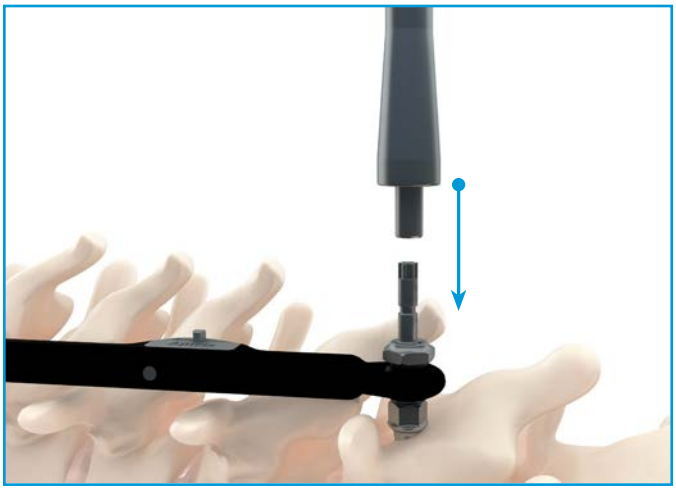
Insert the Extender Screw Insertion Adaptor into the Extender screw and make sure the ApiFix screw and the Extender screw are about parallel when looking along the spine.



STEP 23

To perform the final torque of the ApiFix screw nut, insert the Counter Torque Handle into the Torque Wrench.

Hold the LP Nut Leader by the Counter Torque Handle and then drive the Torque Wrench down on the nut.

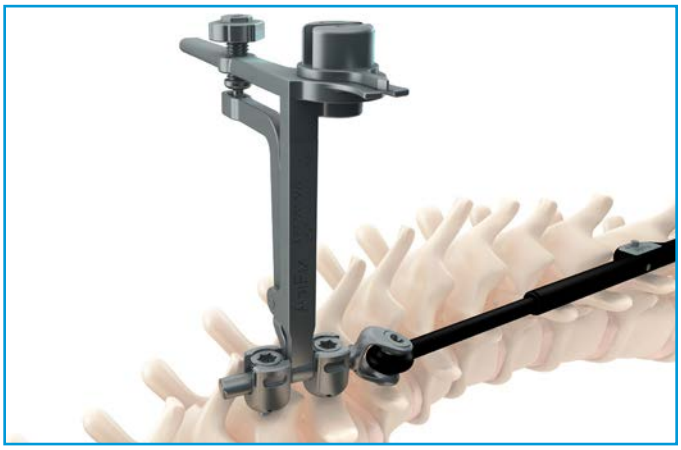


STEP 24

Hold Counter Torque Handle and rotate the Torque Wrench clockwise until you achieve one click.

STEP 25

Attach Unit 1 of the Extender Angle Measurement Tool between the two polyaxial screws. The handle of Unit 1 should always cross over the spine.



STEP 26

Rotate the screw on Unit 1 of the Extender Angle Measurement Tool to lock onto the Extender.

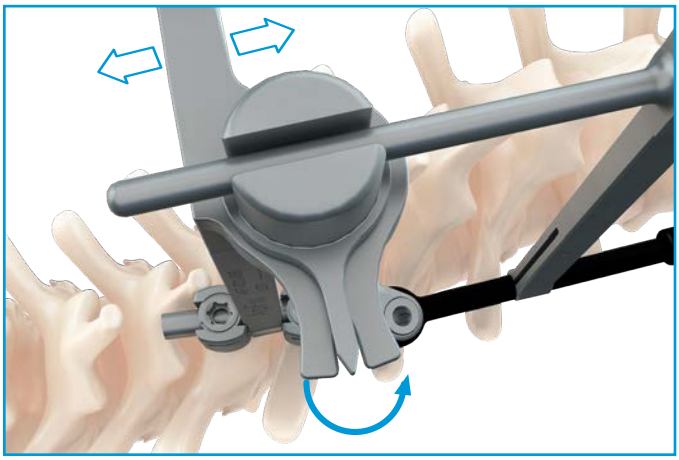
STEP 27

Attach Unit 2 of the Extender Angle Measurement Tool on the Rod and place the sliding pin into the housing of the rotating arrow of Unit 1.

NOTE: The ends of Unit 2 are different sizes to accommodate rod orientation. Utilize appropriate end based on rod orientation.

STEP 28

Use the handle of Unit 1 to achieve an angle of 5°-15°. **The rotating arrow should be on the bottom tab as seen in Figure B**. Rotating the handle towards the head will decrease the angle while rotating the handle towards the sacrum will increase the angle. Prior to rotating the handle, loosen the polyaxial set screws to enable movement of the polyaxial screw heads.



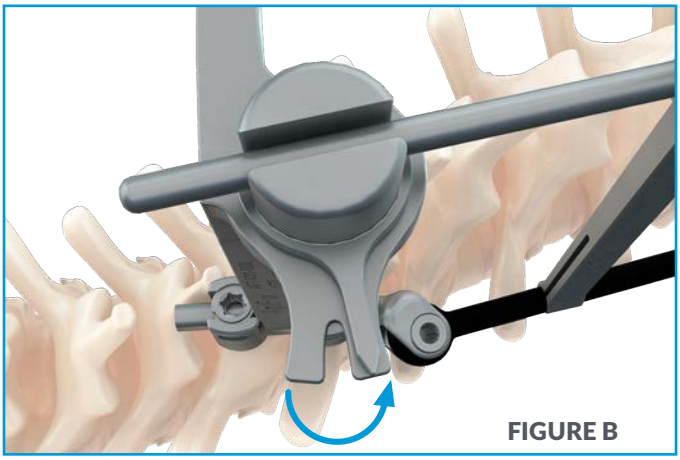
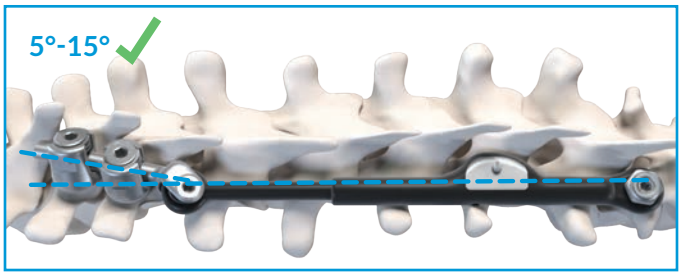


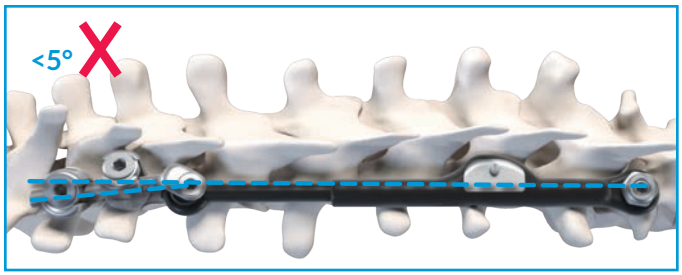
FIGURE B

NOTE: The Extender angle should be between 5°-15° degrees relative to the Rod. The rotating arrow should rest anywhere on the bottom tab to achieve the desired angulation.

NOTE: Avoid an angle < 5° degrees relative to the Rod.

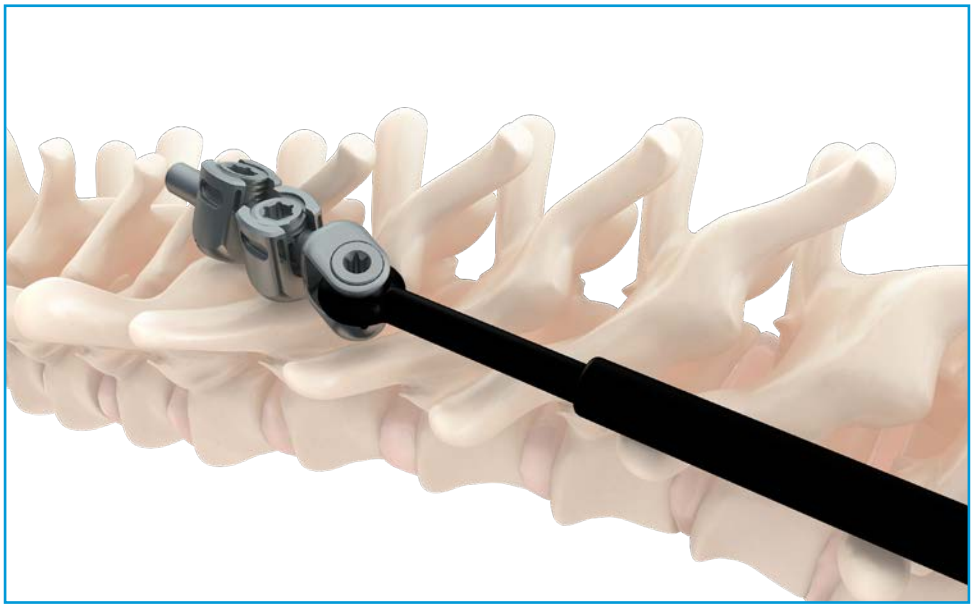
NOTE: Avoid an angle >15° degree relative to the Rod.





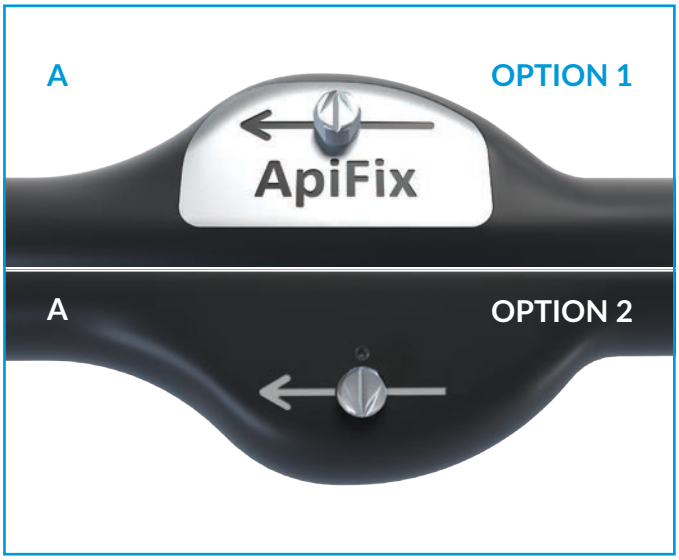
STEP 29

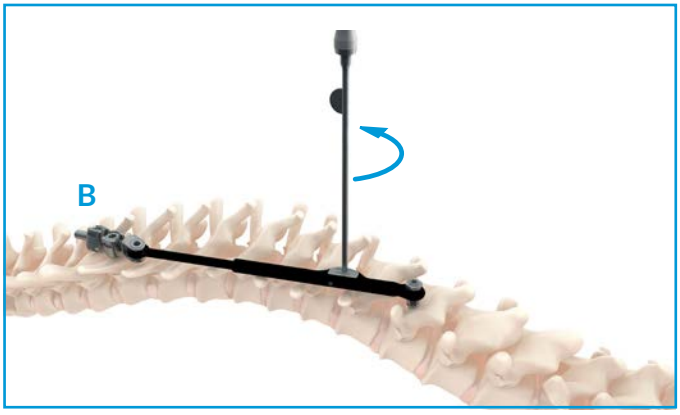
While holding the handle of Unit 1 at the correct angle, tighten the polyaxial set screws without torqueing them.

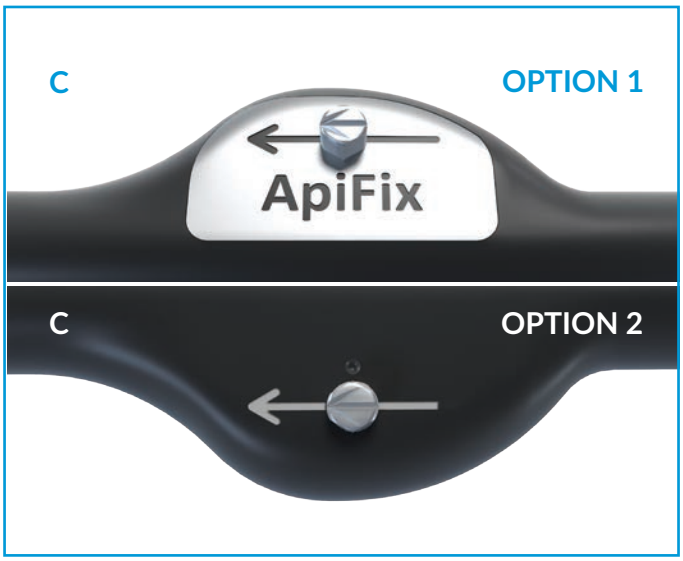


STEP 30

Use the Control Pin Driver to switch the control pin from idle position (Fig. A) to ratchet position (Fig. C).







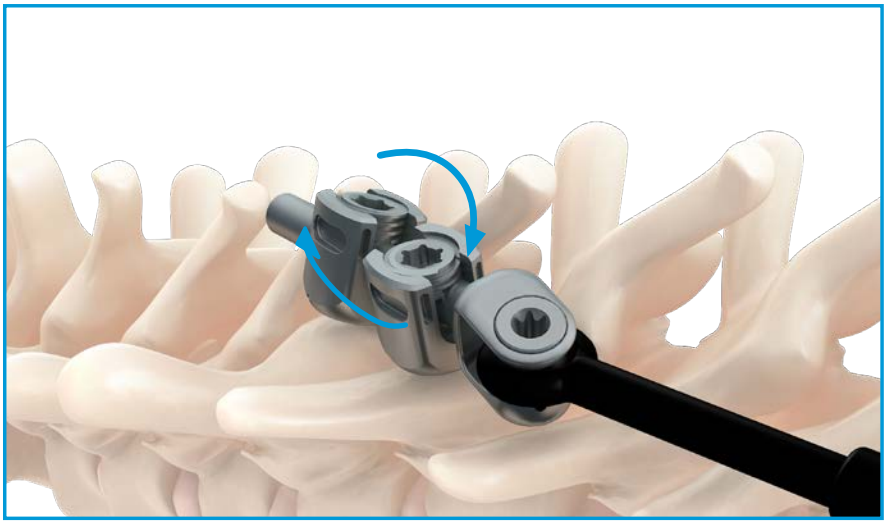
STEP 31

Utilize the Distractor with Force Indicator to expand the Rod. Read and record the distraction indication.

NOTE: After each distraction, repeat Steps 25-29.

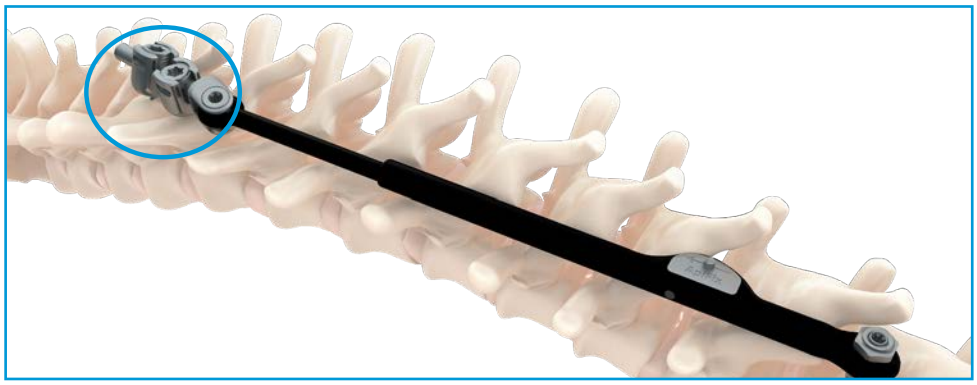
STEP 32

Final torque both polyaxial set screws according to the manufacturer's specification.



STEP 33

Perform standard decortication and bone grafting between the two polyaxial screws.



NOTE: If additional sagittal correction is required, after implantation and final tightening, the ApiFix extender can be contoured using a standard rod bending technique.

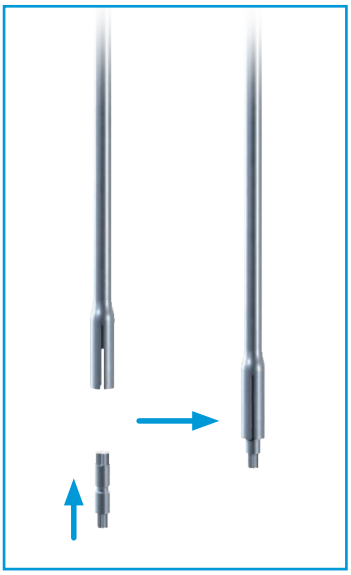
SURGICAL TECHNIQUE STEPS WITHOUT THE EXTENDER

- After placing the distal ApiFix screw, repeat Steps 1-2 to place the proximal ApiFix screw.
- Use the Size Selection Gauge to measure the distance betwen the ApiFix screws. The markings on the Size Selection Gauge should be used to determine appropriate Rod size. Refer to Page 11 Step 5 for the appropriate interface between the ApiFix screws and the Size Selection Gauge.
- Connect the selected Implant Trial to the Trial Handle.
- Use the Implant Trial to make sure there is proper clean space for the Rod.
    - The Implant Trial must be properly set on the hexagon of the ApiFix screws, with no fulcrum motion in between.
    - If any fulcrum effect is present, remove the Implant Trial and clean the area below it.
    - Use the Implant Trial again and verify that no tissue is pushing it from below.
- After selecting the appropriate size Rod, use the Control Pin Driver to switch the control pin from ratchet position to idle position as shown in Step 16.1. Make sure the Rod can elongate freely.
    - You can place the Rod in four orientations as seen on Page 15.
- Insert the Rod on the two ApiFix screws.
- Perform Steps 18-20 for each of the ApiFix screws.
- With the LP Nut Leaders in place, make sure the ApiFix screws are about parallel when looking along the spine.
- Perform Steps 23-24 for each of the ApiFix screws.
- Use the Control Pin Driver to switch the control pin from idle position to ratchet position as seen on Step 30.
- Utilize the Distractor with Force Indicator to expand the Rod.

REMOVAL PROCEDURE

STEP 1

Insert the larger diameter end of the LP Nut Leader into the LP Nut Leader Holder.



STEP 2

Insert the LP Nut Leader into the ApiFix screw and press the ball end of device to leave the LP Nut Leader in the ApiFix screw.

STEP 3

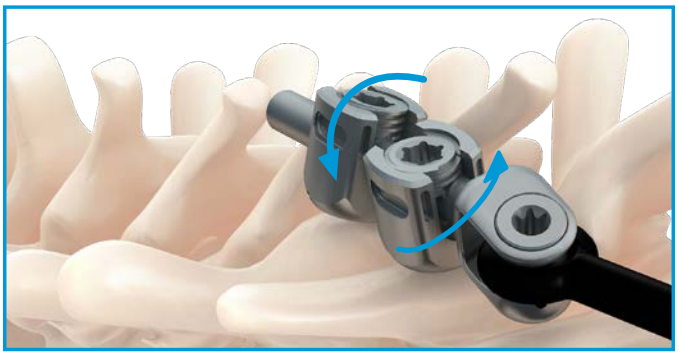
To remove the ApiFix Screw Nut, insert the Counter Torque Handle into the Torque Wrench. Hold the LP Nut Leader by the Counter Torque Handle and the drive the Torque Wrench down on the nut.

STEP 4

Hold Counter Torque Handle and rotate the Torque Wrench counter clockwise until the nut is loosened.

STEP 5

Loosen and remove both polyaxial set screws per the manufacturer's specification.



STEP 6

The MID C rod is now free to be removed.

NOTE

Removed ApiFix implants should be returned to:

ApiFix Ltd.

1 Hacarmel Street
Kochav Yokneam Bldg.
Yokneam Illit 2069207
Israel
info@apifix.com

RETRIEVAL

If participating in the ApiFix US PSSG Clinical Registry and retrieval instructions are needed please refer to: **Retrieval** and **Analysis Protocol** for ApiFix System (**DMS-5587**).

CAUTION: Federal law restricts this device to sale by or the order of a Physician.

CAUTION: Implants components are single-use. Do not reuse.

CAUTION: Only those instruments and implants contained within this system are recommended for use with this technique. Other instruments or implants used in combination or in place of those contained within this system is not recommended, unless otherwise stated.

NOTE: This technique has been provided by one of our medical advisors only as guidance and it is not intended to limit the methods used by trained and experienced surgeons.

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