AVANT MINIMALLY INVASIVE SURGERY

AVANT MIS Instrumentation Surgical Technique

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AVANT MINIMALLY INVASIVE SURGERY

MINIMALLY INVASIVE SURGICAL TECHNIQUE

Techniques described by:

Anis Mekhail, MD
Assistant Clinical Professor at University of Illinois at Chicago
Palos Heights, Illinois

Disclaimer:

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Table of Contents

01. Description

AVANT MIS Spine System is a minimally invasive surgery instrumentation for use with the ASTRA Spine System Extended Tab MIS Screws and other ASTRA Spine System associated implants. AVANT MIS Spine System was designed to provide the following benefits:

- Smaller incisions[3]
- Less tissue disruption[4]
- Less blood loss[1,2]
- Fewer narcotics after surgery while in the hospital[2,4,5]
- Shorter hospital stays[1,2]
- Patients potentially can be ambulatory earlier than patients who underwent traditional open spinal fusion surgery[1]

References

1. Acosta FL, Liu J, Slimack N, Moller D, Fessler R, Koski T: Changes in coronal and sagittal plane alignment following minimally invasive direct lateral interbody fusion for the treatment of degenerative lumbar disease in adults: a radiographic study. Clinical article. J Neurosurg Spine 15:92–96, 2011

2. Fraser J, Gebhard H, Irie D, Parikh K, Härtl R: Iso-C/3-dimensional neuronavigation versus conventional fluoroscopy for minimally invasive pedicle screw placement in lumbar fusion. Minim Invasive Neurosurg 53:184–190, 2010

3. Isaacs. Minimally invasive microendoscopy-assisted transforaminal lumbar interbody fusion. J. Neurosurg: Spine. 3:98-105, 2005.

4. Khoo, Fessler. Microendoscopic Decompressive Laminotomy for the Treatment of Lumbar Stenosis. Neurosurgery. 51 [Suppl 2]: 146-154, 2002.

5. Muramatsu, Hachiya, Morita. Postoperative Magnetic Resonance Imaging of Lumbar Disc Herniation. SPINE. 26(14): 1599-1605, 2001.

6. Park, Won Ha. Comparison of one-level posterior lumbar interbody fusion performed with a minimally invasive approach or a traditional open approach. SPINE 32(5):537-543, 2007.

7. Parker, S.L., et al., Cost-utility analysis of minimally invasive versus open multilevel hemilaminectomy for lumbar stenosis. J Spinal Disord Tech, 2013. 26(1)

8. Perez-Cruet MJ, Beisse R, Pimenta L, Kim DH: Minimally Invasive Spine Fusion: Techniques and Operative Nuances St. Louis, MO, Quality Medical Publishing, 2011

9. Righesso. Comparison of Open Discectomy with Microendoscopic Discectomy in Lumbar Disc Herniations: Results of a Randomized Controlled Trial. Neurosurgery. 61:545-549, 2007.

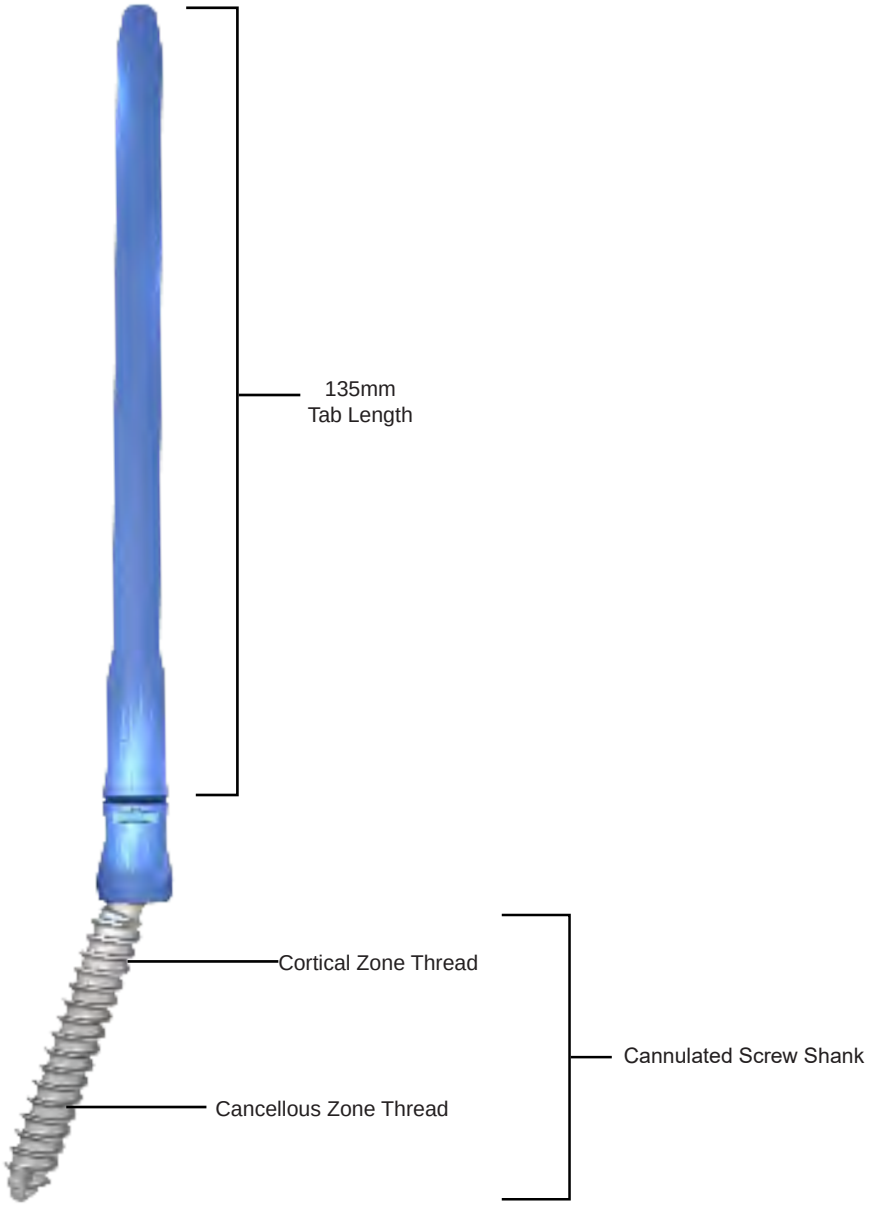
MIS Standard Screw

Extended Tab Head

- 135 mm tab length to accommodate patients with larger frame/above average weight
- Wide range of screw diameters & lengths for diverse anatomical needs
- Extended tab with a slim profile for smaller incisions
- Robust tab design resists premature breakage
- Proximal threads for driver engagement
- Implant has built-in 18mm of reduction to enable reduction without reduction instrumentation
- Several rod deployment options to accomodate surgeon preferred rod placement technique

Screw Shank

- Self-tapping feature to enable insertion without pedicle prep (tap or awl)
- T22 drive feature
- Double lead thread to enable efficient insertion of pedicle screw
- Cortical thread form provides enhanced pedicle fixation
- Cannulation 1.6 mm diameter



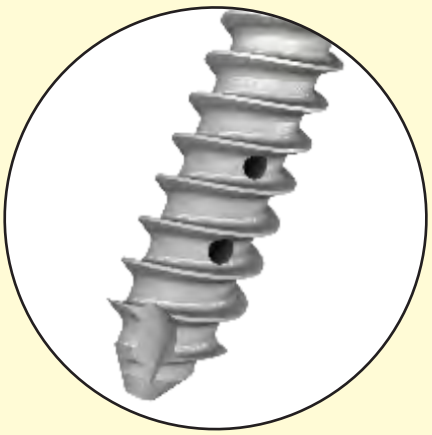
MIS Fenestrated Screw

Extended Tab Head

- 135 mm tab length to accommodate patients with larger frame/above average weight
- Wide range of screw diameters & lengths for diverse anatomical needs
- Extended tab with a slim profile for smaller incisions
- Robust tab design resists premature breakage
- Proximal threads for driver engagement
- Implant has built-in 18mm of reduction to enable reduction without reduction instrumentation
- Several rod deployment options to accomodate surgeon preferred rod placement technique

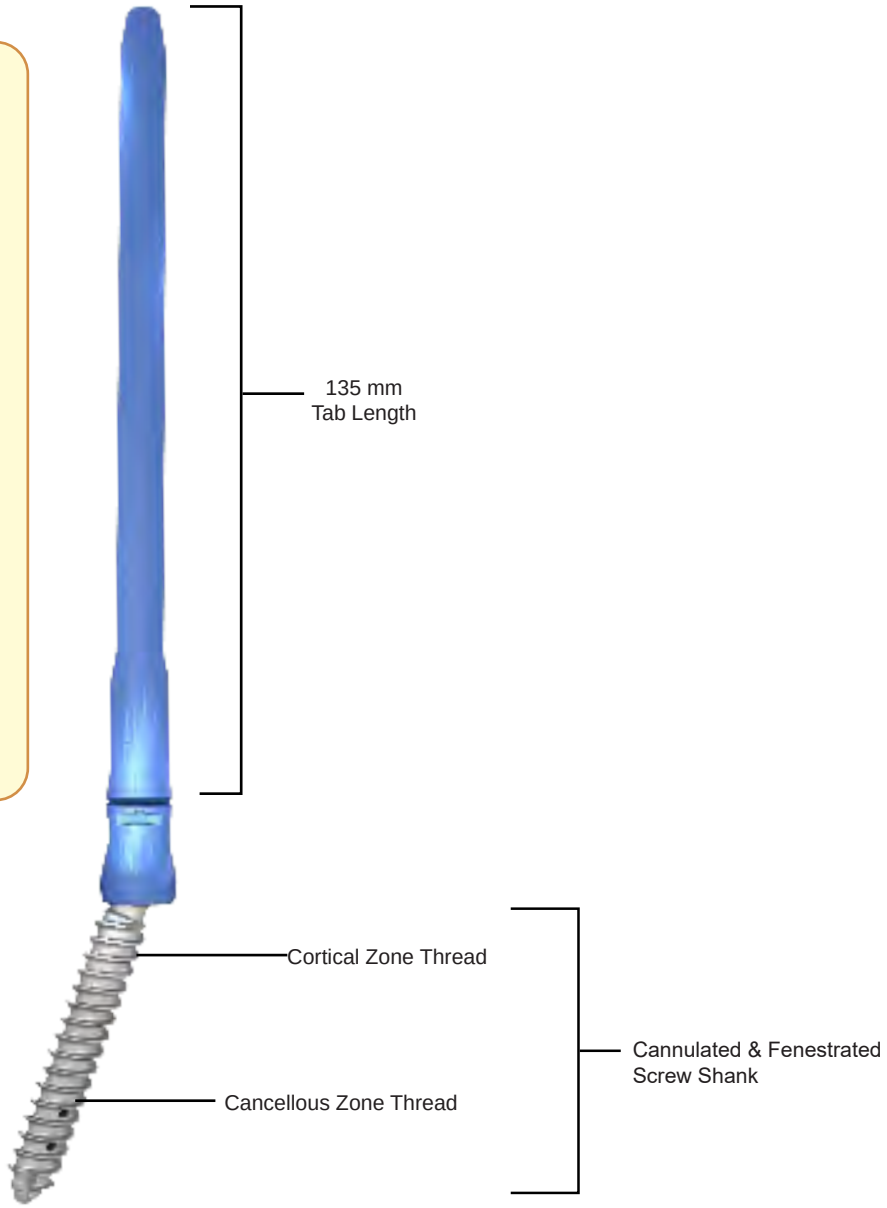
Screw Shank

- Self-tapping feature to enable insertion without pedicle prep (tap or awl)
- T22 drive feature
- Double lead thread to enable efficient insertion of pedicle screw
- Cortical thread form provides enhanced pedicle fixation
- Cannulation 1.6 mm diameter
- 1.5 - 1.7 mm fenestration diameters allow for the option of saline or radiopaque dye delivery into the vertebral body.

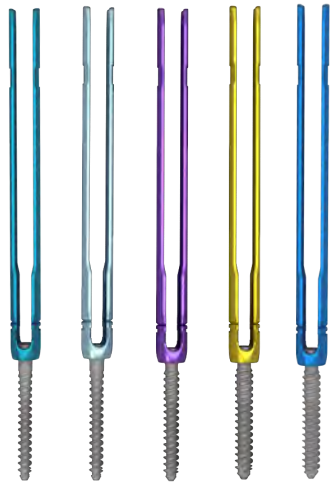


Fenestrations

Both the ASTRA Standard and Extended Tab Fenestrated Screws feature a variable number of fenestrations, depending on screw length. The proximal fenestrations have a slightly smaller diameter than the distal fenestrations to ensure optimum distribution of saline or radiopaque dye.



02. Implant Ordering Information



ASTRA Cannulated Polyaxial Screws, Extended Tab	Catalog n°
Ti MIS Poly Screw Ø4.50 x 30mm	A5P-4530E-C
Ti MIS Poly Screw Ø4.50 x 35mm	A5P-4535E-C
Ti MIS Poly Screw Ø4.50 x 40mm	A5P-4540E-C
Ti MIS Poly Screw Ø4.50 x 45mm	A5P-4545E-C
Ti MIS Poly Screw Ø5.50 x 35mm	A5P-5535E-C
Ti MIS Poly Screw Ø5.50 x 40mm	A5P-5540E-C
Ti MIS Poly Screw Ø5.50 x 45mm	A5P-5545E-C
Ti MIS Poly Screw Ø5.50 x 50mm	A5P-5550E-C
Ti MIS Poly Screw Ø5.50 x 55mm	A5P-5555E-C
Ti MIS Poly Screw Ø6.50 x 35mm	A5P-6535E-C
Ti MIS Poly Screw Ø6.50 x 40mm	A5P-6540E-C
Ti MIS Poly Screw Ø6.50 x 45mm	A5P-6545E-C
Ti MIS Poly Screw Ø6.50 x 50mm	A5P-6550E-C
Ti MIS Poly Screw Ø6.50 x 55mm	A5P-6555E-C
Ti MIS Poly Screw Ø7.50 x 35mm	A5P-7535E-C
Ti MIS Poly Screw Ø7.50 x 40mm	A5P-7540E-C
Ti MIS Poly Screw Ø7.50 x 45mm	A5P-7545E-C
Ti MIS Poly Screw Ø7.50 x 50mm	A5P-7550E-C
Ti MIS Poly Screw Ø7.50 x 55mm	A5P-7555E-C
Ti MIS Poly Screw Ø7.50 x 60mm	A5P-7560E-C
Ti MIS Poly Screw Ø8.50 x 35mm	A5P-8535E-C
Ti MIS Poly Screw Ø8.50 x 40mm	A5P-8540E-C
Ti MIS Poly Screw Ø8.50 x 45mm	A5P-8545E-C
Ti MIS Poly Screw Ø8.50 x 50mm	A5P-8550E-C
Ti MIS Poly Screw Ø8.50 x 55mm	A5P-8555E-C

ASTRA Cannulated Fenestrated Polyaxial Screws, Extended Tab	Catalog n°
Ti MIS Fenestrated Poly Screw Ø4.50 x 30mm	A5P-4530E-F
Ti MIS Fenestrated Poly Screw Ø4.50 x 35mm	A5P-4535E-F
Ti MIS Fenestrated Poly Screw Ø4.50 x 40mm	A5P-4540E-F
Ti MIS Fenestrated Poly Screw Ø4.50 x 45mm	A5P-4545E-F
Ti MIS Fenestrated Poly Screw Ø5.50 x 35mm	A5P-5535E-F
Ti MIS Fenestrated Poly Screw Ø5.50 x 40mm	A5P-5540E-F
Ti MIS Fenestrated Poly Screw Ø5.50 x 45mm	A5P-5545E-F
Ti MIS Fenestrated Poly Screw Ø5.50 x 50mm	A5P-5550E-F
Ti MIS Fenestrated Poly Screw Ø5.50 x 55mm	A5P-5555E-F
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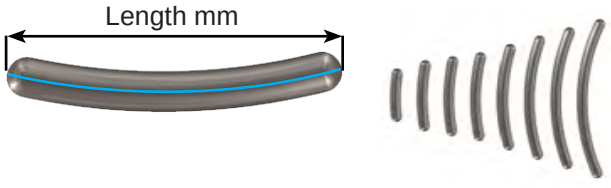
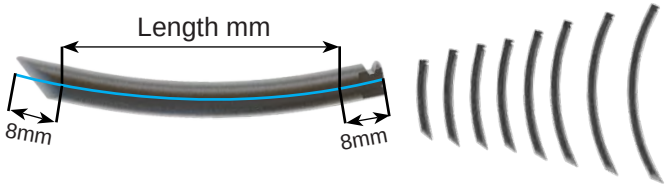
Ti MIS Fenestrated Poly Screw Ø8.50 x 45mm	A5P-8545E-F
Ti MIS Fenestrated Poly Screw Ø8.50 x 50mm	A5P-8550E-F
Ti MIS Fenestrated Poly Screw Ø8.50 x 55mm	A5P-8555E-F

Additional screw lengths are available upon request.

Miscellaneous	Catalog n°
T30 Set Screw	A5S-T30





Titanium Lordosed Rods	Catalog n°
TI Lordosed Rod Ø5.5 x 30mm	A5R-55L-030
TI Lordosed Rod Ø5.5 x 40mm	A5R-55L-040
TI Lordosed Rod Ø5.5 x 45mm	A5R-55L-045
TI Lordosed Rod Ø5.5 x 50mm	A5R-55L-050
TI Lordosed Rod Ø5.5 x 60mm	A5R-55L-060
TI Lordosed Rod Ø5.5 x 70mm	A5R-55L-070
TI Lordosed Rod Ø5.5 x 80mm	A5R-55L-080
TI Lordosed Rod Ø5.5 x 90mm	A5R-55L-090
TI Lordosed Rod Ø5.5 x 100mm	A5R-55L-100
TI Lordosed Rod Ø5.5 x 110mm	A5R-55L-110
TI Lordosed Rod Ø5.5 x 120mm	A5R-55L-120
TI Lordosed Rod Ø5.5 x 130mm	A5R-55L-130
TI Lordosed Rod Ø5.5 x 200mm	A5R-55L-200
Ti Lordosed Rod Ø6.0 x 30mm	A5R-60L-030
Ti Lordosed Rod Ø6.0 x 40mm	A5R-60L-040
Ti Lordosed Rod Ø6.0 x 45mm	A5R-60L-045
Ti Lordosed Rod Ø6.0 x 50mm	A5R-60L-050
Ti Lordosed Rod Ø6.0 x 60mm	A5R-60L-060
Ti Lordosed Rod Ø6.0 x 70mm	A5R-60L-070
Ti Lordosed Rod Ø6.0 x 80mm	A5R-60L-080
Ti Lordosed Rod Ø6.0 x 90mm	A5R-60L-090
Ti Lordosed Rod Ø6.0 x 100mm	A5R-60L-100
Ti Lordosed Rod Ø6.0 x 110mm	A5R-60L-110
Ti Lordosed Rod Ø6.0 x 120mm	A5R-60L-120
Ti Lordosed Rod Ø6.0 x 130mm	A5R-60L-130
Ti Lordosed Rod Ø6.0 x 200mm	A5R-60L-200

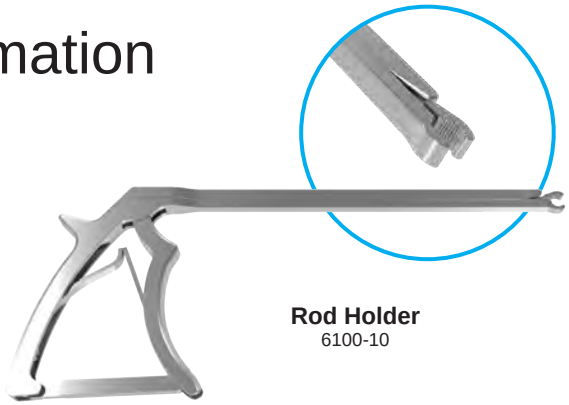
Straight rods are also available.

Titanium Percutaneous MIS Rods	Catalog n°
Ti Percutaneous MIS Rod Ø5.5 x 30mm	A5R-55FL-030
Ti Percutaneous MIS Rod Ø5.5 x 35mm	A5R-55FL-035
Ti Percutaneous MIS Rod Ø5.5 x 40mm	A5R-55FL-040
Ti Percutaneous MIS Rod Ø5.5 x 45mm	A5R-55FL-045
Ti Percutaneous MIS Rod Ø5.5 x 50mm	A5R-55FL-050
Ti Percutaneous MIS Rod Ø5.5 x 55mm	A5R-55FL-055
Ti Percutaneous MIS Rod Ø5.5 x 60mm	A5R-55FL-060
Ti Percutaneous MIS Rod Ø5.5 x 65mm	A5R-55FL-065
Ti Percutaneous MIS Rod Ø5.5 x 70mm	A5R-55FL-070
Ti Percutaneous MIS Rod Ø5.5 x 75mm	A5R-55FL-075
Ti Percutaneous MIS Rod Ø5.5 x 80mm	A5R-55FL-080
Ti Percutaneous MIS Rod Ø5.5 x 90mm	A5R-55FL-090
Ti Percutaneous MIS Rod Ø5.5 x 100mm	A5R-55FL-100
Ti Percutaneous MIS Rod Ø5.5 x 110mm	A5R-55FL-110
Ti Percutaneous MIS Rod Ø5.5 x 120mm	A5R-55FL-120
Ti Percutaneous MIS Rod Ø5.5 x 130mm	A5R-55FL-130
Ti Percutaneous MIS Rod Ø6.0 x 30mm	A5R-60FL-030
Ti Percutaneous MIS Rod Ø6.0 x 35mm	A5R-60FL-035
Ti Percutaneous MIS Rod Ø6.0 x 40mm	A5R-60FL-040
Ti Percutaneous MIS Rod Ø6.0 x 45mm	A5R-60FL-045
Ti Percutaneous MIS Rod Ø6.0 x 50mm	A5R-60FL-050
Ti Percutaneous MIS Rod Ø6.0 x 55mm	A5R-60FL-055
Ti Percutaneous MIS Rod Ø6.0 x 60mm	A5R-60FL-060
Ti Percutaneous MIS Rod Ø6.0 x 65mm	A5R-60FL-065
Ti Percutaneous MIS Rod Ø6.0 x 70mm	A5R-60FL-070
Ti Percutaneous MIS Rod Ø6.0 x 75mm	A5R-60FL-075
Ti Percutaneous MIS Rod Ø6.0 x 80mm	A5R-60FL-080
Ti Percutaneous MIS Rod Ø6.0 x 90mm	A5R-60FL-090
Ti Percutaneous MIS Rod Ø6.0 x 100mm	A5R-60FL-100
Ti Percutaneous MIS Rod Ø6.0 x 110mm	A5R-60FL-110
Ti Percutaneous MIS Rod Ø6.0 x 120mm	A5R-60FL-120
Ti Percutaneous MIS Rod Ø6.0 x 130mm	A5R-60FL-130

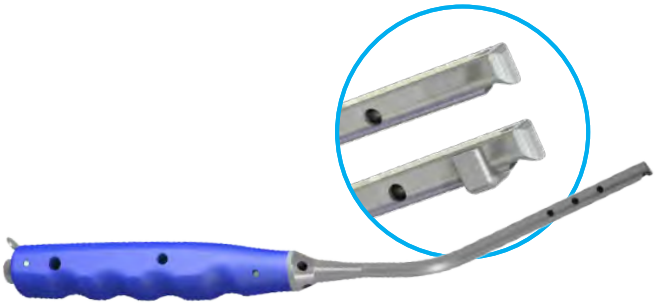
Additional rod lengths are available upon request.

03. Instrument Ordering Information

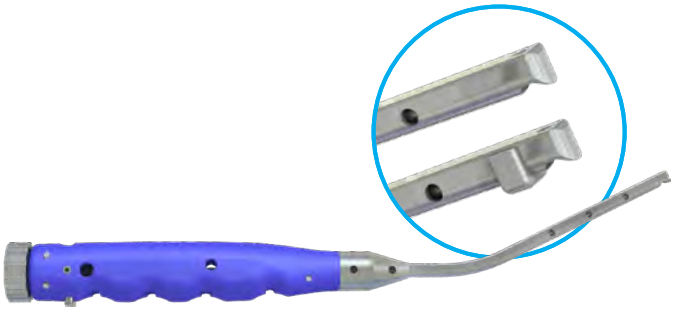
AVANT RCDF Sleeve
6400-47C



Rod Holder
6100-10



Rod Introducer — Push-Button Release
6100-12
Rod Introducer — Push-Button Release and Backstop
6100-12



Rod Introducer — Locking Wheel
6100-12K
Rod Introducer — Locking Wheel and Backstop
6100-12KS

Compression Forceps
6100-42-H

Small Fulcrum
6100-42-F1520

K-wires, Stainless Steel
6400-SW
K-wires, Nitinol
6400-NW

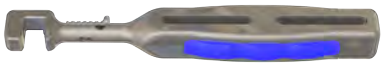
Cannulated Tap, Ø4.5mm
6300-71-45
Cannulated Tap, Ø5.0mm
6300-71-50
Cannulated Tap, Ø5.5mm
6300-71-55
Cannulated Tap, Ø6.5mm
6300-71-65
Cannulated Tap, Ø7.5mm
6300-71-75
Cannulated Tap, Ø8.5mm
6300-71-85

AVANT Polyaxial Screwdriver
6400-02

T22 Hexalobe Driver
6300-22-M

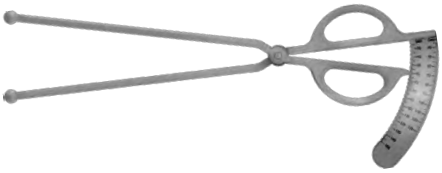
T30 Self Retaining Driver with Dedicated Handle
6000-30-3S
T30 Self Retaining Driver
6400-30S

T30 Hexalobe Driver
6400-30-M

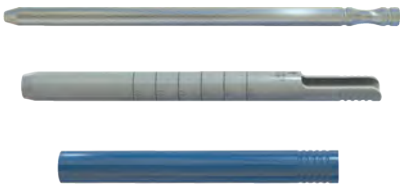


Side-Loading Counter Torque Handle
6400-98S

Extended Tab Remover
6400-91



Rod Caliper
6400-09

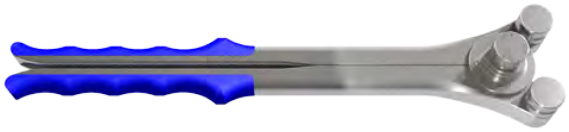


Dilator #1
6400-51
Dilator #2
6400-52
Dilator #3
6400-53

10.5 Nm Torque-Limiting Handle
6300-02

Ratcheting T-Handle
6000-03

Palm Ratcheting Handle
6000-03-P



French Rod Bender
6000-16-S

Fenestrated Screw
Connector for Extended Tab Screws
6300-97-E

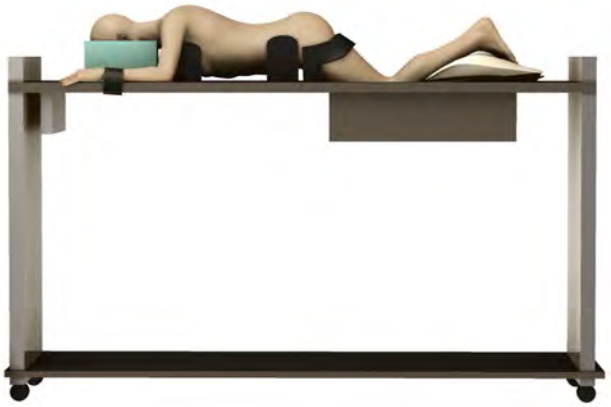
04. Surgical Technique

Patient Positioning

1

Position the patient prone on a radiolucent table that is compatible with a fluoroscopic C-Arm.

All the hardware used to position the patient should also be radiolucent.



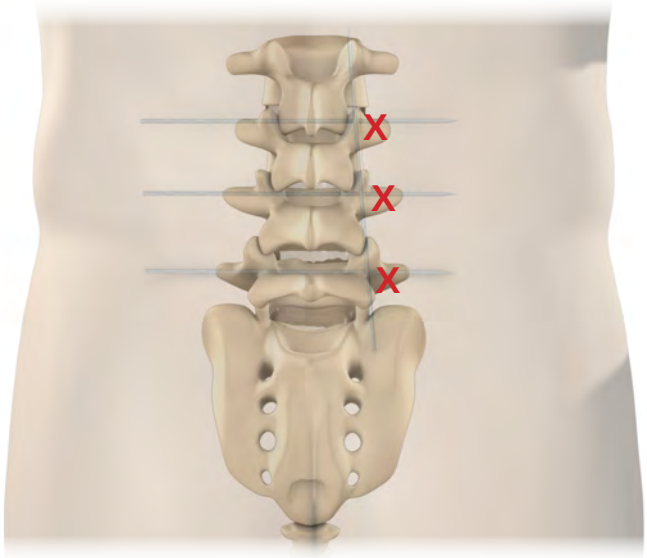
Pedicle Targeting

2

Use AP fluoroscopy to determine the lateral edge of pedicles using a K-wire laid on the skin for reference. Mark this border on the skin with a sterile pen.

Place a wire on the skin perpendicularly to this border and use as a reference to locate the superior borders of the pedicles using fluoroscopy. Also mark this border on the skin with a sterile pen.

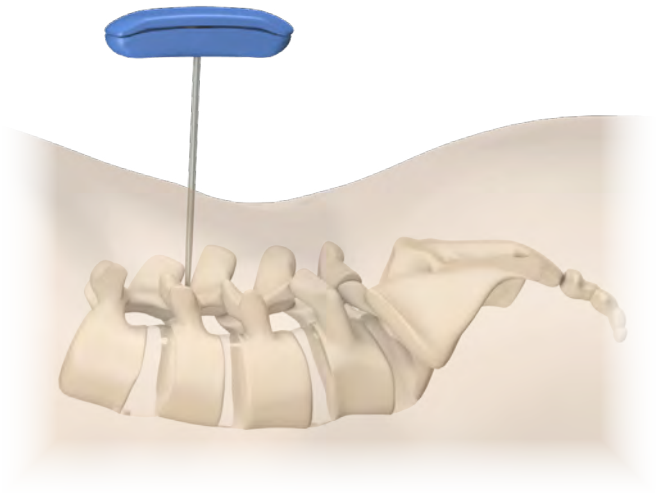
The intersections of these lines are the optimal insertion points for pedicle screws.



Inserting the Targeting Needles

3

Make an incision 2.5cm long at one of the insertion points and introduce a Jamshidi needle into the incision and then to just the surface of the pedicle.



Check Needle Position

4

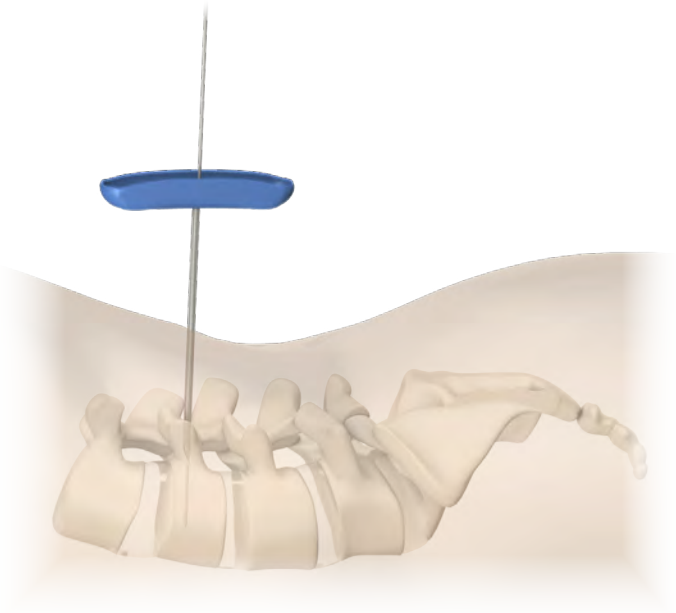
Confirm needle trajectory fluoroscopically. Ensure that it is entering the pedicle at the intersection of its lateral and superior borders. Advance needle fully into the pedicle, and then to the desired depth in the vertebral body.

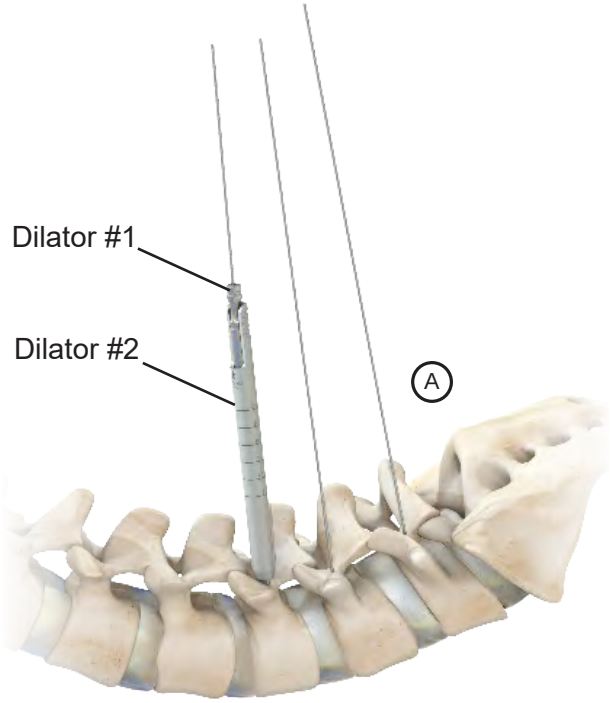
K-Wire Placement

5

Remove the stylet from the targeting needle and insert the K-wire into the needle, down through the pedicle, and into the vertebral body. Confirm its position fluoroscopically. Ensure that the K-wire does not penetrate the anterior wall of the vertebral body.

Once the K-wire is positioned, remove the targeting needle while holding the wire in place. Repeat for each level.





6 Muscle Dilation (Optional)

Dilation is optional when the pedicle is going to be tapped.

To begin dilation, place Dilator #1 over a K-wire and introduce to the level of the pedicle. Then place Dilator #2 over #1 (A), and remove Dilator #1.

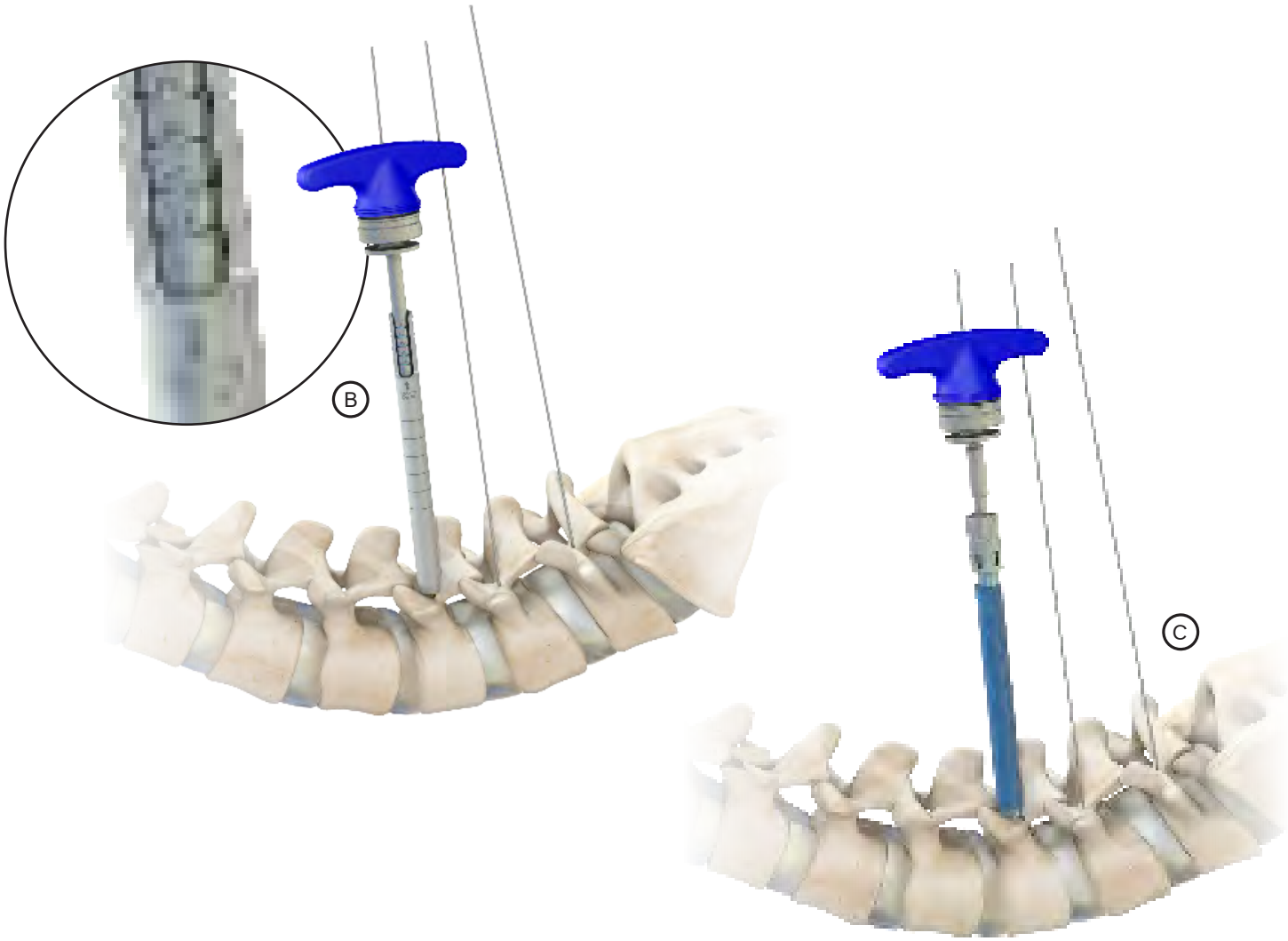
Dilator #2 is non-conductive and can be used to stimulate the tap. Tap the pedicle to the desired depth. The Dilator #2 features a window through which the depth of the tap can be monitored (B).

Dilator #3 is also non-conductive and can be used to stimulate the screw. Slide Dilator #3 over Dilator #2, then remove Dilator #2. Load the Polyaxial Screwdriver (Step 7) and implant screw (Step 9) by passing the screw and screwdriver through the opening of Dilator #3.

When finished, remove the dilator(s) while holding the K-wire.

Repeat for each wire.

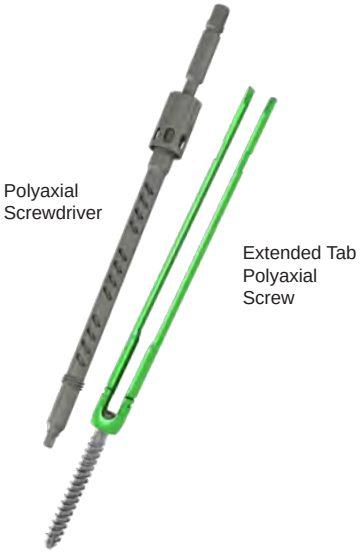
Note: Care should be exercised not to advance the K-wire during tapping.

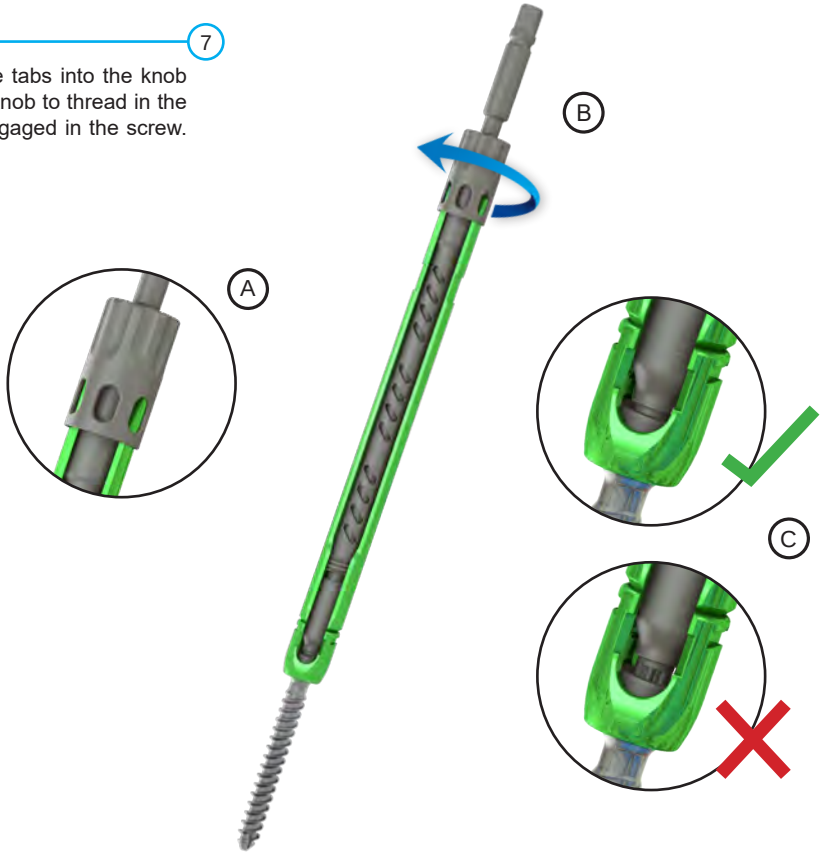


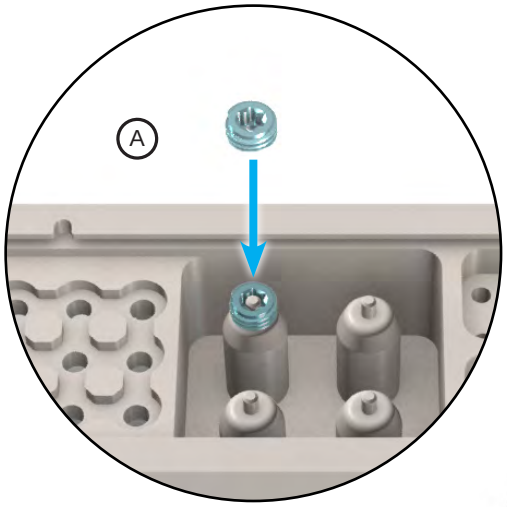
Loading the Polyaxial Screwdriver

7

Insert the screwdriver between the Extended Tabs and tuck the tabs into the knob of the screwdriver (A). Engage the screwdriver tip and turn the knob to thread in the screw head (B). Check to make sure the screwdriver is fully engaged in the screw. The hexalobe tip of the screwdriver should not be visible (C).





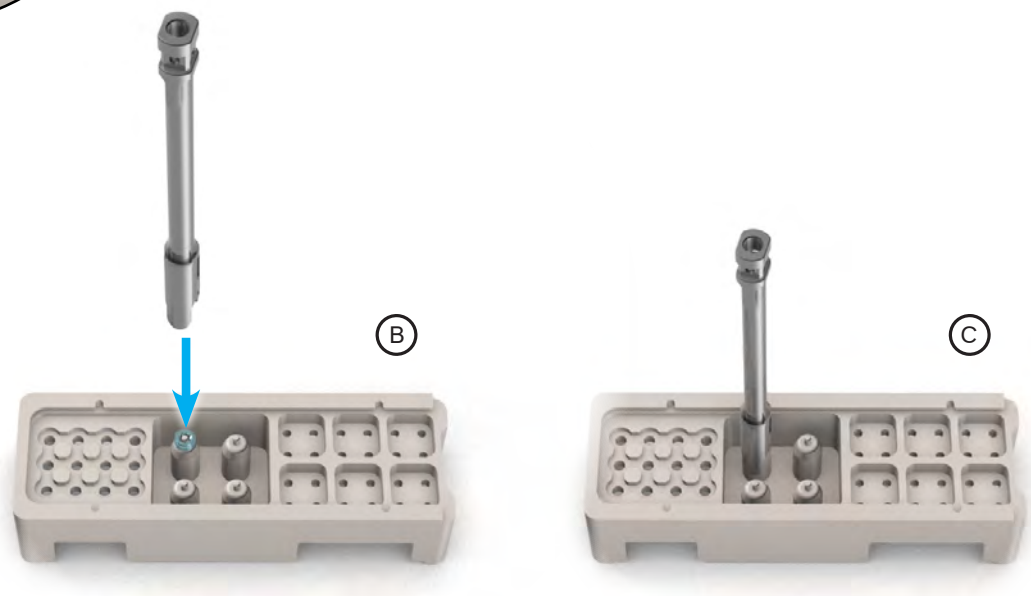


Pre-Loading the Set Screw

8

Place the set screw onto one of the four loading post with the star hexalobe side up (A). Slide the RCDF Sleeve over the loading post with set screw in place (B). Stabilize the RCDF Sleeve with one hand and push the RCDF sleeve down with the palm of the other hand (C).

Note: Be sure to place the caddy on a stable flat surface when loading the set screw into the RCDF Sleeve.



Screw Implantation

9

Attach the Ratcheting Handle to the screwdriver.

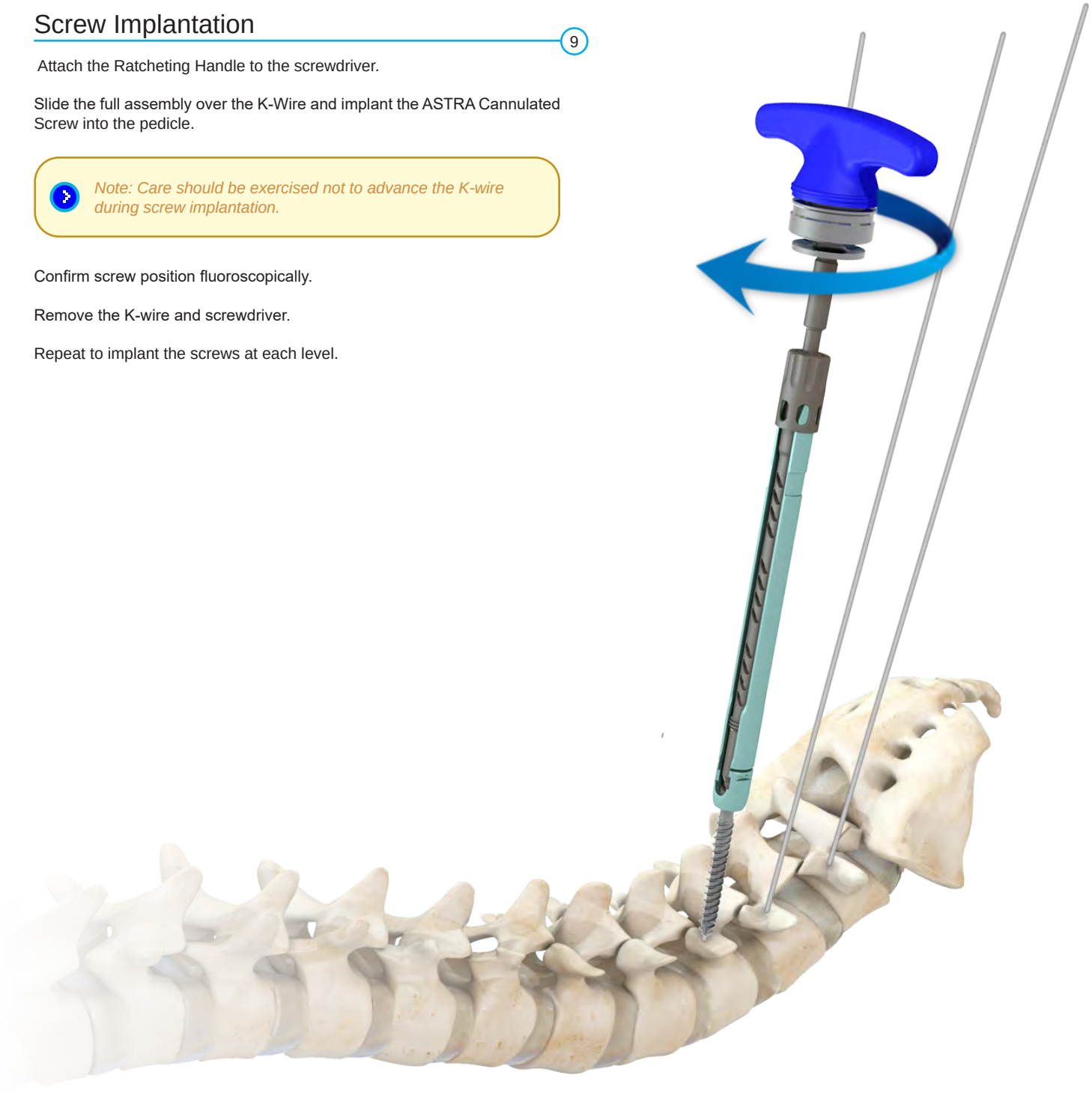
Slide the full assembly over the K-Wire and implant the ASTRA Cannulated Screw into the pedicle.

Note: Care should be exercised not to advance the K-wire during screw implantation.

Confirm screw position fluoroscopically.

Remove the K-wire and screwdriver.

Repeat to implant the screws at each level.



Procedure for Using Saline or Radiopaque Dye with Fenestrated Screws (optional)

10

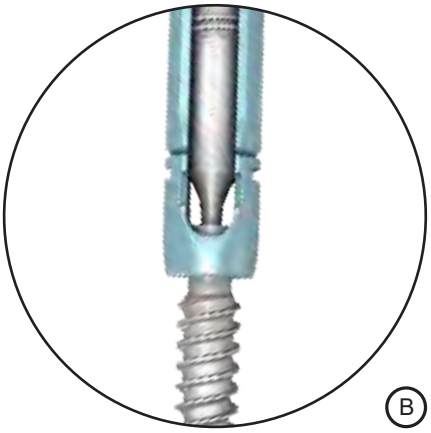
The ASTRA extended tab fenestrated screw along with the fenestrated screw connector for extended tab screw (6300-97-E) are used for the minimally invasive delivery method of saline or radiopaque dye in minimally invasive spinal procedure.

Saline or Radiopaque Dye Delivery

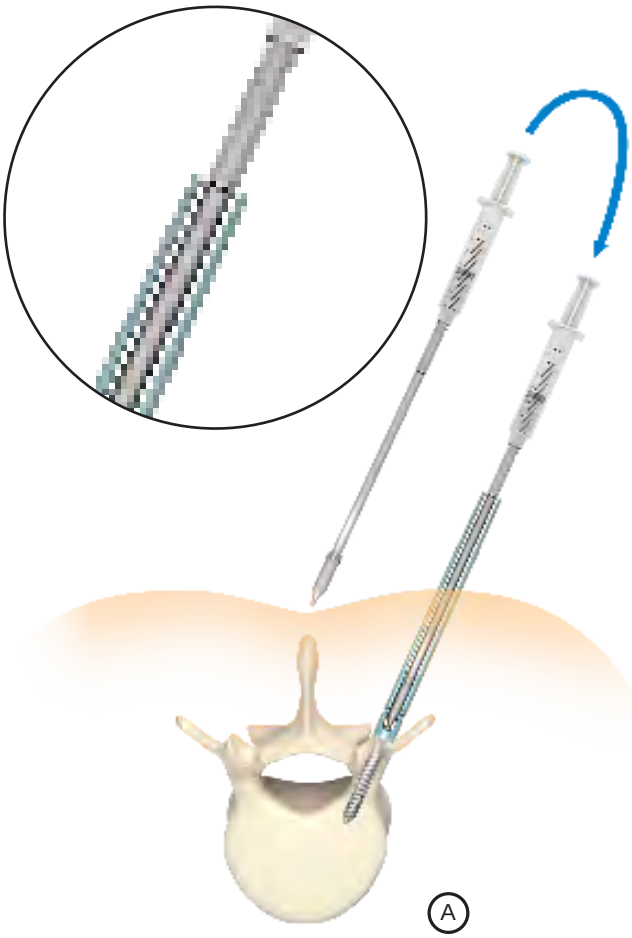
Once the extended tab fenestrated screws are inserted using the same procedure as for the cannulated extended tab screws, follow these steps:

- Transfer the appropriate amount of saline or radiopaque dye into a syringe.
- Connect the syringe to an extended tab fenestrated screw connector (A).
- Inject saline or radiopaque dye into the connector until all the air is expelled.
- Connect the extended tab fenestrated screw connector and syringe assembly to the first extended tab fenestrated Screw and thread securely. The extended tab fenestrated screw connector is fully seated when the laser marked line on the connector aligns with the top of the extended tab tulip.

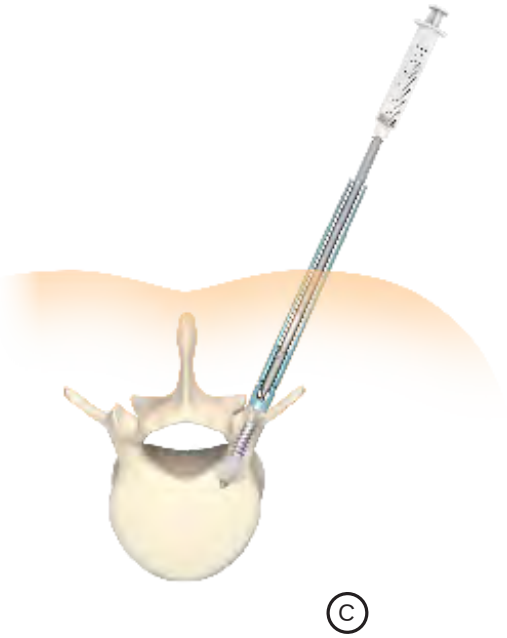
Note: The tip of the extended tab fenestrated screw connector must be aligned with the screw shaft, in order to engage properly (B).



B

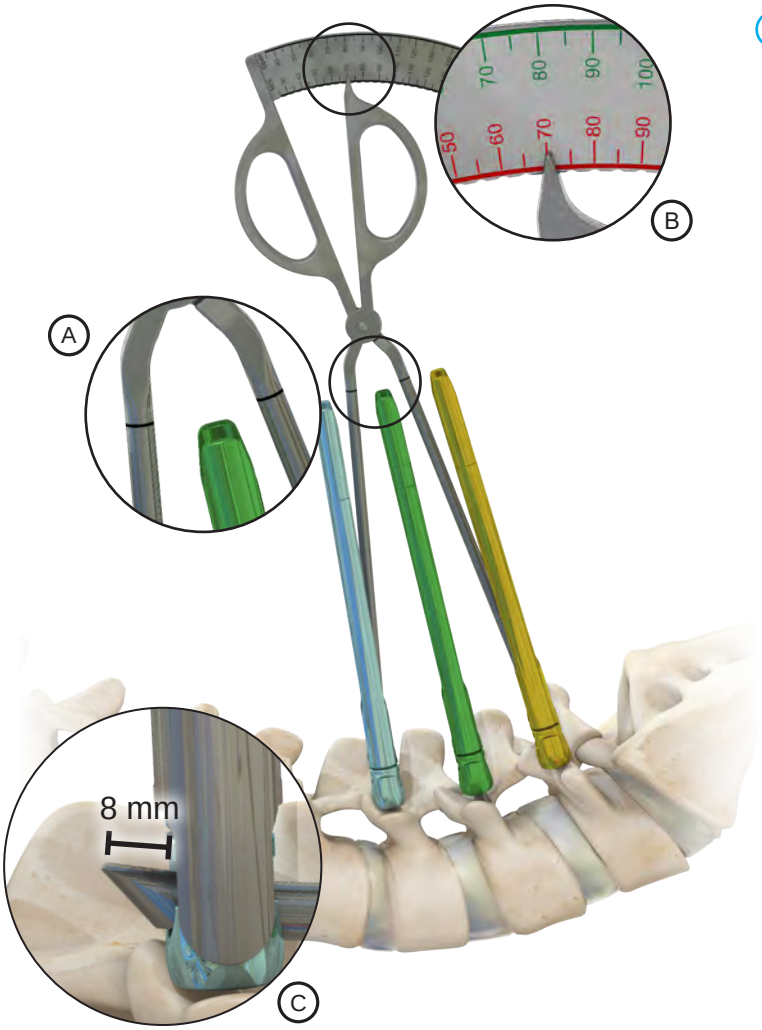


A



C

- Inject saline or radiopaque dye into the vertebral body as required (C).
- Repeat the steps above for each extended tab fenestrated screw



11 Determine Rod Length

The necessary rod length is determined using the Rod Caliper. Insert one arm of the caliper into the RCDF sleeve at the highest level and the other arm into the RCDF sleeve at the lowest level. When inserting each arm, gently squeeze the screw's tabs together to ensure the arm stays within the tabs.

The caliper is properly seated when the top of the tabs aligns with the markings on the caliper arms (A). The metal indicator on the Rod Caliper will show the necessary length (B). This indicated length includes 5 mm overhang on each side for lordosed rods, and 8 mm on each side for percutaneous MIS rods (C).

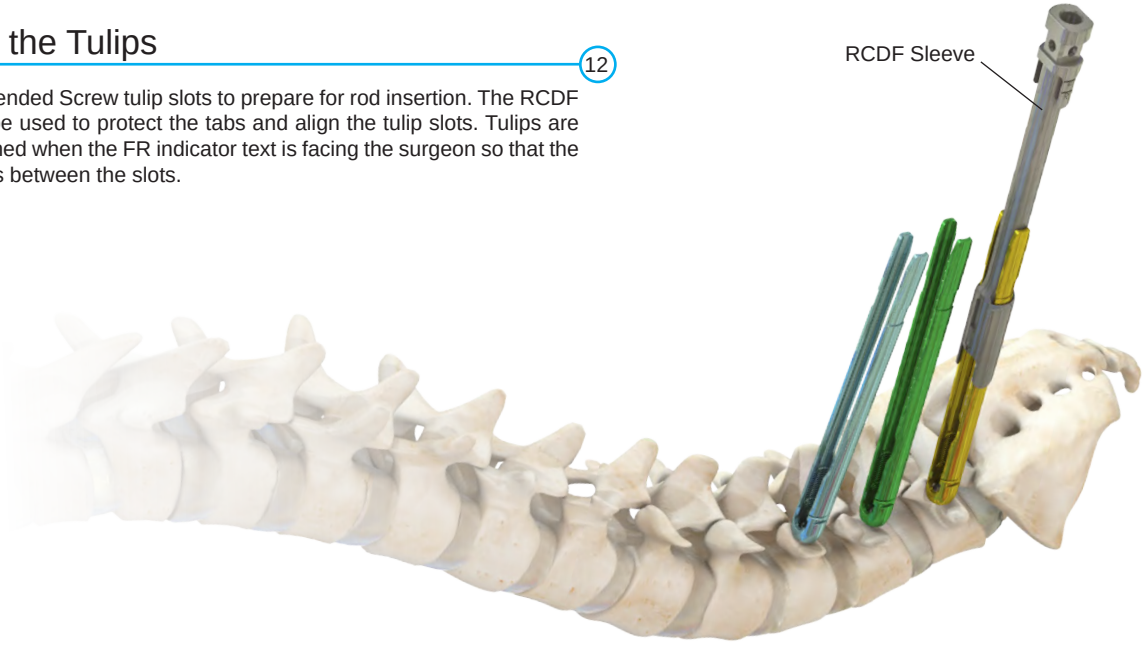
Rod Caliper Numbering

There are two sets of numbers on the Rod Caliper. The green set of numbers on top labeled "OPEN" are for measuring lordosed rods. The red set of numbers on bottom labeled "MIS" are for measuring percutaneous MIS rods.

Aligning the Tulips

12

Align the Extended Screw tulip slots to prepare for rod insertion. The RCDF Sleeve can be used to protect the tabs and align the tulip slots. Tulips are properly aligned when the FR indicator text is facing the surgeon so that the rod may pass between the slots.



Rod Introduction (Muscle Sparing Technique) 13

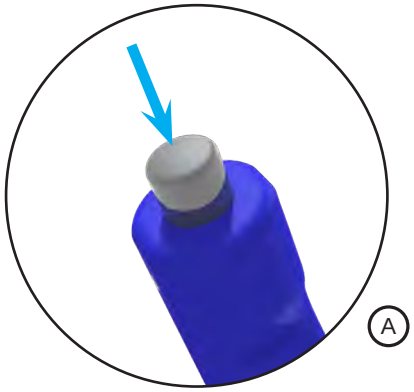
After you have determined the rod length, contour it as needed. Do not reverse bend the rod, this may weaken its structural integrity.

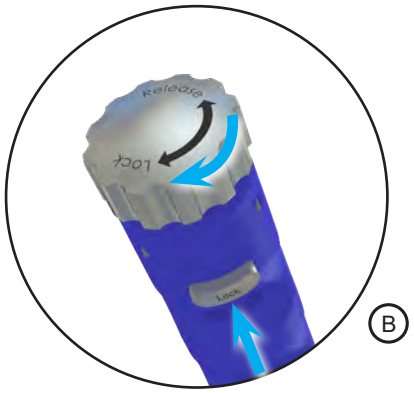
The Rod Introducer is used to insert the rod into the screw heads of the ASTRA Cannulated screw. If using the Rod Introducer with Push-Bottom Release, press the button on the top of the Rod Introducer handle to lock the rod in position (A). If using the Rod Introducer with Locking Wheel, turn the wheel clockwise until the rod is secured, then press the “Lock” button to lock into place (B).

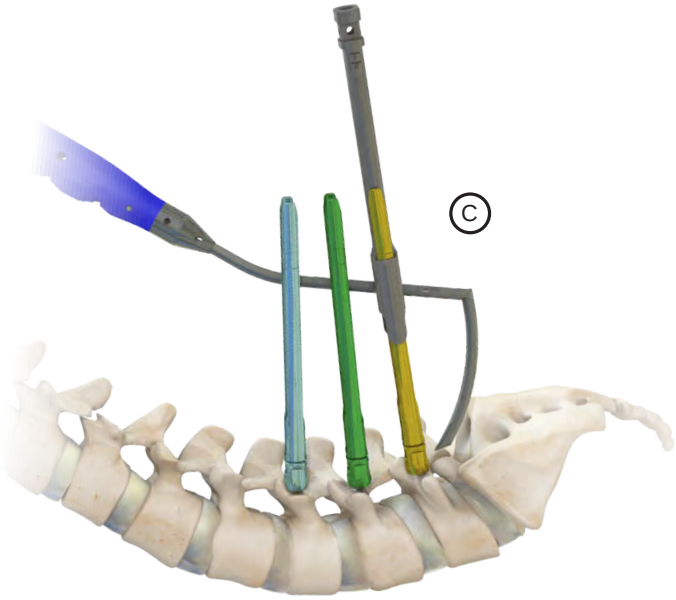
With the rod parallel to the Extended Tabs, insert the rod into the tulip of the most caudal screw (C). Begin to angle the Rod Introducer so that the rod becomes perpendicular with the screws as it advances cranially under the intact soft tissue into the remaining screw tulips (D).

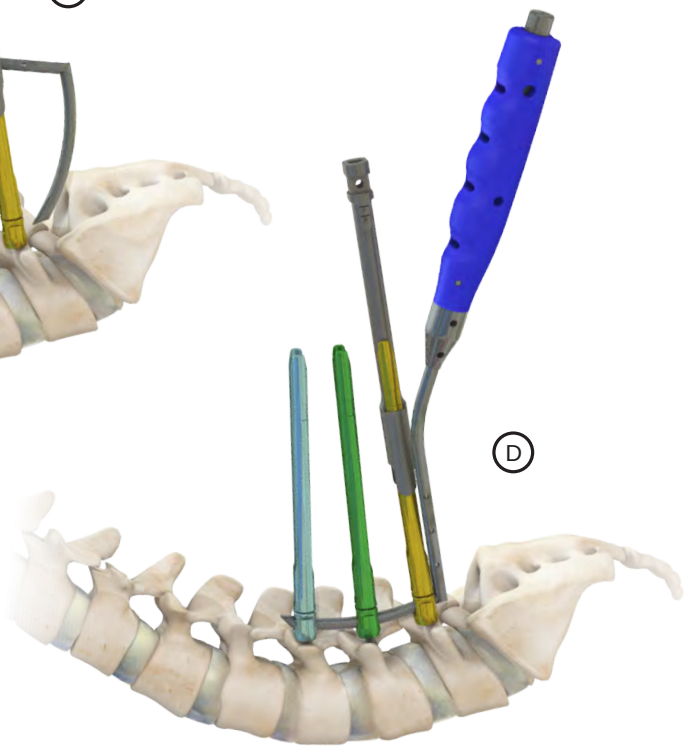
Once the rod is fully inserted, begin set screw implantation.

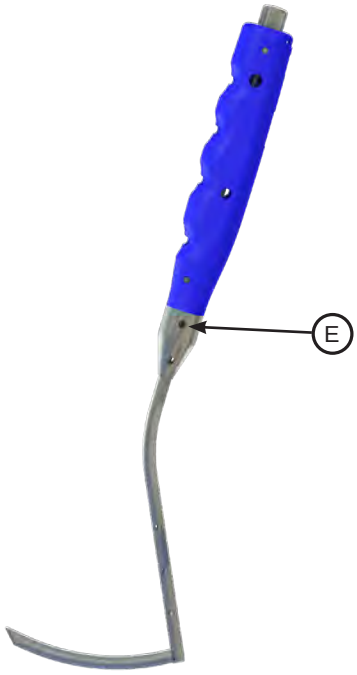
To keep the rod introducer functioning optimally, lubricate before each sterilization cycle (E).











Set Screw Implantation

14

The Set Screw should be pre-loaded into the RCDF sleeve according to the instructions in the “Pre-Loading the Set Screw” step (A).

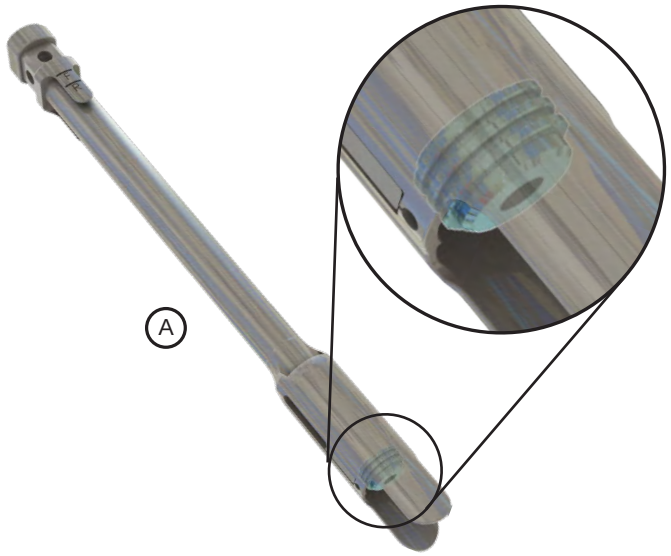
Slide the pre-loaded RCDF Sleeve onto the Extended Tab Screw, while maintaining the rod position with the Rod Inserter.

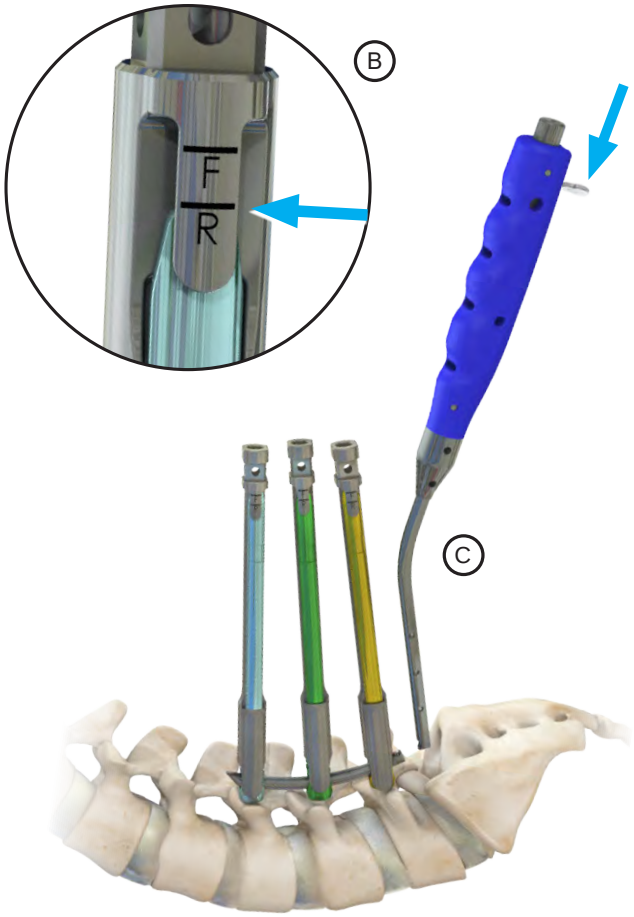
Once the extended tabs reach the “R” line on the RCDF Sleeve (B), begin to thread the set screw into the screw head using the T30 Hexalobe Driver and a Ratcheting Handle. Transition of the Set Screw from RCDF Sleeve to the screw is very smooth. The Set Screw starts leaving the RCDF Sleeve after approximately 6 turns of the T30 Driver.

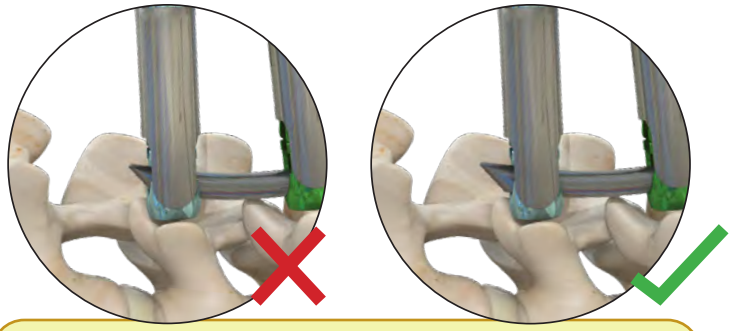
Tighten only enough to allow for compression and distraction of the segments, if needed.

Once the set screws are properly seated, remove Rod Introducer. To release the Rod Introducer from the Percutaneous MIS Rod, deflect the Release Protector out of the way and press down on the Release Spring near the top of the Rod Introducer handle (C). If using the Rod Introducer with Locking Wheel, press the “Unlock” button and turn the wheel counterclockwise until the rod is released.

Confirm the rod’s position fluoroscopically.







Note: Do not tighten the set screw on the tapered section of the Percutaneous MIS Rod. Make sure that the rod is properly positioned so that the set screw can be tightened on the full diameter of the rod and not on the tapered end.

Note: There must be clearance in the fascia to back the Rod Introducer 5mm before pulling up.

Note: To ensure that the rod is properly seated in all the Extended Screw tabs, you can try to slightly rotate each tulip. When the rod is properly seated no rotation should occur.

Rod Introduction (Muscle Splitting Technique) 15

Determine rod length and contour as needed. Do not reverse bend the rod, this may weaken its structural integrity.

The Rod Holder is used to insert the rod into the screw heads of the ASTRA Extended Tab Cannulated screw.

Attach the rod to the Rod Holder. Split the muscle between the tubes, all the way down to the screw head. Slide the rod down inside the previously aligned tube slots.

To ensure that the rod is properly seated in the tubes, try to rotate the tubes. If they don't turn, then the rod is seated.

Confirm the rod's position fluoroscopically.

Set Screw Implantation 16

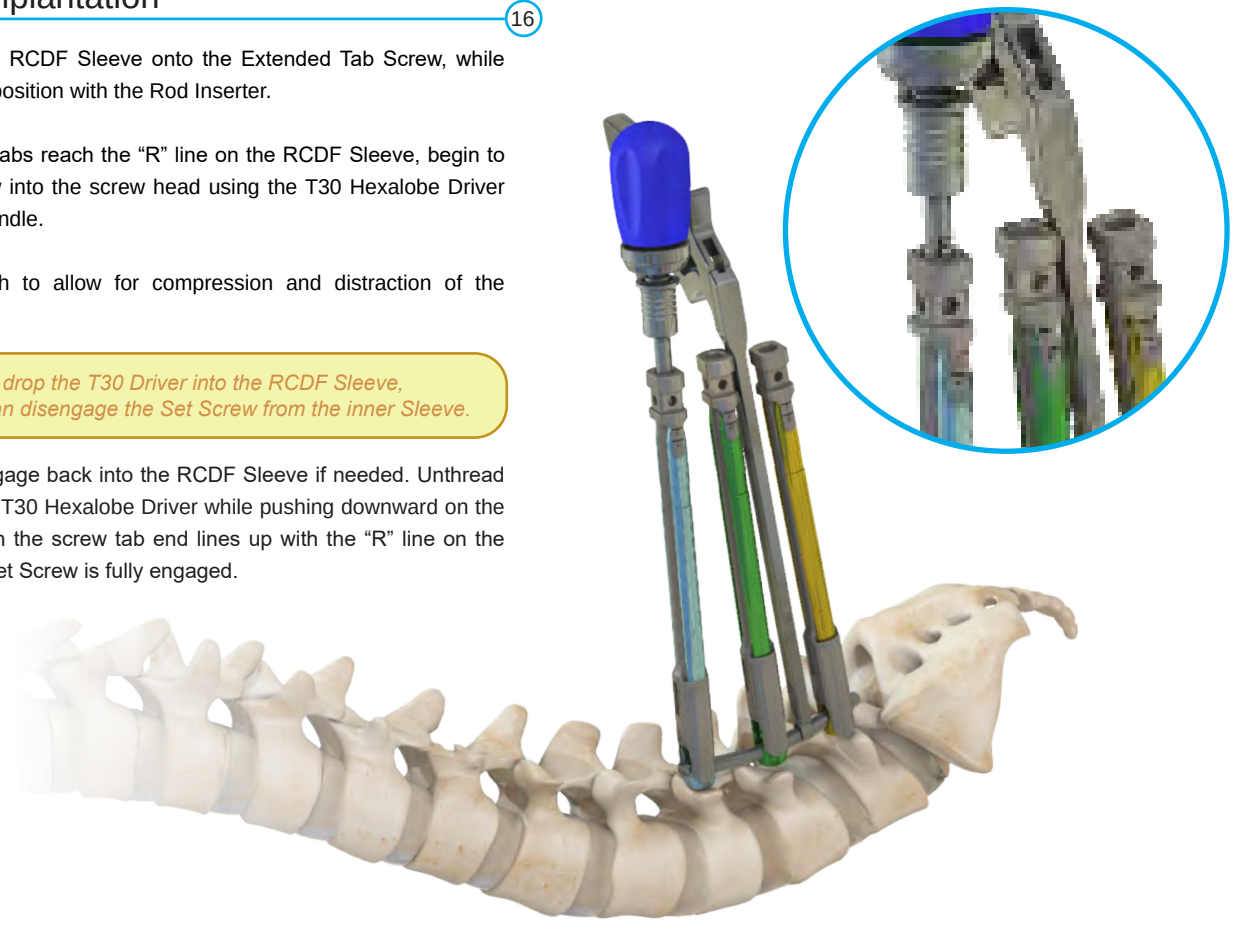
Slide the pre-loaded RCDF Sleeve onto the Extended Tab Screw, while maintaining the rod position with the Rod Inserter.

Once the extended tabs reach the "R" line on the RCDF Sleeve, begin to thread the set screw into the screw head using the T30 Hexalobe Driver and a Ratcheting Handle.

Tighten only enough to allow for compression and distraction of the segments, if needed.

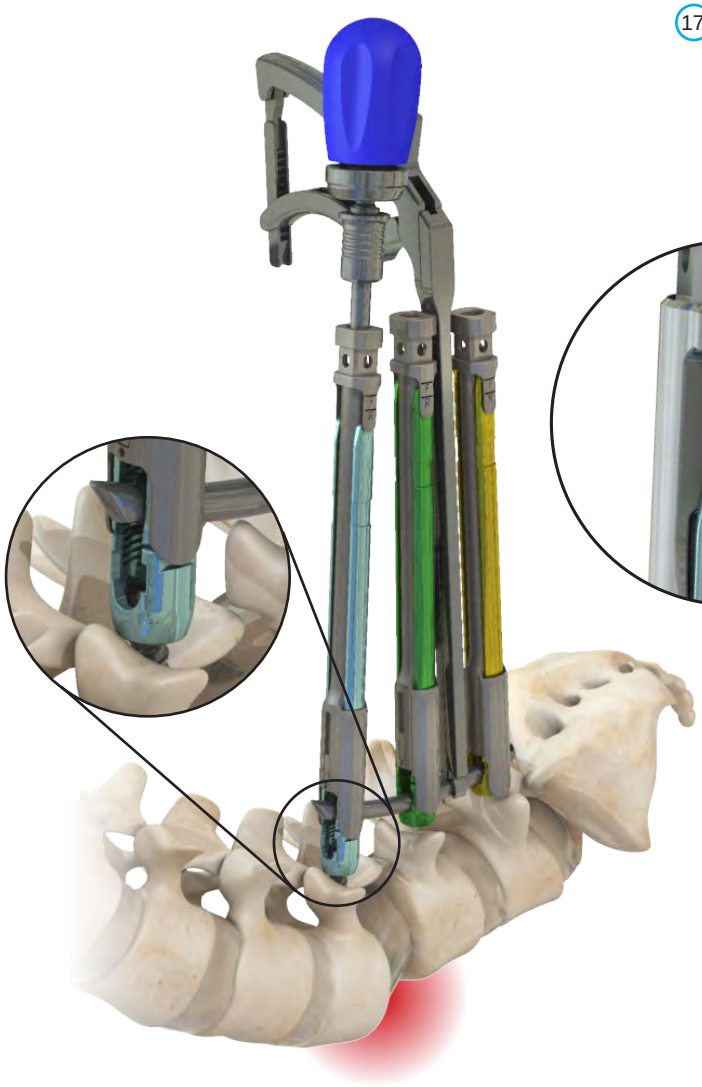
Note: Do not drop the T30 Driver into the RCDF Sleeve, because it can disengage the Set Screw from the inner Sleeve.

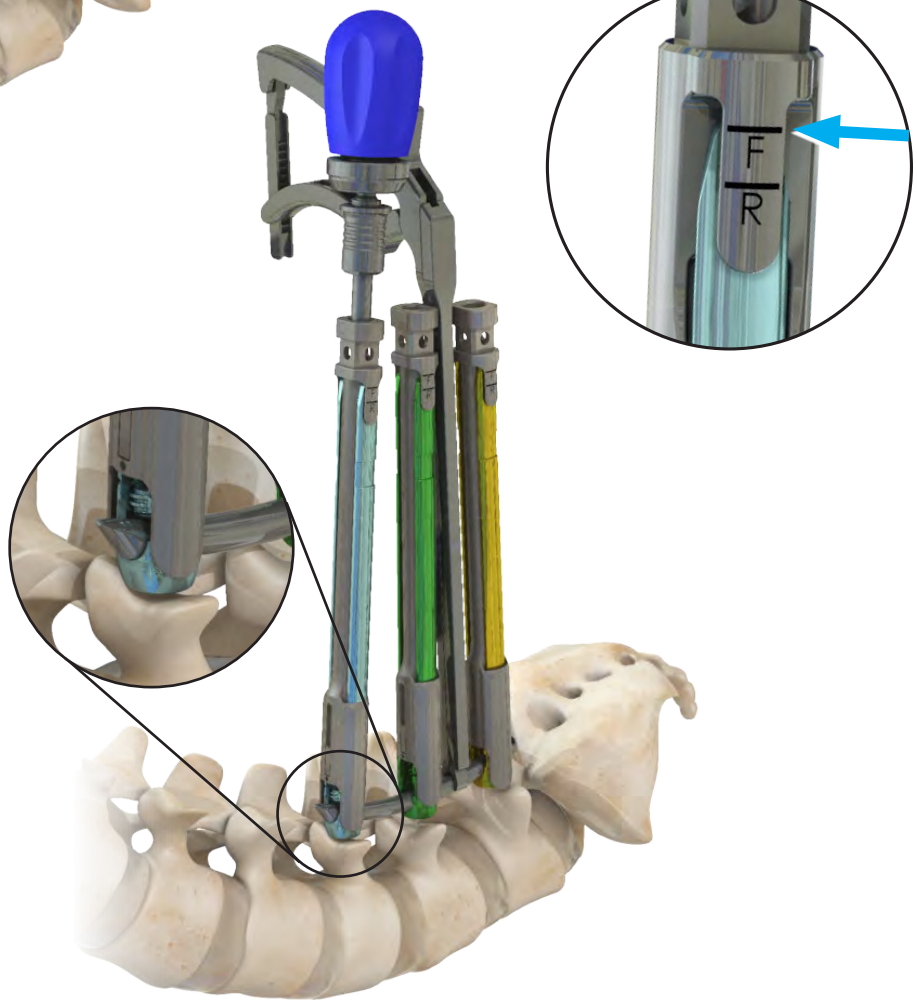
Set Screw can reengage back into the RCDF Sleeve if needed. Unthread the Set Screw using T30 Hexalobe Driver while pushing downward on the RCDF Sleeve. When the screw tab end lines up with the "R" line on the RCDF Sleeve, the Set Screw is fully engaged.



17 Rod Reduction/Spondylolisthesis Reduction

To reduce the rod, fully seat the RCDF Sleeve until the lower incised “R” line (for Reduction) on the RCDF Sleeve will match up with the top of the tab. Thread the set screw until the rod is reduced, at which point the top of the tab will align with the “F” line.





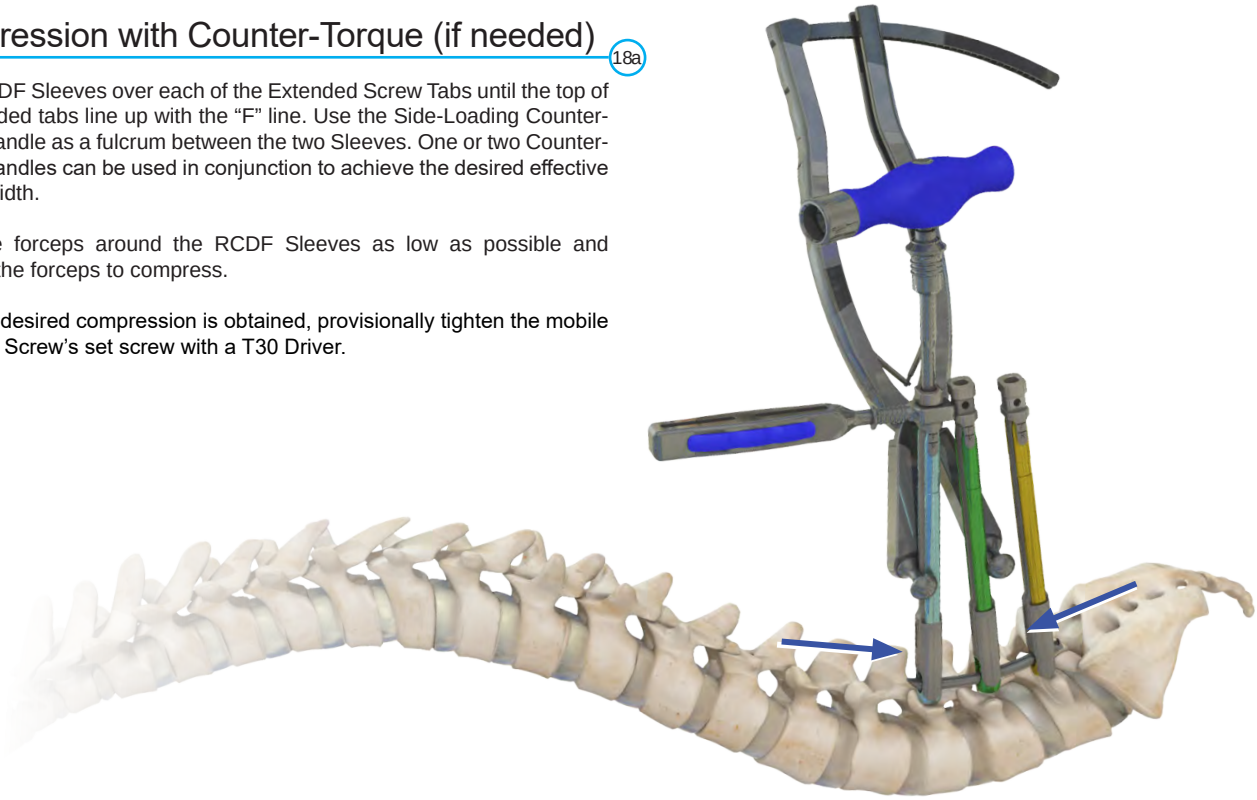
Compression with Counter-Torque (if needed)

18a

Place RCDF Sleeves over each of the Extended Screw Tabs until the top of the extended tabs line up with the “F” line. Use the Side-Loading Counter-Torque Handle as a fulcrum between the two Sleeves. One or two Counter-Torque Handles can be used in conjunction to achieve the desired effective fulcrum width.

Place the forceps around the RCDF Sleeves as low as possible and squeeze the forceps to compress.

Once the desired compression is obtained, provisionally tighten the mobile Extended Screw’s set screw with a T30 Driver.

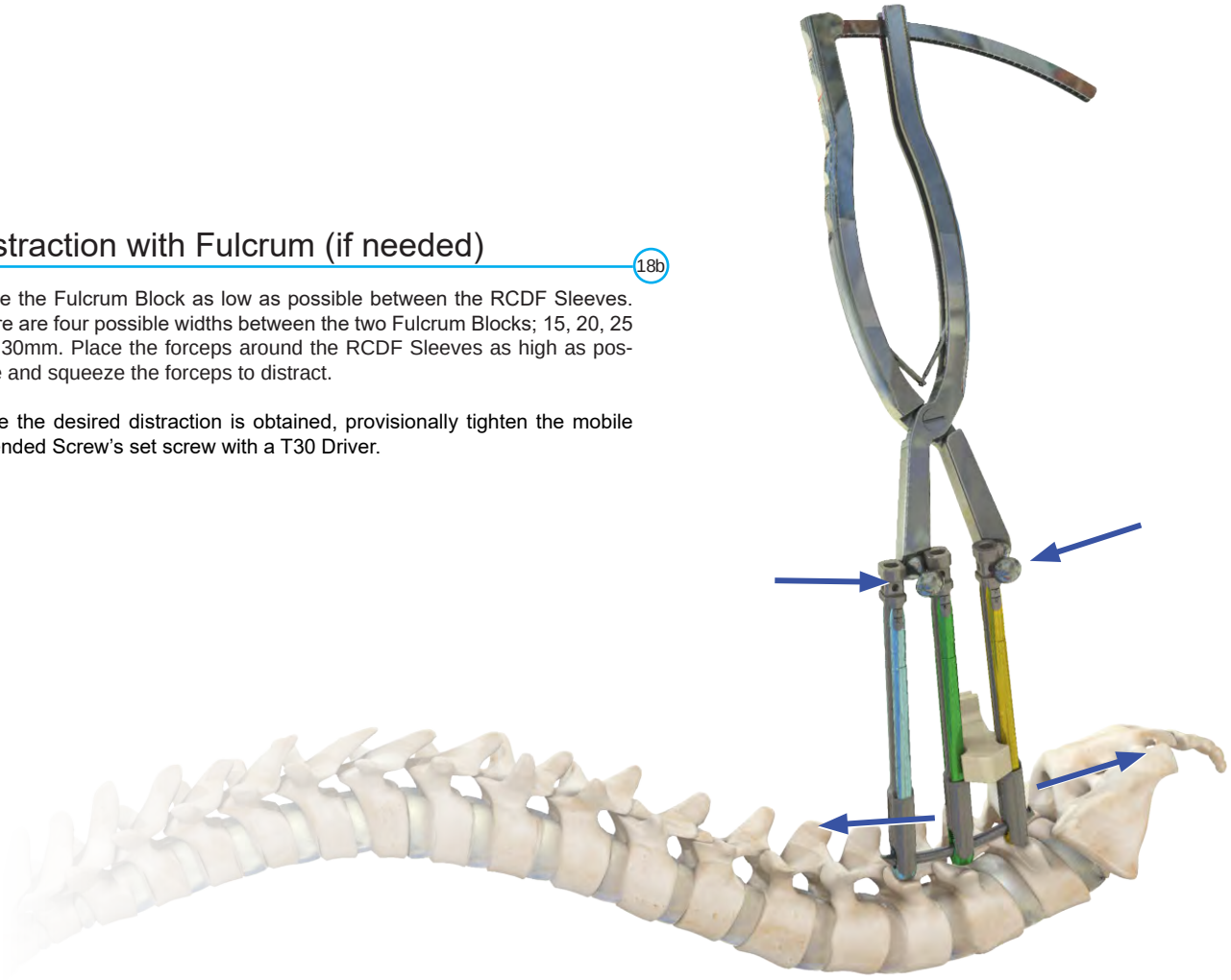


Distraction with Fulcrum (if needed)

18b

Place the Fulcrum Block as low as possible between the RCDF Sleeves. There are four possible widths between the two Fulcrum Blocks; 15, 20, 25 and 30mm. Place the forceps around the RCDF Sleeves as high as possible and squeeze the forceps to distract.

Once the desired distraction is obtained, provisionally tighten the mobile Extended Screw’s set screw with a T30 Driver.



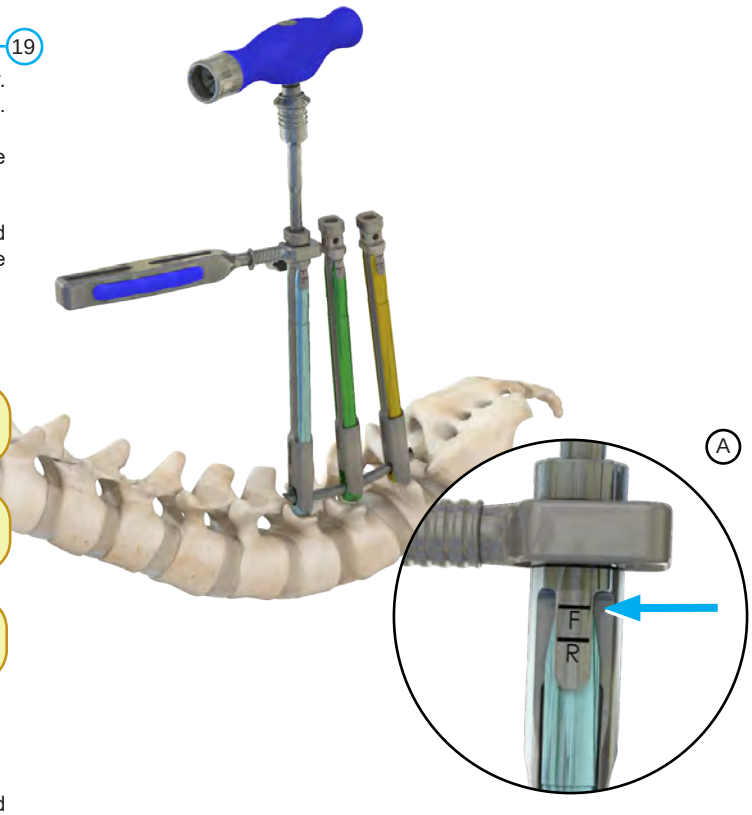
Final Tightening

19

Attach the 10.5 Nm Torque Limiting Handle to the T30 Hexalobe Driver. Place the fork of the Counter Torque Handle in the slot of the RCDF Sleeve.

Be sure that the RCDF Sleeve is engaged with the rod and the top of the extended tabs line up with the “F” line on the RCDF Sleeve (A).

Tighten the set screws of the middle level first, and then the superior and inferior screws. Final tightening can be confirmed when the T30 Hexalobe Driver “F” line passes the RCDF Sleeve’s proximal end.

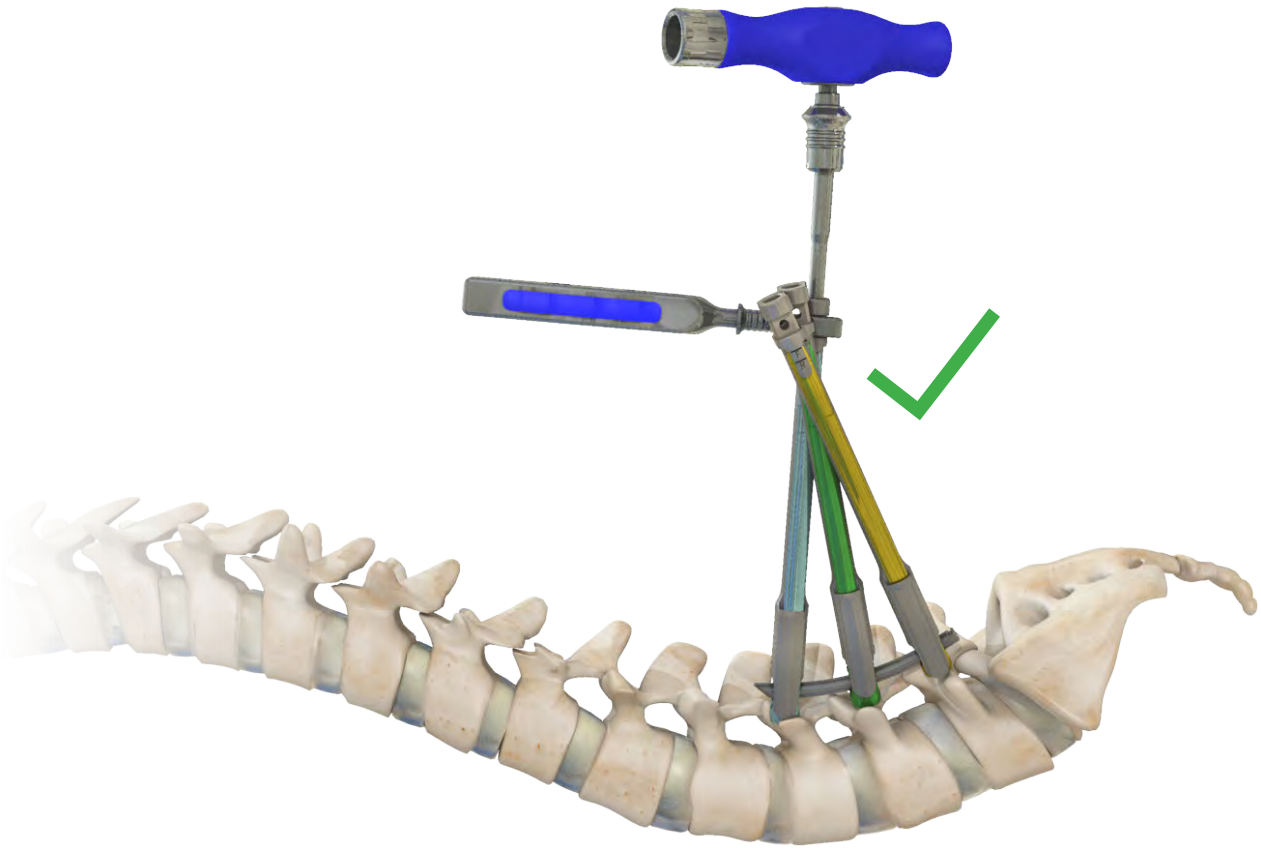


Note: Final tightening ***must*** *be done when Fulcrum and Compression Forceps are removed.*

Note: RCDF Sleeve plus Side Loading Counter Torque can be used for anti-torqueing at any time.

WARNING: *Do not use the Rod Introducer as Counter-Torque.*

It should be noted that, for rods 100mm or shorter, the radius of the rod causes the RCDF Sleeves to cross each other after final tightening. For proper final tightening, RCDF Sleeves must not be forced to align at the top. The accompanying image describes a possible scenario after final tightening. If the rod is straightened (rod radius is increased), or longer rod size is used, then the RCDF Sleeves might not cross after proper final tightening.



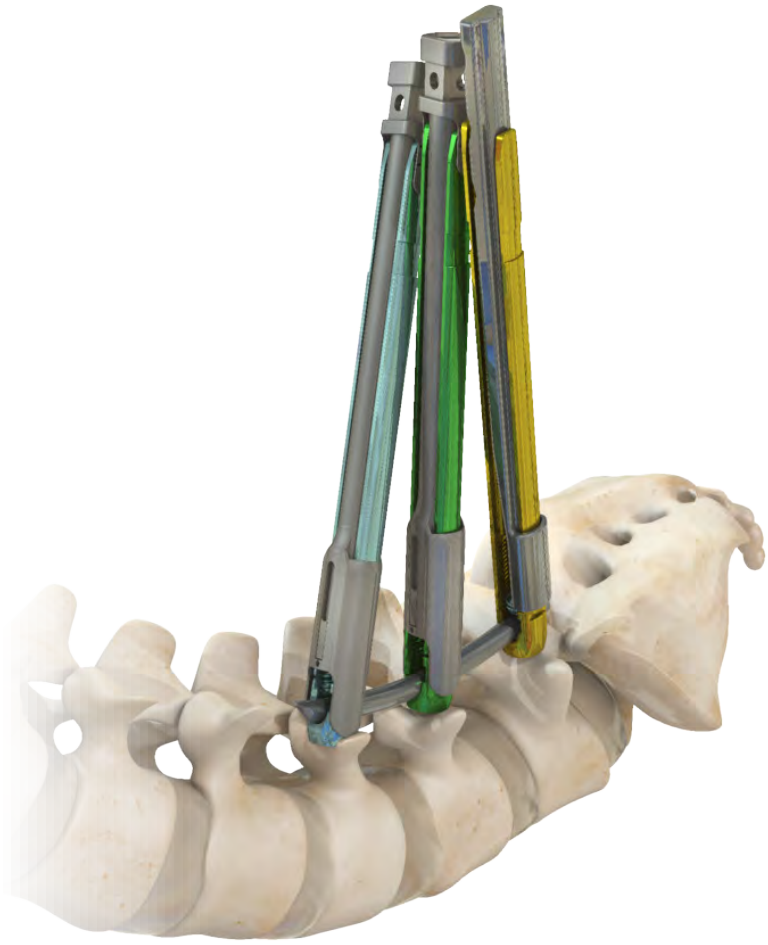
Extended Tab Removal

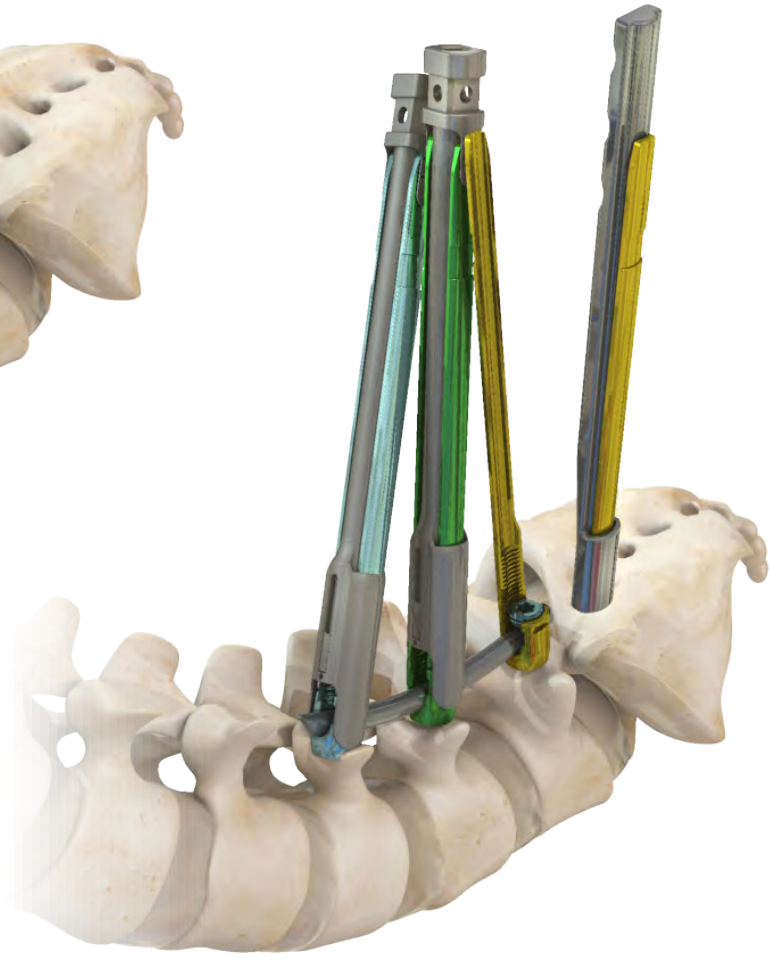
20

Remove the RCDF Sleeve. Slide the Extended Tab Remover over each tab of the Extended Tab Screws. Insert it as far as possible (until the last finger groove). Rock the Extended Tab Remover medial/lateral to break the extended tab.

The Extended Tab Remover is Self-Retaining and will hold the tab as it is removed. Continue this method for all of the Extended Tabs.

Note: Use only the Extended Tab Remover for tab breaking.





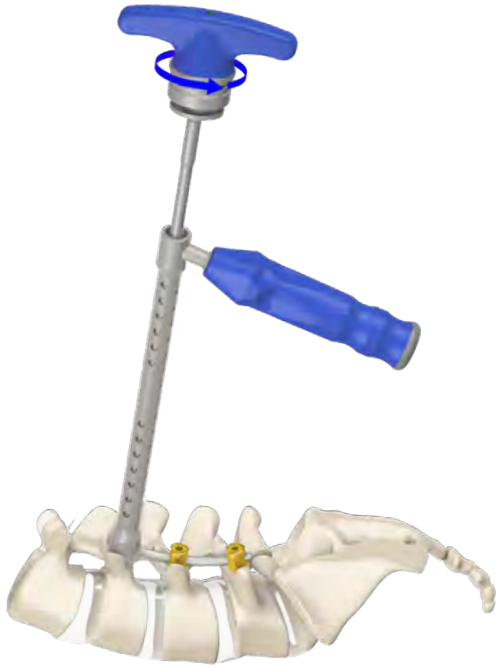
05. Revision and Explantation

Pedicle Screw and Set Screw Removal (if needed)

21

The ASTRA T30 Driver (6000-30-M), Ratcheting T-Handle, and the Anti-torque (6000-98) should be used for the removal of set screws.

Driver tip should be fully engaged in the hexalobe socket of the set screw prior to torque application. Turn counterclockwise and remove the set screw.

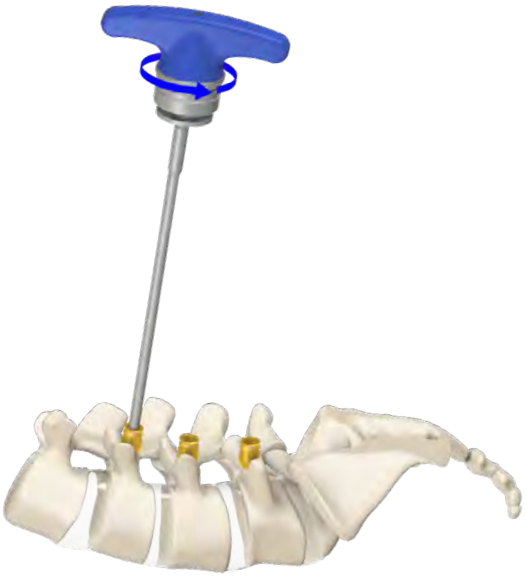


Pedicle Screw Removal (if needed)

22

The ASTRA T22 Driver (6300-22-M) or the ASTRA Polyaxial Screwdriver (6300-89-PS) with a Ratcheting Handle can be used for pedicle screw removal.

Note: The Regular Anti-torque, 6000-98, the ASTRA Polyaxial Screw-driver, 6300-89-PS, and the T22 Screwdriver, 6300-22-M are included in the ASTRA Spine System Degenerative Instruments Case..



06. Instructions for Use

INSTRUMENTS INSTRUCTIONS FOR USE

CONTENTS: Non-Sterile Instruments

CAUTION: USA law restricts this device to sale by or on the order of physician.

Note: Carefully read all instructions and be familiar with the surgical technique(s) prior to the use of any of SpineCraft's systems. Review the instructions for use associated with any SpineCraft Spine implant or instrument to be used in conjunction with any of SpineCraft's systems. Use universal precautions when handling contaminated or biohazardous components.

INSTRUMENTS MATERIALS:

Stainless Steel
Aluminum
Polymeric Materials

DESCRIPTION:

All SpineCraft's systems comprise custom and generic instruments and perforated instrument cases that are generally comprised of aluminum, stainless steel, and/or polymeric materials. The instrument cases may be multi-layered with various trays, holders and silicone mats to hold surgical instrumentation in place during handling and storage.

The perforated instrument cases will allow sterilization of the contents to occur in a steam autoclave utilizing a cleaning, sterilization, and drying cycles that have been validated. Instrument cases do not provide a sterile barrier and must be used in conjunction with a sterilization wrap to maintain sterility.

PROCESSING:

All instruments must be cleaned, disinfected and sterilized before each use; this applies especially to the first-time use after delivery because all instruments are shipped in non-sterile condition (clean and disinfect after removing the transport packaging and sterilize after packaging). Effective cleaning and disinfection is an indispensable prerequisite for effective sterilization. When using instruments, please make sure to keep dirty instruments separate and do not place them back into the instrument tray in order to prevent serious contamination of the equipped instrument tray. Clean/disinfect the dirty instruments, sort them and place them back in the instrument tray, then sterilize the entire equipped instrument tray.

Within the scope of your responsibility for instrument sterility, please ensure that only cleaning/disinfection and sterilization processes which have been appropriately validated in a device-specific and product-specific manner are used, that the employed devices (disinfecting machine, sterilizer) undergo regular maintenance and inspections and that the validated parameters are complied with during each cycle. In addition, please follow all applicable laws in your country as well as the hygiene regulations of the medical practice or hospital in question. This applies especially to the various requirements regarding effective prion inactivation.

INSTRUMENTS CARE AND HANDLING:

1. Failure to follow the instructions provided in this insert may result in instrument breakage and potential adverse effects on user or patient.
2. Use only instruments specifically designed for use with their associated instruments.
3. Surgical instruments and instrument cases are susceptible to damage from prolonged use, and through misuse or rough handling. The following instructions should be followed to minimize damage:
   - Inspect the instruments and instrument case for damage when purchased and after each use and cleaning. Incompletely cleaned instruments should be re-cleaned, and those that need repair set aside for repair service or return to SpineCraft.
   - Thoroughly clean and dry instruments, whether or not they were used or were inadvertently contacted with blood or saline, to reduce corrosion and potential cross-contamination.
4. Health care personnel should conduct testing in the health care facility to assure that the conditions essential to sterilization can be achieved and that specific configuration of the contents is acceptable for the sterilization process and for the requirements at the point of use.
5. AORN and ANSI/AAMI standards, practices and guidelines should be consulted for detailed guidelines for related to proper care, maintenance and handling of surgical instruments and container systems.

WARNINGS AND PRECAUTIONS:

Following are specific warnings, precautions, and adverse effects. These warnings do not include all adverse effects, which can occur with surgery in general; common surgical risks should be explained to the patient prior to surgery.

1. Instruments must be thoroughly cleaned prior to sterilization. Instruments that are not clean may not be effectively sterilized.
2. Automated cleaning may not be effective. A thorough, manual cleaning process is recommended.
3. When handling sharp instruments, use extreme caution to avoid injury.
4. Unless otherwise indicated, instrument sets are provided non-sterile and must be sterilized prior to use.
5. Do not reuse instruments labeled for single use only. Reuse may adversely affect performance of the instrument.
6. Flash autoclaving is not permissible.
7. Instruments should never be flash-autoclaved in an instrument case.
8. Follow the instructions and warnings issued by the suppliers of any cleaning and equipment used.
9. Do not use heated air or radiation sterilization.
10. All instruments, instrument trays and sterilization containers must not be exposed to temperatures of 140°C (284°F) during reprocessing steps.
11. Avoid exposure to saline and hypochlorite solutions, as these will promote corrosion.
12. Remove excessive soil with a disposable wipe.

CLEANING:

LIMITATIONS AND RESTRICTIONS

- Neutral pH enzymatic and cleaning agents are recommended and preferred for cleaning SpineCraft instruments. Alkaline agents with pH≤12 may be used to clean stainless steel and some polymer instruments in countries where required by law or local ordinance; or where prion diseases such as Transmissible Spongiform Encephalopathy (TSE) and Creutzfeldt-Jakob disease (CJD) are a concern.
- Automated cleaning using a washer/disinfector alone may not be effective for Spinal and Biologics Devices. A thorough, manual or combination manual/automated washer cleaning/disinfection process is recommended. It is critical that alkaline cleaning agents be completely and thoroughly neutralized and rinsed from instruments.
- Instruments must be removed from metal or polymer trays for manual or automated cleaning procedures. Instrument trays, cases, and lids must be cleaned separately. Non-sterile, single-use plate and screw implants are an exception to this rule. Plates and screws may remain in the tray or caddy for reprocessing.
- Use of hard water should be avoided. Softened tap water may be used for initial rinsing. Purified water should be used for final rinsing to eliminate mineral deposits on instruments. One or more of the following processes may be used to purify water: ultra-filter (UF), reverse-osmosis (RO), deionized (DI), or equivalent.

MANUAL CLEANING / DISINFECTION PROCEDURE:

Equipment: ultrasonic cleaner, enzymatic cleaner or detergent solution, clean, soft, lint-free single-use cloth or medical grade compressed air. Follow the instructions for use of enzymatic cleaner or detergent solution. Use the following steps:

Step 1	Use a soft nylon-bristled brush to gently scrub the instrument until all visible soil has been removed. Particular attention must be given to crevices, lumens, mated surfaces, connectors, and other hard-to clean areas. Lumens should be cleaned with a long, narrow, soft nylon bristled brush.
Step 2	Rinse/flush instrument and internal components with an enzyme solution (cleaning solution) while actuating instrument (if applicable). (Validation was performed using Enzol as a cleaner)
Step 3	Scrub instrument with soft bristle brush until visibly clean.
Step 4	Immerse the instrument in cleaning solution.
Step 5	Thoroughly and aggressively flush lumens, holes, and other difficult to reach areas with fresh cleaning solution while actuating instrument (if applicable). Flush lumens with cleaning solution using a syringe in order to remove air bubbles from the instruments lumen.
Step 6	Soak in cleaning solution while sonicating for 15 minutes at 40–50kHz.
Step 7	Rinse instrument in purified water for at least 1 minute or until there is no sign of blood or soil on the instrument or in the rinse stream. Thoroughly and aggressively flush lumens, holes, and other difficult to reach areas.

Step 8	Place prepared disinfecting agents in a sonication unit. Completely submerge instrument in disinfection solution. (Validation was performed using 75% Isopropanol for 10 minutes holding time)
Step 9	Thoroughly and aggressively flush lumens, holes, and other difficult to reach areas with prepared disinfecting agent while actuating instrument (if applicable). Flush lumens with cleaning solution using a syringe in order to remove air bubbles from the instruments lumen.
Step 10	Sonicate for 10 minutes at 40-50kHz submersed in the disinfection solution.
Step 11	Rinse instrument in purified water for at least 1 minute.
Step 12	Remove excess moisture from the instrument with a clean, absorbent, and non-shedding wipe or with medical grade compressed air.

Combination Manual/Automated Washer Cleaning/Disinfection Procedure:

Equipment: Washer/disinfector (SpineCraft recommends the use of an EN ISO 15883-1 and -2 compliant cleaning / disinfection device in combination with a suitable load carrier. Follow the instructions for use of the device manufacturer of the processing machine), enzymatic cleaner or detergent solution. Use the following cycle parameters:

Step 1	Use a soft nylon-bristled brush to gently scrub the instrument until all visible soil has been removed. Particular attention must be given to crevices, lumens, mated surfaces, connectors, and other hard-to clean areas. Lumens should be cleaned with a long, narrow, soft nylon bristled brush
Step 2	Rinse/flush instrument and internal components with an enzyme solution (cleaning solution) while actuating instrument (if applicable). (Validation was performed using Enzol as a cleaner).
Step 3	Scrub instrument with soft bristle brush until visibly clean.
Step 4	Immerse the instrument in cleaning solution.
Step 5	Thoroughly and aggressively flush lumens, holes, and other difficult to reach areas with fresh cleaning solution while actuating instrument (if applicable). Flush lumens with cleaning solution using a syringe in order to remove air bubbles from the instruments lumen.
Step 6	Soak in cleaning solution while sonicating for 15 minutes at 40–50kHz.
Step 7	Rinse instrument in purified water for at least 1 minute or until there is no sign of blood or soil on the instrument or in the rinse stream. Thoroughly and aggressively flush lumens, holes, and other difficult to reach areas.
Step 8	Connect the lumens of the instruments to the washing drains using Luer Locks and suitable load carriers, such as MIS trolleys. Instruments without lumens can be reprocessed in instrument baskets.
Step 9	Pre-cleaning using cold tap water for 2min.
Step 10	Cleaning with 0.5% cleaner at 55 °C for 5min with demineralized water
Step 11	Rinsing with demineralized water for 1min.
Step 12	Thermo-disinfection with demineralized water at least 90 °C for 5 min in the washer/disinfector.
Step 13	Hot Air Dry: (95-100°C / 203°F - 212°F): 10 minutes.
Step 14	If instruments were not fully dry after the automated process, remove excess moisture from instruments with a clean, absorbent, and non-shedding wipe or with medical grade compressed air.

Material stability

When choosing the cleaning agent and disinfectant, make sure that they do not contain the following components:

- Anticorrosive/corrosion inhibitors (triethanolamines are particularly problematic)
- Strong organic, mineral and oxidizing acids
- Relatively strong bases (pH must not exceed 12 for instruments made of metal and 10.5 for aluminium/ferrozell ones; neutral or weakly alkaline cleaning agents are recommended)
- Solvents (such as alcohols and acetone) and gasoline
- Oxidizing agents
- Ammonia
- Chlorine and iodine

NOTE: Certain solutions, such as those that are alkaline-based or contain bleach, glutaraldehyde, or formalin may damage some instruments, particularly soft metal instruments. These solutions should not be used on aluminum or anodized aluminum.

PREPARATION FOR DECONTAMINATION:

If possible, the instruments must be reprocessed in a disassembled or opened state.

LIMITATIONS ON REPROCESSING:

1. Repeated processing has minimal effects on instrument life and function.
2. End of useful life is generally determined by wear or damage due to surgical use.

Carefully inspect instruments between uses to verify proper functioning.
Send damaged instruments to a supplier of authorized repair or refurbishment services.

CLEANING INSPECTION:

1. Carefully inspect each instrument before sterilization or storage to ensure the complete removal of soil from surfaces, lumens, holes, and moveable parts, such as push-buttons/release buttons or hinges.
2. If areas are difficult to inspect visually, check for blood by immersing or flushing the instrument in a 3% hydrogen peroxide solution. If bubbling is observed, blood is present. Rinse instruments for a minimum of 1 minute with warm, 85°F - 104°F (30°C - 40°C), tap water after using hydrogen peroxide solution.
3. Instruments that are still dirty must be cleaned and disinfected again.

STERILIZATION:

ASTM F565 or AORN recommended practices for in-hospital sterilization should be followed for all components. In a properly functioning calibrated FDA cleared steam sterilizer effective sterilization may be achieved using the following parameters:

METHOD	CYCLE	TEMPERATURE	EXPOSURE TIME	DRY TIME
Steam	Pre-Vacuum	270° F (132° C)	4 Minutes	30 Minutes

Wrap: The wrap should be FDA cleared for the proposed cycle specifications.

Or

Reusable Rigid Sterilization Containers:

In order to ensure proper sterilization of SpineCraft Instrument Systems when using the Aesculap reusable rigid sterilization containers, the following FDA-cleared Aesculap reusable rigid container configuration shall be used in a pre-vacuum steam sterilization cycle using the above listed sterilization parameters.
Aesculap JN443 and JN445 rigid containers (with corresponding JK490 lid and Aesculap single use filters US751 or US994.
Ensure that the supplied reusable rigid sterilization container is clean and in proper working order prior to sterilization according to the manufacturer's Instructions for Use.
Aesculap rigid containers JN443 and JN445 have been validated ONLY with Aesculap single use filters US751 or US994. For the appropriate use of the proposed Aesculap SterilContainer System Extra Long Size, please consult the Instructions for Use of the Manufacturer
(https://www.aesculapusa.com/products/instructions-for-use).

NOTE: For the use of the Aesculap SterilContainer System for the sterile processing of ORIO-Ti implants and instruments, the contents of the ORIO-Ti implants and instruments cases must be transferred into an appropriate generic mesh basket and placed within the rigid container, according to all other applicable requirements in the Aesculap rigid container Instructions for Use.

THE STERILIZATION PARAMETERS PROVIDED IN THESE INSTRUCTIONS FOR USE SUPERCEDE THOSE LISTED IN THE AESCULAP INSTRUCTIONS FOR USE. ALL OTHER USAGE, CARE AND MAINTENANCE INSTRUCTIONS SPECIFIED IN AESCULAP DOCUMENTATION REMAIN APPLICABLE.

Monitor every load with a PCD containing a BI and a Class 5 integrating indicator.

NOTE: Because of the many variables involved in sterilization, each medical facility should calibrate and verify the sterilization process (e.g. temperatures, times) used for their equipment.

Instruments should be positioned to allow the sterilant to come into contact with all surfaces. All jointed instruments should be in the open or unlocked position with ratchets not engaged. Instruments composed of more than one part or with sliding pieces or removable parts should be dissembled.

Remove all packaging material prior to sterilization. Only sterile implants and instruments should be used in surgery. Always immediately re-sterilize all implant and instrument kits used in surgery as well as any unused kits that were in the surgical suite.

Individual users must validate the cleaning and autoclaving procedures used on-site, including the on-site validation of the recommended minimum cycle parameters provided in this insert.

INSPECTION / FUNCTIONAL TESTING:

1. Inspect all the instruments after cleaning or cleaning/disinfecting for corrosion, damaged surfaces, chips and impurities and separate out all damaged instruments.
2. Visually inspect instruments and instrument cases for damage and / or wear.
3. Check instruments with long slender features (particularly rotating instruments) for distortion.
4. For cutting features, check edges for distortion/large nicks. Edges should be continuous.
5. Articular surfaces for Trials should be smooth and free of cracks and deep nicks.
6. Check action of moving parts to ensure proper operation.
7. For Hinged Instruments, check for smooth movement of hinge without excessive "play."
8. Check locking mechanisms for action.
9. Ensure dissembled instruments readily assemble with mating components and ensure that mating parts fit together without complications.
10. Check instruments with driving or cutting tip to make sure that they are still in good condition. Inspect ends for distortion, cracks and large nicks
11. Screwdrivers tips should be carefully inspected before and after every surgery. SpineCraft recommends that screwdrivers should be replaced at the following maximum intervals:
    - T15, T20 & T22 Drivers should be replaced every 6 months
    - Polyaxial Screwdrivers should be replaced every 6 months
    - Torque-limiting Handles should be carefully inspected before and after every surgery and should be sent back to SpineCraft for torques setting verification & recalibration at the following frequencies:
    - Every 6 months or,
    - After 200 autoclave cycles or,
    - After approximately 3000 actuations (clicks), whichever comes first.

NOTES:

- **If damage or wear is noted that may compromise the proper function of the instrument or instrument case, do not use and contact SpineCraft's customer service or your distributor immediately for a replacement.**
- **If corrosion is noted, do not use and contact SpineCraft's customer service or your distributor for a replacement.**
- **SpineCraft cannot be responsible for performance of instruments if the above recommended timeframes are not adhered to.**

MAINTENANCE:

Reassemble all disassembled instruments. Subject all instruments to a functional test.
Apply surgical-grade lubricant to instruments with hinged/mating surfaces while in the open position.
Apply surgical-grade lubricant to all moveable parts such as push-buttons, sliding sleeves, closures on tongs, latches, threaded spindles, etc.
Surgical-grade lubricant should not be used other than for the above purpose whenever possible. Only surgical-grade lubricant (white oil) should be used which – taking into consideration the maximum applied sterilization temperature – are approved for steam sterilization and feature proven biocompatibility.

Note: As a rule, no surgical-grade lubricant may be applied to silicone parts.

PACKAGING:

It's recommended to use instrument trays to contain instruments that are provided in sets. Double wrap instruments in accordance with local procedures, using standard wrapping techniques such as those described in the current revision of ANSI/AAMI ST79.

CONTAINMENT AND TRANSPORTATION:

1. Reprocess instruments as soon as is reasonably possible after use.
2. Follow hospital protocols when handling contaminated and bio-hazardous materials.
3. Instruments should be cleaned within 30 minutes after use to minimize the potential of staining, damage, and drying.
4. If cleaning must be delayed, immerse instruments in a compatible detergent solution, spray with an instrument pre-soak solution, or cover instruments with a towel moistened with purified water to prevent drying and encrustation of surgical soil.
5. Place the device in its respective position within the instrument tray.
6. The image of the device is marked in its intended position within the tray.

STORAGE:

Store sterile packaged devices in a manner that provides protection from dust, moisture, insects, vermin, and extremes of temperature and humidity.

LIMITED WARRANTY:

SpineCraft's non-sterile instruments are sold with a limited warranty to the original purchaser against defects in workmanship and materials. Any other express or implied warranties, including warranties of merchantability or fitness, are hereby disclaimed.

If more than 2 years have elapsed between the date of issue/revision of this document, and the date of patient consultation, contact SpineCraft for current information.
For product information or questions pertaining to service or any non-conformities, please contact your local distributor or SpineCraft customer service by calling 1 877-731-SPINE (877-731-7746) or 630-920-7300.

SpineCraft
777 Oakmont Lane - Westmont, IL 60559, USA
TEL + 1 630 920 7300 - FAX + 1 630 920 7310
TF + 1 877 731 SPINE (+ 1 877 731 7746)
www.spinecraft.com