PathFinder NXT®

Minimally Invasive Pedicle Screw System

zimmer

Surgical Technique

Solutions by the people of Zimmer Spine.

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Intuitive procedure. MIS advantage.
From the people of Zimmer Spine.

Whether accessing the surgical site through an MIS approach for fusion or helping restore the patient's natural anatomy, the *PathFinder NXT* System offers both the new and experienced MIS surgeon powerful options and repeatable performance. While preserving the option of a traditional Wiltse approach, the *PathFinder NXT* System also gives the surgeon true percutaneous rod placement and posterolateral fusion options. This next-generation system builds on the successful legacy of the original *PathFinder*® Minimally Invasive Pedicle Screw System to increase the efficiency of an MIS procedure benefiting the surgeon, patient, and OR staff.

Once again, redefining innovation with simplicity. From the people of Zimmer Spine.

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Device Description

The Zimmer Spine *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 *PathFinder NXT* System.

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

Indications/Contraindications

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.

PathFinder NXT Implants

Polyaxial Screw (4.5 – 7.5mm)
3505-4530 to 3505-7560

Percutaneous Pre-Bent Rod (30 - 100mm)
3510-030 to 3510-100

Percutaneous Straight Rod (100 - 240mm)
3512-100 to 3512-240

Pre-Bent Standard Rod (40 – 80mm)
3313-040 to 3313-080

Straight Standard Rod (100, 510mm)
3311-100, 3311-510

Closure Top
3301-1

Key Instruments

Pedicle Access Tool (PAT)

PAT Handle
3555-020

PAT Tap (4.0 – 7.0mm)
3554-040 to 3554-070

When used without the Trocar, the PAT Tool allows for traditional bone tapping.

PAT Trocar
3555-010

When used with the Trocar, the PAT instrument facilitates the combined functions of a Targeting Needle, Bone Awl and Tap.

Standard Instrumentation

Bone Aspirator
3555-300

Used over the PAT Tap and in conjunction with a Luer lock syringe. Facilitates removal of bone marrow from the vertebral body.

Inline Rasp
3556-010

Used over the PAT Tap to decorticate the pedicle.

Extender Sleeve, Reduction Style - Long
3557-2300

Lock Pin - Long
3557-0001

Sleeves attach to polyaxial screws and facilitate rod delivery and construct manipulation. Built-in reduction threads enable fine-tuned rod seating and 30mm of vertebral body reduction. The long Sleeve is utilized as a Middle Sleeve for multi-level procedures.

C-Shaped Extender Sleeve, Reduction Style - Short
3557-1300

Lock Pin - Short
3557-1001

Sleeves attach to polyaxial screws and facilitate rod delivery and construct manipulation. Built-in reduction threads enable fine-tuned rod seating and 30mm of vertebral body reduction. The short, C-Shaped Extender Sleeve is utilized on the most superior and inferior pedicles, for either single-level or multi-level procedures.

Percutaneous Rod Caliper
3561-10, 3561-2

Provides 35mm-100mm rod measurement for either a percutaneous or a mini-open approach.

Fixed Percutaneous Rod Holder
3573-10

Facilitates percutaneous rod delivery.

Final Driver – Short
3570-1

Final Driver - Long
3570 -2

The Final Driver provides the final locking torque to the closure top. Short and long drivers are provided. Shaft markings provide indications of closure top position when fully seated.

Closure Top Driver – Short
3566-2

Closure Top Driver – Long
3566-1

Captured driver with indicators for provisional closure top seating. Knurled ends allow for initial insertion without the use of a T-Handle.

Surgical Technique

Incision Planning

Step 1

Patient Positioning

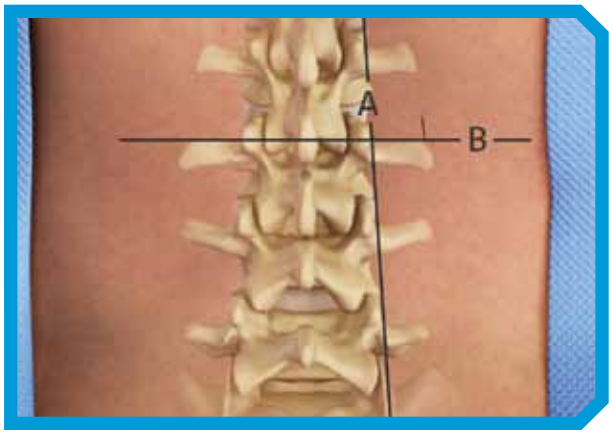
Position the patient prone on a radiolucent table with adequate clearance for a fluoroscopic C-arm. Check other hardware for radiolucency.

Step 2

Pedicle Location

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.

Step 3

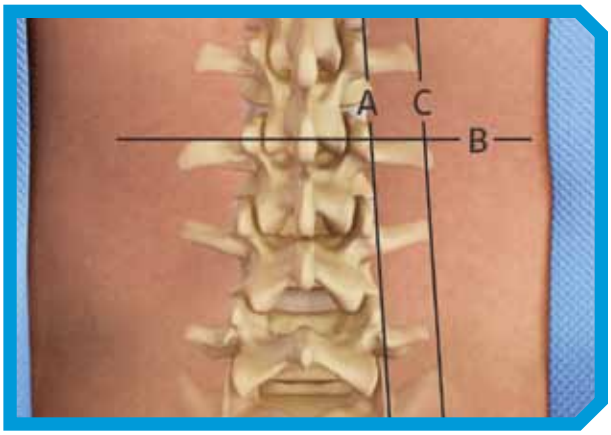


Marking Pedicle's Superior Border

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.

Step 4



Incision Planning

Due to the depth of soft tissue and muscle, draw a second vertical line 2 - 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.**

Approach & Pedicle Access

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.

Step 5

Targeting Needle Docking

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 6

Confirm Targeting Needle Position

Reference an A/P image, confirming the needle's position at the pedicle's lateral, superior margin.

Step 7

Confirm Targeting Needle Position

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.

Step 8

Final Positioning

Advance the Targeting Needle into the vertebral body.

Step 9

K-Wire Insertion

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.

Step 10

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 11

Pedicle Preparation

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.

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 Preparation

Select the appropriate Tap for the desired screw size based on the chart below.

Screw Size	Tap
4.5mm	4.0mm
5.5mm	5.0mm
6.5mm	6.0mm
7.5mm	7.0mm

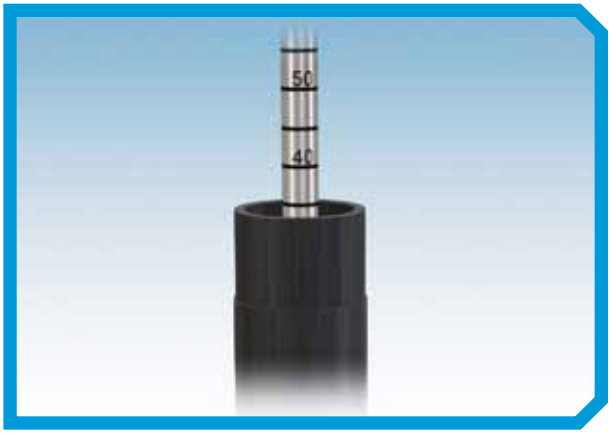
Step 12

Pedicle Tapping

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 13



Screw Selection

Determine the screw length by checking the markings on the Tap. Note where depth markings intersect with the top of Dilator C.

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.

Bone Aspiration Option

Step 14

Bone Aspiration (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.

Posterolateral Fusion Option

Step 15

Facet / Bone Decortication (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.**

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.

Step 16

Tap Removal

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.**

Step 17a

Extender Sleeve, Lock Pin Attachment

Insert the Lock Pins into the Extender Sleeve by aligning the interior tracks.

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.

Step 17b

Lock Pin Setting

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 Use with C-Shaped Extender Sleeves)

Step 18 *Option 1a*

Sleeve Attachment

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.

Step 18 *Option 1b*

Lock Pin, Set Screw Seating

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.

Screw Assembly Tool Attachment Option (For Use with Middle Extender Sleeves)

Step 18 *Option 2a*

Screw Insertion

Place the screw in the Assembly Tool with the laser–marked line on the screw facing outwards. Ensure that the screw is fully seated.

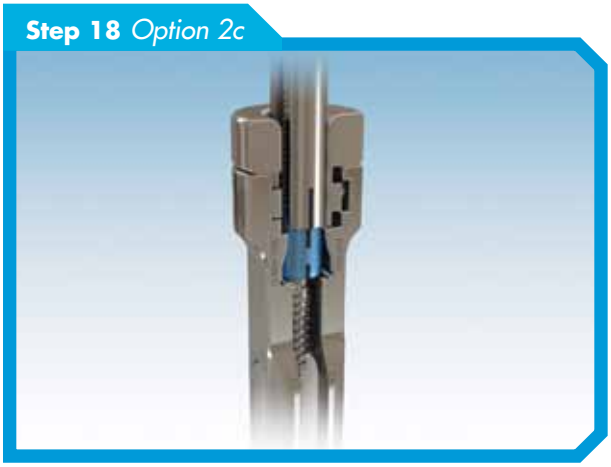
Note: *The Screw Assembly Tool must be used to assemble screws to Middle Extender Sleeves.*

Step 18 *Option 2b*

Sleeve Insertion

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.

Step 18 *Option 2c*



Sleeve Attachment

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.

Note: *The Screw Assembly Tool must be used to assemble screws to Middle Extender Sleeves.*

Step 18 *Option 2d*

Final Assembly

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.

Step 18 *Option 2e*

Screw, Sleeve Removal

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

Step 19

Screwdriver Attachment

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.

Step 20

Pedicle Screw Insertion

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.**

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.

Muscle Plane Dilation Option (Mini-Open Technique)

Step 21

Tissue Dilation Wedge (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

Step 22

Additional Screw Placement

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.

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.

Step 23a

Rod Caliper Assembly

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.

Step 23b

Rod Caliper Assembly

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.

Step 24

Rod Length Estimation

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)

Step 25 *Option 1*

Rod Placement

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 additional options 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)

Step 25 *Option 2a*

Rod Placement

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.

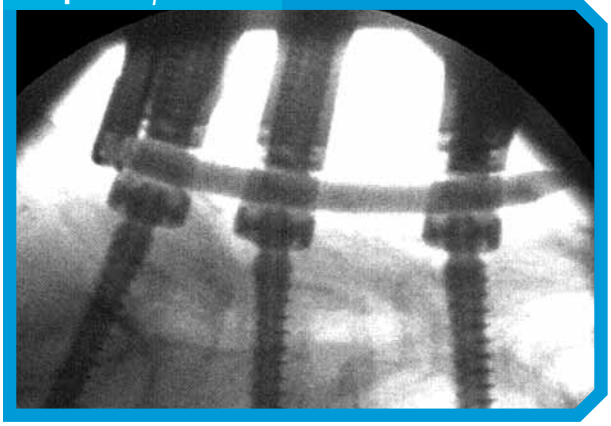
Note: ***The rod is fully seated when the knob is finger tight.***

Step 25 *Option 2b*

Rod Insertion

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.

Step 25 *Option 2c*



Rod Positioning

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

Step 26

Closure Tops Placement

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

Step 27 *Option 1*

Rod Holder Removal (Mini-Open Technique)

Ensure that the closure tops are placed before disengaging the Rod Holder. Remove the Rod Holder from the incision.

Step 27 *Option 2*

Rod Holder Removal (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

Step 28 *Option 1*

Reduction with Extender Sleeves (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 28 *Option 2*

Reduction with Power Knob (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.

Step 28 *Option 3*

Reduction with Reduction Forceps (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

Step 29a

Prepare Compressor (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.

Step 29b

Insert Compressor (if necessary)

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.

Step 29c

Set Pivot Point (if necessary)

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.

Step 29d

Compression (if necessary)

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.***

Step 29e

Compressor Removal (if necessary)

Loosen the knob on the Compressor, release the ratchet, and remove the Closure Top Driver and Compressor from the Extender Sleeves.

Distraction Option

Step 30

Distraction (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.***

Complete the Construct

Step 31

Final Tightening

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.***

Revision / Removal Option

Step 32

Dissection / Location

Dissect to each pedicle screw. Using the Axis Finder, locate the rod and the outer diameter of the polyaxial screw's head.

Step 33

Closure Top Removal

Attach the Closure Top Driver with a Modular Handle to unlock and remove each closure top. Repeat for each screw.

Step 34

Rod Removal (if necessary)

Remove each rod from the construct with the Fixed Grip 5.5mm Rod Holder.

Step 35

Screw Removal (if necessary)

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.

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.

Appendix

Pedicle Access Tool

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
4.5mm	4.0mm
5.5mm	5.0mm
6.5mm	6.0mm
7.5mm	7.0mm

Step 1

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 (2 – 8mm) extends from the PAT Tap's tip.

Step 2

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.

Step 3

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

Bone Aspiration (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

Step 1

Facet / Bone Decortication

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 the pedicle to the desired depth.

K-wire Insertion Option

K-wire Insertion

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.

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.

PAT Removal

PAT Tap Removal

Set the PAT T-Handle to the “non-ratcheting” position then re-attach it to the Tap.

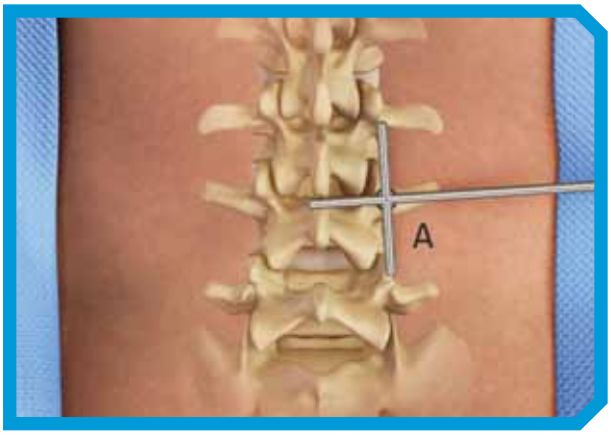
Switch the Ratcheting Handle to the “reverse” position to remove the Tap.

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.

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.

Incision Planning Guide

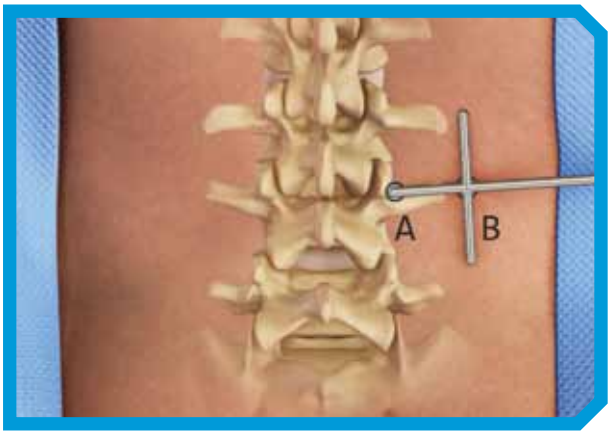
Step 1



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.

Step 2



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 2 - 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 & Pedicle Access** section of this manual for completing incisions.

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

PathFinder NXT Kit Contents

Module 3500-0001-PL

Screw Consumables

Part Number	Description	Standard Kit Quantity
3505-4530	Cannulated Polyaxial Screw 4.5 x 30	4
3505-4535	Cannulated Polyaxial Screw 4.5 x 35	4
3505-4540	Cannulated Polyaxial Screw 4.5 x 40	4
3505-4545	Cannulated Polyaxial Screw 4.5 x 45	4
3505-5530	Cannulated Polyaxial Screw 5.5 x 30	4
3505-5535	Cannulated Polyaxial Screw 5.5 x 35	4
3505-5540	Cannulated Polyaxial Screw 5.5 x 40	6
3505-5545	Cannulated Polyaxial Screw 5.5 x 45	6
3505-5550	Cannulated Polyaxial Screw 5.5 x 50	4
3505-5555	Cannulated Polyaxial Screw 5.5 x 55	2
3505-5560	Cannulated Polyaxial Screw 5.5 x 60	2
3505-6530	Cannulated Polyaxial Screw 6.5 x 30	4
3505-6535	Cannulated Polyaxial Screw 6.5 x 35	6
3505-6540	Cannulated Polyaxial Screw 6.5 x 40	6
3505-6545	Cannulated Polyaxial Screw 6.5 x 45	6
3505-6550	Cannulated Polyaxial Screw 6.5 x 50	6
3505-6555	Cannulated Polyaxial Screw 6.5 x 55	4
3505-6560	Cannulated Polyaxial Screw 6.5 x 60	4
3505-7530	Cannulated Polyaxial Screw 7.5 x 30	2
3505-7535	Cannulated Polyaxial Screw 7.5 x 35	4
3505-7540	Cannulated Polyaxial Screw 7.5 x 40	6
3505-7545	Cannulated Polyaxial Screw 7.5 x 45	6
3505-7550	Cannulated Polyaxial Screw 7.5 x 50	6
3505-7555	Cannulated Polyaxial Screw 7.5 x 55	4
3505-7560	Cannulated Polyaxial Screw 7.5 x 60	2

Screw Packaging

Part Number	Description	Standard Kit Quantity
3559-3	Screw Assembly Tool	2
3590-45	4.5mm Pedicle Screw Caddy	1
3590-55	5.5mm Pedicle Screw Caddy	1
3590-65	6.5mm Pedicle Screw Caddy	1
3590-75	7.5mm Pedicle Screw Caddy	1
3590-06	Implant Base	1
3590-14	Accessory Bin Mat	1
07.01260.001	Generic Stackable Lid Assembly	1

Rod Consumables

Part Number	Description	Standard Kit Quantity
3313-040	Pre-Bent Rod, 5.5mm, 40mm	2
3313-045	Pre-Bent Rod, 5.5mm, 45mm	2
3313-050	Pre-Bent Rod, 5.5mm, 50mm	2
3313-055	Pre-Bent Rod, 5.5mm, 55mm	2
3313-060	Pre-Bent Rod, 5.5mm, 60mm	2
3313-065	Pre-Bent Rod, 5.5mm, 65mm	2
3313-070	Pre-Bent Rod, 5.5mm, 70mm	2
3313-075	Pre-Bent Rod, 5.5mm, 75mm	2
3313-080	Pre-Bent Rod, 5.5mm, 80mm	2
3510-030	Percutaneous Pre-Bent Rod, 30mm	2
3510-035	Percutaneous Pre-Bent Rod, 35mm	2
3510-040	Percutaneous Pre-Bent Rod, 40mm	2
3510-045	Percutaneous Pre-Bent Rod, 45mm	2
3510-050	Percutaneous Pre-Bent Rod, 50mm	2
3510-055	Percutaneous Pre-Bent Rod, 55mm	2
3510-060	Percutaneous Pre-Bent Rod, 60mm	2
3510-065	Percutaneous Pre-Bent Rod, 65mm	2
3510-070	Percutaneous Pre-Bent Rod, 70mm	2
3510-075	Percutaneous Pre-Bent Rod, 75mm	2
3510-080	Percutaneous Pre-Bent Rod, 80mm	2
3510-085	Percutaneous Pre-Bent Rod, 85mm	2
3510-090	Percutaneous Pre-Bent Rod, 90mm	2
3510-095	Percutaneous Pre-Bent Rod, 95mm	2
3510-100	Percutaneous Pre-Bent Rod, 100mm	2
3512-100	Percutaneous Straight Rod, 100mm	2
3512-120	Percutaneous Straight Rod, 120mm	2
3512-140	Percutaneous Straight Rod, 140mm	2
3512-160	Percutaneous Straight Rod, 160mm	2
3512-180	Percutaneous Straight Rod, 180mm	2
3512-200	Percutaneous Straight Rod, 200mm	2
3512-220	Percutaneous Straight Rod, 220mm	2
3512-240	Percutaneous Straight Rod, 240mm	2
3311-100	Straight Rod, Blue, Ti 5.5mm x 100mm	2
3311-510	Straight Rod, Blue, Ti 5.5mm x 510mm	2
3301-1	Open Implant Closure Top, 5.5mm, Ti	20

Rod Packaging

Part Number	Description	Standard Kit Quantity
3590-05	Closure Top Caddy	1
3590-07	Rod Base	1
3590-08	Pre-Bent Rod Tray	1
07.01260.001	Generic Stackable Lid Assembly	1

Module Number 3500-0002-PL

Instrumentation Consumables

	Part Number	Description	Standard Kit Quantity
	1001-18	K-Wire, Trocar Tip	12
	3550-19	Nitinol K-Wire, Trocar Tip	12
*	1913-010	Targeting Needle with Luer Lock	4
*	3551-300	Tissue Dilator C, Radiolucent	2
*	3554-100	Pedicle Access Tool Sheath	2
*	3555-300	Pedicle Access Tool Aspiration Adapter	2
	3555-010	Pedicle Access Tool Trocar	2

Standard Instruments Tray I

	Part Number	Description	Standard Kit Quantity
	3550-100	Nitinol K-Wire Dispenser (Bottom)	1
	1011-18	Stainless Steel K-Wire Dispenser (Top)	1
*	3555-020	Pedicle Access Tool Handle	2
*	2760-1	Bone Funnel	1
	2755-1	Bone Tamp (6mm and 10mm)	1
	3557-2300	Extender Sleeve, Reduction Style, Long	4
	3557-0001	C-Shaped Sleeve Locker, Long	4
	3557-1300	C-Shaped Extender Sleeve, Reduction Style, Short	4
	3557-1001	C-Shaped Sleeve Locker, Short	4
*	1155-4	Cannulated T-Handle Bone Awl III	1
*	3556-010	Pedicle Access Tool Inline Rasp	1
*	3551-010	Tissue Dilator A (Bottom)	1
*	3551-020	Tissue Dilator B (Top)	1
	1161-2	5/64" Male Hex Screwdriver II	2
	3570-1	Final Driver Short	1

Taps

	Part Number	Description	Standard Kit Quantity
*	3554-040	Pedicle Access Tool Tap 4.0mm	2
*	3554-050	Pedicle Access Tool Tap 5.0mm	2
*	3554-060	Pedicle Access Tool Tap 6.0mm	2
*	3554-070	Pedicle Access Tool Tap 7.0mm	1

*Cannulated Item

Standard Instrument Tray II

	Part Number	Description	Standard Kit Quantity
	3561-10	Percutaneous Rod Calipers - 1	1
	3561-2	Percutaneous Rod Calipers - 2	1
	3573-10	Fixed Percutaneous Rod Holder (Bottom)	1
	3566-2	Closure Top Capture Driver, Short	2
*	3558-2	Reduction Screwdriver	2
	3562-1	Fixed Grip 5.5mm Rod Holder	1
	3568-3	Counter Torque Wrench	1
*	3572-1	Modular T-Handle 1/4" Square, 3-Position Ratcheting Torque Limiting 90 in-lbs (10.2 N-m)	1
*	3564-200	Palm Handle, 1/4 in (6.35mm) Square, Non-Ratching	1
*	3571-1	Modular Straight Handle, 1/4" Square, 3-Position Ratcheting	1

Manipulation Tray I

	Part Number	Description	Standard Kit Quantity
*	3567-20	Power Knob Rod Reducer, Long	1
*	3567-10	Power Knob Rod Reducer, Short	1
	3567-3	Square Knob Adapter	1
	3570-2	Final Driver Long	1
*	3570-10	Distractor	1
*	3569-1	Compressor	1
	3565-1	Percutaneous Rod Pusher	1
	3566-1	Closure Top Capture Driver, Long	2

*Cannulated Item

Manipulation Tray II

	Part Number	Description	Standard Kit Quantity
	3560-1	Tissue Dilation Wedge	1
	3559-2	Targeting Incision Guide Template (Bottom)	1
*	3558-50	Cannulated Dorsal Height and Revision Tool (Top)	1
	872-1	French Rod Bender	1
*	3572-2	Modular T-Handle 1/4" Square, Non-Ratcheting Torque Limiting 90 in-lbs (10.2 N-M)	1
	3568-10	Transverse Counter Torque Tube, Short	1
	3568-20	Transverse Counter Torque Tube, Long	1
	3590-09	Standard Tray I	1
	3590-10	Tap Tray Insert	1
	3590-11	Standard Tray II	1
	3590-12	Manipulation Tray I	1
	3590-13	Manipulation Tray II	1
	3590-15	Manipulation Tray II Accessory Bin Mat	1
	3590-24	Tap Tray Accessory Bin Mat	1
	07.01260.001	Generic Stackable Lid Assembly	4

*Cannulated Item

Module Number 3500-0010-PL

Classic Tray

	Part Number	Description	Standard Kit Quantity
*	1913-020	Tageting Needle with Beveled Edge	4
	1163-1	Rod Holder	1
	1167-3	Sleeve Based Forceps Reducer	1
	1169-2	Rod Caliper II	1
*	3552-140	Cannulated Awl-Tap, 4.0mm	1
*	3552-150	Cannulated Awl-Tap, 5.0mm	1
*	3552-160	Cannulated Awl-Tap, 6.0mm	1
*	3552-170	Cannulated Awl-Tap, 7.0mm	1
*	3552-240	Cannulated Drill-Awl-Tap, 4.0mm	1
*	3552-250	Cannulated Drill-Awl-Tap, 5.0mm	1
*	3552-260	Cannulated Drill-Awl-Tap, 6.0mm	1
*	3552-270	Cannulated Drill-Awl-Tap, 7.0mm	1
	3557-0001	C-Shaped Sleeve Locker, Long	2
	3557-1000	C-Shaped Extender Sleeve, Short (Non-Reduction)	4
	3557-1001	C-Shaped Sleeve Locker, Short	4
	3557-2000	Extender Sleeve, Long (Non-Reduction)	2
	3557-3000	Extender Sleeve, Short (Non-Reduction)	2
	3557-3300	Reduction Style Extender Sleeve, Short	2
*	3558-1	Classic Screwdriver	2
*	3568-30	Universal Counter Torque Tube, Short	1
*	3568-40	Universal Counter Torque Tube, Long	1
	3590-16	Classic Tray	1
	3590-22	Classic Tray Insert	1
	3590-23	Classic Tray Accessory Bin Mat	1
	07.01260.001	Generic Stackable Lid Assembly	1

*Cannulated Item

Module Number 3500-0011-PL

Revision Consumables

Part Number	Description	Standard Kit Quantity
1001-18	K-Wire, Trocar Tip	12

Instruments

	Part Number	Description	Standard Kit Quantity
	852-2	Ratcheting T-Handle II	1
	1011-18	K-Wire Dispenser	1
*	1159-5	Axis Finder (*PathFinder*)	1
*	1160-3	*PathFinder* Bone Screw Adjuster	1
	2155-1	Universal Driver	1
*	3558-50	Cannulated Dorsal Height and Revision Driver	1
	3562-1	Fixed Grip 5.5mm Rod Holder	1
	3566-2	Closure Top Capture Driver, Short	1
*	3568-4	Axis Finder (*PathFinder NXT*)	1
	3590-17	Revision Tray	1
	3590-18	*PathFinder NXT* Thermoformed Revision Insert	1
	3590-19	*PathFinder NXT* Thermoformed Revision Insert Lid	1
	3590-20	*PathFinder* Thermoformed Revision Insert	1
	3590-21	*PathFinder* Thermoformed Revision Insert Lid	1
	07.01260.001	Generic Stackable Lid Assembly	1

*Cannulated Item

Warnings and Precautions

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.
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 MINIOPEN 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

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L1554 Rev G per DCR 10462