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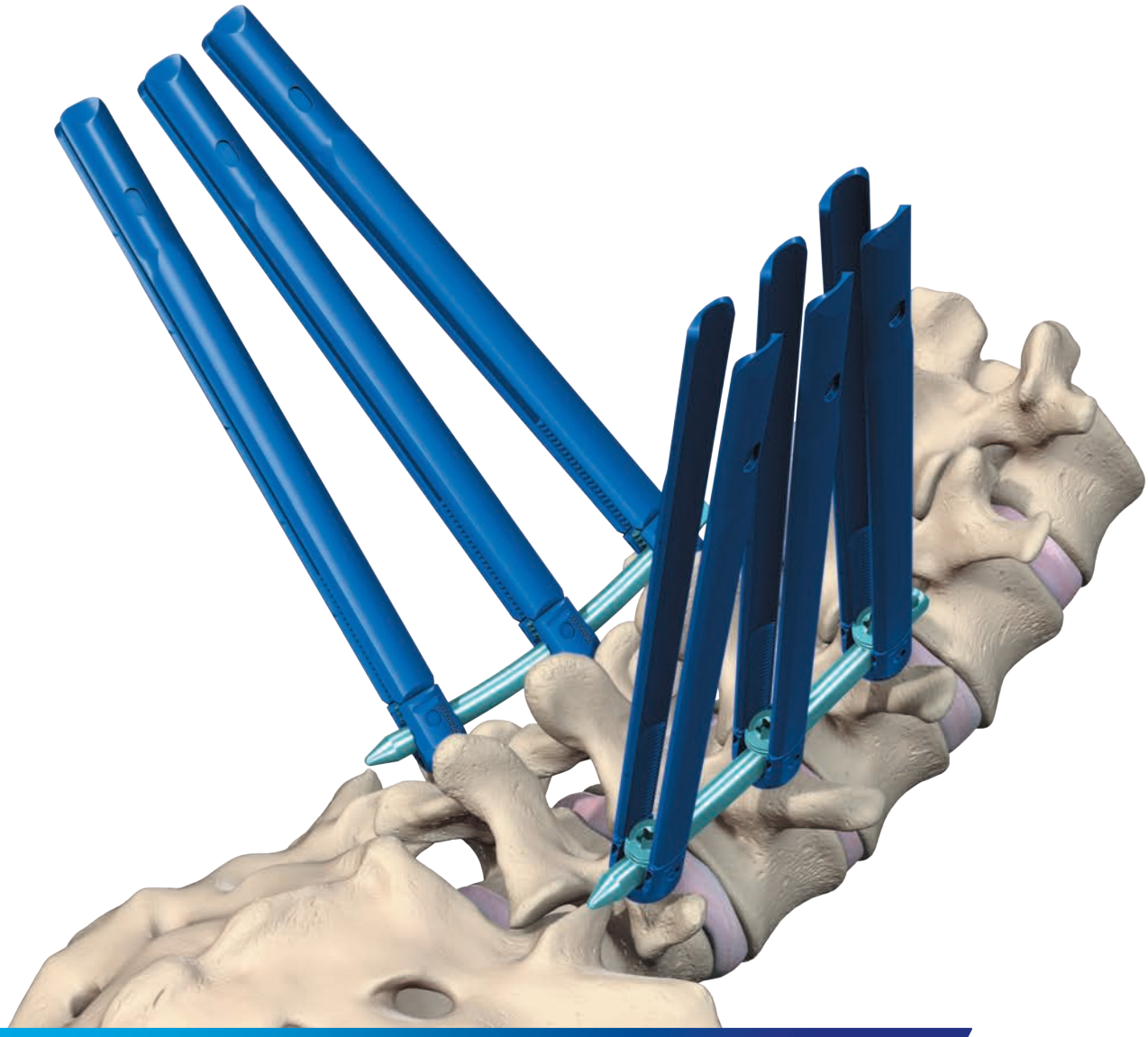
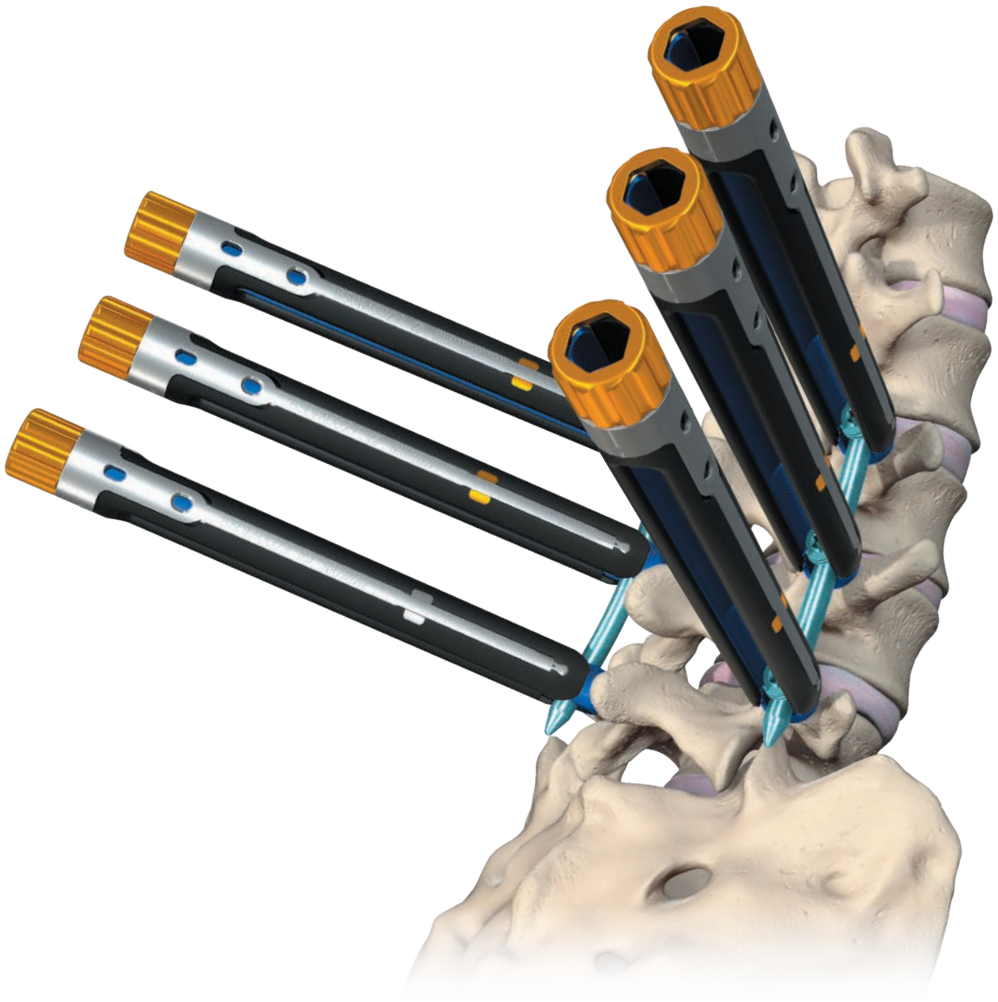


Thoracolumbar Solutions

Vital™ MIS Spinal Fixation System

Surgical Technique Guide



The Vital MIS Spinal Fixation System is a percutaneous screw delivery system that offers a broad range of cannulated implants and specialized instrumentation for a minimalized, percutaneous or mini-open approach. The system was designed to provide surgeons with the flexibility to utilize instrumentation based on their personal technique, preference and specific patient needs.

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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.

VITAL MIS IMPLANT FEATURES

Integrated Extension Tabs

Fully machined integrated extension tabs remove the concern for weld breaks.

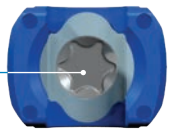
- Open extended tab design allows for increased visualization and easier placement of percutaneous rods.
- 30 mm of integrated reduction threads.

Multiple Instrument Connection Features

- The multiple pedicle screw head connection points allow various instruments to quickly and securely attach, simplifying manipulation maneuvers.
- After the disposable, integrated extension tabs have been removed, all Vital (open) instrumentation is compatible with Vital MIS screws.

Fully Threaded Cannulated Dual-lead Screw Shank

- Self-tapping fully threaded cannulated screw shank designed to improve the starting characteristics and improve bone screw fixation while reducing insertion torque.
- Improves surgeon efficiency by allowing pedicle screw insertion twice as fast as comparable single lead pedicle screws without sacrificing pull-out strength.[1]

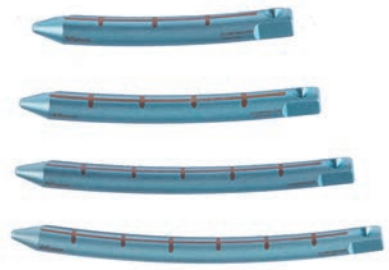


T27 Hexalobe Drive Feature

- Screws and closure tops utilize a T27 drive feature (one of the largest in the industry): 30% stronger than a T25 (MDT), 90% greater strength than a T20 (D/S).

Dual-lead Reverse Angle Thread Closure Top

- Dual-lead reverse angle thread designed to improve engagement, advance quickly and help prevent head splay.
- Closure top design supports loosening after final tightening and re-tightening of closure top without performance loss.



Percutaneous Rod Options

- Pre-bent and straight rod options standard in the set.
- Pre-bent rods can attach to rod holders in either lordotic or kyphotic orientation to accommodate thoracic or lumbar curves.

VITAL MIS INSTRUMENT FEATURES

Pedicle Access Tool (PAT)

- Minimizes steps by combining a pedicle targeting needle and a tap into one instrument.

Pedicle Access Screw Insertion Tool (PASIT)

- Minimizes steps by providing a direct-to-screw insertion option for surgeons.

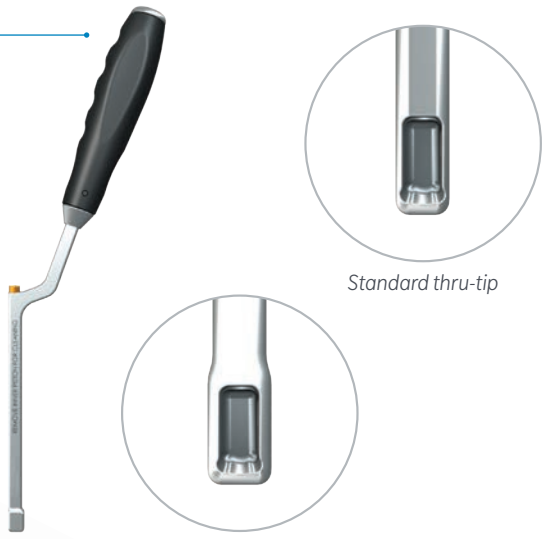
Reinforcement Sleeve

- Connects to the head of the pedicle screw (below perforation), adding strength to the extended tabs to allow for reduction, compression and distraction maneuvers.

Multiple Rod Inserters

- Standard thru-tip option allows the tip of the rod inserter to pass through the extended tabs of the pedicle screw for direct rod placement.

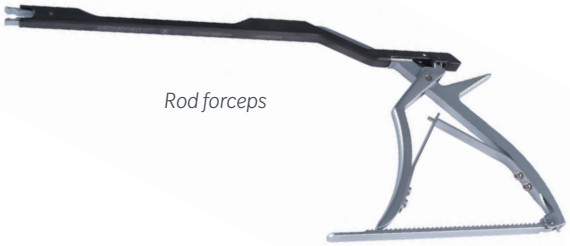
- Standard stop-tip option provides a positive stop against the head of the pedicle screw aiding in proper rod placement.



Standard thru-tip

Standard stop-tip

- Rod forceps allow for direct placement of a rod in mini-open/Wiltse approach.



Rod forceps

PREOPERATIVE PLANNING

The following Surgical Technique Guide describes the recommended placement and use of the Vital MIS Spinal Fixation System components.

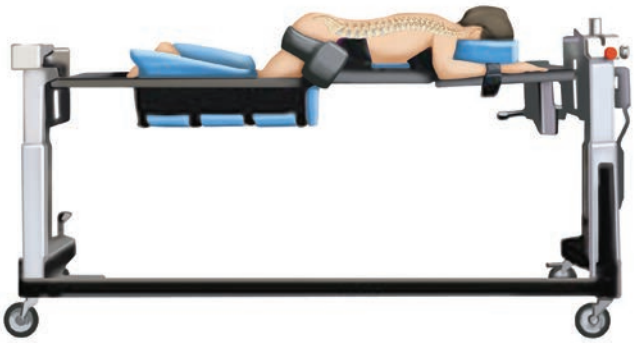


Figure 1

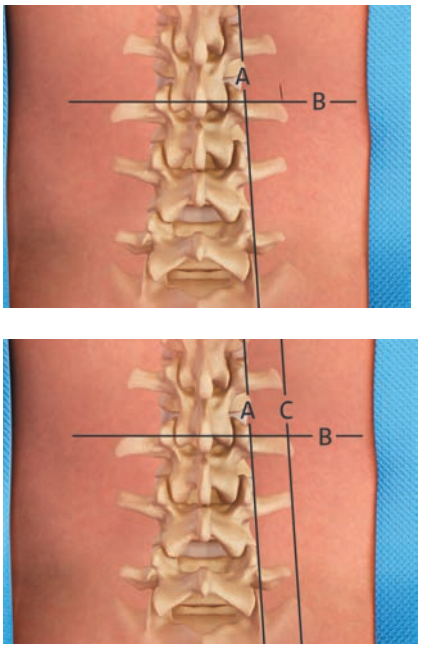
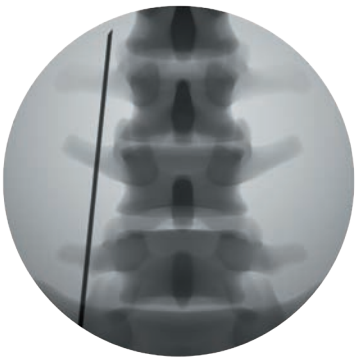


Figure 2

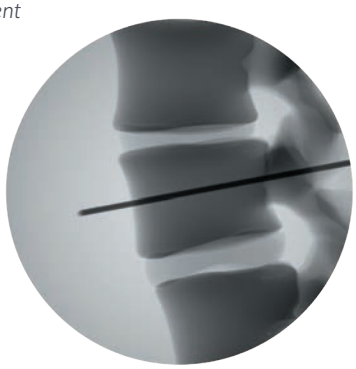
PATIENT POSITIONING AND MARKING

- The patient is positioned prone (Figure 1) for a posterior approach to the thoracolumbar spine, and then draped in a conventional manner following aseptic techniques.
- Fluoroscopically locate the pedicle's lateral border by placing a guidewire in a cephalad/caudal orientation on the skin.
- With a sterile pen, mark a vertical line, line "A," on the skin.
- Position the guidewire 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 2 cm–3 cm lateral to line "A." This is line "C," and delineates the incision site (Figure 2).
- An oblique view directly down the pedicle can also be utilized to identify the ideal skin entry point.

  Note: *Greater subcutaneous tissue requires greater lateral distance of skin incision.*

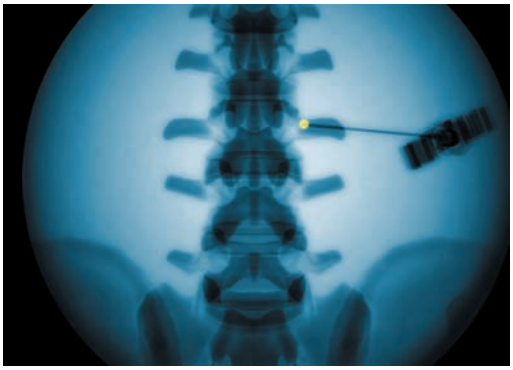


A/P Alignment



Lateral Alignment

Figure 3



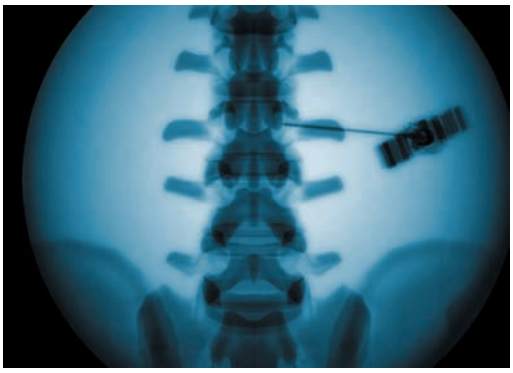


Figure 4

PEDICLE TARGETING

- When visualizing the anatomy, the superior endplates on the A/P radiograph should be parallel, as well as showing perfect symmetry of the pedicles in their relation to the spinous process (Figures 3).

  Note: *When targeting the S1 pedicle, a Ferguson view is recommended.*

- On the lateral radiograph, the endplates and pedicles should be parallel to ensure that the depth trajectory of the instrumentation is in-line with the A/P radiograph (Figure 3).
- A spinal needle can be utilized to localize the anatomy and verify the trajectory required for the individual pedicles. Upon confirmation of the trajectory, the skin can be marked accordingly for the incision.
- Due to the nature of the pedicle anatomy, care should be taken to ensure that the starting point of the targeting needle begins in the proper trajectory and plane (Figure 4).

SURGICAL TECHNIQUE

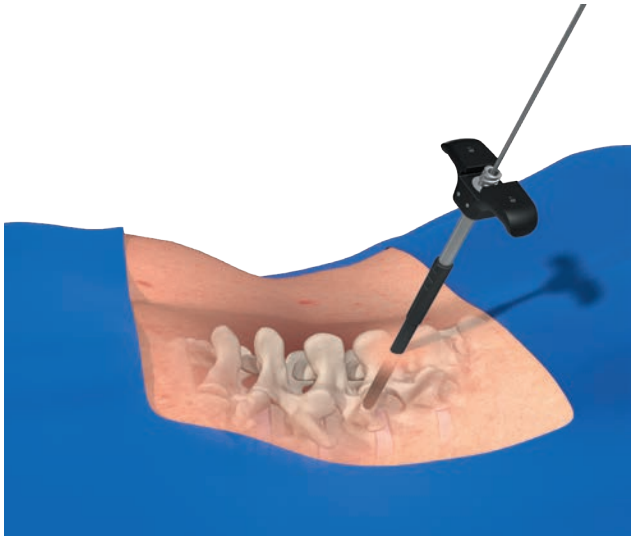


Figure 5

PEDICLE PREPARATION

- Make an incision in the skin and fascia approximately 16 mm wide for each screw.
- Place a targeting needle on the pedicle, advancing it into the pedicle, paying attention to follow the pedicular column. Final position is verified via A/P and Lateral fluoroscopic imaging.

  Tip: *From a true A/P view, the proper starting point is at the intersection of the facet and transverse process. On the right side, this is the 3 o'clock position on the lateral wall of the pedicle and on the left side, this is the 9 o'clock position on the lateral wall of the pedicle.*
- The pedicle is perforated with the targeting needle and the needle is advanced into the vertebral body following the pedicle trajectory. This trajectory is typically parallel to the endplate with 10° to 12° of lateral to medial angulation.
- Remove the inner stylus of the targeting needle.
- With the inner stylus of the targeting needle removed, place the guidewire within the needle cannula (Figure 5).

  Tip: *The guidewire slap hammer may be utilized for more control when introducing or removing the guidewire.*

  Note: *The guidewire should be placed so that the distal end is approximately 60-70% across the vertebra.*

  Note: *There are both trocar and blunt tip guidewires available in the set.*
- Remove the lower portion of the targeting needle, taking care that the guidewire maintains purchase in the vertebra.
- Repeat pedicle targeting and preparation for all indicated levels.

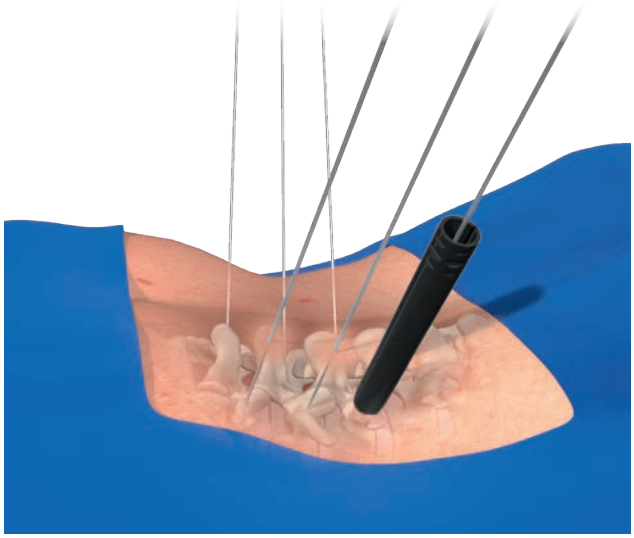


Figure 6

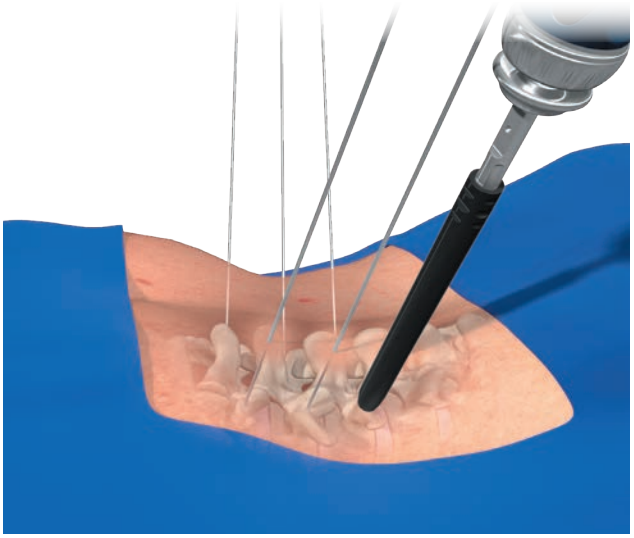


Figure 7

DILATION (OPTIONAL)

- Sequentially place each of the dilators over the guidewire, starting with the starter dilator and finishing with the x-large dilator. Make sure each dilator sits firmly against the bony anatomy.

  Note: *Positioning of the starter dilator can be confirmed with lateral fluoroscopy. The other dilators within the set are radiolucent.*

TAP INSERTION

- Select the appropriate size tap and assemble the tap to a handle.

  Note: *The Vital MIS System taps are dimensionally the same as the corresponding pedicle screws.*

- Remove the starter dilator (Figure 6).
- Place the tap over the guidewire, and through the middle dilator until it is docked against the pedicle.
- Turn the handle clockwise to advance the tap into the pedicle until the tap has reached the appropriate depth (Figure 7).

  Tip: *Depth markings on taps are in 10 mm increments and may be utilized to ensure preferred depth is reached.*

  Note: *Do not tap past the length of the guidewire. Max tap depth of 50 mm.*

- Remove the tap from the vertebra by turning the handle counterclockwise until the tap has been completely removed from the pedicle, taking care that the guidewire maintains purchase in the vertebra.
- Repeat these steps for each subsequent pedicle.

ALTERNATIVE PEDICLE PREPARATION TECHNIQUE

Figure 8

Figure 8a

Figure 9

ASSEMBLY OF PEDICLE ACCESS TOOL (PAT)

The pedicle access tool (Figure 8) can be used to combine the traditional steps of using a pedicle targeting needle to place a guidewire and tapping. The PAT instrument combines a cortex-breaking stylus with the tap so that direct tapping may occur.

- Select the appropriate size PAT tap (ø4.5 mm or ø5.5 mm) and assemble the PAT tap to the PAT handle.

  Note: *If a ø6.5 mm or larger tap is required, the standard MIS tap may be utilized.*

- Slide the PAT stylus down through the PAT handle and thread the PAT stylus into the top of the PAT handle (Figure 9). Check that the tip of the PAT stylus is protruding from the tip of the PAT tap. There should be approximately 3.5 mm of protrusion (Figure 8a).
- Tap to the desired depth as indicated by depth markings.
- Remove PAT stylus and replace it with a guidewire.
- Carefully remove the PAT tap, making sure to maintain the depth of the guidewire.

PEDICLE SCREW INSERTION

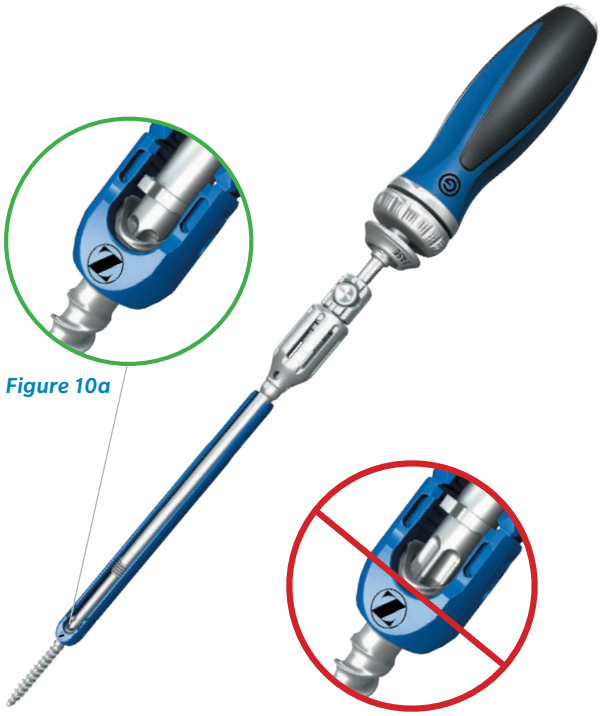


Figure 10a

Figure 10

Figure 10b

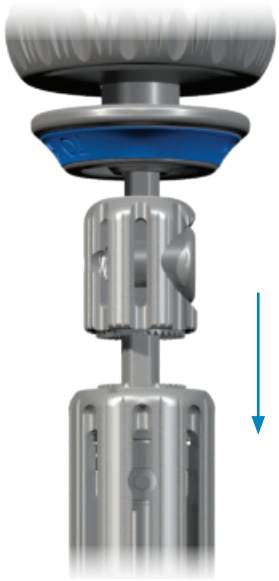


Figure 11

SCREW INSERTION

- Remove the middle dilator, leaving only the guidewire and large dilator.
- Select the appropriate length and diameter pedicle screw.

  Note: *Determine proper pedicle screw size based on anatomy. Undersized screws can break, causing instability.*
- Pass the screwdriver through the extended tabs until the threaded portion of the screwdriver reaches the reduction threads of the screw .
- Align the tip of the driver with the head of the screw shank and begin to thread the driver into the reduction threads (Figure 10).

  Note: *If the driver won't advance, the tip of the driver may not be properly aligned with the pedicle screw shank.*
- Continue to turn the driver until it can no longer be advanced. Ensure the screw shank is straight, rigidly aligned with the shaft of the inserter and that the tip of the screwdriver is fully seated into the shank of the screw (Figure 10a). If the tip of the screwdriver is not fully seated (Figure 10b), loosen the screwdriver, realign the tip of the screwdriver with the shank of the screw and tighten the driver again.

  Note: *The short screwdriver (850M0020) is designed to engage only the first few threads of the extended tabs. The optional long screwdriver (850M0021) is designed to fully seat into the head of the pedicle screw.*
- Once the screwdriver is fully inserted into the screw, press the button on the locking collar at the top of the screwdriver, slide it down and release (Figure 11). When engaged correctly, the screwdriver will not move and the outer cage will not unthread.

PEDICLE SCREW INSERTION *(continued)*

Figure 12

Figure 13

EXTENDED TAB REINFORCEMENT OPTIONS

- If the tab sleeve is desired, simply insert the narrow end of the tab sleeve over the extended tabs until a soft click is felt (Figure 12).

  Tip: *Take care when removing any instrument from the screw while the tab sleeve is attached. It is recommended to keep one hand on the tab sleeve when removing instruments to prevent unwanted removal of sleeve.*

- If the reinforcement sleeve is desired, simply insert the reinforcement sleeve over the extended tabs in the unlocked position. When fully seated, a "U" will show through the sleeve to indicate the "unlocked" position. Turn the gold knob on the sleeve clockwise to lock it to the screw. When fully seated and locked, an "L" will show through the sleeve to indicate the "locked position".

  Note: *If the gold knob of the reinforcement sleeve is tight, the hex end of the reinforcement sleeve counter torque may be used to loosen the gold knob (Figure 13).*

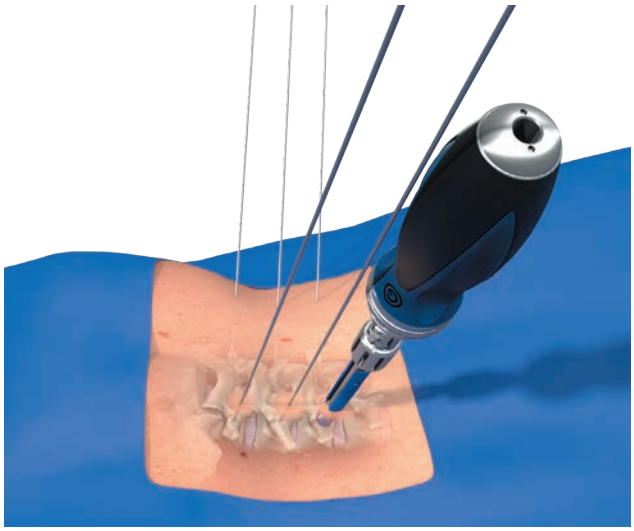


Figure 14

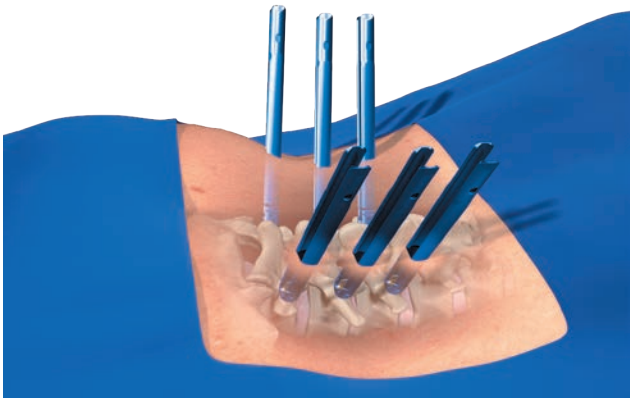


Figure 15

SCREW INSERTION

- Insert the pedicle screw over the guidewire, through the large dilator, and drive it to the desired depth. Ensure that the pedicle screw head is not buried against the anatomy and that polyaxial range of motion is maintained if appropriate. (Figure 14).

  Note: *It is recommended that the guidewire be removed before the screw is fully inserted.*

- Remove the guidewire using the guidewire slap hammer. Depress the lever of the slap hammer and slide it over the proximal end of the wire. Release the lever and gently slap the hammer in an upward direction. Once removed, depress the lever of the slap hammer again to release the wire.

  Note: *If bone around the screw head needs to be removed, a bone planar is included standard in Instrument Kit 1.*

- After each pedicle screw is inserted, verify positioning with fluoroscopic imaging.

- Remove the screwdriver from the pedicle screw by first depressing the locking collar button on the screwdriver and sliding it up. Then turn the locking cage counterclockwise until it has released from the pedicle screw head.

- Repeat the above steps for the subsequent pedicles (Figure 15).

  Note: *If pedicle screw height adjustment is needed, the final driver may be inserted, or any of the T27 drivers may be used.*

  Tip: *The counter-torque instrument (850M0054) may be used as a head turner if needed*

ALTERNATIVE SCREW INSERTION TECHNIQUE

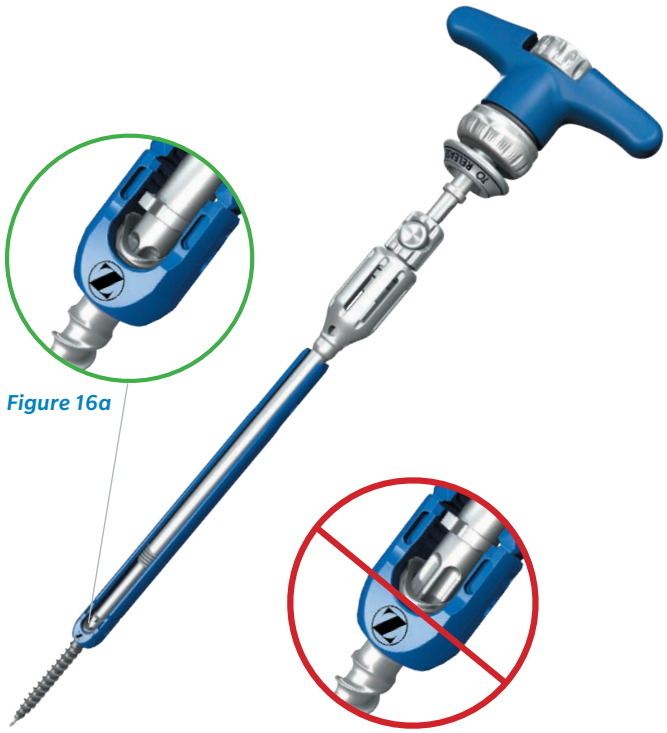


Figure 16a

Figure 16

Figure 16b

Figure 17

Figure 18

ASSEMBLY OF PEDICLE ACCESS SCREW INSERTION TOOL (PASIT)

- The PASIT instrument combines a cortex-breaking stylus with the screwdriver so direct-to-screw insertion may occur.
- Select the appropriate length and diameter pedicle screw.

  Note: *Determine the proper pedicle screw size based on anatomy. Undersized screws can break, causing instability.*
- Assemble the screwdriver to the PAT Handle
- Pass the screwdriver through the extended tabs until the threaded portion of the screwdriver reaches the reduction threads of the screw .
- Align the tip of the screwdriver with the head of the pedicle screw shank and begin to thread the screwdriver into the reduction threads (Figure 16).

  Note: *If the screwdriver won't advance, the tip of the screwdriver may not be properly aligned with the pedicle screw shank.*
- Continue to turn the driver until it can no longer be advanced. Ensure that the screw shank is straight, rigidly aligned with the shaft of the inserter and that the tip of the screwdriver is fully seated into the shank of the screw (Figure 16a). If the tip of the screwdriver is not fully seated (Figure 16b), loosen the screwdriver, realign the tip of the screwdriver with the shank of the screw and tighten the driver again.
- Once the screwdriver is fully inserted into the screw, press the button on the locking collar at the top of the screwdriver, slide it down and release (Figure 17). When engaged correctly, the screwdriver will not move and the outer cage will not unthread.
- Select the appropriate size PASIT stylus (Figure 18) that corresponds to the length of the pedicle screw intended for insertion.

Figure 19

Figure 20

- Slide the PASIT stylus down through the PAT handle and thread the PASIT stylus into the top of the PAT handle (Figure 19). Check that the tip of the PASIT stylus is protruding from the tip of the pedicle screw. There should be approximately 3.5 mm of protrusion (Figure 20).
- To insert, determine pedicle screw trajectory using A/P and lateral fluoroscopy in the same manner in which the jamshidi is used for pedicle targeting (Figures 3 and 4). The 3.5 mm of stylus protruding from the tip of the PASIT instrument should be docked into the bone by lightly tapping the PAT handle with a mallet. Once proper trajectory is determined, turn the PAT handle to advance the pedicle screw into the bone. A/P and lateral fluoroscopy should be used during pedicle screw insertion to ensure that proper pedicle screw trajectory is maintained. Once the tip of the pedicle screw has passed the pedicle and entered the vertebral body, remove the PASIT stylus.
- Finish insertion of the pedicle screw ensuring that the pedicle screw head is not buried against the anatomy and that polyaxial range of motion is maintained if appropriate.

  Note: *If bone around the screw head needs to be removed, a bone planar is included standard in Instrument Kit 1.*
- After each pedicle screw is inserted, verify positioning with fluoroscopic imaging.
- Remove the screwdriver from the pedicle screw by first depressing the locking collar button on the screwdriver and sliding it up. Then turn the locking cage counterclockwise until it has released from the pedicle screw head.
- Repeat the above steps for the subsequent pedicles.

  Note: *If pedicle screw height adjustment is needed, the final driver may be inserted, or any of the T27 drivers may be used.*

  Tip: *The counter-torque instrument (850M0054) may be used as a head turner if needed.*

ROD SELECTION AND PREPARATION

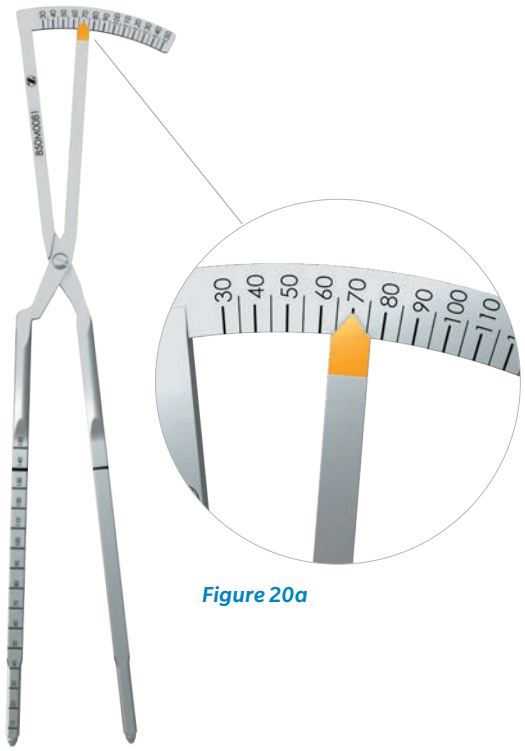


Figure 20a

Figure 20

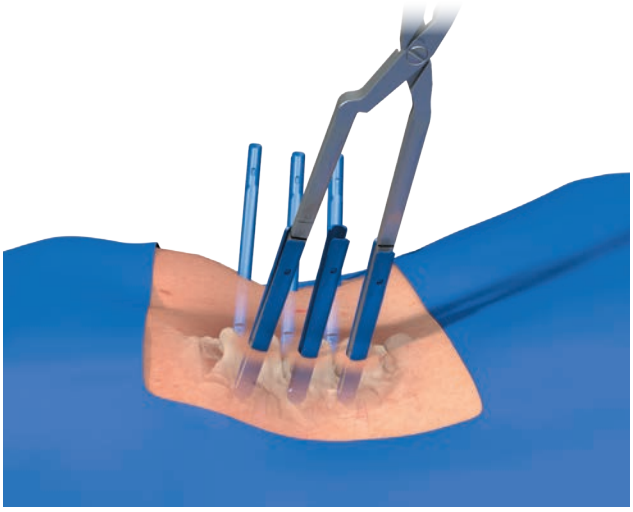


Figure 21

ROD MEASUREMENT

- Start by inserting the posts of the caliper (Figure 20) into the superior and inferior screw heads.
- Make sure the posts of the caliper are fully inserted into the head of the screw using the available markings on the caliper as a guide (Figure 21). If the posts are not fully inserted, the measurement may be compromised.
- The gold arrow at the top of the caliper will point to the corresponding rod size (Figure 20a). No additional measurements or calculations must be made to account for the bullet nose and connector end of the rod.
- If the length indicated by the calipers is between sizes, it is recommended that the larger size rod be used.

Tip: *The length of rod can be influenced directly by a number of factors, including the amount of reduction or compression anticipated after rod insertion. Reduction of the rod will often reduce the radius of curvature of the rod, making it shorter than anticipated. Compression often has the opposite effect and can make the rod longer than anticipated. Taking these common procedural steps into account when determining rod length will help in choosing the correct rod.*

Caution: *To prevent premature material fatigue, avoid reversing a previously contoured rod or creating a sharp bend in a straight rod.*

Note: *Rods are measured and labeled in length according to their functional length. The bullet nose of the rod adds an additional 6 mm and the connection end adds an additional 8 mm.*

Figure 22

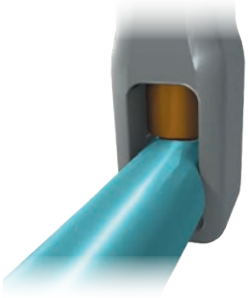


Figure 23

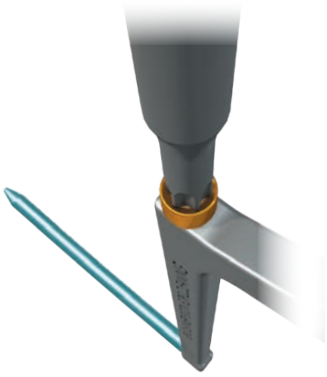


Figure 24

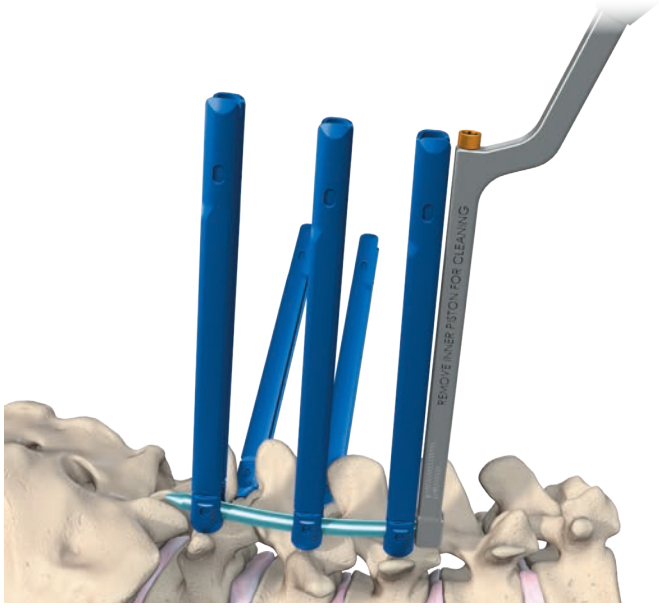


Figure 25

ROD INSERTION

- Assemble the rod inserter piston to the rod inserter (Figure 22) but do not fully advance; allowing for the rod to be loaded.
- With the rod selected, align the connection end of the rod with the distal end of the rod inserter (Figure 23).

  Note: *The geometry of the rod connection will allow the rod to be attached in either a lordotic or kyphotic orientation.*
- Secure the rod to the rod inserter by tightening the rod inserter piston with the closure top inserter and palm handle until the rod is secure (Figure 24). Ensure the rod is securely connected to the rod inserter.
- Making sure the tabs of the screw are aligned, guide the nose of the rod down through the length of the tabs. Once the nose of the rod is as deep as the screw heads, begin to sweep the rod across each screw. Turn the rod from vertical to horizontal, guiding the tip of the rod through each rod slot of each screw (Figure 25).
- Continue to guide the rod into the screws until the tip of the rod extends past the last screw head.

  Note: *There are two rod inserter options. 850M0041 Thru-tip and 850M0042 Stop-tip.*

Standard thru-tip

Standard stop-tip

ROD SELECTION AND PREPARATION *(continued)*

Figure 26a

Figure 26

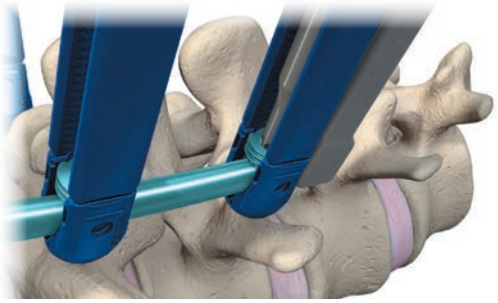


Figure 27

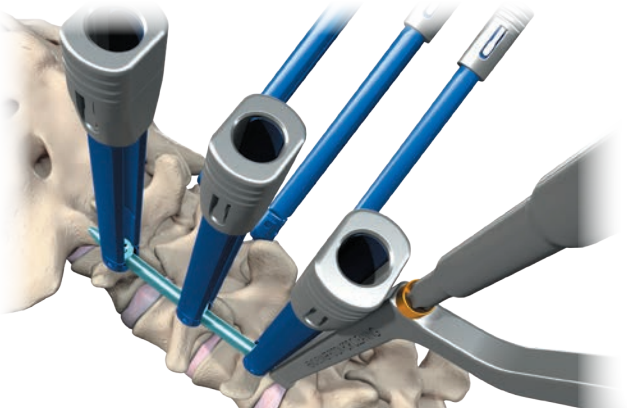


Figure 28

CLOSURE TOP INSERTION AND ROD REDUCTION

- A tab sleeve must be placed on each extended tab prior to closure top insertion to constrain the extended tabs during closure top insertion and prevent cross threading. Each tab sleeve clicks on and off with a push or pull (Figure 26).
- The reinforcement sleeve(s) must be used during rod reduction. The reinforcement sleeve fully constrains the extended tabs and allows the pedicle screw to withstand reduction loads. To attach the reinforcement sleeve to the pedicle screw, insert the reinforcement sleeve over the extended tabs in the unlocked position. When fully seated, a "U" will show through the sleeve to indicate the "unlocked" position. Turn the gold knob on the sleeve clockwise to lock it to the screw. When fully seated and locked, an "L" will show through the sleeve to indicate the "locked position".
- Connect the closure top inserter to a palm handle.
- Place a closure top on the tip of the closure top inserter and ensure that the closure top is securely retained.
- Insert the closure top through the tab sleeve or reinforcement sleeve and into the extended tab of the pedicle screw until it rests at the reduction threads.
- Turn the closure top inserter until the depth band aligns with the top of the extended tabs. At this point the closure top is fully inserted (Figure 26a).
- Repeat this process at each screw until the rod is fully reduced and seated in the pedicle screw (Figure 27).

  Tip: *Ensure all closure tops are only provisionally tightened at this point in the procedure as additional manipulation may be needed.*

- Remove the rod inserter by loosening the rod inserter piston with the closure top inserter until the piston is loose (Figure 28). The piston may be retained by the rod inserter or may be fully removed. Rock the rod inserter toward the construct to release from the rod.

COMPRESSION AND DISTRACTION

Figure 29

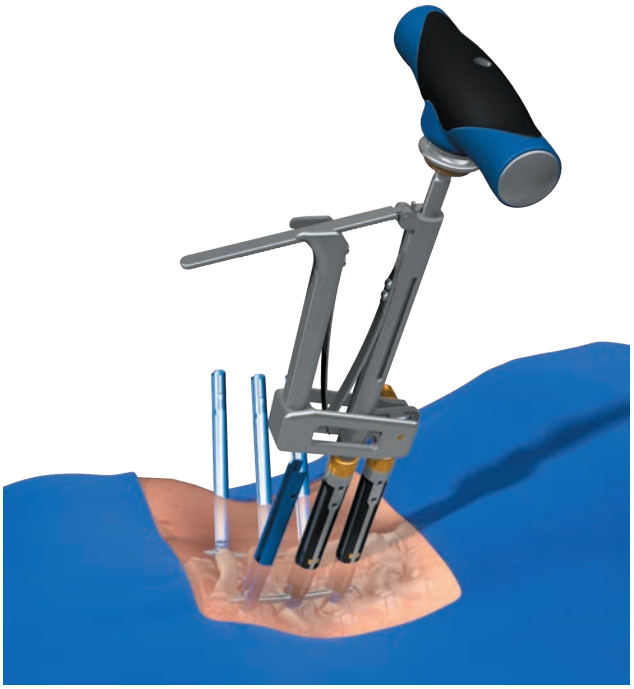


Figure 30

COMPRESSION

- Upon completion of rod insertion and closure top placement, perform final tightening for one of the closure tops. At the adjacent level, ensure that the closure top is in place but is loose enough to allow the rod to slide.
- Before compression is performed, ensure that reinforcement sleeves are placed over the tops of the screws that will be compressed. A reinforcement sleeve must be assembled to each screw that interfaces with the compressor.
- Slide the fixed post of the compressor down the reinforcement sleeve of the pedicle screw that has been final tightened. Ensure the post seats on the drive feature of the closure top.
- Loosen the knob of the compressor such that the tube of the compressor is free to slide and angulate.
- Place the long final driver, with the torque-limiting handle (90 in-lb/10.2 Nm) attached, down through the tube of the compressor into the drive feature of the closure top (Figure 29).
- Check that the depth marking on the long final driver sits just below the top of the reinforcement sleeves, to ensure it is fully seated.
- Ensure there is space between the reinforcement sleeves such that compression can take place. Once achieved, tighten the gold knob of the compressor clockwise until it stops to establish the fulcrum. The compressor is now ready to compress.
- Squeeze the handles of the compressor. Engage the ratchet if holding the compression through the compressor is desired (Figure 30). Over-compression is not recommended as it may compromise the pedicle.

Provisional tightening

- With the desired amount of compression achieved, use the long final driver with the 90 in-lb torque-limiting handle to provisionally tighten the closure top.
- Once tightened, remove the long final driver from the compressor and lift the compressor out of the pedicle screw.
- Perform these steps at each adjacent level, moving linearly, if multi-level compression is desired.

COMPRESSION AND DISTRACTION *(continued)*

Figure 31

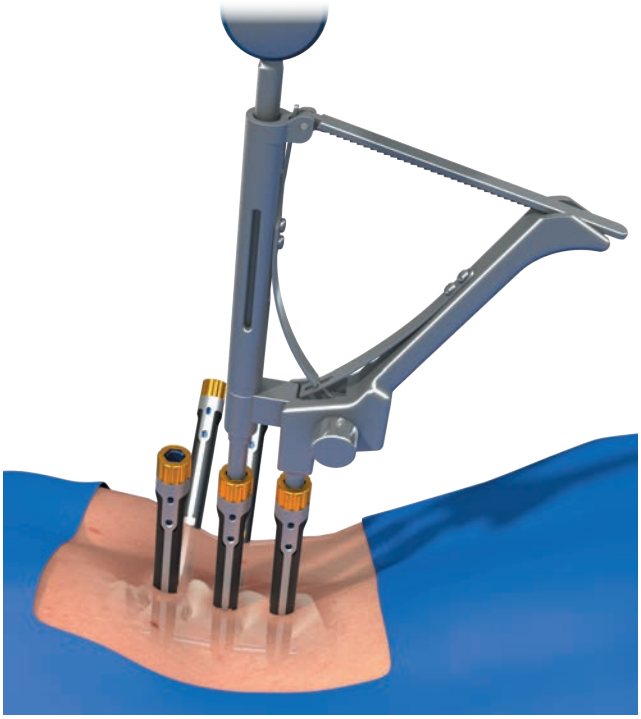


Figure 32

DISTRACTION

- Upon completion of rod insertion and closure top placement, perform final tightening for one of the closure tops. At the adjacent level, ensure that the closure top is in place but is loose enough to allow the screw to slide along the rod.
- Before distraction is performed, ensure that reinforcement sleeves are placed over the tops of the screws that will be distracted. A reinforcement sleeve must be assembled to each screw that interfaces with the distractor.
- Slide the fixed post of the distractor down the reinforcement sleeve of the pedicle screw that has been final tightened. Ensure the post seats in the drive feature of closure top.
- Loosen the knob of the distractor such that the tube of the distractor is free to slide and angulate.
- Place the long final driver, with the torque-limiting handle (90 in-lb/10.2 Nm) attached, down through the tube of the distractor into the drive feature of the closure top (Figure 31).
- Check that the depth marking on the long final driver sits just below the top of the reinforcement sleeves, to ensure it is fully seated.
- Ensure there is space between the reinforcement sleeves such that distraction can take place. Once achieved, tighten the gold knob of the distractor clockwise until it stops to establish the fulcrum. The distractor is now ready to distract.
- Squeeze the handles of the distractor. Engage the ratchet if holding the distraction through the distractor is desired (Figure 32). Over-distraction is not recommended, as it may compromise the pedicle.

Provisional tightening

- With the desired amount of distraction achieved, use the long final driver with the 90 in-lb torque-limiting handle to provisionally tighten the closure top.
- Once tightened, remove the long final driver from the distractor and lift the distractor out of the pedicle screw.
- Perform these steps at each adjacent level, moving linearly, if multi-level distraction is desired.

FINAL TIGHTENING

Figure 33

Figure 34

FINAL TIGHTENING

- Place the torque-limiting handle (90 in-lb/10.2 Nm) on the gold-capped final driver.
- Slide the counter-torque down over the screw tabs until it comes to rest.
- Slide the final driver down through the counter-torque and into the closure top, making sure the T27 tip is fully engaged (Figure 33).
- Turn the torque-limiting handle until it makes an audible click. A second click is unnecessary but may be done if desired.
- Repeat this process at each screw until the construct is rigid, ensuring all closure tops are final tightened.

  Note: *If final tightening with the reinforcement sleeve in place, the reinforcement sleeve counter torque may be used* (Figure 34).

TAB REMOVAL

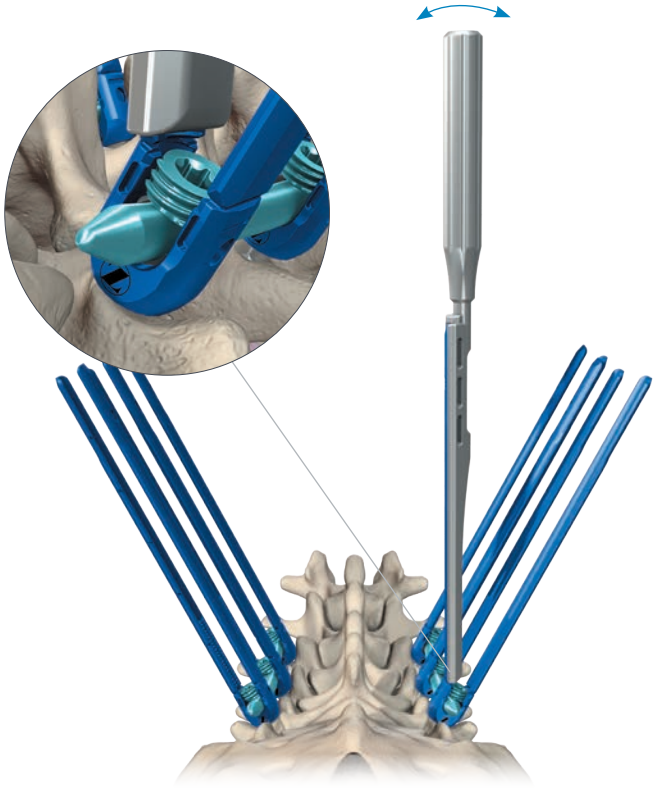


Figure 35

TAB REMOVAL

With the construct complete and the final positions of the screws verified, the extended tabs must be individually removed with the tab breaker (Figure 35).

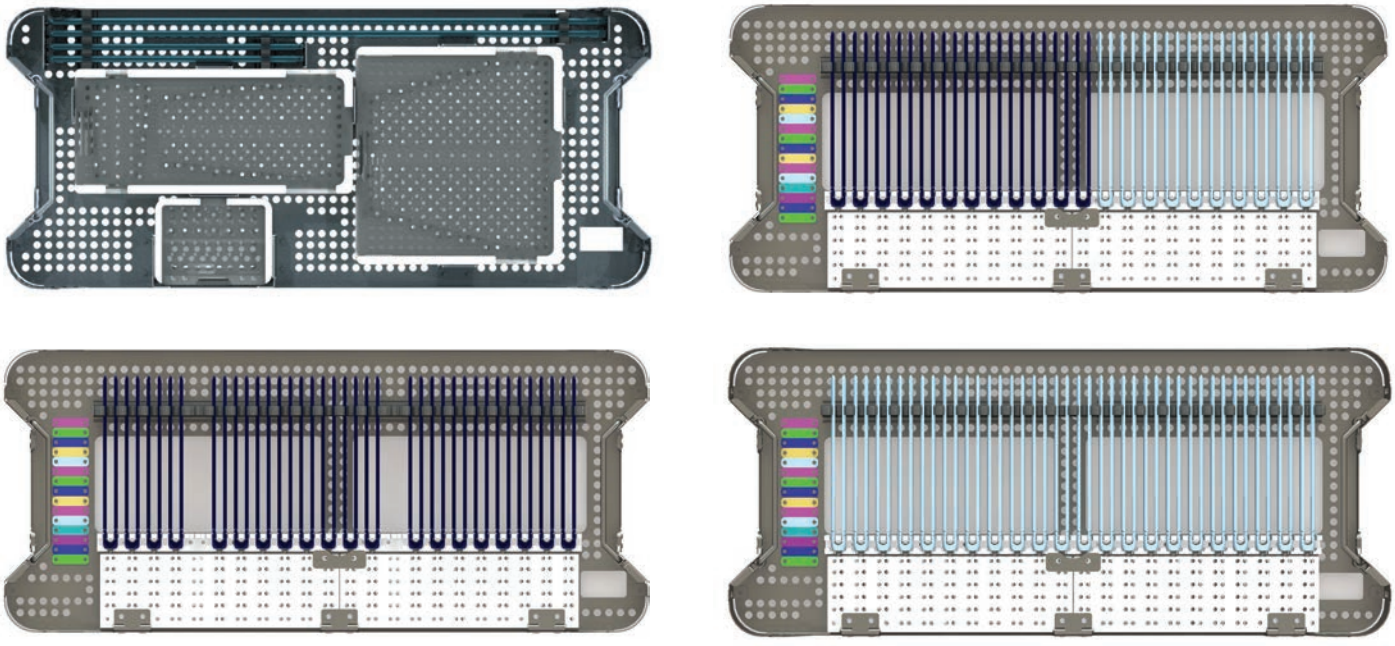
- Place the tab breaker over one extended tab at a time with the tab breaker rail running along the inside of the extended tab. Slide the tab breaker down the tab until it bottoms out.
- Rock the tab breaker back and forth in a medial/lateral direction until the extended tab separates from the screw.
- Remove the retained extended tab from the tab breaker before moving to the next extended tab.

IMPLANT REMOVAL INSTRUCTIONS

Identify the anatomical locations of the implants

- Remove the closure tops by turning the closure top counterclockwise using the T27 final driver. The counter-torque may be used to provide additional leverage to loosen the closure top.
- When all closure tops have been removed, the rod may be removed manually with a pair of forceps.
- When the rod has been removed, the screwdriver or any of the starter drivers can be used to remove the screw.

IMPLANT KIT CONTENTS

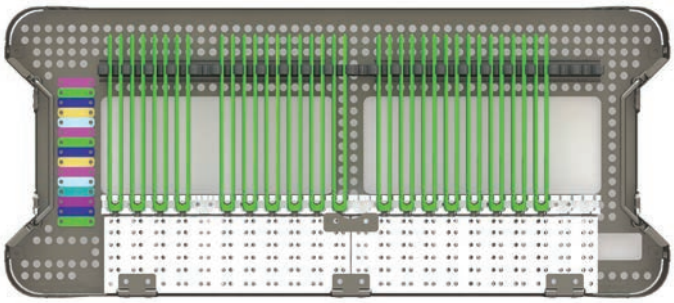


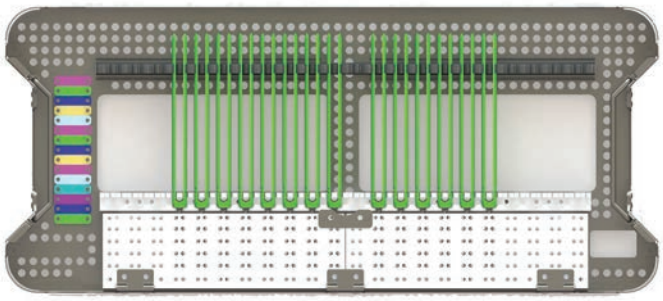
Vital MIS Implant Kit 1
Kit Number: PCR800M1201

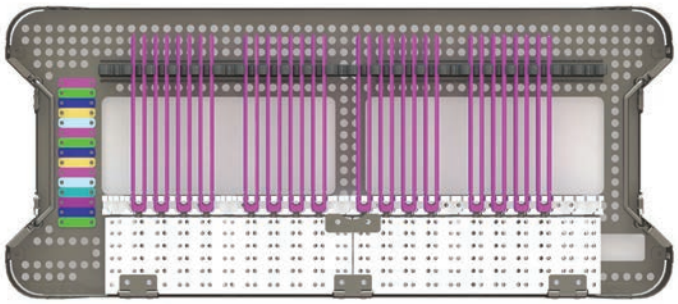
DESCRIPTION	QTY	PART NUMBER
ø5.5 x 35 mm, MIS Polyaxial Screw	4	824M5535
ø5.5 x 40 mm, MIS Polyaxial Screw	8	824M5540
ø5.5 x 45 mm, MIS Polyaxial Screw	8	824M5545
ø5.5 x 50 mm, MIS Polyaxial Screw	8	824M5550
ø5.5 x 55 mm, MIS Polyaxial Screw	4	824M5555
ø6.5 x 35 mm, MIS Polyaxial Screw	4	824M6535
ø6.5 x 40 mm,MIS Polyaxial Screw	8	824M6540
ø6.5 x 45 mm, MIS Polyaxial Screw	8	824M6545
ø6.5 x 50 mm, MIS Polyaxial Screw	8	824M6550
ø6.5 x 55 mm, MIS Polyaxial Screw	4	824M6555
ø5.5 x 30 mm, MIS Curved Ti Rod	4	815M1030
ø5.5 x 35 mm, MIS Curved Ti Rod	4	815M1035
ø5.5 x 40 mm, MIS Curved Ti Rod	4	815M1040
ø5.5 x 45 mm, MIS Curved Ti Rod	4	815M1045
ø5.5 x 50 mm, MIS Curved Ti Rod	4	815M1050
ø5.5 x 55 mm, MIS Curved Ti Rod	4	815M1055

DESCRIPTION	QTY	PART NUMBER
ø5.5 x 60 mm, MIS Curved Ti Rod	4	815M1060
ø5.5 x 65 mm, MIS Curved Ti Rod	4	815M1065
ø5.5 x 70 mm, MIS Curved Ti Rod	4	815M1070
ø5.5 x 75 mm, MIS Curved Ti Rod	4	815M1075
ø5.5 x 80 mm, MIS Curved Ti Rod	4	815M1080
ø5.5 x 90 mm, MIS Curved Ti Rod	4	815M1090
ø5.5 x 100 mm, MIS Curved Ti Rod	4	815M1100
ø5.5 x 110 mm, MIS Curved Ti Rod	4	815M1110
ø5.5 x 120 mm, MIS Curved Ti Rod	4	815M1120
ø5.5 x 130 mm, MIS Curved Ti Rod	4	815M1130
ø5.5 x 140 mm, MIS Curved Ti Rod	4	815M1140
ø5.5 x 150 mm, MIS Curved Ti Rod	4	815M1150
ø5.5 x 200 mm, MIS Straight Ti Rod	4	815M3200
ø5.5 x 450 mm, MIS Straight Ti Rod	4	815M5450
Closure Tops	14	07.02010.001

IMPLANT KIT CONTENTS *(continued)*







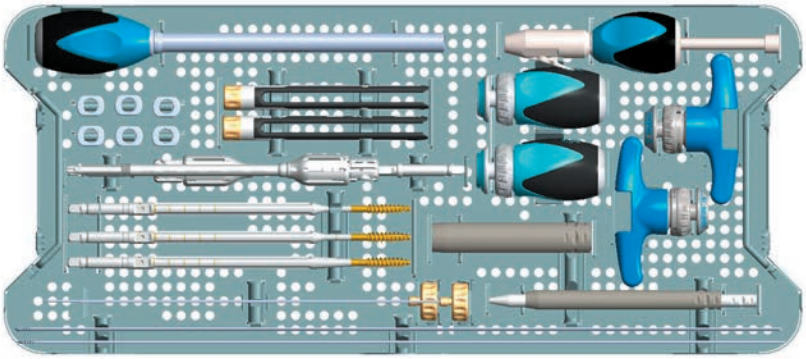
Vital MIS Implant Kit 2
Kit Number: PCR800M1202

DESCRIPTION	QTY	PART NUMBER
ø7.5 x 35 mm, MIS Polyaxial Screw	4	824M7535
ø7.5 x 40 mm, MIS Polyaxial Screw	6	824M7540
ø7.5 x 45 mm, MIS Polyaxial Screw	8	824M7545
ø7.5 x 50 mm, MIS Polyaxial Screw	6	824M7550
ø7.5 x 55 mm, MIS Polyaxial Screw	4	824M7555
ø8.5 x 40 mm, MIS Polyaxial Screw	4	825M8540
ø8.5 x 45 mm, MIS Polyaxial Screw	4	825M8545
ø8.5 x 50 mm, MIS Polyaxial Screw	4	825M8550
ø8.5 x 55 mm, MIS Polyaxial Screw	4	825M8555
ø8.5 x 60 mm, MIS Polyaxial Screw	4	825M8560

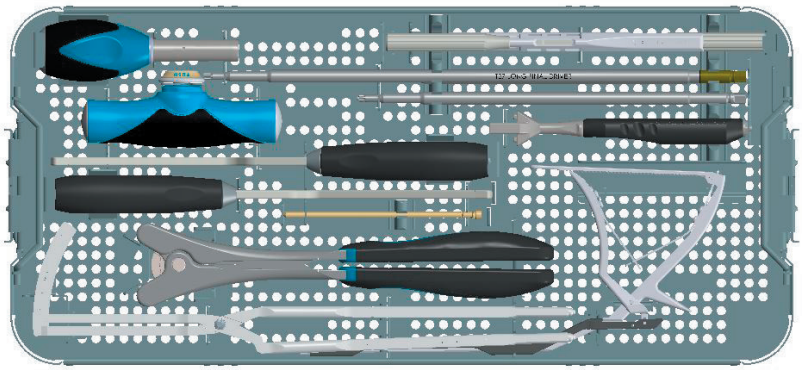
Vital MIS Implant Kit 3
Kit Number: PCR800M1203

DESCRIPTION	QTY	PART NUMBER
ø4.5 x 30 mm, MIS Polyaxial Screw	4	824M4530
ø4.5 x 35 mm, MIS Polyaxial Screw	4	824M4535
ø4.5 x 40 mm, MIS Polyaxial Screw	4	824M4540
ø4.5 x 45 mm, MIS Polyaxial Screw	4	824M4545

INSTRUMENT KIT CONTENTS



Top Tray



Bottom Tray

Vital MIS Instrument Kit 1
Kit Number: PCR800M1600

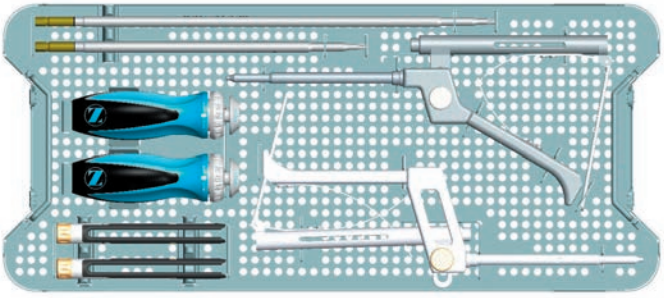
Top Tray

DESCRIPTION	QTY	PART NUMBER
Guidewire, Trocar	8	14-500361
Guidewire, Blunt	8	14-500360
Guidewire Slaphammer	1	850M0056
Starter Dilator	1	850M0016
Middle Dilator, Short	1	854M0017
Large Dilator, Short	1	854M0018
X-Large Dilator, Short	1	850M0019
Pedicle Access Tool T-Handle w/ Ratchet	2	850M0053
Pedicle Access Tool, Tap Stylus, Short	2	850M4000
Pedicle Access Tool, Tap, ø4.5 mm, Short	1	850M6045
Pedicle Access Tool, Tap, ø5.5 mm, Short	1	850M6055
Tap, ø4.5 mm, Short	1	850M5045
Tap, ø5.5 mm, Short	1	850M5055
Tap, ø6.5 mm, Short	1	850M5065
Tap, ø7.5 mm, Short	1	850M5075
Bone Planar	1	850M0066
Cannulated Driver, Short	2	850M0020
Tab Sleeve	6	850M0061
Reinforcement Sleeve	4	850M0029

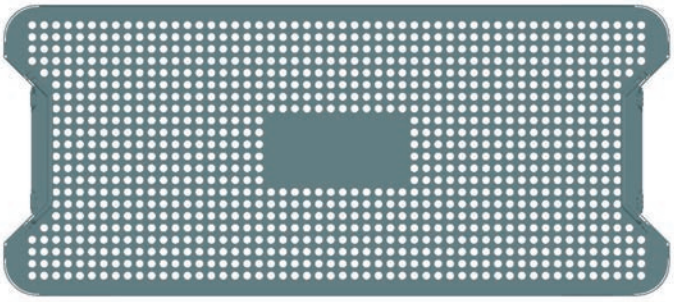
Bottom Tray

DESCRIPTION	QTY	PART NUMBER
Torque-limiting T-handle	1	07.02053.001
T27 Final Driver	1	850M0022
T27 Final Driver, Long	1	850M0025
French Rod Bender	1	07.02092.001
Rod Inserter with Stop	1	850M0042
Rod Inserter, Thru	1	850M0041
Rod Inserter Locking Piston	1	850M0043
Tab Breaker	2	850M0080
Rod Caliper	1	850M0081
Closure Top Inserter	2	850M0078
Rod Forceps	1	850M0060
Reinforcement Sleeve Counter-torque Wrench	1	850M0028
Counter-torque, Short-slotted	1	850M0054

INSTRUMENT KIT CONTENTS *(continued)*



Top Tray



Bottom Tray

Vital MIS Instrument Kit 2
Kit Number: PCR800M1700

Top Tray

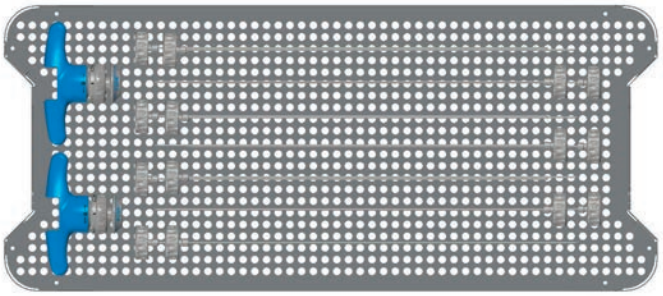
DESCRIPTION	QTY	PART NUMBER
Ratcheting Straight Handle	2	07.02051.001
Reinforcement Sleeve	2	850M0029
Compressor	1	850M0058
Distractor	1	850M0068
T27 Final Driver, Long	1	850M0025
T27 Final Driver	1	850M0022

Bottom Tray

Empty

Vital MIS Optional Instruments

DESCRIPTION	PART NUMBER
Jamshidi T-handle Targeting Needle, Trocar	850M0001
Jamshidi T-handle Lower Shaft	850M0002
Jamshidi Sleeve	850M0003
Jamshidi T-handle Targeting Needle, Bevel	850M0004
Cannulated Driver, Standard	850M0021
Bone Aspirator Adapter	850M0076
Long Counter-torque, Rod-capture	850M0049
Rod Pusher	850M0046



Pedicle Access Screw Insertion Tool Kit
Kit Number: PCR800M1400

DESCRIPTION	QTY	PART NUMBER
Ratcheting PAT T-handle	2	850M0053
Short PAT (PASIT) Stylus, 30 mm	2	850M4030
Short PAT (PASIT) Stylus, 35 mm	2	850M4035
Short PAT (PASIT) Stylus, 40 mm	2	850M4040
Short PAT (PASIT) Stylus, 45 mm	2	850M4045
Short PAT (PASIT) Stylus, 50 mm	2	850M4050
Short PAT (PASIT) Stylus, 55 mm	2	850M4055
Short PAT (PASIT) Stylus, 60 mm	2	850M4060

Disposable Jamshidi Needle Kit
Kit Number: 14-571181

DESCRIPTION	QTY	PART NUMBER
Needle	8	14-501659

INSTRUMENT OVERVIEW

Guidewire	PART NUMBER
Trocar, Threaded	14-500361
Blunt, Threaded	14-500360

Bone Planar	PART NUMBER
	850M0066

Pedicle Access Tool Stylus	PART NUMBER
	850M4000

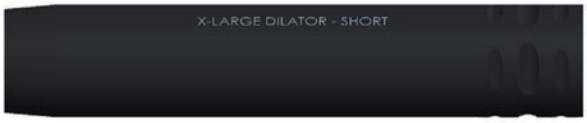
Short Cannulated PAT Taps	PART NUMBER
ø4.5 mm	850M6045
ø5.5 mm	850M6055

Short Cannulated Taps	PART NUMBER
ø4.5 mm	850M5045
ø5.5 mm	850M5055
ø6.5 mm	850M5065
ø7.5 mm	850M5075

Starter Dilator	PART NUMBER
	850M0016

Middle Dilator, Short	PART NUMBER
	854M0017

Large Dilator, Short	PART NUMBER
	854M0018



X-Large Dilator, Short	PART NUMBER
	854M0019

T27 Final Driver	PART NUMBER
	850M0022

T27 Final Driver, Long	PART NUMBER
	850M0025

INSTRUMENT OVERVIEW *(continued)*

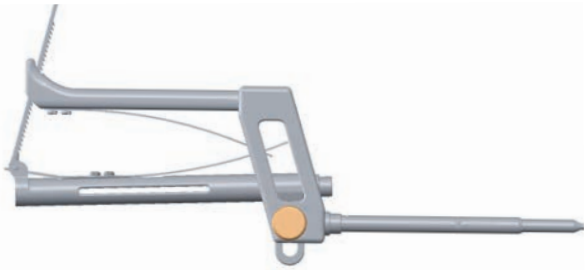
Screw Driver	PART NUMBER
Extended Tab Driver, Short	850M0020

Reinforcement Sleeve Counter-torque Wrench	PART NUMBER
	850M0028

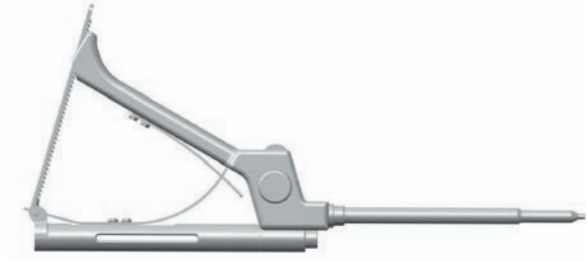
Reinforcement Sleeve	PART NUMBER
	850M0029

French Rod Bender	PART NUMBER
	07.02092.001

Rod Forceps	PART NUMBER
	850M0060



Compressor	PART NUMBER
	850M0058



Distractor	PART NUMBER
	850M0068

Counter-torque, Short-slotted	PART NUMBER
	850M0054

Guidewire Slap Hammer	PART NUMBER
	850M0056

Rod Caliper, Long	PART NUMBER
	850M0081

T27 Closure Top Inserter	PART NUMBER
	850M0078

Tab Sleeve	PART NUMBER
	850M0061

Tab Breaker	PART NUMBER
	850M0080

Rod Inserter - Stop	PART NUMBER
	850M0042

Rod Inserter - Thru	PART NUMBER
	850M0041

Rod Inserter Piston	PART NUMBER
	850M0043

Torque-limiting T-handle	PART NUMBER
90 in-lb/10.2 Nm	07.02053.001

Ratcheting Pedicle Access Tool T-handle	PART NUMBER
	850M0053

Ratcheting Straight Handle	PART NUMBER
	07.02051.001

Ratcheting Palm Handle	PART NUMBER
	07.02105.001

OPTIONAL INSTRUMENTS

Jamshidi Targeting Needle - Trocar	PART NUMBER
	850M0001

Rod Pusher	PART NUMBER
	850M0046

Jamshidi Targeting Needle - Bevel	PART NUMBER
	850M0004

Cannulated Driver, Standard	PART NUMBER
	850M0021

Targeting Needle - Lower Shaft	PART NUMBER
	850M0002

Long Counter-torque, Rod-capture	PART NUMBER
	850M0049

Targeting Needle Insulation Sleeve	PART NUMBER
	850M0003

Bone Aspiration Adapter	PART NUMBER
	850M0076

IMPORTANT INFORMATION ON THE VITAL MIS SPINAL FIXATION SYSTEM

Vital

The Vital Spinal Fixation System is a subsystem of the Vitality Spinal Fixation System.

Device Description

The Vitality Spinal Fixation System is a thoracolumbar and sacroiliac fixation system designed to aid in the surgical correction of several types of spinal conditions. The system consists of a variety of spinal rods, pedicle screws, hooks and connectors intended only to provide temporary stabilization during the development of a solid fusion of the spine with bone graft. The system can be rigidly locked into a variety of configurations, with each construct being customized to the patient's anatomy. All implants are single use only and should not be reused under any circumstances. The implant system is intended to be removed after solid fusion has occurred.

The system also includes instrumentation for insertion, securing and removal of the implants. All implants are made from medical grade titanium alloy; select rods are also available in medical grade cobalt chromium alloy. Implants made from medical grade titanium, medical grade titanium alloy, and medical grade cobalt chromium may be used together. Never use titanium, titanium alloy and/or cobalt chromium with stainless steel in the same implant construct. The Vitality Spinal Fixation System is compatible with components from other cleared spinal fixation systems. See Indications below.

Indications

The Vitality Spinal Fixation System implants are non-cervical spinal fixation devices intended for posterior pedicle screw fixation (T1 S2/ilium), posterior hook fixation (T1 L5), or anterolateral fixation (T8 L5). Pedicle screw fixation is indicated for skeletally mature patients and for adolescent patients.

These devices are indicated as an adjunct to fusion for all of the following indications: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), deformities or curvatures (i.e., scoliosis, kyphosis and/or lordosis, Scheuermann's Disease), tumor, stenosis, pseudoarthrosis and/or failed previous fusion. When used as an adjunct to fusion, the Vitality Spinal Fixation System is intended to be used with autograft and/or allograft.

In addition the Vitality Spinal Fixation System is intended for treatment of severe spondylolisthesis (Grade 3 and 4) of the L5–S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft, having implants attached to the lumbosacral spine and or ilium with removal of the implant after attainment of a solid fusion. Levels of pedicle screw fixation for these patients are L3-sacrum/ilium.

When used for posterior non-cervical pedicle screw fixation in pediatric patients, the Vitality System implants are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. The Vitality System is intended to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

The use of the Vitality Spinal Fixation System in skeletally mature patients may include the fixation of the Instinct® Java™ Spinal Fixation System* hooks, APEX Spinal System™* hooks, or fixation of the Universal Clamp® Spinal Fixation System* to the rods of the Vitality Spinal Fixation System. The Vitality Spinal Fixation System may also be used in skeletally immature patients when connected with the Universal Clamp Spinal Fixation System.

In order to achieve additional levels of fixation in skeletally mature patients, the Vitality Spinal Fixation System may be connected to the Virage® OCT Spinal Fixation System* and the Instinct Java Spinal Fixation System offered by Zimmer Biomet Spine, using rod connectors.

Contraindications

The Vitality System is not designed or sold for any use except as indicated. **DO NOT USE THE VITALITY SYSTEM IMPLANTS IN THE PRESENCE OF ANY CONTRAINDICATION.**

- Insufficient bone quantity, severe osteoporosis or other condition that might compromise rigid fixation of the device.
- A history of infection, active systemic infection or infection localized to the site of the proposed implantation.
- Suspected or documented metal allergy or intolerance.
- A disorder affecting the normal process of bone remodeling, including but not limited to severe osteoporosis involving the spine, excessive bone reabsorption, osteopenia, a primary or metastatic tumor involving the spine or certain metabolic disorders of osteogenesis.
- Iliac screws and offset connectors should not be used in cases of tumor or trauma of the sacrum, when additional screw fixation in S1 is not possible.
- Other relative contraindications include obesity, pregnancy, certain degenerative diseases, 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

** These optional components are not approved in all regions.*

IMPORTANT INFORMATION ON THE VITAL MIS SCREW SYSTEM *(continued)*

Warnings and Precautions

Following are specific warnings, precautions and adverse effects associated with use of the Vitality System that should be understood by the surgeon and explained to the patients. General surgical risk should be explained to the patients prior to surgery.

- Implantation of the Vitality System should be performed only by experienced spinal surgeons.
- All implants are intended for 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
- Metal sensitivity has been reported following exposure to orthopedic implants. The most common metallic sensitivities (nickel, cobalt and chromium) are present in medical grade stainless steel and cobalt-chrome alloys.
- Universal precautions should be observed by all end users that work with contaminated or potentially contaminated medical devices. Caution should be exercised when handling devices with sharp points or cutting edges to prevent injuries during and after surgical procedures and reprocessing.
- Warning: The safety and effectiveness of pedicle screw spinal systems have been established only for spinal conditions with significant mechanical instability or deformity requiring fusion with instrumentation. These conditions are significant mechanical instability or deformity of the thoracic, lumbar and sacral spine secondary to severe spondylolisthesis (grades 3 and 4) of the L5–S1 vertebra, degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor and failed previous fusion (pseudoarthrosis). The safety and effectiveness of these devices for any other conditions are unknown.
- Warning: The safety and effectiveness of this device has not been established for use as part of a growing rod construct. The device is only intended to be used when definitive fusion is being performed at all instrumented levels.
- Additional Warnings for Pediatric Patients: The use of pedicle screw fixation in the pediatric population may present additional risks when patients are of smaller stature and skeletally immature. Pediatric patients may have smaller spinal structures (pedicle diameter or length) that may preclude the use of pedicle screws or increase the risk of pedicle screw malpositioning and neurological or vascular injury. Patients who are not skeletally mature undergoing spinal fusion procedures may have reduced longitudinal spinal growth, or may be at risk for rotational spinal deformities (the “crankshaft phenomenon”) due to continued differential growth of the anterior spine.
- Precaution: The implantation of pedicle screw spinal systems should be performed only by experienced spinal surgeons with specific training in the use of this pedicle screw spinal system because this is a technically demanding procedure presenting a risk of serious injury to the patient.
- Additional Precautions for Pediatric Patients: The implantation of pedicle screw spinal systems in pediatric patients should be performed only by experienced spinal surgeons with specific training in the use of this pedicle screw spinal system in pediatric patients because this is a technically demanding procedure presenting a risk of serious injury to the patient.

Preoperative and operating procedures, including knowledge of surgical techniques, good reduction, and proper selection and placement of the implants are important considerations in the successful utilization of the system in pediatric patients. The selection of the proper size, shape and design of the implant for each patient is crucial to the safe use of this device in pediatric patients.

Additional preoperative, intraoperative and postoperative warnings and precautions:

Preoperative

- Usage of automated cleaning processes without supplemental manual cleaning may not result in adequate cleaning of instruments.
- Proper handling, decontamination (including pre-rinsing, washing, rinsing and sterilization), storage and utilization are important for the long and useful life of all surgical instruments. Even with correct use, care and maintenance, they should not be expected to last indefinitely. This is especially true for cutting instruments (e.g., bone awls/drills) and driving instruments (e.g., drivers). These items are often subjected to high loads and/or impact forces. Under such conditions, breakage can occur, particularly when the item is corroded, damaged, nicked or scratched.
- Never use titanium, titanium alloy, and/or cobalt chromium with stainless steel in the same implant construct; otherwise, galvanic corrosion may occur.
- Zimmer Biomet does not specify the maximum number of times a re-usable instrument may be re-used. The useful life of these instruments is highly dependent on a number of factors including the frequency and manner in which they are used and the handling they experience in between uses. Inspection and, where appropriate, functional testing prior to using, is the best way to determine whether or not an individual device should be used.

Intraoperative

- If contouring of the implant is necessary for optimal fit, the contouring should be gradual and avoid any notching or scratching of the implant surface. Do not repeatedly or excessively bend the implant. Do not reverse bend the rods.
- Pedicle bone integrity should be verified.
- Care should be taken during pedicle preparation to avoid penetrating too deep.
- Care should be taken during bone preparation to avoid damage to the pedicle and to the surgical instruments.
- Care should be taken to minimize soft tissue damage during surgery.
- Care should be taken to avoid removing excess material from the lamina.
- Care should be taken to avoid cross-threading screws and closure tops.
- If any implant or instrument comes in contact with a non-sterile surface it should not be used.

Postoperative

- 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 fracture. The patient should understand that an 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.
- The Vitality System is a temporary internal fixation device. Internal fixation devices are designed to stabilize the operative site during the normal healing process. After healing occurs, these devices serve no functional purpose and should be removed. Implant removal should be followed by adequate postoperative management to avoid fracture or refracture.

Adverse Effects

Complications and adverse reactions have been reported with the use of similar spinal instrumentation systems. These adverse effects, including the possibility of death, should be discussed with the patient prior to surgery.

- Non-union, delayed union
- Bending or fracture of implant. Fraying, kinking, loosening, bending or breaking of any or all implant components.
- Loosening of or migration of the implant
- Metal sensitivity or allergic reaction to a foreign body
- Infection
- Decrease in bone density due to stress shielding
- Pain, discomfort, or abnormal sensations due to the presence of the device
- Loss of the natural curvature of the spine
- Modification of the spinal geometric corrections of the vertebral and/or intervertebral height and/or of the reduction in spinal deformities
- Vascular and/or nerve damage due to surgical trauma or presence of the device.
- Neurological difficulties including bowel and/or bladder dysfunction, impotence, retrograde ejaculation and paraesthesia.
- Bursitis
- Dural leak
- Paralysis
- Death
- Erosion of blood vessels due to the proximity of the device, leading to hemorrhage and/or death
- Additional surgery may be required to correct any of these potential adverse effects
  - Additional Potential Adverse Effects for Pediatric Patients:
  - Inability to use pedicle screw fixation due to anatomic limitations (pedicle dimensions, distorted anatomy)
  - Pedicle screw malpositioning, with or without neurological or vascular injury
  - Proximal or distal junctional kyphosis
  - Pancreatitis

Other adverse events related to pedicle screw fixation, such as screw or rod bending, breakage, or loosening, may also occur in pediatric patients and pediatric patients may be at increased risk for device-related injury because of their smaller stature.

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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.*

eLabeling: The Instructions for Use can be accessed online by visiting the website and using the KEY-CODE provided on the product label and as shown below. Additional translations are also available in electronic format for download. To request a paper copy of the Instructions for Use, contact Zimmer Biomet Spine at the phone number provided.

Consult Instructions for Use on this website:
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