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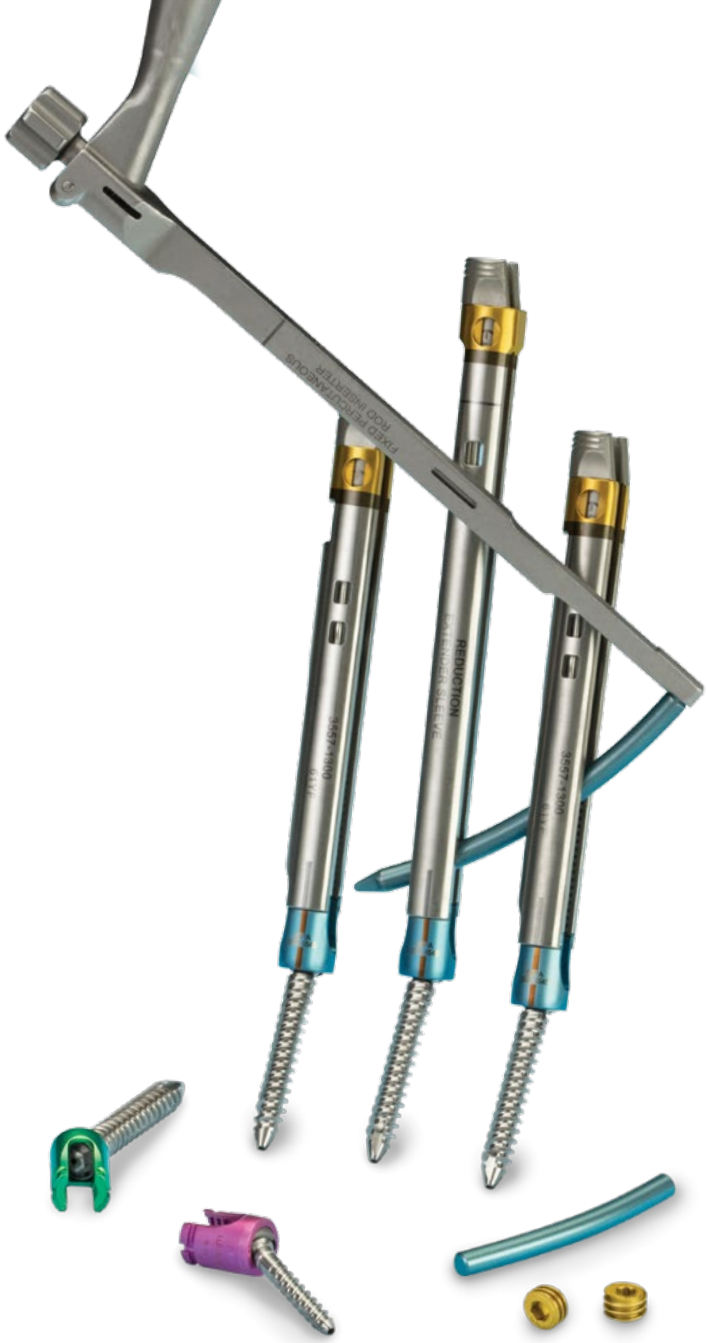

Thoracolumbar Solutions

PathFinder NXT®

Minimally Invasive Pedicle Screw System

Surgical Technique Guide

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Zimmer Biomet Spine does not practice medicine. This technique was developed in conjunction with health care professionals. This document is intended for surgeons and is not intended for laypersons. Each surgeon should exercise his or her own independent judgment in the diagnosis and treatment of an individual patient, and this information does not purport to replace the comprehensive training surgeons have received. As with all surgical procedures, the technique used in each case will depend on the surgeon's medical judgment as the best treatment for each patient. Results will vary based on health, weight, activity and other variables. Not all patients are candidates for this product and/or procedure.

PATIENT POSITIONING AND INCISION PLANNING

- Position the patient prone on a radiolucent table with adequate clearance for a fluoroscopic C-arm.
- Check other hardware for radiolucency.
- Obtain true A/P image for the targeted vertebral body.
- The pedicles should be symmetrical to each other with the spinous process centered between them. The superior endplate should be parallel.

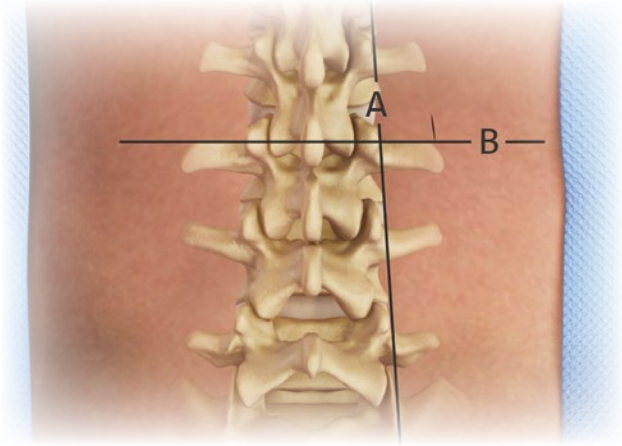


Figure 1
Marking pedicle's superior border

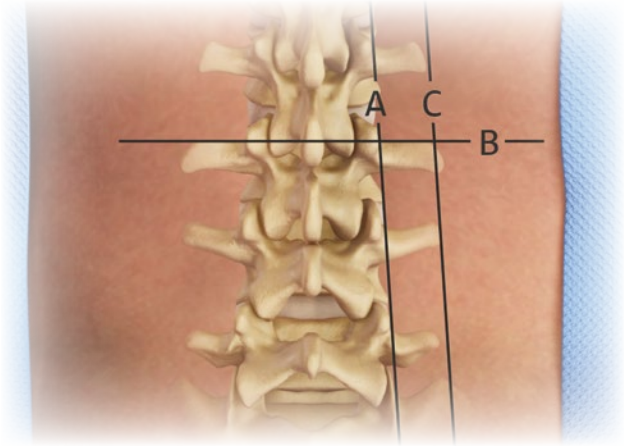


Figure 2
Incision planning

STEP 1

- Fluoroscopically locate the pedicle's lateral border by placing a K-wire in a cephalad/caudal orientation on the skin.
- With a sterile pen, mark a vertical line, line "A," on the skin.
- Position the K-wire perpendicular to "A" and with a slightly superior bias over the pedicle.
- Confirm fluoroscopically and mark with a horizontal line on the skin, line "B."
- Repeat marking line "B" for each vertebral body to be instrumented, first ensuring to reposition the C-arm for proper A/P view of each level.
- The intersection of lines "A" and "B" marks the optimal pedicle entry.
- Due to the depth of soft tissue and muscle, draw a second vertical line 2cm–3cm lateral to line "A." This is line "C," and delineates the incision site.
- An oblique view directly down the pedicle can also be utilized to identify the ideal skin entry point.

  Note: *Greater obesity requires greater lateral distance.*

PEDICLE ACCESS AND APPROACH

Choose a rod insertion technique. If percutaneous rod placement is desired, make a skin incision ~2.0cm over each pedicle. If "mini-open" (modified Wiltse) rod placement is desired, make a 3.0cm incision connecting the pedicles. Incise the skin and the facial layer. Use blunt dissection to locate the pedicle entry point.

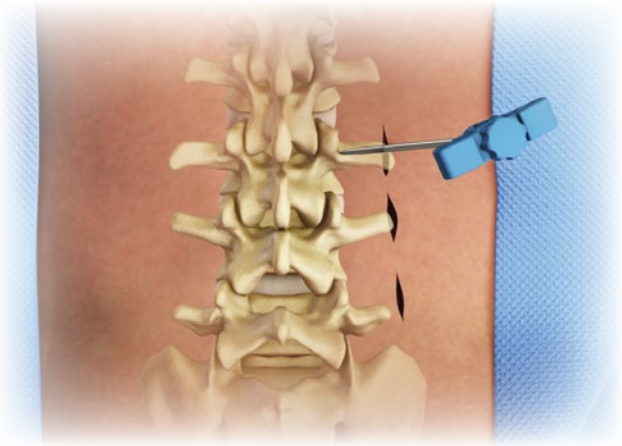


Figure 3
Targeting needle docking

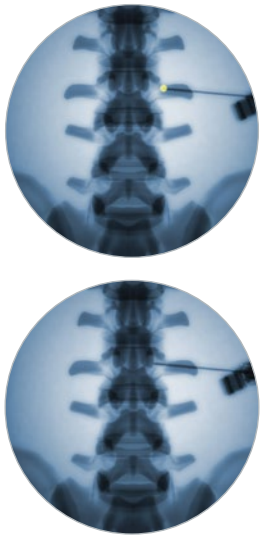


Figure 4
Confirm targeting needle position

STEP 2

- Ensure that the **trocar** is completely seated in the **targeting needle**.
- Pass the tip through the skin starting at the incision and aim towards the intersection of "A" and "B." Care should be taken while targeting to help prevent damage to neurological structures.
- If "steering" of the targeting needle is preferred, a **beveled targeting needle** is available.
- Once the tip of the targeting needle is docked to the pedicle, align the needle with the desired screw trajectory.

  Tip: Dilator A *can be used for blunt dissection prior to inserting targeting needle.*

STEP 3

- Reference an A/P image, confirming the needle's position at the pedicle's lateral, superior margin.
- Tap the targeting needle lightly with a mallet, advancing it into the pedicle. On an A/P image, the targeting needle should approach the middle of the pedicle cylinder when the distal tip of the needle enters the vertebral body.
- Reference both lateral and A/P images, confirming the targeting needle's placement. A direct lateral image will ensure that the needle's trajectory matches the pedicle's anatomy.

Figure 5
Final positioning

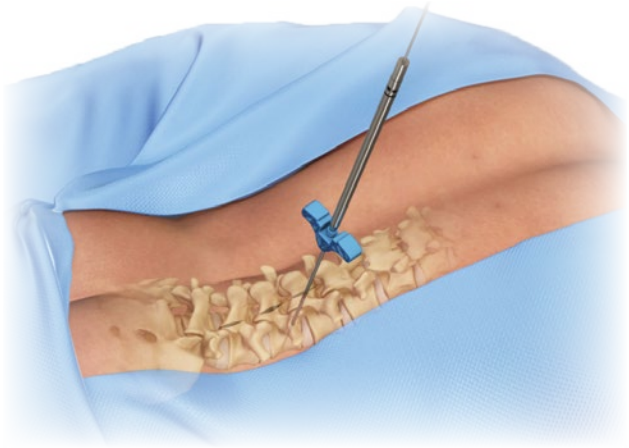


Figure 6
K-wire insertion

STEP 4

- Advance the targeting needle into the vertebral body.

STEP 5

- Remove the needle's inner trocar and insert a **K-wire** through the cannula. To prevent the K-wire from bending during advancement, place dilator A over the K-wire until it rests against the top of the targeting needle. Impact the K-wire with a mallet and monitor its position using fluoroscopy.
- Advance the K-wire to the desired depth beyond the tip of the targeting needle. When the K-wire is in position, remove the targeting needle while holding the K-wire to ensure that it remains in position. To minimize fluoroscopic imaging during K-wire placement, repeat these steps for each K-wire prior to inserting screws.

Note: *Active K-wire management is critical throughout procedure to prevent unintended removal or potentially dangerous anterior advancement of the K-wire. Always ensure that any instrument passed over the K-wire remains collinear to prevent kinking.*

PEDICLE ACCESS AND APPROACH *(continued)*

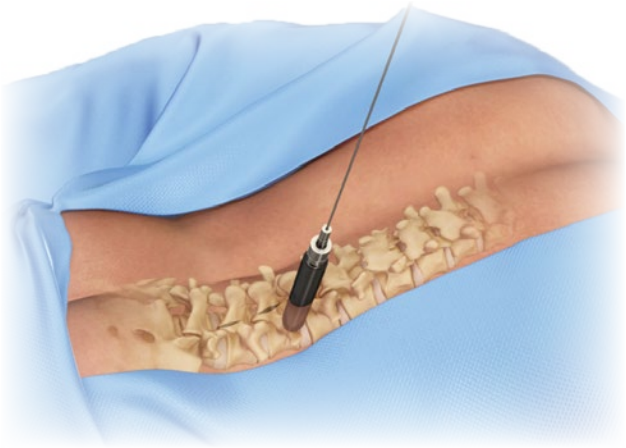


Figure 7
Muscle dilation

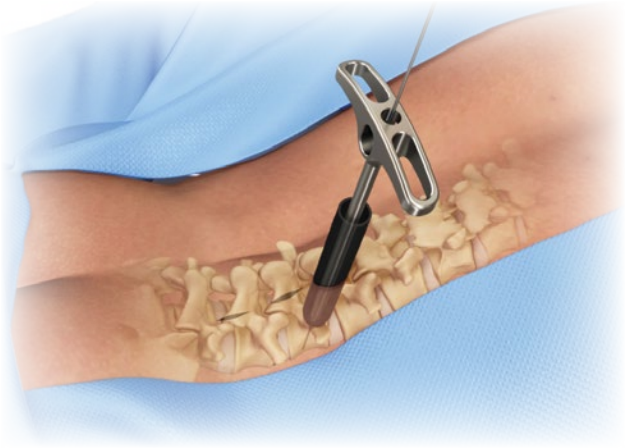


Figure 8
Pedicle preparation

STEP 6

Muscle Dilation

- Create a working channel by dilating the muscle tissue. Place dilator A over the K-wire and insert it through the skin down to the boney anatomy.
- In sequence, place **dilators B and C** over the K-wire to the solid line of the preceding dilator.
- Remove the inner two dilators, leaving radiolucent dilator C in place.

STEP 7

- Pass the **cannulated bone awl** over the K-wire to further perforate the cortical bone.
- Apply axial pressure and rotate until the cortical wall is penetrated. The shaft of the awl has a stop that will limit penetration to 20mm. Remove the awl.

PEDICLE PREPARATION

SCREW SIZE	TAP
ø4.5mm	4.0mm
ø5.5mm	5.0mm
ø6.5mm	6.0mm
ø7.5mm	7.0mm

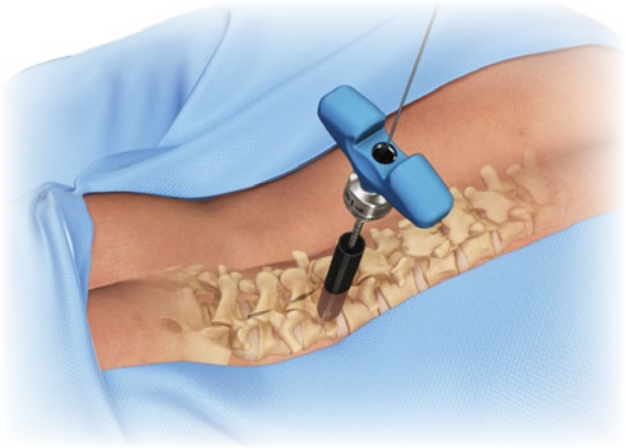


Figure 9
Pedicle tapping

Figure 10
Screw selection

STEP 8

- Select the appropriate tap for the desired screw size based on the chart above.
- Connect the modular **PAT T-handle** to the **tap**.
- Pull the outside collar away from the handle and rotate to the "Forward" position.
- Insert over the K-wire. Advance the tap into the pedicle while regularly verifying fluoroscopically that it does not advance beyond the K-wire's distal tip.

  Note: *Although PathFinder NXT Pedicle Screws have a self-tapping feature, it is recommended to use the correct size tap during pedicle preparation. This is particularly important where larger screws are used, or in cases of hard bone. The PathFinder NXT System tapping instruments include the Pedicle Access Tool (PAT), the* ***cannulated awl-tap****, and the* ***cannulated drill-awl-tap****.*

STEP 9

- Determine the screw length by checking the markings on the tap. Note where depth markings intersect with the top of dilator C.

BONE ASPIRATION AND POSTEROLATERAL FUSION OPTION

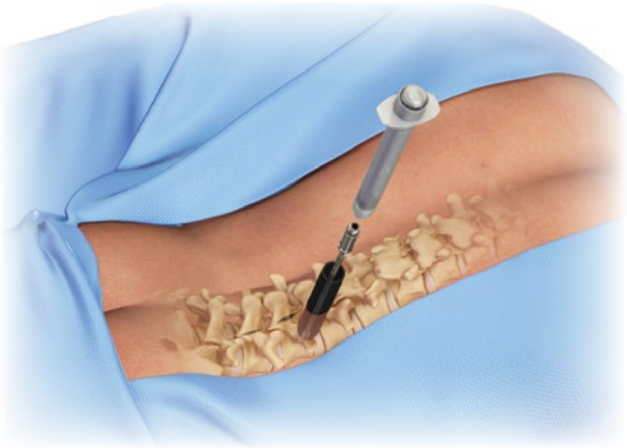


Figure 11
Bone aspiration

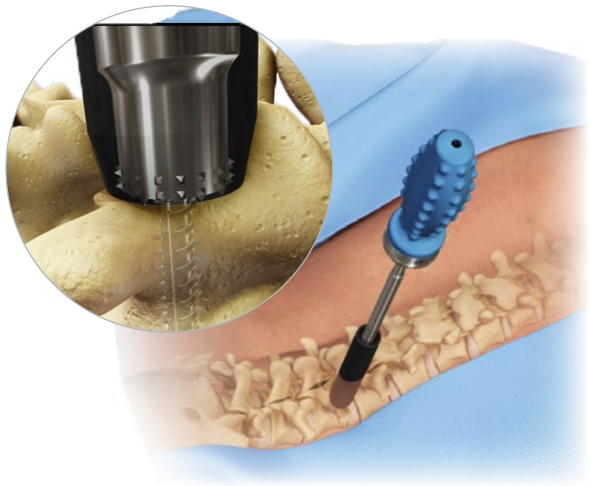


Figure 12
Facet/bone decortication

STEP 10 (IF NECESSARY)

- If desired, use the **PAT aspiration adapter** to remove bone marrow.
- Remove the PAT T-handle and K-wire while leaving the tap inserted in the vertebral body. The adapter slides over the modular connection of the tap and is held in place by an **O-ring**.
- Attach a standard syringe with a **luer connection** and withdraw bone marrow aspirate if desired. Re-insert the K-wire prior to removing tap and inserting screw.

STEP 11 (IF NECESSARY)

- Ensure that the K-wire is removed.
- Connect the **modular handle** to the **inline rasp** and set the handle to the "Forward" position. Slide the assembly over the tap.
- Turn the handle to advance the rasp. Reference the marking indicated on dilator C to decorticate the pedicle to the desired depth. The inline rasp is marked at 5mm and 10mm respectively.
- Autograft or allograft may be placed across decorticated surfaces for posterolateral fusion using the **bone tamp** and **bone funnel**.

  Note: *This system is intended only to provide stabilization during the development of a solid fusion with autograft or allograft. This step is required to develop a solid fusion mass.*

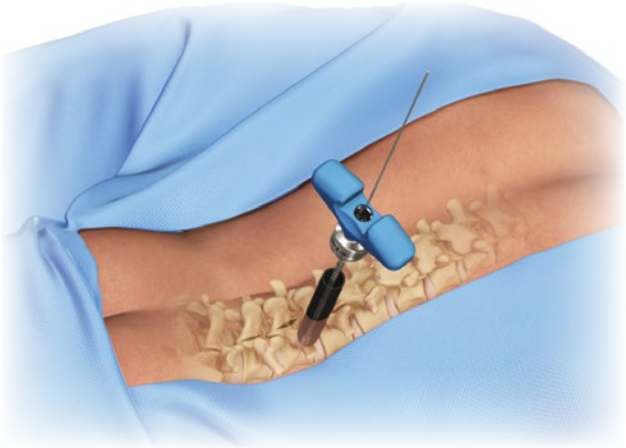


Figure 13
Tap removal

STEP 12

- Set the PAT T-handle to the "non-ratcheting" position and re-attach it to the tap.
- Re-insert the K-wire. Switch the **ratchet handle** to the "Reverse" position to remove the tap.

Tip: *To properly manage the K-wire, remove the* ***modular T-handle*** *before the tap is fully removed. Then, while holding the K-wire, turn the tap counterclockwise until fully removed from the interior of the pedicle.*

EXTENDER SLEEVE ATTACHMENT

Multiple extender sleeve options are available to facilitate pedicle screw insertion. **Reduction sleeves** (gold with thick marked band) are threaded 30mm at the pedicle screw end to offer rod reduction capabilities. **Classic extender sleeves** do not contain this feature. Determine which extender sleeve option and length is appropriate before assembling the pedicle screw.

Note: Short middle extender sleeves *are also available in reduction style and classic options.*

Figure 14
Extender sleeve, lock pin attachment

Figure 15
Lock pin setting

STEP 13

- Insert the **lock pins** into the **extender sleeve** by aligning the interior tracks.
- Engage the elbows in the lock pin in the first window. The extender sleeve is now prepared to load a screw.

MANUAL ATTACHMENT OPTION (FOR C-SHAPED EXTENDER SLEEVES)

Figure 16
Sleeve attachment

Figure 17
Lock pin, set screw seating

STEP 14, OPTION A

- Insert the polyaxial screw head into the distal end of the extender sleeve and rotate 90° such that the laser mark on the polyaxial screw is aligned with the laser mark on the extender sleeve.
- Verify that the lock pins align with the divots in the polyaxial screw. Push lock pins until fully seated. Use the **hex driver** to fully seat the set screw.

  Note: *It is recommended to use tissue dilator C to confirm that the polyaxial screw is properly loaded to the extender sleeve. If tissue dilator C interferes with the polyaxial screw and extender sleeve, reassemble the device.*

SCREW ASSEMBLY TOOL ATTACHMENT OPTION (FOR MIDDLE EXTENDER SLEEVES)

Figure 18
Screw and sleeve insertion

Figure 19
Sleeve attachment

STEP 14, OPTION B

- Place the screw in the **assembly tool** with the laser-marked line on the screw facing outwards. Ensure that the screw is fully seated.
- Rotate the top of the assembly tool clockwise until it stops. Insert the extender sleeve while aligning the laser mark on the assembly tool and extender sleeve.

  Note: *The screw assembly tool must be used to assemble screws to middle extender sleeves.*
- Rotate the top of the assembly tool counterclockwise until it stops. The laser mark on the extender sleeve should align with the laser mark on the screw.

Figure 20
Final assembly

Figure 21
Screw, sleeve removal

- Fully seat the lock pins. Use the hex driver to fully seat the set screw. The **polyaxial screwdriver** can be inserted before removing from the tool if desired.

- Remove by sliding the extender sleeve/screw from the screw assembly tool.
- The screw should not disengage from the extender sleeve if properly assembled.
- Attempt to pull apart the middle sleeve's arms to confirm proper engagement with screw.

IMPLANT PLACEMENT

Figure 22
Screwdriver attachment

STEP 15

- Select the appropriate screwdriver based on extender sleeve selection (gold **reduction screwdriver** or **classic screwdriver**).
- To attach the polyaxial screw to the screwdriver, slide the shaft of the screwdriver down the extender sleeve, align the hex on the screwdriver with the screw shank hex and tighten the assembly by threading the outer shaft with the mating threads.
- Ensure that the screw shank is collinear with the screwdriver and that the distal tip of the screw does not toggle. Attach either the **ratcheting straight handle** or T-handle to the screwdriver and set to the "Forward" position.

  Note: *It is recommended to use Tissue Dilator C to confirm that the polyaxial screw is properly loaded to the extender sleeve. If Tissue Dilator C interferes with the polyaxial screw and extender sleeve, you should reassemble.*

Figure 23
Pedicle screw insertion

STEP 16

- Advance the assembly over the K-wire until the screw docks on the pedicle, then rotate the handle clockwise to advance the screw. Take care to keep the assembly collinear with the K-wire, using fluoroscopy to confirm its depth and trajectory. Advance the screw until it reaches the vertebral body's posterior wall. Remove the K-wire and continue to advance the screw until the head component reaches the pedicle. The **long extender sleeve** has a laser mark to indicate when the screw is approaching full insertion. The **short extender sleeve** will be flush with the top of dilator C when the screw is approaching full insertion.
- Adjust the modular handle to the "Reverse" position and turn the screwdriver one quarter turn counterclockwise to ensure polyaxial function of the screw.
- Remove the screwdriver, modular handle and dilator, leaving only the screw/extender sleeve assembly. Fluoroscopically confirm accurate pedicle targeting and proper screw placement.
- After the screwdriver is removed, the **dorsal height and revision tool** may be used to adjust the position of any implanted pedicle screw.

  Note: *While rotating the handle on the screwdriver to advance the screw into the pedicle, maintain a secure connection by not holding the shaft of the driver.*

MUSCLE PLANE DILATION OPTION (MINI-OPEN TECHNIQUE)

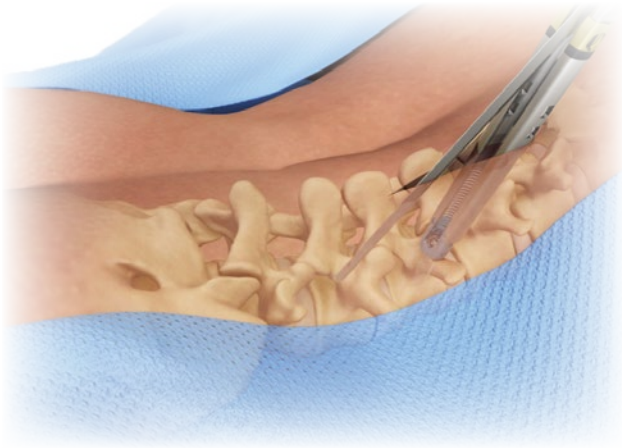


Figure 24
Tissue dilation wedge

STEP 17 (IF NECESSARY)

- Place the **tissue dilation wedge** down the extender sleeve's channel to the screw head.
- Gently split the muscle by wanding the wedge toward the next pedicle, creating a working plane and path for rod placement.
- Face the barb toward any resisting soft tissue or fascia and pull up on the wedge.

ADDITIONAL IMPLANT PLACEMENT

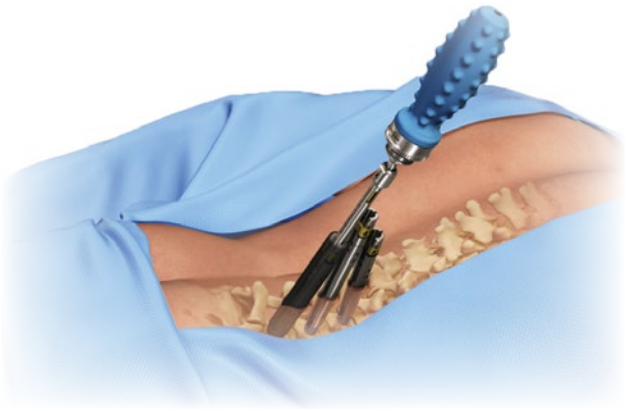


Figure 25
Additional screw placement

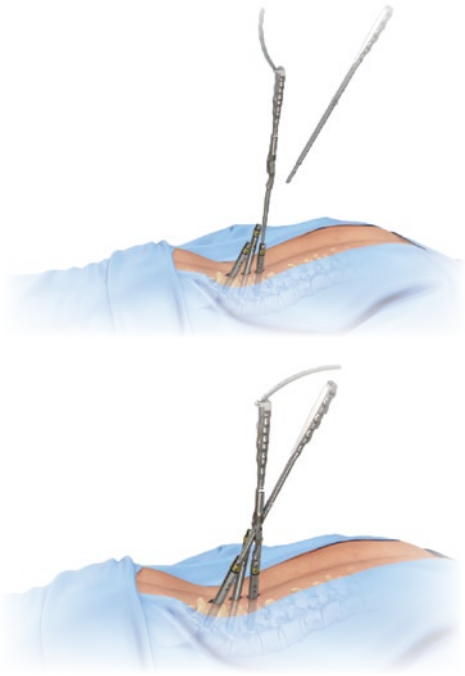


Figure 26
Rod caliper assembly

STEP 18

- Repeat screw placement for all required pedicle screws. If fusing more than one level, **middle extender sleeves** will be required for intermediate screws.
- The screw assembly tool is recommended when attaching a polyaxial screw to a middle extender sleeve. Refer to the extender sleeve attachment section of this manual.

STEP 19

- At least one **C-shaped extender sleeve** is required for use with the **rod calipers**.
- Rotate the C-shaped extender sleeves so the interior tracks face each other. If using a middle extender sleeve, move it laterally to avoid interference with the rod caliper. Slide **arm #1** (caliper with the measurement arm) down the C-shaped extender sleeve until the ball tip rests within the tulip head, as shown.
- With the flats facing each other, insert **arm #2** through arm #1, then fully into the extender sleeve at the opposite end of the construct.
- Ensure that the stop pin of arm #2 is also resting on the pivot slot of arm #1. While holding arm #2, ensure that the ball tips of both arms of the rod calipers are fully seated in the tulip heads slot of arm #1 and that the stop pin of arm #2 is resting on the pivot.

ADDITIONAL IMPLANT PLACEMENT *(continued)*

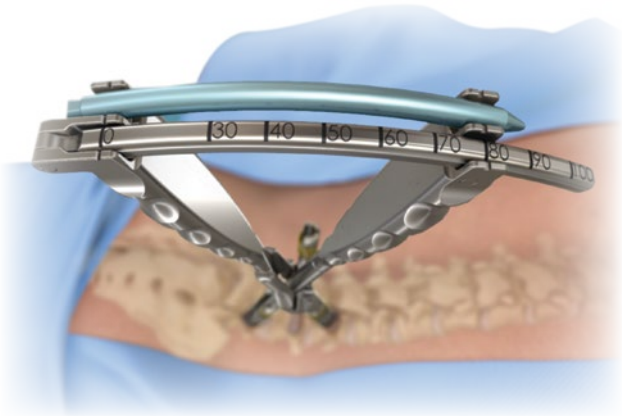


Figure 27
Rod length estimation

STEP 20

- Flip down the measuring rod and determine the rod's length based on the opposing slots on the top of the measuring device.
- Contour the rod if necessary. Do not apply reverse bending to a pre-bent rod, as this may weaken the final construct. Remove calipers.

Note: *Rod length with proper overhang can be confirmed by placing the rod in the saddles located at the top of the caliper assembly. Each saddle represents the pedicle screw's tulip head. The grooves on each saddle represent the center of the tulip head.*

Note: *For 30mm rod selection, confirm proper overhang with fluoroscopy.*

ROD PLACEMENT (MINI-OPEN TECHNIQUE)

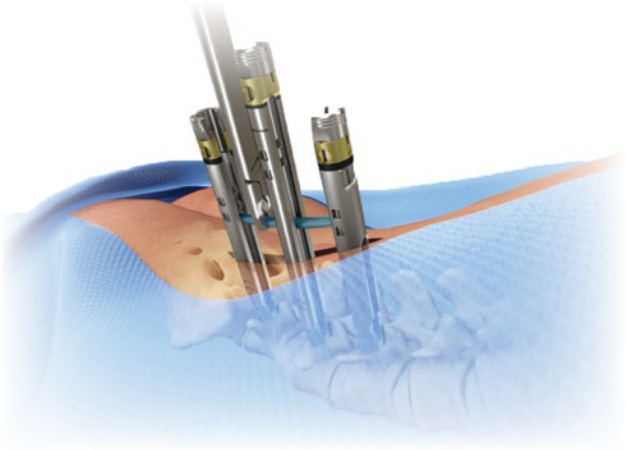


Figure 28
Rod placement

STEP 21, OPTION A

- Using the **fixed grip 5.5mm rod holder**, grasp the rod approximately 2cm from its end. Turn the end C-shaped extender sleeves so that the slots are facing each other.
- Slide the long end of the rod through the middle extender sleeve and angle the short end into the closest C-shaped extender sleeve. The rod holder has an angled slot and end hooks that retain the rod as an additional option to facilitate rod insertion.
- Push down on the rod, guiding it through the extender sleeves until it engages into all extender sleeves and seats firmly into the tulip heads. Fluoroscopically confirm rod position. If necessary, use the **rod pusher** to seat the rod into the screws' tulip heads.
- Manipulate the rod to ensure correct lordotic orientation and proper extension beyond the tulip heads and confirm with fluoroscopy.

ROD PLACEMENT (FIXED ANGLED PERCUTANEOUS TECHNIQUE)

Figure 29
Rod placement

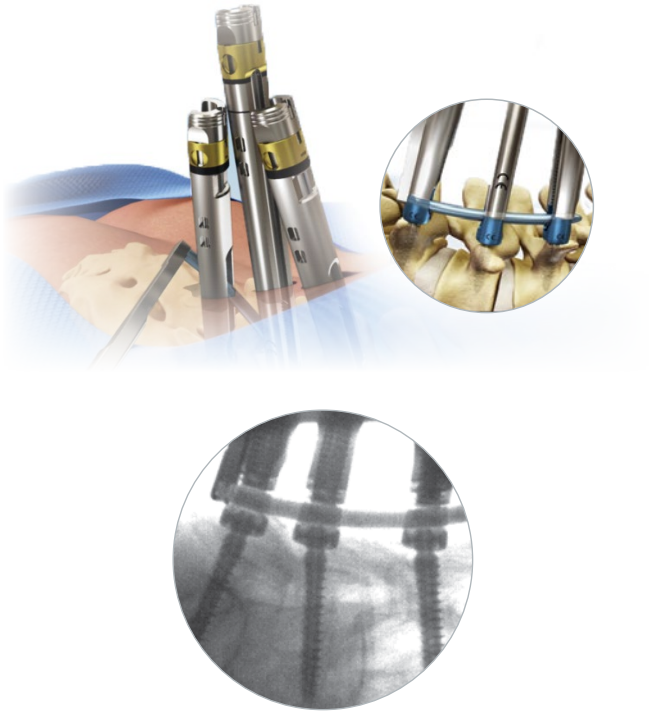


Figure 30a, b
Rod positioning

STEP 21, OPTION B

- Place the square end of the appropriately sized percutaneous rod into the housing with the divot and curvature facing upward. If using a straight rod, the dashed line will face upward.
- Turn the set screw knob located at the top of the rod holder clockwise until it seats fully on the percutaneous rod.

  Note: *The rod is fully seated when the knob is finger tight.*
- Adjust the extender sleeves so their slots are aligned. Rotate the C-shaped extender sleeve that will be used for rod insertion, orienting its slot facing away from the other sleeves. Insert the rod into the out turned extender sleeve and incision, keeping the shaft of the **fixed percutaneous rod holder** lateral to the sleeve. Guide the rod through each extender sleeve while slowly bringing the shaft of the fixed percutaneous rod holder parallel to the C-shaped extender sleeve. Fully seat the rod. Manipulate the rod to ensure proper extension beyond the tulip heads and confirm with fluoroscopy.
- Use the rod pusher, if desired, to assist in rod positioning. The rod is fully seated when the laser marks on the **percutaneous rod inserter** or rod pusher align with the appropriate extender sleeve. Manipulate the rod to ensure proper extension beyond the tulip heads and confirm with fluoroscopy.

CLOSURE TOP PLACEMENT

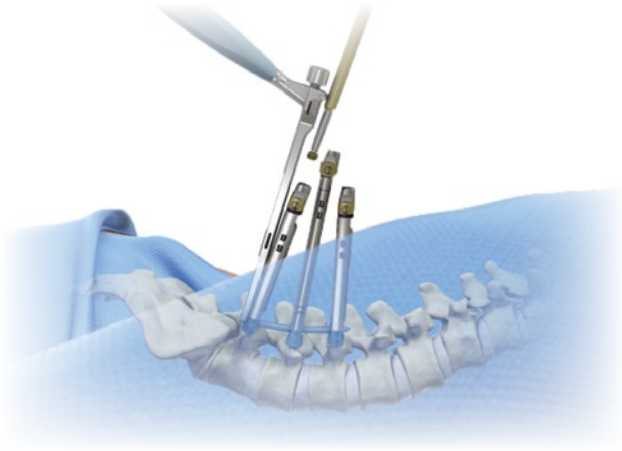


Figure 31
Closure top placement

STEP 22

- Correct rod placement should be checked prior to inserting closure tops. Each extender sleeve should resist attempted axial rotation if the rod is inserted properly.
- Place a **closure top** on the distal end of the **closure top driver**. Slowly rotate the closure top counterclockwise to help avoid cross-threading until it drops and seats in the extender sleeve or screw head.
- Once the closure top is engaged, thread into place to provide a finger-tight provisional lock. The closure top driver has laser marks that serve as a visual aid in seating the closure top. The closure top is seated in the screw head when the mark is flush with the top of the extender sleeve.

  Note: *closure top drivers should be used only to insert and provisionally tighten closure tops. A separate* ***final driver*** *is to be used during final tightening.*

ROD HOLDER REMOVAL

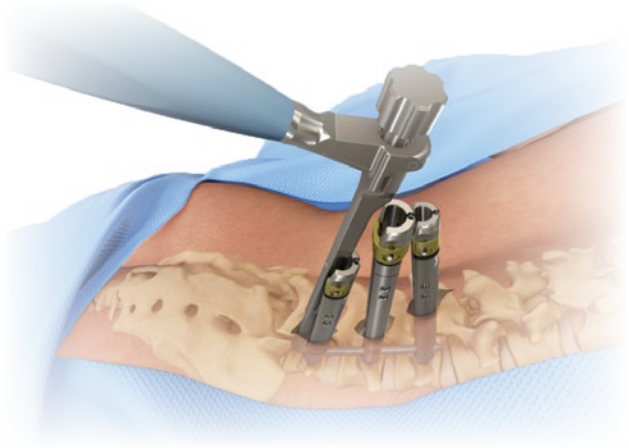


Figure 32
Rod holder removal

STEP 23, OPTION A

Mini-Open Technique

- Ensure that the closure tops are placed before disengaging the rod holder. Remove the rod holder from the incision.

STEP 23, OPTION B

Fixed Angled Percutaneous Technique

- Ensure that at least one closure top is in place before disengaging the rod holder.
- For multi-level constructs, it is recommended that at least two closure tops are inserted and provisionally tightened prior to releasing the rod from the rod holder. This will aid in maintaining correct coronal alignment.
- Disengage the rod from the rod holder by rotating the knob counterclockwise until stopped. The knob should be fully loosened prior to removal. Translate the distal tip of the rod holder away from the screw/rod construct and remove from the incision.

REDUCTION OPTION

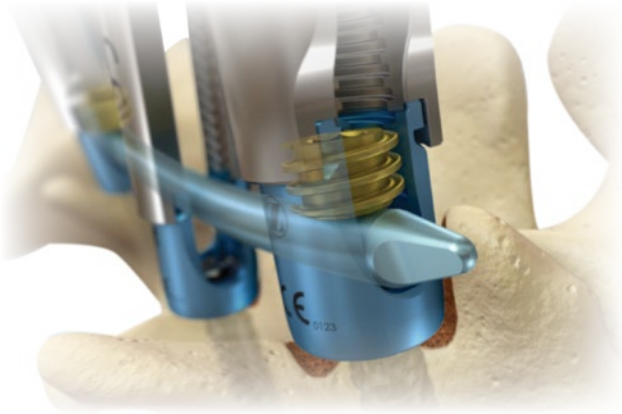


Figure 33
Reduction with extender sleeves

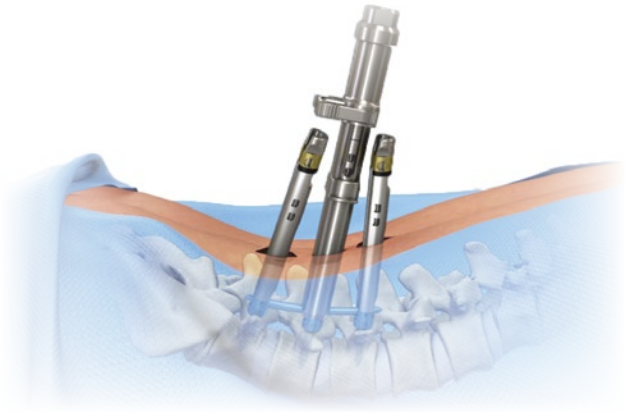


Figure 34
Reduction with power knob

STEP 24, OPTION A (IF NECESSARY)

- Each **reduction extender sleeve** can be used to reduce the rod into position utilizing the closure top and closure top driver. It is recommended that the **counter torque tube** is inserted over the middle extender sleeve for additional stability when utilizing the reduction threads.

STEP 24, OPTION B (IF NECESSARY)

- For reduction up to 30mm, the **power knob reducer** may be used. Ensure that the sleeve on the power knob reducer is in the starting position by turning the square nut counterclockwise until the sleeve is fully retracted.
- Squeeze the tabs on the **reduction knob**, slide it over the extender sleeve, and snap into the dimples on the sleeve to engage.
- Rotate the square knob clockwise to achieve the desired reduction. If extra torque is needed, a **square knob adapter** is available that can be attached to a modular T-handle.
- Monitor fluoroscopically and attach the **counter torque wrench** to the power knob reducer tube; then provisionally tighten the closure top. Remove the power knob reducer by squeezing the tabs and sliding off the extender sleeve.

REDUCTION OPTION *(continued)*

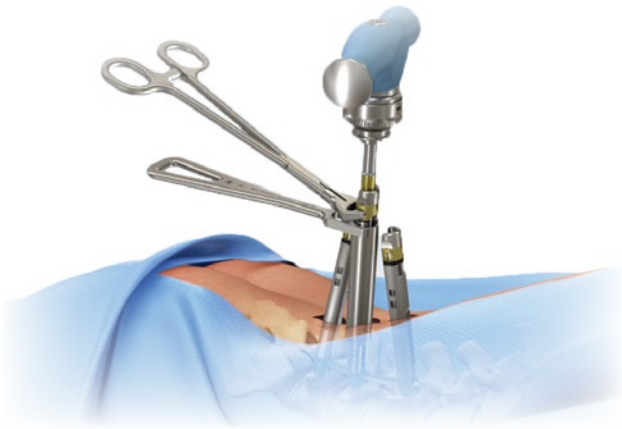


Figure 35
Reduction with reduction forceps

STEP 24, OPTION C (IF NECESSARY)

- Spondylolisthesis can be reduced up to 10mm with the **reduction forceps**.
- Place the **universal counter torque tube** over the extender sleeve. Connect the reduction forceps to the dimples on the proximal end of the sleeve.
- Gradually press down on the forceps' handles until the instrument is parallel with the handle of the counter torque tube; then provisionally tighten the closure top. Monitor fluoroscopically.

COMPRESSION OPTION

Figure 36
Prepare compressor

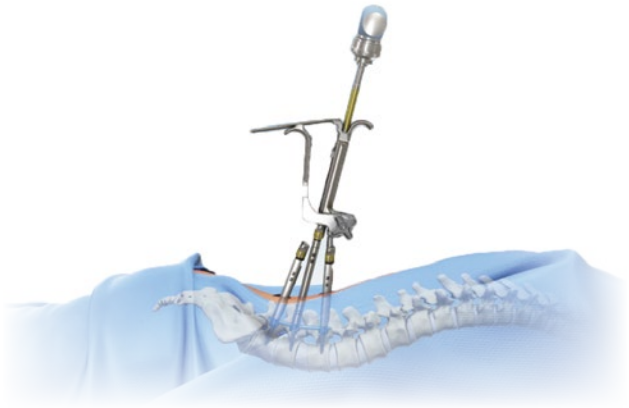


Figure 37
Insert compressor

STEP 25 (IF NECESSARY)

- Provisionally lock one of the closure tops in order to create a fixed point from which to compress.
- Loosen the knob on the **compressor** and slide the closure top driver with a **modular T-handle driver** into the handle of the compressor.
- Dilator C can be placed over the middle extender sleeve for stability. Insert the fixed stem of the compressor into the sleeve with the provisionally locked closure top.
- Insert the closure top driver into the sleeve of the screw to be compressed.
- Loosen the closure top.
- Engage the ratchet on the compressor's handle.

COMPRESSION OPTION *(continued)*

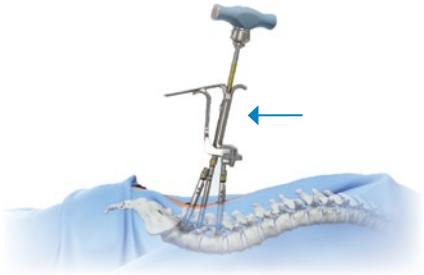


Figure 38
Set pivot point

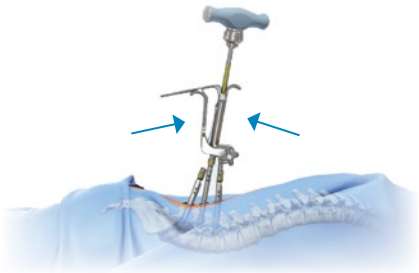


Figure 39
Compression

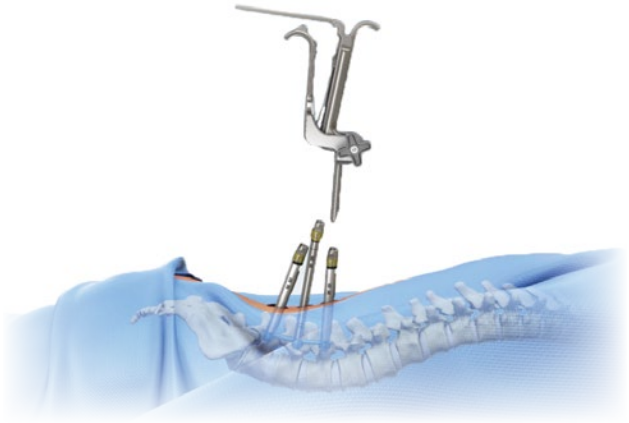


Figure 40
Compressor removal

STEP 25 *(continued)*

- Slightly squeeze the handle of the compressor until the extender sleeves are approximately parallel. While the ratchet holds this gap, lock the knob on the side of the compressor until tight.
- Squeeze the handles until the desired amount of compression is achieved. Confirm with fluoroscopy. Provisionally tighten the closure top to hold the construct.

  Note: *Final tightening of the closure tops should not be performed through the compressor or* ***distractor****.*
- Loosen the knob on the compressor, release the ratchet, and remove the closure top driver and compressor from the extender sleeves.

DISTRACTION OPTION

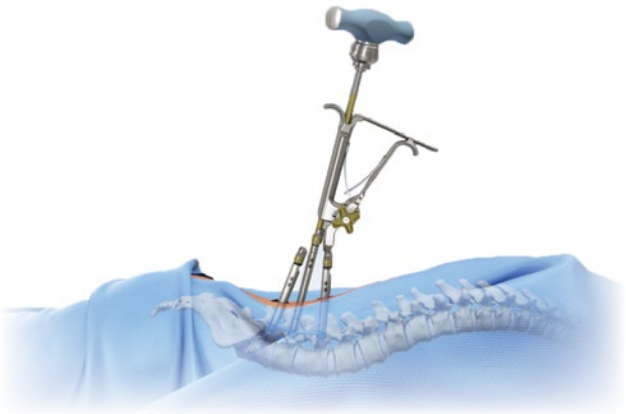


Figure 41
Distraction

STEP 26 (IF NECESSARY)

- Use the closure top driver with a modular T-handle to provisionally tighten the closure top to create a fixed point from which to distract. Turn the distractor's knob counterclockwise to loosen the slide. Insert the fixed stem of the distractor into the extender sleeve of the screw that was provisionally tightened. Insert the closure top driver assembly through the handle into the adjacent level's sleeve and loosen the closure top.
- Engage the ratchet on the distractor handle and lock the knob by rotating it clockwise. Dilator C can be placed over the middle extender sleeve for stability. Squeeze the handles until the desired distraction is achieved. Confirm with fluoroscopy. Provisionally tighten the adjacent level closure top with the closure top driver assembly. Loosen the knob on the distractor, release the ratchet, and remove the closure top driver and the distractor from the extender sleeves.

  Note: *Distractor features a gold knob.*

FINAL TIGHTENING, REVISION AND REMOVAL

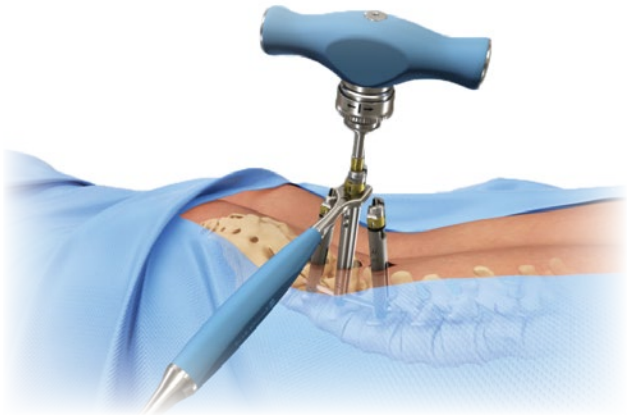


Figure 42
Final tightening

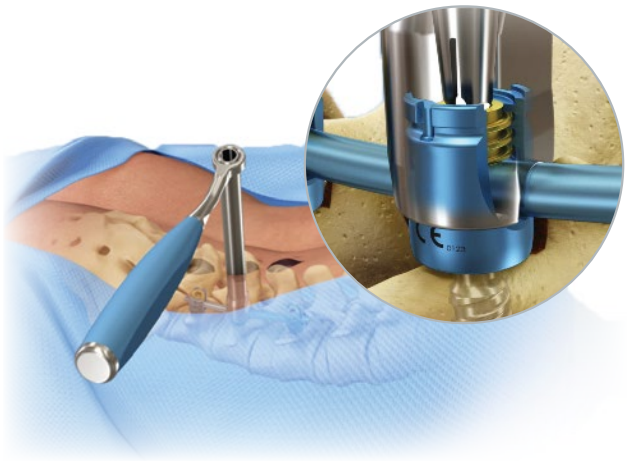


Figure 43
Dissection/Location

STEP 27

- Fluoroscopically confirm rod and screw position. Place the counter torque wrench on the extender sleeve. Using the final driver (long or short) assembled to a modular T-handle (set to the "Forward" position), firmly tighten the closure top, while applying a downward force to the driver handle.
- Apply counter torque while turning the T-handle—do not over-rotate the wrench. One "click" indicates sufficient tightening. Repeat for each screw.
- Remove each extender sleeve by first loosening the set screw, removing the lock pins then rotating the sleeve 90° and lifting it from the pedicle screw.

  Note: Transverse counter torque reduction tubes *and universal counter torque reduction tubes are available.*

STEP 28

- Dissect to each pedicle screw. Using the **axis finder**, locate the rod and the outer diameter of the polyaxial screw's head.

Figure 44
Closure top removal

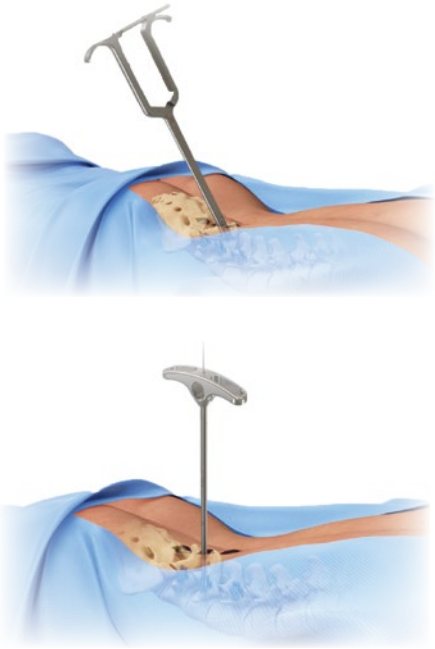


Figure 45
Rod and screw removal

STEP 29

- Attach the closure top driver with a modular handle to unlock and remove each closure top. Repeat for each screw.

STEP 30

- Remove each rod from the construct with the **fixed grip 5.5mm rod holder**.
- Expose the cannulation of each pedicle screw. Insert a K-wire into the cannulation. Guide the revision tool over the K-wire and engage it with the pedicle screw's hex.
- Remove pedicle screw and K-wire as a unit. Repeat for each pedicle screw.

APPENDIX

PEDICLE ACCESS TOOL (PAT)

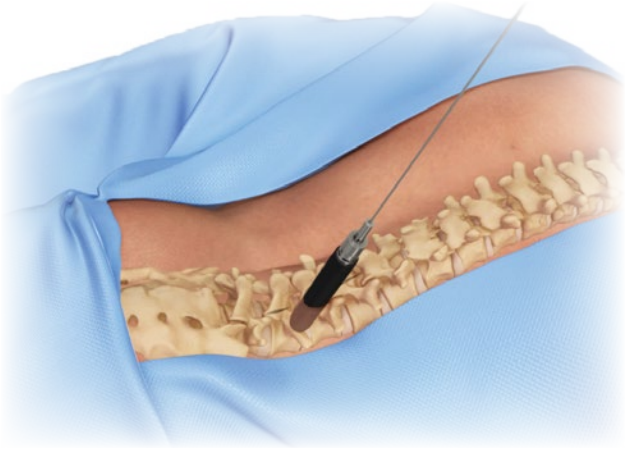
This tool enables users to combine the functionality of a targeting needle, a **bone awl** and a **bone tap** into one efficient step (prior to K-wire insertion). Use of the PathFinder NXT PAT is intended to reduce fluoroscopy time and enables the use of advanced posterolateral fusion instrumentation such as rasps.

Select an appropriate tap based on the desired screw size.

SCREW SIZE	TAP
ø4.5mm	4.0mm
ø5.5mm	5.0mm
ø6.5mm	6.0mm
ø7.5mm	7.0mm

PAT ASSEMBLY

- Attach the **PAT handle** to the **PAT tap** and set to the "Forward" position. Insert the **PAT trocar** into the assembly.
- Thread the trocar into the PAT handle counterclockwise until the desired length (2mm–8mm) extends from the PAT tap's tip.



MUSCLE DILATION

- Plan incision in the usual manner (see Incision Planning section of this manual).
- To shield the tissue from the tap's threads during insertion, sequentially dilate starting with dilator A; then place dilator B over dilator A; finally place dilator C over dilator B and insert until flush with the solid line on dilator B. Remove dilator A and B leaving dilator C in place. Insert the PAT assembly through dilator C.
- **The PAT sheath** can be used prior to serial dilation. With the PAT tap in place, remove the PAT sheath and proceed with dilator B and dilator C.

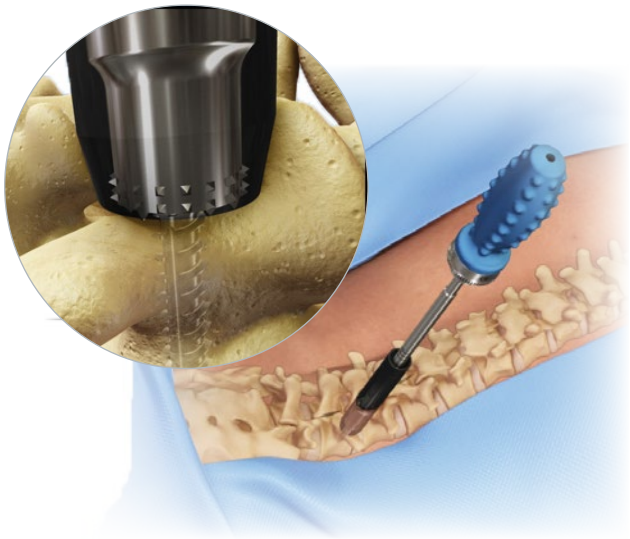
APPENDIX *(continued)*

PEDICLE TARGETING

- Create a reference A/P image, confirm the tap's position at the pedicle's lateral, superior margin.
- Tap lightly with a mallet, advancing the PAT trocar into the pedicle. On an A/P image, the tip should approach the middle of the pedicle cylinder when the tap is one third of the way into the vertebral body. Reference both lateral and A/P images, confirming the PAT's placement. A direct lateral image will ensure that the needle's trajectory matches the pedicle's anatomy. Advance the PAT to desired depth within the vertebral body using the ratcheting handle. Determine the screw length by checking the markings on the tap. Note where the depth markings intersect with the top of the dilator C.

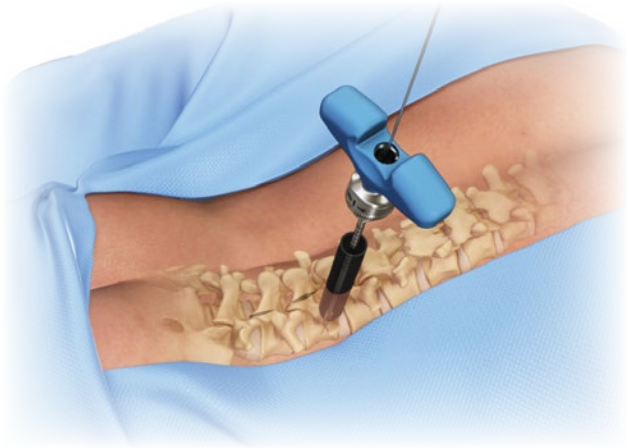
BONE ASPIRATION OPTION (IF NECESSARY)

- If desired, use the PAT aspiration adapter to remove bone marrow. Unthread the PAT trocar from the handle clockwise, then remove the **PAT T-handle** while leaving the PAT inserted in the vertebral body.
- The adapter slides over the modular connection of the **PAT shaft** and is held in place by an O-ring. Attach a standard syringe with a Luer connection and withdraw bone marrow aspirate if desired.



POSTEROLATERAL FUSION OPTION

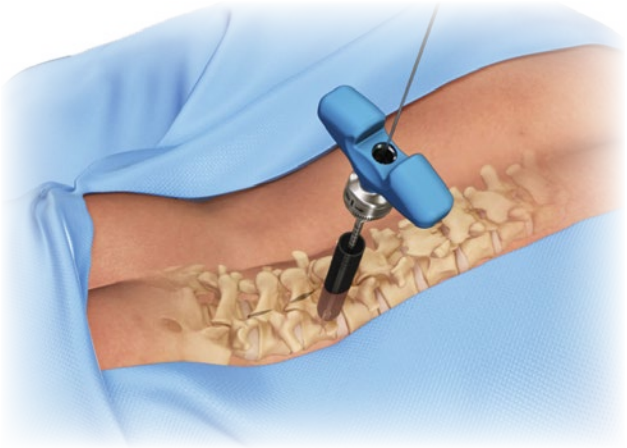
- Connect the modular handle to the inline rasp and set to the "Forward" position. Slide the assembly over the PAT. Turn the handle to advance the inline rasp. Reference the marking indicated on dilator C to decorticate the pedicle to the desired depth.



K-WIRE INSERTION OPTION

- Insert a K-wire through the PAT tap while monitoring under fluoroscopy. To prevent the K-wire from bending, place dilator A over the K-wire until it rests against the top of the PAT tap. Impact the K-wire with a mallet and monitor its position using fluoroscopy. Advance the K-wire to the desired depth beyond the tip of the PAT tap.

APPENDIX *(continued)*

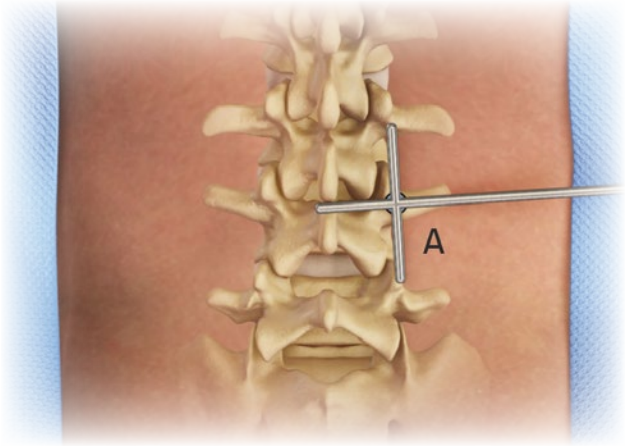


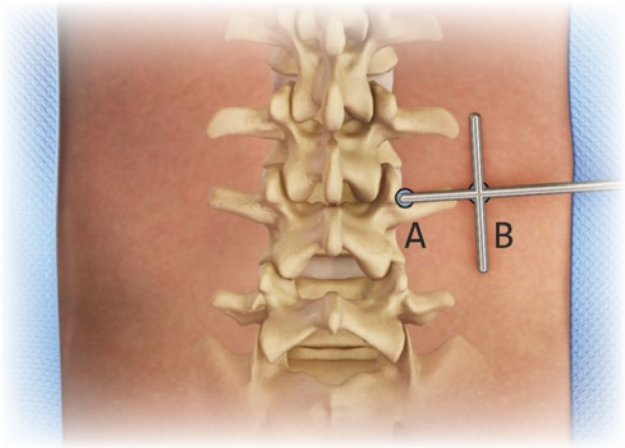
PAT REMOVAL

- Set the PAT T-handle to the “non-ratcheting” position then re-attach it to the tap.
- Switch the ratcheting handle to the "Reverse" position to remove the tap.

  Tip: *To properly manage the K-wire, remove the modular T-handle before the tap is fully removed. Then, while holding the K-wire, turn the tap counterclockwise until it’s fully removed from the interior of the pedicle.*

INCISION PLANNING GUIDE





APPROACH PLANNING

- Mark the pedicle entry point and skin incision point using the **targeted incision guide template** and fluoroscopy. Fluoroscopically locate the pedicle's lateral and superior borders, then position the cross on the guide template with a slightly superior bias over the pedicle. With a sterile pen, mark the pedicle point "A" on the skin.

INCISION PLANNING

- Each prong on the targeted incision guide template is 3cm long for reference. To account for the depth of soft tissue and muscle, position the edge of the guide on point "A". With a sterile pen, mark skin incision point "B" on the skin 2cm–3cm lateral to point "A." An oblique view directly down the pedicle can also be used to identify the ideal skin entry point.
- Refer to the Approach and Pedicle Access section of this manual for completing incisions.

Note: *The larger the patient, the greater the lateral distance.*

KIT CONTENTS

Screw Consumables
Kit Number: 3500-0001-PL

DESCRIPTION	PART NUMBER
Cannulated Polyaxial Screw, ø4.5mm × 30mm	3505-4530
Cannulated Polyaxial Screw, ø4.5mm × 35mm	3505-4535
Cannulated Polyaxial Screw, ø4.5mm × 40mm	3505-4540
Cannulated Polyaxial Screw, ø4.5mm × 45mm	3505-4545
Cannulated Polyaxial Screw, ø5.5mm × 30mm	3505-5530
Cannulated Polyaxial Screw, ø5.5mm × 35mm	3505-5535
Cannulated Polyaxial Screw, ø5.5mm × 40mm	3505-5540
Cannulated Polyaxial Screw, ø5.5mm × 45mm	3505-5545
Cannulated Polyaxial Screw, ø5.5mm × 50mm	3505-5550
Cannulated Polyaxial Screw, ø5.5mm × 55mm	3505-5555
Cannulated Polyaxial Screw, ø5.5mm × 60mm	3505-5560
Cannulated Polyaxial Screw, ø6.5mm × 30mm	3505-6530
Cannulated Polyaxial Screw, ø6.5mm × 35mm	3505-6535
Cannulated Polyaxial Screw, ø6.5mm × 40mm	3505-6540
Cannulated Polyaxial Screw, ø6.5mm × 45mm	3505-6545
Cannulated Polyaxial Screw, ø6.5mm × 50mm	3505-6550
Cannulated Polyaxial Screw, ø6.5mm × 55mm	3505-6555
Cannulated Polyaxial Screw, ø6.5mm × 60mm	3505-6560
Cannulated Polyaxial Screw, ø7.5mm × 30mm	3505-7530
Cannulated Polyaxial Screw, ø7.5mm × 35mm	3505-7535
Cannulated Polyaxial Screw, ø7.5mm × 40mm	3505-7540
Cannulated Polyaxial Screw, ø7.5mm × 45mm	3505-7545
Cannulated Polyaxial Screw, ø7.5mm × 50mm	3505-7550
Cannulated Polyaxial Screw, ø7.5mm × 55mm	3505-7555
Cannulated Polyaxial Screw, ø7.5mm × 60mm	3505-7560
Screw Assembly Tool	3559-3

Rod Consumables
Kit Number: 3500-0003-PL

DESCRIPTION	PART NUMBER
Pre-bent Rod, ø5.5mm × 30mm*	3313-030
Pre-bent Rod, ø5.5mm × 35mm*	3313-035
Pre-bent Rod, ø5.5mm × 40mm	3313-040
Pre-bent Rod, ø5.5mm × 45mm	3313-045
Pre-bent Rod, ø5.5mm × 50mm	3313-050
Pre-bent Rod, ø5.5mm × 55mm	3313-055
Pre-bent Rod, ø5.5mm × 60mm	3313-060
Pre-bent Rod, ø5.5mm × 65mm	3313-065
Pre-bent Rod, ø5.5mm × 70mm	3313-070
Pre-bent Rod, ø5.5mm × 75mm	3313-075
Pre-bent Rod, ø5.5mm × 80mm	3313-080
Pre-bent Rod, ø5.5mm × 85mm*	3313-085
Pre-bent Rod, ø5.5mm × 90mm*	3313-090
Pre-bent Rod, ø5.5mm × 95mm*	3313-095
Pre-bent Rod, ø5.5mm × 100mm*	3313-100
Percutaneous Pre-bent Rod, ø5.5mm × 30mm	3510-030
Percutaneous Pre-bent Rod, ø5.5mm × 35mm	3510-035
Percutaneous Pre-bent Rod, ø5.5mm × 40mm	3510-040
Percutaneous Pre-bent Rod, ø5.5mm × 45mm	3510-045
Percutaneous Pre-bent Rod, ø5.5mm × 50mm	3510-050
Percutaneous Pre-bent Rod, ø5.5mm × 55mm	3510-055
Percutaneous Pre-bent Rod, ø5.5mm × 60mm	3510-060
Percutaneous Pre-bent Rod, ø5.5mm × 65mm	3510-065
Percutaneous Pre-bent Rod, ø5.5mm × 70mm	3510-070
Percutaneous Pre-bent Rod, ø5.5mm × 75mm	3510-075
Percutaneous Pre-bent Rod, ø5.5mm × 80mm	3510-080
Percutaneous Pre-bent Rod, ø5.5mm × 85mm	3510-085
Percutaneous Pre-bent Rod, ø5.5mm × 90mm	3510-090
Percutaneous Pre-bent Rod, ø5.5mm × 95mm	3510-095
Percutaneous Pre-bent Rod, ø5.5mm × 100mm	3510-100
Percutaneous Straight Rod, ø5.5mm × 100mm	3512-100
Percutaneous Straight Rod, ø5.5mm × 110mm *	3512-110
Percutaneous Straight Rod, ø5.5mm × 120mm	3512-120
Percutaneous Straight Rod, ø5.5mm × 130mm*	3512-130
Percutaneous Straight Rod, ø5.5mm × 140mm	3512-140
Percutaneous Straight Rod, ø5.5mm × 150mm*	3512-150
Percutaneous Straight Rod, ø5.5mm × 160mm	3512-160
Percutaneous Straight Rod, ø5.5mm × 170mm*	3512-170
Percutaneous Straight Rod, ø5.5mm × 180mm	3512-180
Percutaneous Straight Rod, ø5.5mm × 190mm*	3512-190

*Non standard, order separately

Rod Consumables *(continued)*
Kit Number: 3500-0003-PL

DESCRIPTION	PART NUMBER
Percutaneous Straight Rod, ø5.5mm × 200mm	3512-200
Percutaneous Straight Rod, ø5.5mm × 210mm*	3512-210
Percutaneous Straight Rod, ø5.5mm × 220mm	3512-220
Percutaneous Straight Rod, ø5.5mm × 230mm*	3512-230
Percutaneous Straight Rod, ø5.5mm × 240mm	3512-240
Straight Rod, Blue, Ti, ø5.5mm × 100mm	3311-100
Straight Rod, Blue, Ti, ø5.5mm × 510mm	3311-510
Open Implant Closure Top, 5.5mm, Ti	3301-1
Closure Top Caddy	3590-05

Standard Instrument Tray I
Kit Number: 3500-0002-PL-A

DESCRIPTION	PART NUMBER
K-wire, Trocar Tip	1001-18
Nitinol K-wire, Trocar Tip	3550-19
Targeting Needle with Luer Lock*	1913-010
Tissue Dilator C, Radiolucent*	3551-300
Pedicle Access Tool Sheath*	3554-100
Pedicle Access Tool Aspiration Adapter*	3555-300
Pedicle Access Tool Trocar	3555-010
Nitinol K-wire Dispenser (Bottom)	3550-100
Stainless Steel K-wire Dispenser, Top	1011-18
Pedicle Access Tool Handle*	3555-020
Bone Funnel*	2760-1
Bone Tamp, 6mm or 10mm	2755-1
Extender Sleeve, Reduction Style, Long	3557-2300
C-Shaped Sleeve Locker, Long	3557-0001
C-Shaped Sleeve Locker, Short	3557-1001
C-Shaped Extender Sleeve, Reduction Style, Short	3557-1300
Cannulated T-handle Bone Awl III*	1155-4
Pedicle Access Tool Inline Rasp*	3556-010
Tissue Dilator A, Bottom*	3551-010
Tissue Dilator B, Top*	3551-020
5/64" Male Hex Screwdriver II	1161-2
Pedicle Access Tool Tap, 4.0mm*	3554-040
Pedicle Access Tool Tap, 5.0mm*	3554-050
Pedicle Access Tool Tap, 6.0mm*	3554-060
Pedicle Access Tool Tap, 7.0mm*	3554-070

*Cannulated item

Standard Instrument Tray II
Kit Number: 3500-0002-PL-B

DESCRIPTION	PART NUMBER
Percutaneous Rod Calipers—Part 1	3561-1
Percutaneous Rod Calipers—Part 2	3561-2
Fixed Percutaneous Rod Holder (Bottom)	3573-1
Closure Top Capture Driver, Short	3566-2
Reduction Screwdriver*	3558-2
Fixed Grip 5.5mm Rod Holder	3562-1
Counter Torque Wrench	3568-3
Modular T-handle 1/4" Square, 3-Position, Ratcheting Torque Limiting 90 in-lbs (10.2 N-m)*	3572-1
Palm Handle, 1/4" (6.35mm) Square, Non-ratcheting*	3564-200
Modular Straight Handle, 1/4" Square, 3-Position Ratcheting*	3571-1
Final Driver Short	3570-1

Manipulation Tray I
Kit Number: 3500-0002-PL-C

DESCRIPTION	PART NUMBER
Power Knob Rod Reducer, Long*	3567-20
Power Knob Rod Reducer, Short*	3567-10
Square Knob Adapter	3567-3
Final Driver Long	3570-2
Distractor*	3570-10
Compressor*	3569-1
Percutaneous Rod Pusher	3565-1
Closure Top Capture Driver, Long	3566-1

KIT CONTENTS *(continued)*

Manipulation Tray II
Kit Number: 3500-0002-PL-D

DESCRIPTION	PART NUMBER
Tissue Dilation Wedge	3560-1
Targeting Incision Guide Template, Bottom	3559-2
Cannulated Dorsal Height and Revision Tool, Top	3558-50
French Rod Bender	872-1
Modular T-handle 1/4" Square, Non-ratcheting Torque Limiting 90 in-lbs (10.2 N-m)	3572-2
Transverse Counter Torque Tube, Short	3568-10
Transverse Counter Torque Tube, Long	3568-20

Revision Consumables and Instruments
Kit Number: 07.01487.401

DESCRIPTION	PART NUMBER
K-wire, Trocar tip	1001-18
Ratcheting T-handle II	852-2
K-wire Dispenser	1011-18
Axis Finder, PathFinder*	1159-5
PathFinder Bone Screw Adjuster*	1160-3
Universal Driver	2155-1
Cannulated Dorsal Height and Revision Driver*	3558-50
Fixed Grip 5.5mm Rod Holder	3562-1
Closure Top Capture Driver, Short	3566-2
Axis Finder, PathFinder NXT*	3568-4

*Cannulated item

Classic Tray
Kit Number: 07.01487.402

DESCRIPTION	PART NUMBER
Targeting Needle with Beveled Edge*	1913-020
Rod Holder	1163-1
Sleeve Based Forceps Reducer	1167-3
Rod Caliper II	1169-2
Cannulated Awl-Tap, 4.0mm*	3552-140
Cannulated Awl-Tap, 5.0mm*	3552-150
Cannulated Awl-Tap, 6.0mm*	3552-160
Cannulated Awl-Tap, 7.0mm*	3552-170
Cannulated Drill-Awl-Tap, 4.0mm*	3552-240
Cannulated Drill-Awl-Tap, 5.0mm*	3552-250
Cannulated Drill-Awl-Tap, 6.0mm*	3552-260
Cannulated Drill-Awl-Tap, 7.0mm*	3552-270
C-Shaped Sleeve Locker, Long	3557-0001
C-Shaped Extender Sleeve, Short, Non-Reduction	3557-1000
C-Shaped Sleeve Locker, Short	3557-1001
Extender Sleeve, Long, Non-Reduction	3557-2000
Extender Sleeve, Short, Non-Reduction	3557-3000
Reduction Style Extender Sleeve, Short	3557-3300
Classic Screwdriver*	3558-1
Universal Counter Torque Tube, Short*	3568-30
Universal Counter Torque Tube, Long*	3568-40

SUPPORTING INSTRUMENTATION AND IMPLANTS

Polyaxial Screws	PART NUMBER
4.5mm–7.5mm	3505-4530–3505-7560

Percutaneous Straight Rods	PART NUMBER
100mm–240mm	3512-100–3512-240

Straight Standard Rods	PART NUMBER
100mm	3311-100
510mm	3311-510

Pedicle Access Tool	PART NUMBER
Pedicle Access Tool Handle	3555-020
PAT Taps, 4.0mm–7.0mm	3554-040–3554-070

Pedicle Access Tool Trocar	PART NUMBER
	3555-010

Percutaneous Pre-bent Rods	PART NUMBER
30mm–100mm	3510-030–3510-100

Pre-bent Standard Rod	PART NUMBER
40mm–80mm	3313-040–3313-080

Closure Top	PART NUMBER
	3301-1

Inline Rasp	PART NUMBER
	3556-010

Bone Aspirator	PART NUMBER
	3555-300

SUPPORTING INSTRUMENTATION AND IMPLANTS *(continued)*

Extender Sleeve, Reduction Style, Long	PART NUMBER
Extender Sleeve, Reduction Style, Long	3557-2300
Lock Pin, Long	3557-0001

C-Shaped Extender Sleeve, Reduction Style, Short	PART NUMBER
C-Shaped Extender Sleeve, Reduction Style, Short	3557-1300
Lock Pin, Short	3557-1001

Extender Sleeve, Reduction Style, Long	PART NUMBER
Percutaneous Rod Caliper—1	3561-1
Percutaneous Rod Caliper—2	3561-2

Fixed Percutaneous Rod Holder	PART NUMBER
	3573-1

Final Drivers	PART NUMBER
Final Driver, Short	3570-1
Final Driver, Long	3570-2

Closure Top Drivers	PART NUMBER
Closure Top Driver, Long	3566-1
Closure Top Driver, Short	3566-2

IMPORTANT INFORMATION ON THE PATHFINDER NXT MINIMALLY INVASIVE PEDICLE SCREW SYSTEM

Device Description

The PathFinder NXT System consists of polyaxial cannulated screws and rods and is intended to provide temporary stabilization following surgery to fuse the spine. A range of spinal rod lengths included with the PathFinder NXT System allows the surgeon to place polyaxial pedicle screws through an open or mini-open procedure.

The PathFinder NXT System is designed to aid in the surgical correction of several types of spinal conditions. This system is intended only to provide stabilization during the development of a solid fusion with autograft or allograft. These implants are intended to be removed after the development of a solid fusion mass.

Refer to the PathFinder NXT Minimally Invasive Pedicle Screw System Indications for Use for complete information on the NXT System.

The PathFinder NXT System only allows the placement of 5.5mm titanium rods.

Components of the PathFinder NXT System are offered in titanium alloy Ti6Al4V ELI (ASTM F-136) and unalloyed Titanium (ASTM F67).

The PathFinder NXT instrumentation system is comprised of instruments and perforated instrument cases that are generally comprised of aluminum, stainless steel, Nitinol, and/or polymeric materials.

Indications

1. When intended for pedicle screw fixation from T1–S1, the PathFinder NXT System is intended to be used with 5.5mm rods 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 thoracic, lumbar and sacral spine: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis), tumor, and failed previous fusion.
2. As a pedicle screw system placed between L3 and S1, the indications for the PathFinder NXT System, used with 5.5mm rods, include Grade 3 or Grade 4 spondylolisthesis, when utilizing autograft or allograft, when affixed to the posterior lumbosacral spine, and is intended to be removed after solid fusion is established.

Contraindications

1. Disease conditions which have been shown to be safely and predictably managed without the use of internal fixation devices are relative contraindications to the use of these devices.
2. Active systemic infection or infection localized to the site of the proposed implantation are contraindications to implantation.
3. Severe osteoporosis is a relative contraindication because it may prevent adequate fixation of spinal anchors and thus preclude the use of this or any other posterior spinal instrumentation system.
4. Any entity or condition that totally precludes the possibility of fusion, i.e., cancer, kidney dialysis or osteopenia, is a relative contraindication. Other relative contraindications include obesity, pregnancy, certain degenerative disease, and foreign body sensitivity. In addition, the patient's occupation or activity level or mental capacity may be relative contraindications to this surgery. Specifically, some patients may, because of their occupation or lifestyle, or because of conditions such as mental illness, alcoholism or drug abuse, place undue stresses on the implant.

See also the WARNINGS, PRECAUTIONS and ADVERSE EFFECTS sections of this manual.

Warnings

Following are specific warnings, precautions, and adverse effects that should be understood by the surgeon and explained to the patient. These warnings do not include all adverse effects that can occur with surgery in general, but are important considerations particular to metallic internal fixation devices. General surgical risks should be explained to the patient prior to surgery.

1. IN THE U.S.A., THIS PRODUCT HAS LABELING LIMITATIONS.
2. 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 secondary to degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor and failed previous fusion (pseudarthrosis). The safety and effectiveness of these devices for any other conditions is unknown.

IMPORTANT INFORMATION ON THE PATHFINDER NXT MINIMALLY INVASIVE PEDICLE SCREW SYSTEM *(continued)*

3. BENEFIT OF SPINAL FUSIONS UTILIZING ANY PEDICLE SCREW FIXATION SYSTEM HAS NOT BEEN ADEQUATELY ESTABLISHED IN PATIENTS WITH STABLE SPINES. Potential risks identified with the use of this device system, which may require additional surgery, include:
   a. Device component fracture.
   b. Loss of fixation.
   c. Non-union.
   d. Fracture of the vertebra.
   e. Neurological injury.
   f. Vascular or visceral injury
4. CORRECT SELECTION OF THE IMPLANT IS EXTREMELY IMPORTANT. The potential for satisfactory fixation is increased by the selection of the proper size, shape and design of the implant. While proper selection can help minimize risks, the size and shape of human bones present limitations on the size, shape, and strength of implants. Metallic internal fixation devices cannot withstand activity levels equal to those placed on normal healthy bone. No implant can be expected to withstand indefinitely the unsupported stress of full weight bearing.
5. IMPLANTS CAN BREAK WHEN SUBJECTED TO THE INCREASED LOADING ASSOCIATED WITH DELAYED UNION OR NON-UNION. Internal fixation appliances are load sharing devices which are used to obtain an alignment until normal healing occurs. If healing is delayed or does not occur, the implant may eventually break due to metal fatigue. The degree or success of union, loads produced by weight bearing, and activity levels will, among other conditions, dictate the longevity of the implant. Notches, scratches or bending of the implant during the course of surgery may also contribute to early failure. Patients should be fully informed of the risks of implant failure.
6. MIXING METALS CAN CAUSE CORROSION. There are many forms of corrosion damage and several of these occur on metals surgically implanted in humans. General or uniform corrosion is present on all implanted metals and alloys. The rate of corrosive attack on metal implant devices is usually very low due to the presence of passive surface films. Dissimilar metals in contact, such as titanium and stainless steel, accelerate the corrosion process of stainless steel and more rapid attack occurs. The presence of corrosion compounds released into the body system will also increase. Internal fixation devices, such as rods, hooks, wires, etc. which come into contact with other metal objects, must be made from like or compatible metals.
7. PATIENT SELECTION. In selecting patients for internal fixation devices, the following factors can be of extreme importance to the eventual success of the procedure:
   a. The patient's weight. An overweight or obese patient can produce loads on the device that can lead to failure of the appliance and the operation.
   b. The patient's occupation or activity. If the patient is involved in an occupation or activity that includes substantial walking, running, lifting or muscle strain, the resultant forces can cause failure of the device.
   c. A condition of senility, mental illness, alcoholism, or drug abuse. These conditions, among others, may cause the patient to ignore certain necessary limitations and precautions in the use of the appliance, leading to implant failure or other complications.
   d. Certain degenerative diseases. In some cases, the progression of degenerative disease may be so advanced at the time of implantation that it may substantially decrease the expected useful life of the appliance. For such cases, orthopaedic devices can only be considered a delaying technique or temporary relief.
   e. Foreign body sensitivity. Where material sensitivity is suspected, appropriate tests should be made prior to material selection or implantation.
   f. Smoking. Patients who smoke have been observed to experience higher rates of pseudarthrosis following surgical procedures where bone graft is used.

Precautions

1. THE IMPLANTATION OF PEDICLE SCREW SPINAL SYSTEMS SHOULD BE PERFORMED ONLY BY EXPERIENCED 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.
2. SURGEONS SHOULD HAVE KNOWLEDGE OF HOW TO TARGET PEDICLE SCREWS USING FLUOROSCOPY AND K-WIRE WHEN UTILIZING A MINI-OPEN OR PERCUTANEOUS SURGICAL TECHNIQUE.
3. SURGICAL IMPLANTS MUST NEVER BE REUSED. An explanted metal implant should never be re-implanted. Even though the device appears undamaged, it may have small defects and internal stress patterns that may lead to early breakage.

4. CORRECT HANDLING OF THE IMPLANT IS EXTREMELY IMPORTANT. Contouring of the metal implants should only be performed with proper equipment. The operating surgeon should avoid any notching, scratching or reverse bending of the devices when contouring. Alterations will produce defects in surface finish and internal stresses which may become the focal point for eventual breakage of the implant. Bending of screws will significantly decrease fatigue life and may cause failure.
5. REMOVAL OF THE IMPLANT AFTER HEALING. Metallic implants can loosen, fracture, corrode, migrate, possibly increase the risk of infection, cause pain, or stress shield bone even after healing, particularly in young, active patients. The surgeon should carefully weigh the risk versus benefits when deciding whether to remove the implant. Implant removal should be followed by adequate postoperative management to avoid refracture. If the patient is older and has a low activity level, the surgeon may choose not to remove the implant thus eliminating the risk involved with a second surgery.
6. ADEQUATELY INSTRUCT THE PATIENT. Postoperative care and the patient's ability and willingness to follow instructions are one of the most important aspects of successful bone healing. The patient must be made aware of the limitations of the implant and that physical activity and full weight bearing have been implicated in bending or fracture. The patient should understand that a metallic implant is not as strong as normal, healthy bone and will fracture if excessive demands are placed on it in the absence of complete bone healing. An active, debilitated, or demented patient who cannot properly use weight-supporting devices may be particularly at risk during postoperative rehabilitation.
7. "The DEVICE has not been evaluated for safety and compatibility in the MR environment. The DEVICE has not been tested for heating or migration in the MR environment."
8. All implants and some instruments are intended for single-use only; refer to the product label to determine if the instrument is single use only. Single-use devices should not be re-used. Possible risks associated with re-use of single-use devices include:
   - Mechanical malfunction.
   - Transmission of infectious agents.

NOTES

Disclaimer: *This document is intended exclusively for physicians and is not intended for laypersons. Information on the products and procedures contained in this document is of a general nature and does not represent and does not constitute medical advice or recommendations. Because this information does not purport to constitute any diagnostic or therapeutic statement with regard to any individual medical case, each patient must be examined and advised individually, and this document does not replace the need for such examination and/or advice in whole or in part.*

Caution: *Federal (USA) law restricts this device to sale by or on the order of a physician. Rx Only. Please refer to the package inserts for important product information, including, but not limited to, indications, contraindications, warnings, precautions, adverse effects, and patient counseling information.*

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