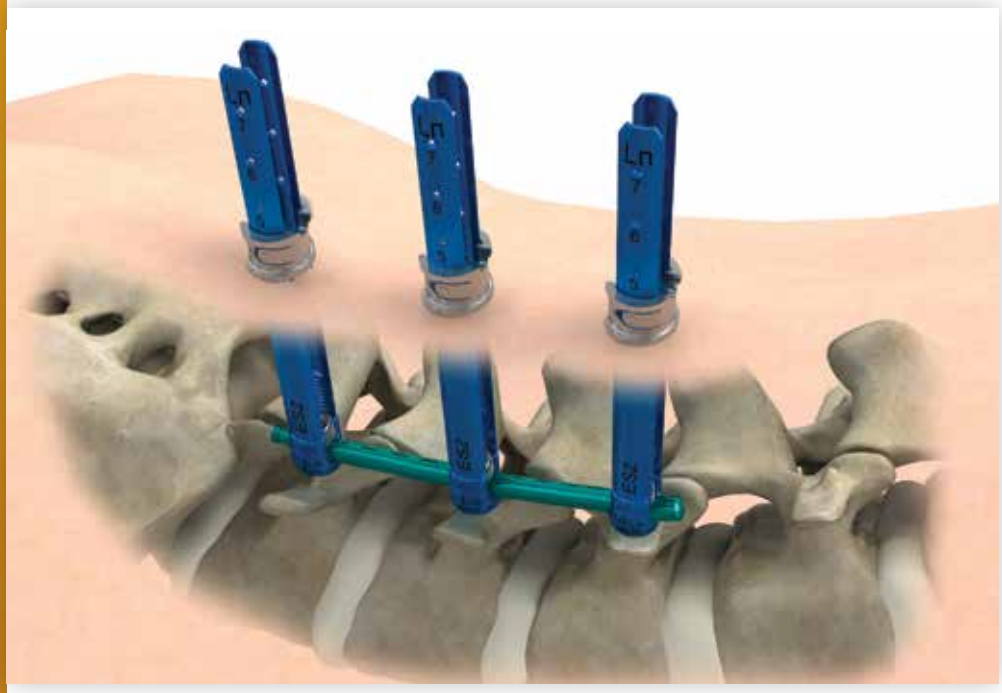
stryker

ES2®
Spinal System



Surgical technique

LITe®
Less Invasive Technologies

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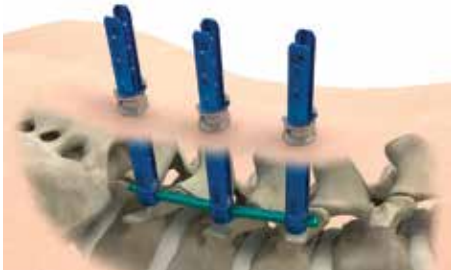
Acknowledgments:

Stryker's Spine division wishes to thank the following surgeons for their dedication and contributions to the development of the ES2 Spinal System.

Ralph Mobbs, MD
Jeffrey Roh, MD
James Schwender, MD
Christopher Yeung, MD

Introduction



Note: No acid or alkaline solvents should be used in the cleaning of anodized components.

Note: Upon the completion of each surgical procedure, use adequate suction and irrigation to ensure the removal of any existing non-implantable materials.

Note: This is intended as a guide only. There are multiple techniques, and as with any surgical procedure, a surgeon should be thoroughly trained before proceeding.

One primary objective of Stryker's Less Invasive Technologies (LITe) is to replicate the clinical results of the corresponding open procedure.

The **ES2 Spinal System** is the latest spinal fixation system in our LITe platform. It has been developed with experienced surgeons' input to provide efficiency, simplicity and security for MIS procedures. ES2 provides surgeons a low profile fixation solution along with streamlined instrumentation making it simple for the entire OR team to deliver to the patient. Developed with Stryker's leading technology from over 20+ years of successful implant systems, ES2 delivers an outstanding system for your MIS procedures.

Important

This surgical technique sets forth detailed, recommended procedures for using the ES2 Spinal System. It offers guidance that you should heed but as with any such technical guide, each surgeon must consider the particular needs of each patient and make appropriate adjustments when necessary and as required.

Always refer to the package insert, product label and/or instructions before using any implant or instrument.

Key design features

The integration of the blade with the screw offers:
- The blade-screw interface is designed to offer strength and security during the procedure
- 15mm of threads to help reduce rods into the screw head

The screw is built on the Xia 3 design delivering:
- A low profile implant which may reduce the need for a large incision
- Cortical/cancellous thread design for anatomical adaptation
- Acceptance of a 5.5mm and 6.0mm rod diameter

The 6-point star feature on the bone screw is designed to:
- Allow for faster and more intuitive engagement with the Polyaxial Screwdriver
- Prevent stripping of the connection between the screw and Polyaxial Screwdriver
- Allow for easy re-engagement of the Polyaxial Screwdriver or Polyadjustment Driver for screw position adjustments

The Ring has been designed with efficiency and simplicity in mind to:
- Hold the blades secure while inserting into patient
- Clip in place to maintain its positioning on the blades
- Include a notch to allow for rod contouring and measuring
- Be low profile to maximize visibility

Surgical technique

Patient positioning

The ES2 Spinal System can be used under local, epidural, spinal or general anesthesia. General anesthesia is commonly used since it is the most comfortable for the patient and allows immediate postoperative neurological assessment.

The patient is prepped and draped in the usual sterile manner for posterior fusion with pedicle screw fixation.

Skin marking

Using Anterior(A)/Posterior(P) imaging, place a **K-Wire** across the mid-line of the targeted pedicles. There are three guidewire options offered with the ES2 Spinal System:

- Nitinol K-Wire
- Stainless Steel K-Wire
- Y-Wire

Note: The Nitinol K-Wire is 550mm in length. The Stainless Steel K-Wire is 500mm in length. The Y-Wire is 559mm in length.

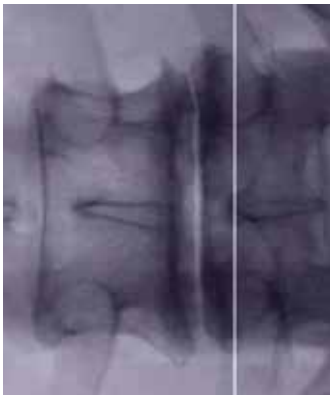
Note: The Y-Wire is made of Nitinol Alloy which also contains Nickel (Ni).

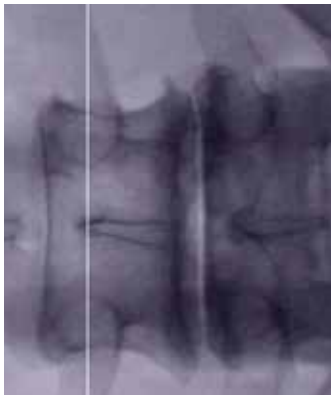
Note: To avoid targeting errors, make sure there is a true A/P view of the vertebral body by verifying that the superior endplate is parallel, or in line, with the x-ray beam.

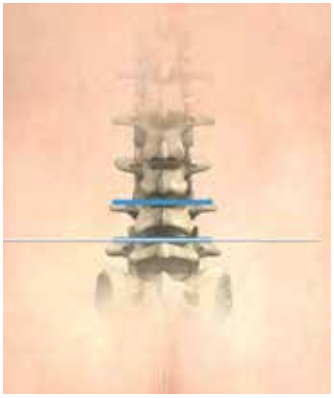
Stainless Steel K-Wire Sharp	**48230230**
Stainless Steel K-Wire Blunt	**48230231**
Nitinol K-Wire Sharp	**48280233**
Nitinol K-Wire Blunt	**48280232**
Y-Wire (five two-packs)	**FC-128-22-B-2**
Y-Wire (pack of two)	**FC-128-22-B-2S**
Y-Wire (five four-packs)	**FC-128-22-B-4**
Y-Wire (pack of four)	**FC-128-22-B-4S**

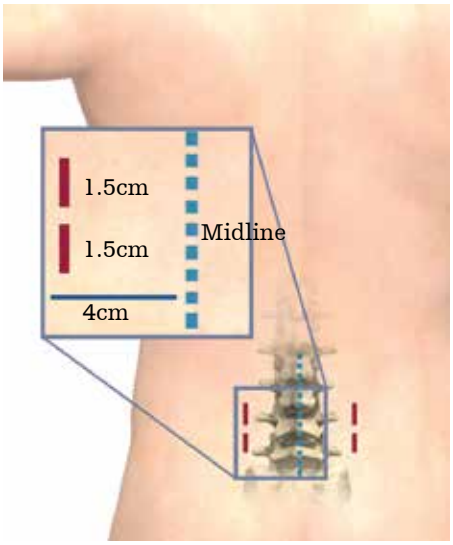
The Y-Wire is intended for use by surgeons to assist with the proper introduction and placement of orthopedic instruments and implants.

The Y-Wire is designed to limit inadvertent advancement of the guidewire outside the desired tissue placement. Upon exiting a cannula, the distal tips will deploy to stop further advancement past the desired location. Please see page 8 for the Y-Wire placement technique, which differs slightly from the standard K-Wire placement technique.







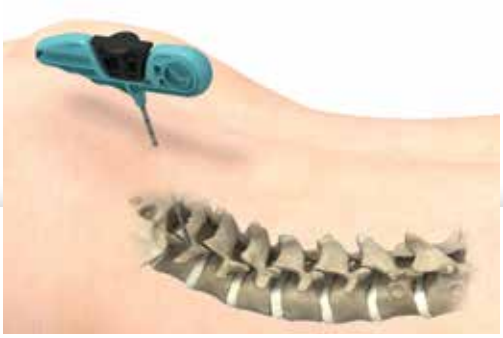


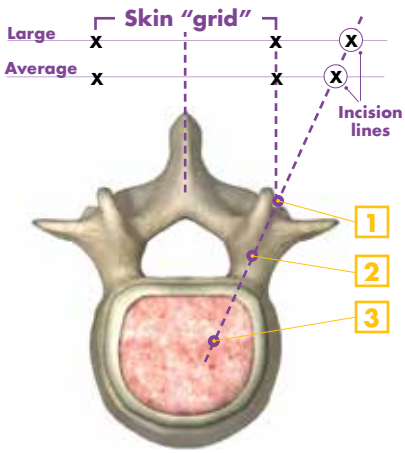
Carefully determine the appropriate entry point and trajectory for the ES2 screw. The entry point for percutaneous pedicle screws is approximately 4-5cm off mid-line with a more lateral trajectory. Incise the skin. A fascial incision may be done to make tissue dilation easier.

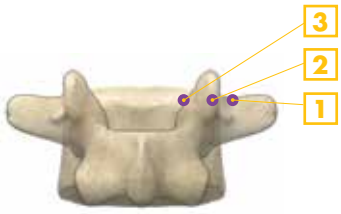
Note: If tissue dilation is difficult, the fascial incision may need to be increased.

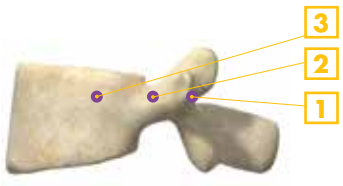
K-Wire insertion

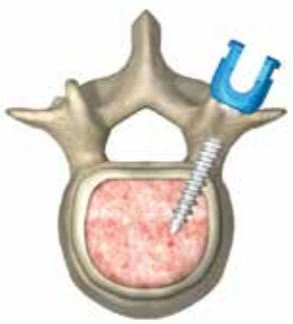
Insert a needle through the skin incision to the intersection of the facet and transverse process. Confirm that the needle is in the appropriate pedicle starting point determined by using both A/P and lateral images.





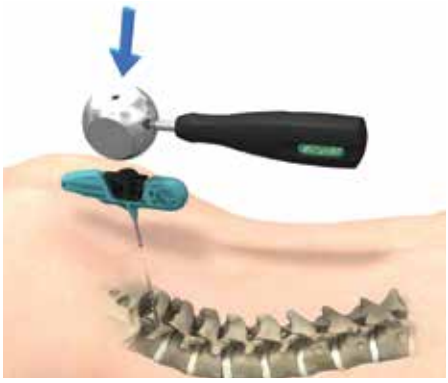






Proper targeting of the pedicle

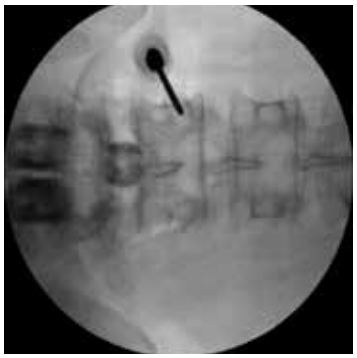
1. Make sure the incision is appropriately placed with consideration of the patient's anatomy. The larger the patient's muscle, adipose tissue and fascia posteriorly, the more lateral the incision.
2. The needle should be "docked" onto the lateral aspect of the pedicle as shown by box 1. This should be confirmed with A/P flouroscopy.
3. The needle is advanced 20 to 25mm so that the needle is beyond the medial border of the pedicle and into the vertebral body, box 2 and box 3.
4. Use of fluoroscopy can confirm proper placement of the needle prior to K-Wire insertion.

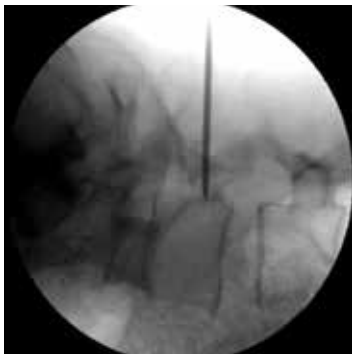


Slap Hammer **48280120**

Use the needle to gain access to the pedicle by advancing the needle partially through the pedicle using the **Slap Hammer**.

As the needle advances through the pedicle, it should approach the medial wall of the pedicle on the A/P images and should approach the base of the pedicle on the lateral images. When the needle reaches the medial wall on the A/P image, verification must be performed in the lateral image to ensure that the needle is past the base of the pedicle and starting to enter the vertebral body.





Note: The TN-100, TN-200, TN-300, and TN-400 are each packaged with a diamond tip stylet and a bevel tip stylet.

Bevel tip needles:

Tiger Cub - Jam Shidi Needle	**TN-100**
Tiger Needle Express - Jam Shidi Needle	**TN-200**
Tiger Needle Express with Broach - Jam Shidi Needle	**TN-300**
Tiger Needle - Jam Shidi Needle	**TN-400**
Needle 11 Gauge 6 Inch	**2090-9051**
Needle 8 Gauge 6 Inch	**2090-9052**
Fenestrated Needle 8 Gauge 6 Inch	**2090-9053**

Diamond tip needles:

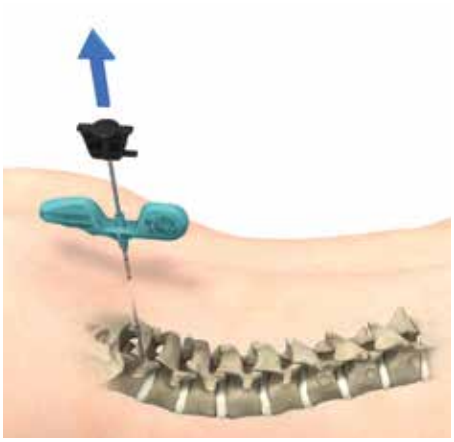
Jam Shidi 10 Gauge 9 Inch	**48237110**
Jam Shidi 10 Gauge 5 Inch	**48237105**
Jam Shidi 11 Gauge 5 Inch	**48237115**
Jam Shidi 13 Gauge 5 Inch	**48237135**
Tiger Cub - Jam Shidi Needle	**TN-100**
Tiger Needle Express - Jam Shidi Needle	**TN-200**
Tiger Needle Express with Broach - Jam Shidi Needle	**TN-300**
Tiger Needle - Jam Shidi Needle	**TN-400**
Needle 11 Gauge 4 Inch	**2090-9027**
Needle 11 Gauge 6 Inch	**2090-9028**
Needle 8 Gauge 6 Inch	**2090-9029**
Fenestrated Needle 8 Gauge 6 Inch	**2090-9030**
Needle 8 Gauge 8 Inch	**2090-9047**

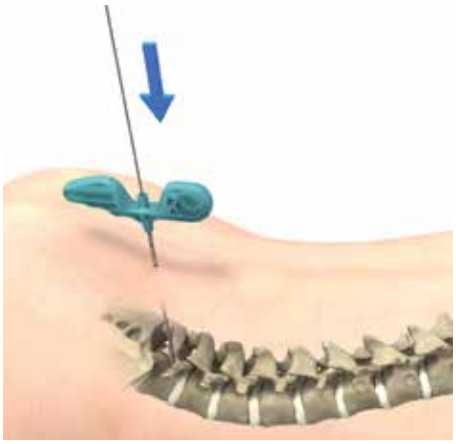
Note: The diameter of the ES2 K-Wire is 1.3mm. The diameter of the Y-Wire is 1.28mm.

Note: The Radius Spinal System K-Wire is not compatible with the ES2 Spinal System; the diameter of the Radius K-Wire is 1.5mm.

Note: The K-Wire and Y-Wire are single use instruments. The Y-Wire is a sterile packaged instrument.

With the needle in place just past the base of the pedicle, remove the inner stylet of the needle. The removal of the needle inner stylet allows the K-Wire to be inserted through the needle into the pedicle. Caution should be heeded with regard to the position of the K-Wire in order to avoid advancement of the K-Wire too anteriorly.

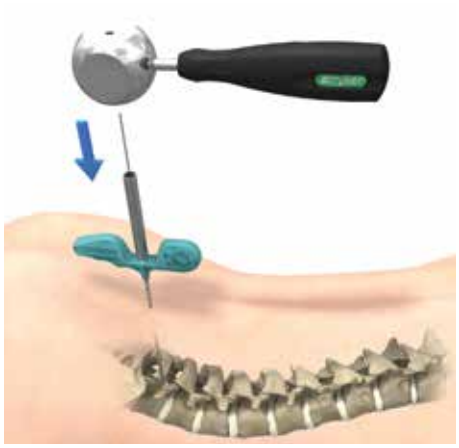




K-Wire Guide Tube* **48230235**

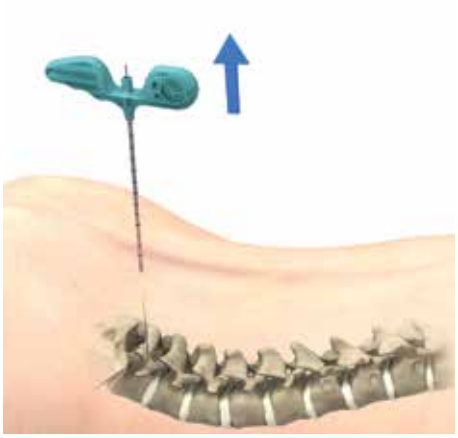
The **K-Wire Guide Tube** can be used to ease insertion of the K-Wire through the needle and into the pedicle.

***Note:** Guide Tube is not included in the standard instrument set, but can be pulled from the Mantis set.



Advance the K-Wire by hand or use the Slap Hammer to impact the K-Wire in hard bone.

Once the K-Wire is inserted, remove the K-Wire Guide Tube, if used, and the outer shaft of the needle. Take care to hold the K-Wire in position when removing the outer shaft of the needle.

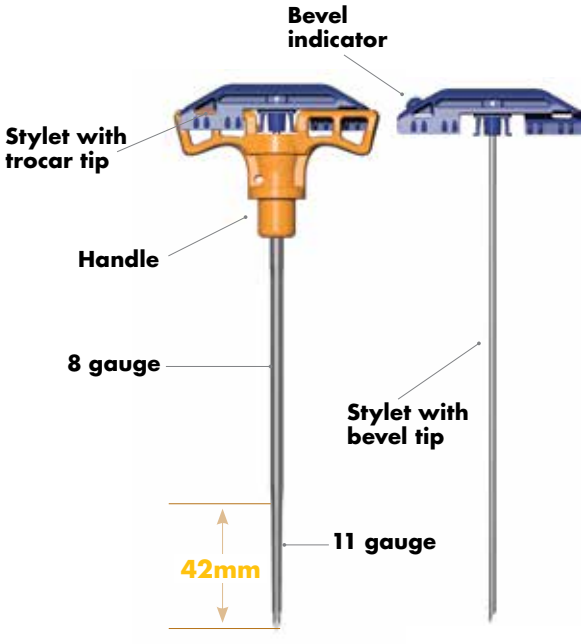


Y-Wire insertion

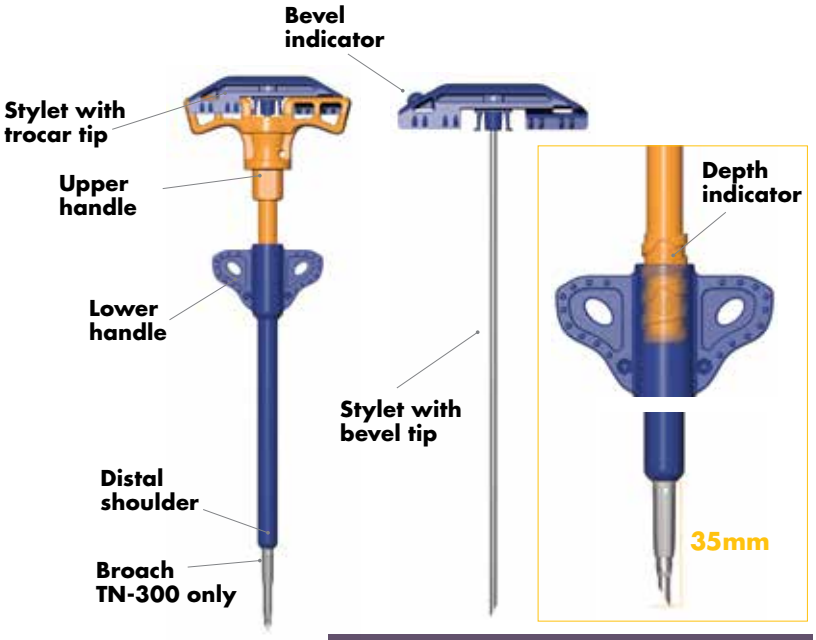
Remove the needle and stylets from the sterile packaging aseptically. Care should be taken to avoid the sharp tip of the needle and auxiliary stylet. Make sure that the components of the needle are intact and undamaged. Do not utilize if any of the components are damaged.

The needle family includes four unique offerings:

TN-100 Tiger Cub



TN-200/TN-300 Tiger Needle Express



Note: The TN-200 and TN-300 are identical except that the TN-300 has a broach distal end.

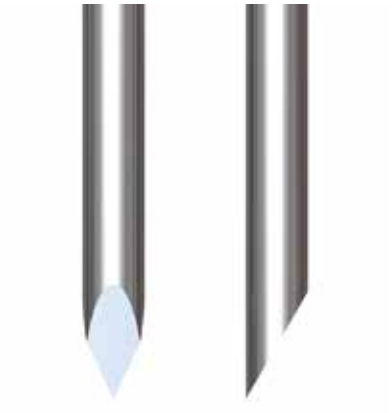
TN-400 Tiger Needle

Note: 20mm represents an example of the measured depth. The depth is variable from 20mm-45mm.

	Diameter	Tip length range	Compatibility
TN-100	2.9mm (11 gauge)	42mm	Compatible with Y-Wires up to Ø1.5mm
TN-200	2.9mm (11 gauge)	15mm – 35mm	Compatible with Y-Wires up to Ø1.5mm
TN-300	2.9mm (11 gauge)	15mm – 35mm	Compatible with Y-Wires up to Ø1.5mm
TN-400	3.7mm (10 gauge)	20mm – 45mm	Compatible with Y-Wires up to Ø1.5mm

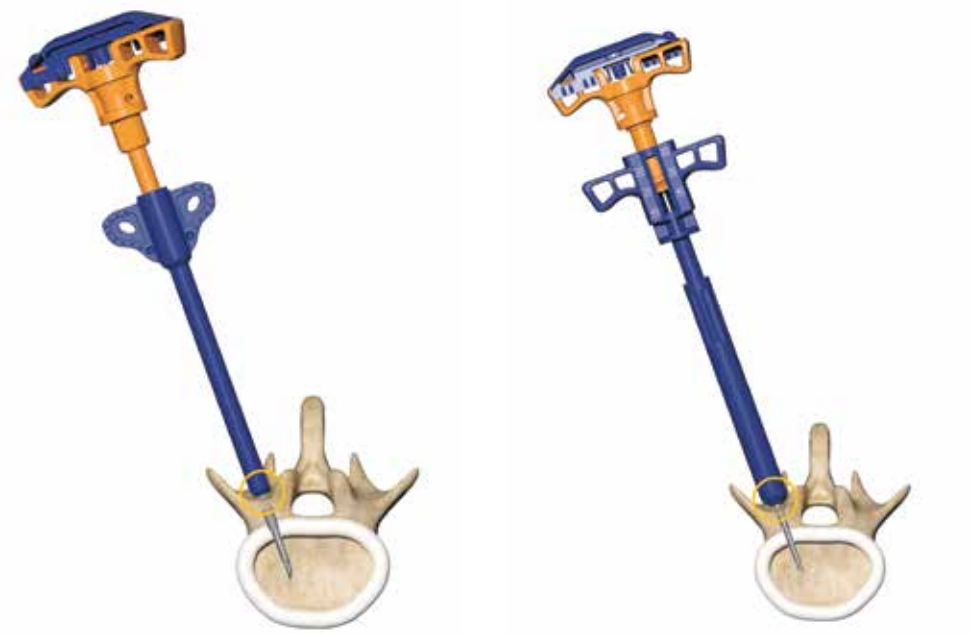
Warning:
- For the **TN-100**, ensure that the upper handle and stylet are fully assembled prior to advancing through tissue. Advancing the cannula without a stylet may result in device malfunction or patient injury.
- For the **TN-200, TN-300** and **TN-400**, ensure that the upper handle, lower handle and a stylet are fully assembled prior to advancing through tissue. Advancing the device with any of these three components missing may result in device malfunction or patient injury.

Each package comes with one cannula, one stylet with beveled tip and one stylet with diamond tip.



Orient the needle perpendicular to the bone surface and advance the needle by hand or with the aid of a mallet. Confirm needle placement using fluoroscopic guidance. The needle path should be adjusted to ensure a tract which is fully within the confines of the pedicle.

For the **TN-200** and **TN-300**, the needle will stop advancing when the distal shoulder of the needle contacts bone. For the **TN-400**, the needle will stop advancing when the distal end of the Jack Screw contacts bone. There is no positive stop on the **TN-100**.



Warning: Advancing the TN-100 beyond the anterior wall of the vertebral body may cause serious injury. Advancing the TN-200, TN-300 or TN-400 beyond the allowable "stop" depth within the vertebral body may cause serious injury.

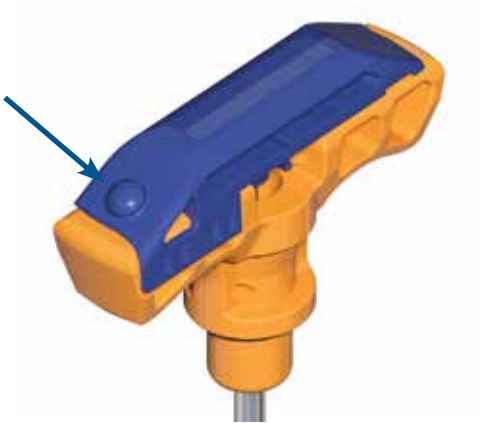
Further advance the tip by rotating the handle while applying downward pressure. For the TN-200, TN-300 and TN-400, rotate the upper handle relative to the lower handle while applying downward pressure. A reduction in resistance to tip advancement indicates penetration into the medullary cavity.

Each rotation of the TN-200, TN-300 and TN-400 upper handle advances the tip approximately 5mm. The exposed length of the **TN-200** and **TN-300** is indicated on the thread of the upper handle. The exposed tip length of the **TN-400** can be read on the depth indicator of the lower handle. The bottom of the orange thread indicates the depth.

If using the trocar tip, ensure that the stylet handle is properly seated and locked in place.

If the beveled tip stylet is desired, remove the trocar tip stylet from the needle and replace it with the beveled tip stylet. Ensure that the stylet handle is properly seated and locked in place. Take note of the bevel indicator on the handle of the bevel tip stylet, which represents the orientation of the bevel.

Warning: Use while the stylet is not interlocked may result in device malfunction or patient injury.



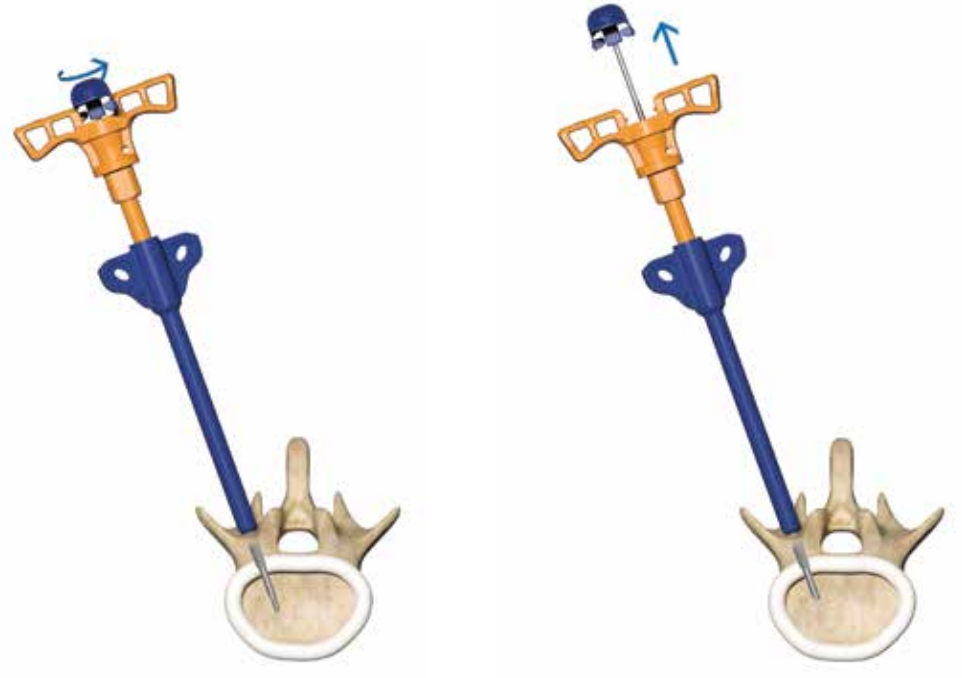
Note: If using the Y-Wire, the needle should be inserter at least 1/3 into the vertebral body. This will allow the Y-Wire to go further into the vertebral body so that subsequent instruments do not pinch the bifurcated tip.

Tip exposure

The **TN-200** and **TN-300** are supplied with the tip exposed 35mm. Counter rotate the upper handle relative to the lower handle to retract the exposed length of the needle tip to the desired length. The exposed length is indicated on the thread of the upper handle.

The **TN-400** is supplied with the tip exposed 20mm. Rotate the upper handle relative to the lower handle to extend the exposed length of the needle tip.

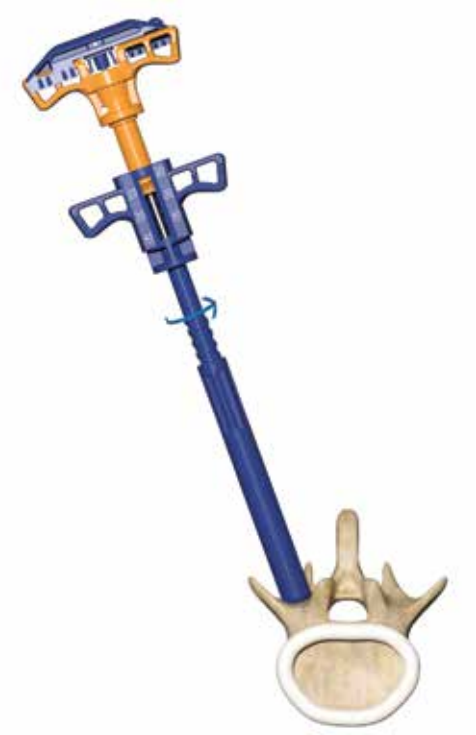
Once the desired tip depth is achieved, the stylet can be removed if desired. Counter rotate the stylet handle and pull proximally.



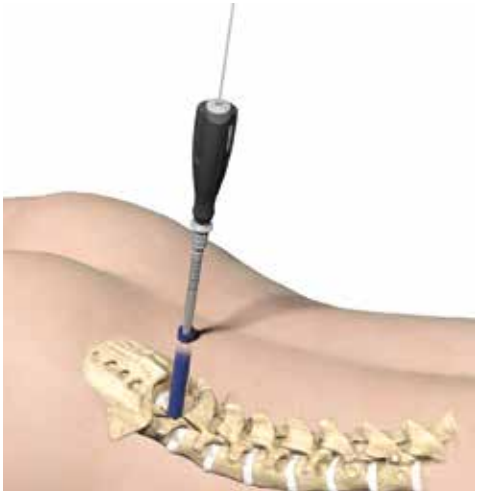
Warning: The larger diameter of the **TN-300** broach and loading from its use can stress and potentially fracture a pedicle. Ensure pedicle geometry is appropriate for use with devices which includes a broach prior to use.

Note: The outer diameter of the **TN-300** broach creates a hole that is too large for an Ø4.5 screw. Therefore, the **TN-300** can only be used with an Ø5.5 or larger ES2 screw.

The **TN-300** incorporates a broach above the distal tip which can be used to expand the pedicle. To utilize this feature, rotate the lower handle to further open the pedicle.



If using the **TN-400**, the Jack Screw may be left in place after removing the needle. To do so, remove the needle from the vertebra by counter rotating the lower handle relative to the Jack Screw. The needle may be completely removed leaving the Jack Screw in place for subsequent surgical steps. For example, the ES2 awl and taps may be utilized through the Jack Screw.



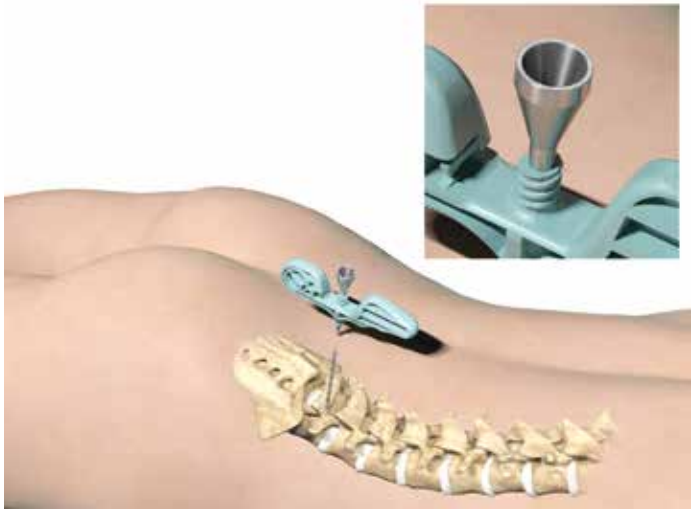
Note: Instruments with a maximum diameter of 2.3mm (11 gauge) may be passed through the inner portion of the TN-400 cannula.
Instruments with a maximum diameter of 8.5mm may be passed through the Jack Screw with the cannula removed.

If using the Y-Wire with any other Jam Shidi Needle, except for the **TN-100, TN-200, TN-300** or **TN-400** needles, the funnel must be used. The funnel acts as an adaptor to ensure compatibility between the Y-Wire and Jam Shidi Needle.

The Funnel is provided non-sterile. The Funnel requires sterilization prior to use.

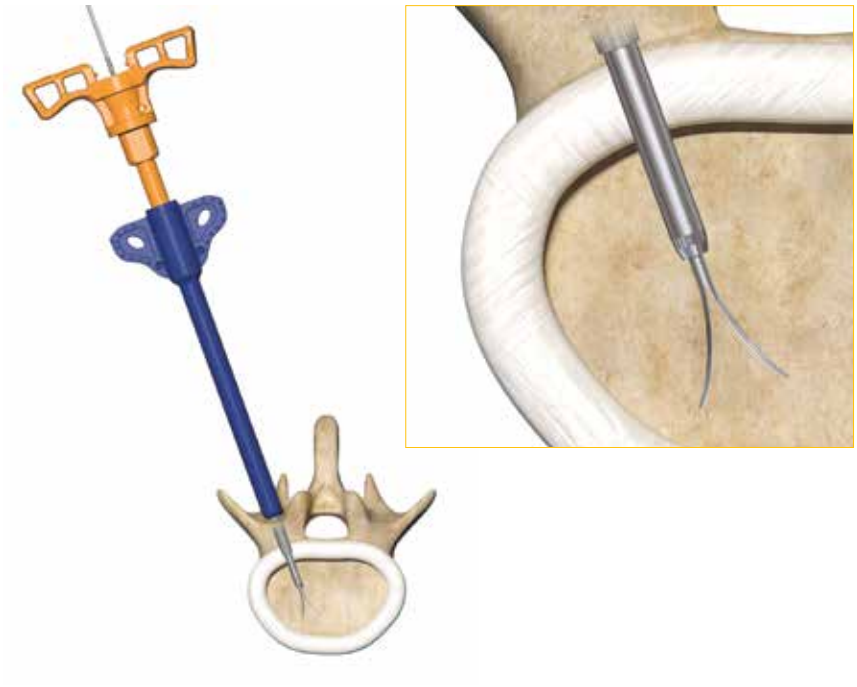
Attach the distal end of the funnel into the proximal end of the cannula and feed the splayed tip of the guidewire through the funnel into the cannula. The funnel compresses the guidewire tip so it may enter and pass through the cannula.

Use of the funnel is not needed when using the Y-Wire with the **TN-100, TN-200, TN-300** or **TN-400** Tiger needles.



Under fluoroscopic guidance, slowly feed the guidewire through the cannula into position. Care should be used to make sure that the tips will not deploy in an unsafe manner. This can be accomplished by making sure the cannula is positioned properly.

Once the tip exits the cannula, the tip will splay open and restrict further advancement of the guidewire. Obtain final radiographic images to confirm proper guidewire placement.



After the guidewire has been properly placed and the placement has been verified, the cannula can be removed.

While keeping the guidewire straight, slowly slide the cannula along the guidewire until the cannula is completely disengaged from the guidewire. If the cannula seizes up, stop. Let the guidewire relax and return to its original shape. Then slowly start again.

Care should be taken to ensure that instruments and implants do not push down with force or pinch the splayed tip. There is potential for breakage of the guidewire if too much force is applied.

Once a screw is in place, the Y-Wire may be removed. Ensure there is enough space between the distal tip of the instrument or implant and the proximal portion of the deployed guidewire tips. Pull the guidewire straight out in the opposite direction it was inserted. Take care not to twist or bend while removing guidewire.

Inspect Y-Wire upon removal for breakage.

Dilator 1 **48281000**

Note: The etched lines on Dilator 1 represent the top of the short and long blades respectively.

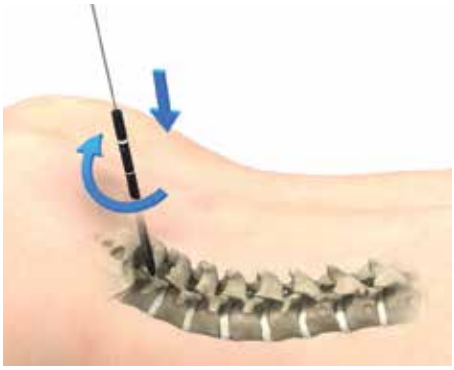
Note: The markings on Dilator 1 in relation to the skin are used to determine the appropriate blade length ("Sh" for Short and "Ln" for Long). The screw blade length should be based on where the top of the skin contacts the dilator. If the skin is below the etched line designated "Sh" choose the "Sh" or short blade length for the screw. If the skin is on the etched line designated "Sh" or in between the etched lines, choose the "Ln" or long blade screw.

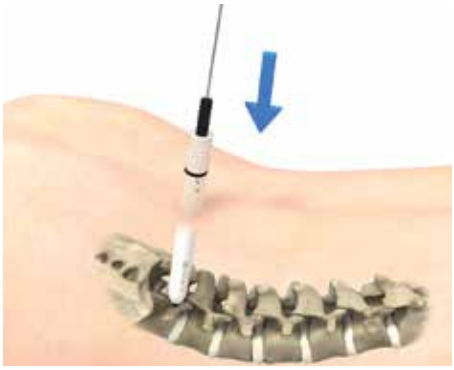
Note: If the "Ln" blades are too short, Mantis can be used with size 5 blades.

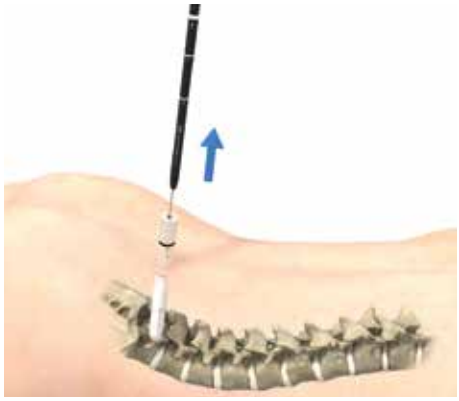
Note: The center of the first ring hole on the blade is 10mm from the top of the blade. If the skin is within 10mm of the top of the blade, consider moving to a longer blade marked "Ln."

Dilation

Place **Dilator 1** over the K-Wire or Y-Wire and down into the incision. Advance Dilator 1 through the soft tissue and lumbodorsal fascia towards the pedicle. Confirm the position of Dilator 1 against the bony anatomy between the facet and the transverse process using imaging.







Slide **Dilator 2** over Dilator 1 to penetrate and gently dissect the soft tissue down to the pedicle. Dilator 2 is made out of Radel, a plastic material that provides the necessary insulation for neuromonitoring signals. This material may not appear clearly on fluoroscopic imaging. Dilator 1 has a laser marked line to indicate the position of Dilator 2 when Dilator 2 is fully seated against the bony anatomy.

Dilator 2 **48282000**

Remove Dilator 1 after inserting and fully seating Dilator 2. Take care to maintain the position of the K-Wire or Y-Wire within the pedicle when removing Dilator 1.

Pedicle preparation

The modular pedicle preparation instrumentation can be attached to any one of the following cannulated handles:

T-Handle* **48289205**

T-Handle, Ratchet **48289200**

Round Handle* **48289305**

Round Handle, Ratchet **48289300**

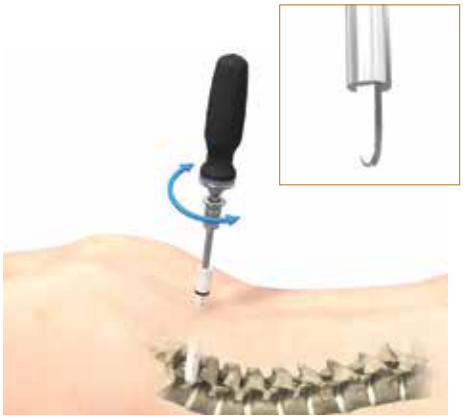
Short T-Handle, Ratchet, Cannulated **48769210**

Cannulated Modular Awl **48280200**

Note: The awl has a stop at 12mm.

Note: It is recommended that the awl is used to create a pilot hole prior to tapping.

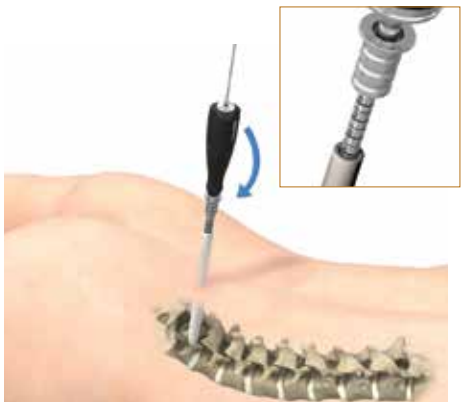
With Dilator 2 in place, prepare the pedicle by placing the **Cannulated Modular Awl** with selected handle over the K-Wire or Y-Wire and insert into the pedicle with a twisting motion. Do not pinch the bifurcated tip of the Y-Wire with the distal tip of the awl. Hold the K-Wire in position when removing the awl. Apply downward pressure to the Y-Wire when removing the awl to prevent unintentional removal. If necessary, use the cannulation of the Slap Hammer to impact the awl.



Note: If using the Tap Sleeve, insert Dilator 1, then insert the Tap Sleeve over Dilator 1.

Note: The Tap Sleeve is made out of Radel, a plastic material that provides the necessary insulation for neuromonitoring signals.

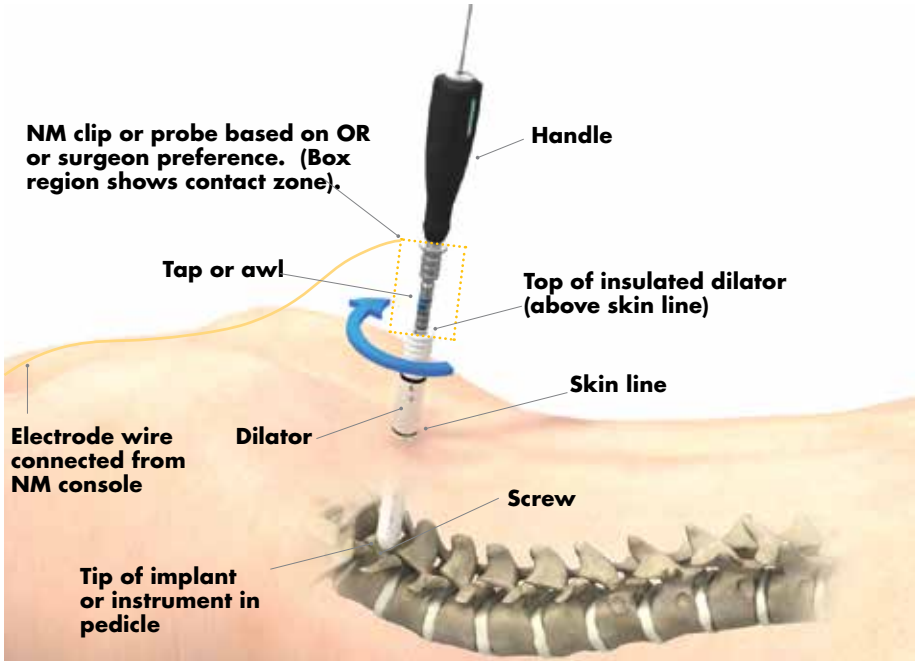
The **Cannulated Modular Taps** with selected handle are used to further prepare the screw pathway. The taps are designed to be used with either Dilator 2 for taps 4.5mm-7.5mm in diameter or the **Tap Sleeve** for taps 4.5mm-8.5mm in diameter. The taps are laser etched with 5mm increments to help indicate the depth of the tap within the pedicle as well as to help determine proper screw length.



*Not available in Standard Instrument Set

Note: The awl and taps can be stimulated with neuromonitoring signals when used within Dilator 2 or the Tap Sleeve. With the handle attached to either the awl or tap, the shaft of the instrument within Dilator 2 or the Tap Sleeve, and the distal tip of the instrument within bone, neuromonitoring signals can be applied to the exposed metal area of the instrument above Dilator 2 or the Tap Sleeve.

Typical neuromonitoring setup for ES2



Ø4.5mm Cannulated Modular Tap	**48280145**
Ø5.5mm Cannulated Modular Tap	**48280155**
Ø6.5mm Cannulated Modular Tap	**48280165**
Ø7.5mm Cannulated Modular Tap	**48280175**
Ø8.5mm Cannulated Modular Tap	**48280185**

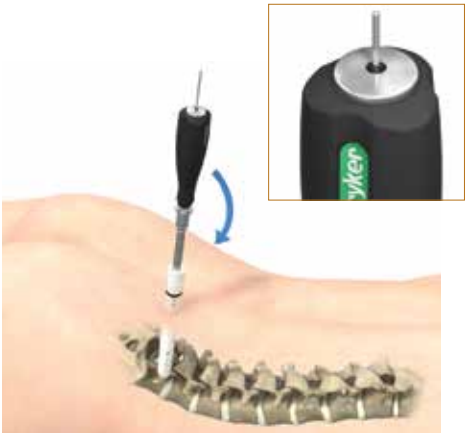
Tap Sleeve (Ø8.5mm) **48280100**

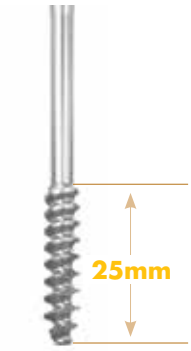
Note: The length of the threads on the taps is 25mm.

Note: The diameter of the taps is line-to-line, i.e. equal to the diameter of the screws.

Note: If using the Tap Sleeve, slide the Tap Sleeve up the tap shaft from the tip to engage the friction fit. This prevents the Tap Sleeve from sliding off the tap.

The ES2 Screws are self-tapping with a cutting flute to potentially eliminate the tapping step. The screws may be inserted immediately after the awl is used to penetrate the bone cortex. However, tapping the pedicle is recommended.





Check pedicle depth by reading the depth from the Tap Sleeve as it moves along the proximal shaft of the tap. There are markings at 30, 40 and 50mm. Make sure the Tap Sleeve is seated against the bone prior to tapping to ensure the depth readings from the tap are representative of the tap position within the pedicle.

Do not pinch the bifurcated tip of the Y-Wire with the distal tip of the tap. Hold the K-Wire in position when removing the tap. Apply downward pressure to the Y-Wire when removing the tap to prevent unintentional removal.

Note: When using the 4.5mm or 5.5mm taps in cases of sclerotic or metastasized bone, the awl must be used for preparation.

Note: The K-Wire has 10mm increment markings to be used for reference to determine the depth of the instruments in the pedicle.

Note: Cantilevering the awl and taps while in the pedicle may damage the K-Wire.

K-Wire management

As the awl or tap advances into the pedicle, the proximal end will move relative to the markings on the K-Wire. If this does not occur during insertion, the procedure should be stopped and imaging should be used to verify the position of the K-Wire in relation to the awl or tap.

Note: Do not pinch the bifurcated tip of the Y-Wire with a awl, tap or other instrument.

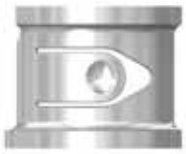
Y-Wire management

As the awl or tap is removed from the pedicle, downward pressure should be applied to the Y-Wire to prevent unintentional removal.

Screw insertion

With the pedicle pathway prepared and proper screw length, blade length and diameter determined, prepare the screw for insertion.

Orient the **Ring** with the notch facing up. Position the Ring in the top hole of the blade.



Ring **48281202**

Polyaxial Screwdriver assembly

Step 1: Insert the inner shaft up through the distal end of the outer shaft.

Step 2: Slide the locking nut over the inner shaft with the serrated teeth positioned facing downward.

Step 3: Fully insert the inner shaft into the handle quick connect mechanism.

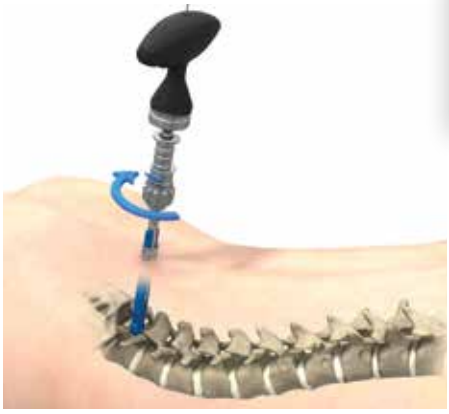
Polyaxial Screwdriver **48280310**

Load screw onto Polyaxial Screwdriver

Step 1: Hold the screw by the threaded portion and engage the inner shaft into the saddle of the screw head.

Step 2: Fully seat the inner shaft into the screw head and engage the 6-point star feature. Turn the outer shaft clockwise until the threads of the shaft are fully engaged with the threads of the screw head.

Step 3: Depress the button on the locking nut and slide the locking nut forward into the outer shaft to lock the screw to the Polyaxial Screwdriver.



Insert **Dilator 3** over either Dilator 2 or the Tap Sleeve. With Dilator 3 in place, Dilator 2 or the Tap Sleeve can be removed. Hold the K-Wire in position when removing the dilator or sleeve. Apply downward pressure to the Y-Wire when removing the dilator or sleeve to prevent unintentional removal.

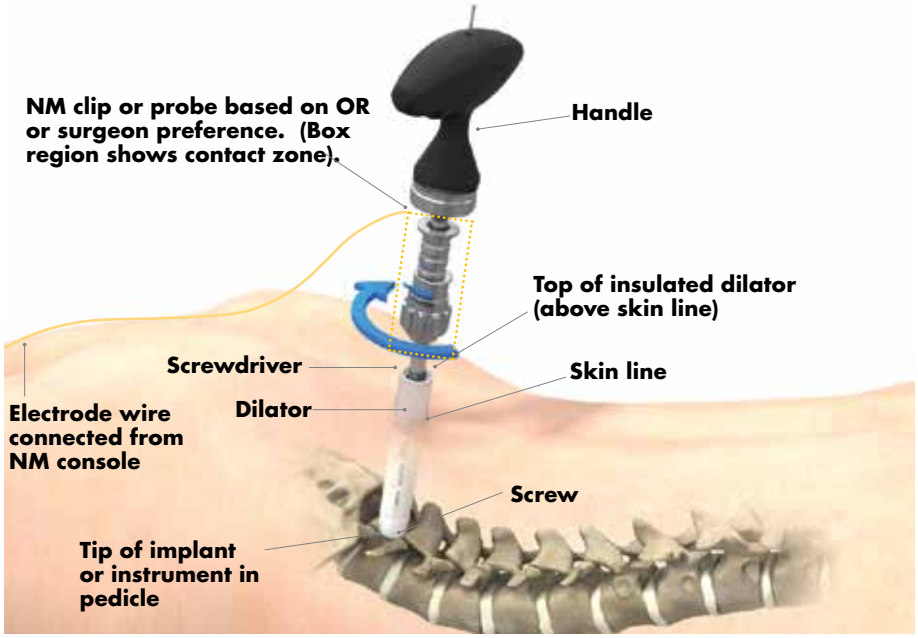
Dilator 3 **48280091**

Note: Dilator 3 is made out of Radel.

Note: The screwdriver and screw can be stimulated with neuromonitoring signals when used within Dilator 3. With the handle attached to the screwdriver, the shaft of the instrument within Dilator 3, and the distal tip of the screw within bone, neuromonitoring signals can be applied to the exposed metal area of the instrument or screw blades above Dilator 3.

Note: DO NOT use the Ring if using Dilator 3. Once the screw is inserted and the Polyaxial Screwdriver and Dilator 3 are removed, the Ring can be loaded onto the blades to help maintain their open position.

Typical neuromonitoring setup for ES2

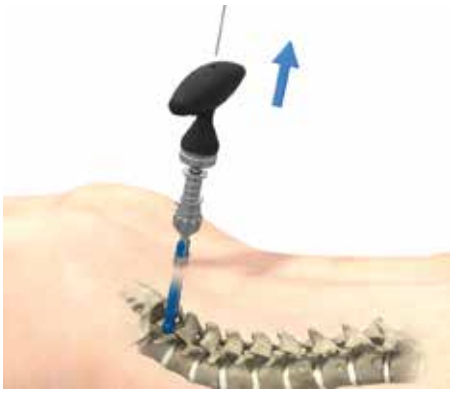


Power indication note: ES2 screws can be inserted with the use of Stryker's RemB Universal Driver or the CD3 Cordless Driver with the Power Adaptor attached to the ES2 Polyaxial Screwdriver. Please refer to the appropriate surgical technique from Stryker's Instruments division when using power for screw insertion with ES2.

Navigation indication note: The ES2 system can be used with Stryker's Navigated Mantis instruments. The Navigated Mantis instruments are dedicated instruments for pedicle preparation and screw insertion. Please refer to Stryker's Navigated Spine Instruments Quick Guide for instruction on using the Navigated Mantis instruments with ES2.

Place the screw and Polyaxial Screwdriver over the K-Wire or Y-Wire and advance through Dilator 3 to the opening created in the pedicle. Drive the screw into the pedicle; remove the K-Wire or Y-Wire when the tip of the screw reaches the end of the pedicle to prevent it from advancing.

Take care not to insert the screw too far into the bone, thereby limiting its polyaxial capabilities making it more difficult to pass the rod during subsequent procedural steps.



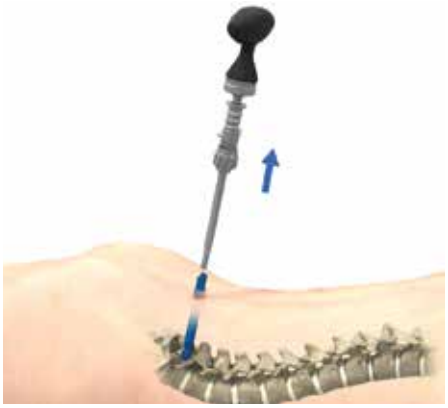
Disengage Polyaxial Screwdriver from screw

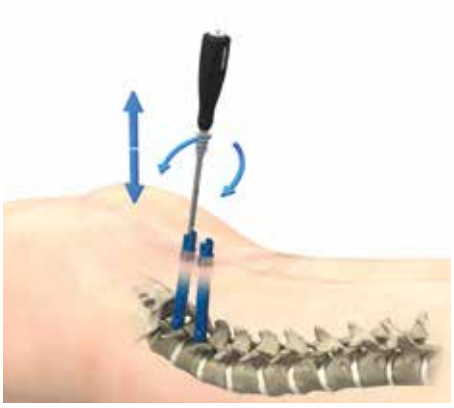
Once the screw is placed:

Step 1: Depress the button on the locking nut and slide the locking nut back up out of the outer shaft along the inner shaft.

Step 2: Turn the outer shaft counterclockwise to disengage the threads of the shaft from the threads of the screw head.

Step 3: Pull upward on the Polyaxial Screwdriver.





Note: The orientation and placement of the Ring can be changed after removal of the Polyaxial Screwdriver.

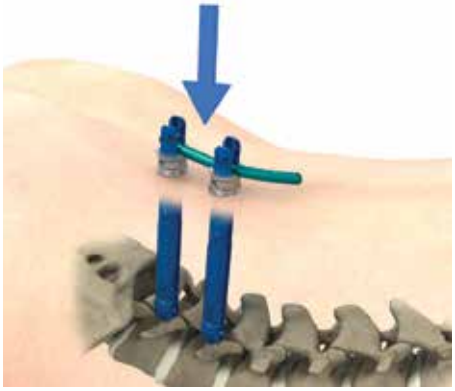
Remove Dilator 3 from the wound.

Repeat the process for additional screws.

Polyadjustment Driver **48280086**

Screw adjustment

The screw positions may be adjusted as needed using the modular **Polyadjustment Driver** with selected handle. Imaging should be used to confirm desired placement of screw.



Rod Selection, contouring and insertion

The ES2 Spinal System offers a comprehensive selection of **Hex End Rods**. The ES2 Screw can accept both 5.5mm and 6.0mm rod diameters. The system rods are offered in titanium alloy and Vitallium, in straight and pre-bent configurations. This versatility is designed to present various size and stiffness options to meet a spectrum of surgical needs.

Ti Hex Straight Rod 5.5mm
482807(020-190, 480, 600)

Ti Hex Rad Rod 5.5mm
482806(030-130)

Vitallium Hex Straight Rod 5.5mm
482808(020-190, 480, 600)

Ti Hex Straight Rod 6.0mm
48287(030-200, 480, 600)

Ti Hex Rad Rod 6.0mm
48286(030-130)

Vitallium Hex Straight Rod 6.0mm
482805(020-190, 480, 600)

Rod length determination

Using the rings to determine rod length

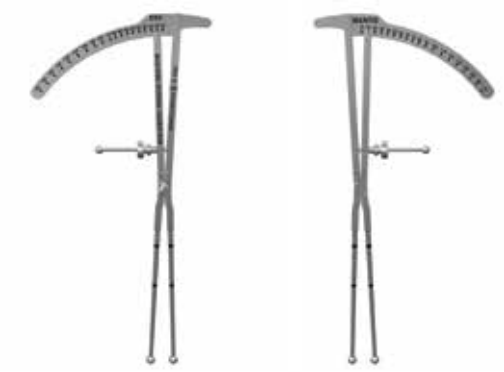
Position the rings along the blades of the screws at the same hole level (1-7). With the rings at the same level and the blades held upright and parallel, place the **Rod Template** into the notches on the rings. Use the Rod Template to aid in determining the length and contour of the rod.

Rod Template, 100mm
48282100

Rod Template, 200mm
48282200

Note: A rod can be used instead of the Rod Template if desired.

Note: The length designations on the 5.5mm diameter rods indicate the working length of the rod and do not include the leading tip or hex end. The length designation is for reference only as cutting or bending the rod may change the length of the rod.



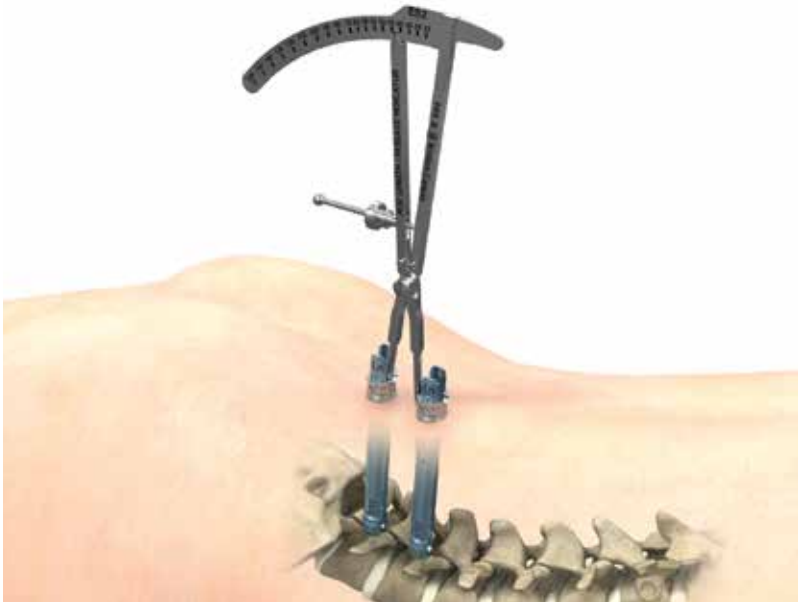
Rod Length/Passage Indicator
48280186

Note: The Mantis scale is for the Mantis Spinal System 6.0mm diameter straight titanium rods. The ES2 scale should be used for the 5.5mm diameter titanium and Vitallium rods, the Mantis Spinal System 6.0mm diameter Vitallium rods, and the Mantis Spinal System 6.0mm diameter rad titanium rods.

Note: The design of the Rod Length/ Passage Indicator is optimized to determine the rod Length over one to two levels.

Using the Rod Length/Passage Indicator to determine rod length

Pass the ball tips of the Rod Length/Passage Indicator down through the blades into the screw heads. Simultaneously angle the blades to match the angle of the indicator arms. Verify the ball tips are fully seated in the screw heads using fluoroscopic imaging or the blade lengths laser markings on the arms. Read the rod length indicated on the appropriate system scale.



The **French Benders** are used to contour the rod as needed.

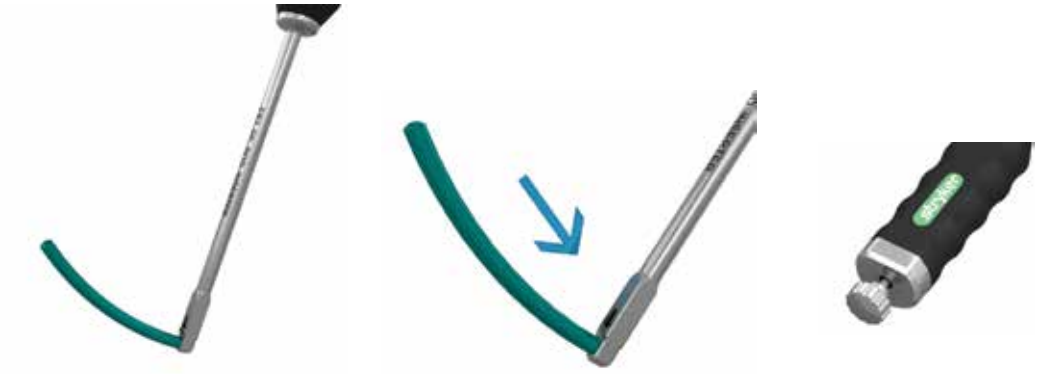
French Bender **48280087**

The hex end of the rods provides a rigid connection between the rod and the **Rod Inserter** to allow for easy insertion and manipulation. There are three types of Rod Inserters available:

- 90° Fixed Rod Inserter
- 110° Fixed Rod Inserter
- Adjustable Rod Inserter* (see important note)

90° Rod Inserter
48280090

110° Rod Inserter
48280110



***Note: The distal tip of the Adjustable Rod Inserter will not fit through the blades.** Use caution when inserting the rod with the Adjustable Rod Inserter. Trying to force the inserter through the blades may cause them to move outwardly.

Important notes: <u>Do Not</u> excessively rotate the driving nut below 0° or above 20° as this could cause the Rod Inserter to malfunction.

The Rod Inserter should be properly lubricated between uses.

The Adjustable Rod Inserter from Mantis can also be used (not included in standard instrument set).

Adjustable Rod Inserter*
48480001

*Not included in standard instrument set

Note: The hex end rods are laser marked with a dotted line to indicate their orientation. Ensure that the line is facing up when attached to the Rod Inserter.

Note: The Rod Inserter should be disassembled for cleaning. To disassemble, press the button on the handle and turn the Rod Inserter Shaft counterclockwise. Once the threaded portion is released pull the Rod Inserter Shaft out of the handle.

Important note: Do Not mallet the Rod Inserter.

Rod Inserter assembly

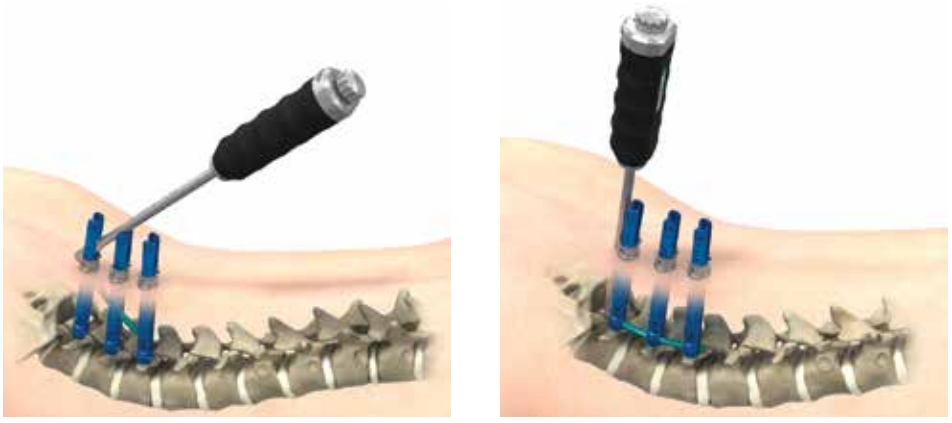
While depressing the button on the Rod Inserter handle, insert the Rod Inserter Shaft into the proximal end of the Rod Inserter. Advance the Rod Inserter Shaft through the Rod Inserter and engage the threaded portion. Place the hex end of the rod into the hex opening on the distal end of the Rod Inserter. Lock the rod into position by twisting the knob on the Rod Inserter Shaft clockwise until fully engaged with the rod.

Note: The opening of the Ring at the most cephalad screw should be oriented in the cephalad direction and the opening of the Ring at the most caudal screw should be oriented in the caudal direction. The rod is to be inserted from the open side of the Ring.

Note: Ensure that the rod overhangs the last screw head to allow for secure fixation. Also, the hex end of the rod should not be within the first screw head.

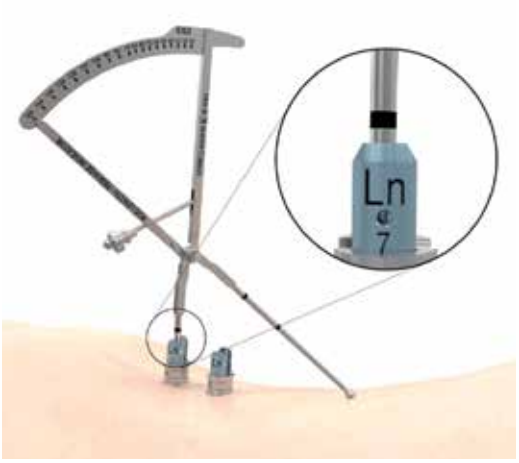
Note: The positioning of the rod between the blades can be visualized directly or with fluoroscopic imaging or using the Rod Length/Passage Indicator.

Insert the rod percutaneously from either the most cephalad or caudal screw through the blades. Guide the rod through each pair of blades.

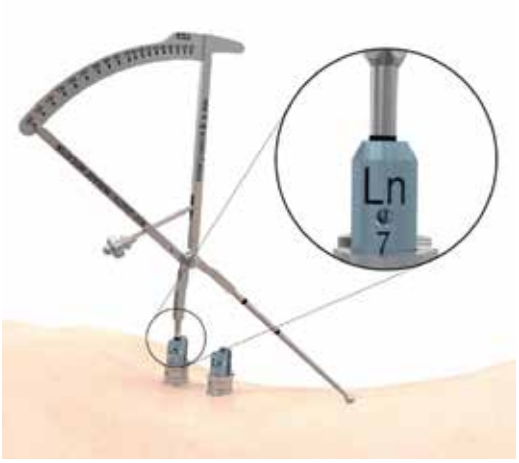


Using the Rod Length/Passage Indicator to determine rod passage through the blades

Open the indicator as wide as necessary. Place one of the indicator arms down through the blades. If the rod is contained within the blades or screw head, the blade length markings on the arm will be proud of the top of the blade. If the rod is not within the blades or screw head, the blade length markings will line up with the top of the blade.



Rod passes within screw blades



Rod **not** passed within screw blades

Blocker insertion

Load the **Blocker** onto the tip of the **Blocker Inserter** by engaging the hex.

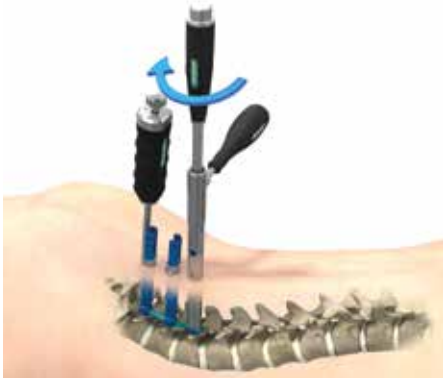
Blocker **48289999**

Blocker Inserter **48280085**

Modular Blocker Inserter **48280187**

Note: The laser etched markings on the Blocker should be facing upward when loading the Blocker Inserter.

Note: The **Modular Blocker Inserter** is used with a selected system handle.



Warning: The Modular Blocker Inserter is not indicated to be used with power.

Note: The Ring must be removed prior to using the Counter Torque Tube.

Note: The laser markings and windows on the Counter Torque Tube correspond to the blade lengths to indicate when the Counter Torque Tube is fully seated.

Use the **Counter Torque Tube** as an insertion tube to facilitate the alignment of the Blocker within the blades to prevent cross-threading. The Counter Torque Tube can also be used to help direct the rod downward into the screw head if the rod is slightly proud.

Slide the Blocker Inserter and Blocker through the Counter Torque Tube and into the blades. Thread the Blocker, in a clockwise rotation, through the reduction threads of the blades and into the screw head.

Counter Torque Tube **48280080**

Note: With the Blocker Inserter inside of the Counter Torque Tube and the tip loaded with a Blocker slightly in front of the distal end of the Counter Torque Tube, the Blocker and Blocker Inserter will help to maintain the open position of the blades as the Counter Torque Tube slides down.

Note: There are 15mm of reduction threads built into the blades.

Note: The Blocker Inserter is not intended to be used for final tightening.

Note: If additional torque is needed to insert the Blockers, the **Hex-End T-Handle** can be used with the hex-end of the Blocker Inserter.

Note: There is a mechanical stop to indicate that the Rod Inserter Shaft is fully out of the groove on the hex end rod.

Note: Sometimes the soft tissue may make disengaging the Rod Inserter from the rod difficult. Make sure the Rod Inserter is in line with the axis of the rod and pull the Rod Inserter directly back off the hex end of the rod. Do not impact the Rod Inserter when disengaging it from the rod.

Note: The Counter Torque Tube should be used over the blades while reducing the rod into place with the Blocker to prevent outward movement of the blades.

Insert Blockers into all of the screws.

Once the rod is sufficiently captured within the screws by the Blockers, detach the Rod Inserter from the rod by turning the knob on the Rod Inserter Shaft in a counterclockwise direction. Pull the Rod Inserter back along the axis of the rod to disengage the Rod Inserter from rod.

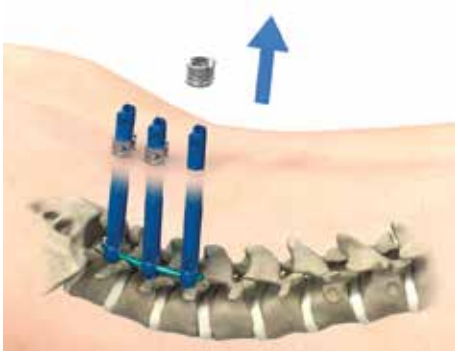
Hex-End T-Handle **48280097**

Rod reduction

The built in threaded feature of the blades allows for 15mm of rod reduction in addition to the 5mm within the screw head. If additional rod reduction is needed, the Counter Torque Tube can be used to help push the rod down into the screw head.

Compression/Distraction Shaft
48280082

Compression/Distraction Hinge
48280083

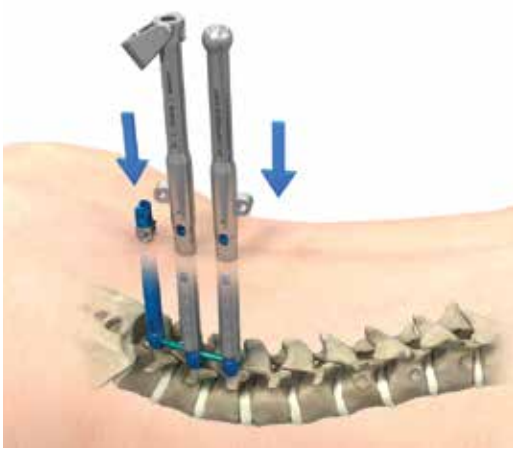


Note: The Ring must be removed prior to using the Compression and Distraction Shaft and Hinge.

Compression and distraction

Single-level compression and distraction

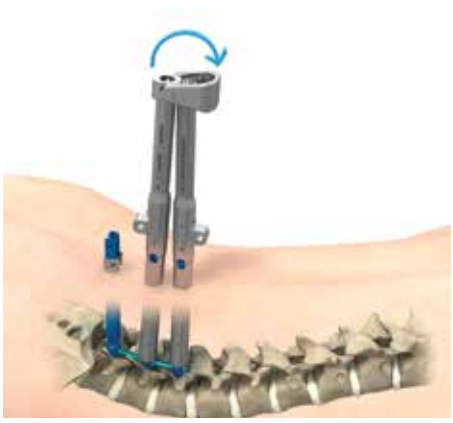
To achieve compression and distraction, insert the Compression and Distraction Shaft and Hinge over the blades of the two adjacent screws at the selected levels.



Note: The laser markings and windows on the Compression and Distraction Shaft and Hinge correspond to the blade lengths to indicate when the shaft and hinge are fully seated.

With the Compression and Distraction Shaft and Hinge in place, orient the eyelets facing in the cephalad and caudal directions.

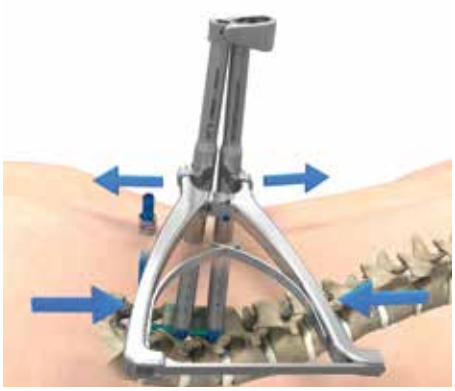
Join the tops of the Compression and Distraction Shaft and Hinge using the connecting feature.



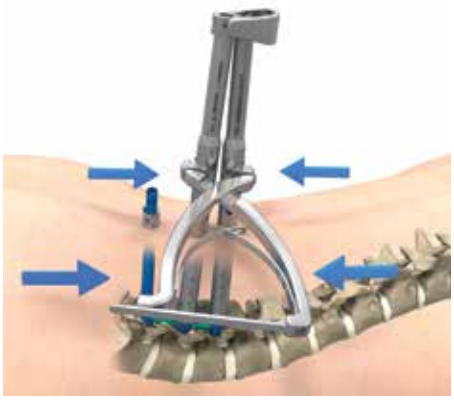
Distractor **48284070**

Compressor **48284075**

To distract, insert the **Distractor** into the eyelets of the Compression and Distraction Shaft and Hinge. Squeeze the Distractor to apply the appropriate amount of distraction.



To compress, insert the **Compressor** into the eyelets of the Compression and Distraction Shaft and Hinge. Squeeze the Compressor to apply the appropriate amount of compression.



Once the necessary compression or distraction is applied, the Compression and Distraction Shaft and Hinge can be removed.

Note: The Compression and Distraction Shaft and Hinge are cannulated to allow for Blocker introduction or adjustment. It is recommended to use the Hex-End T-Handle with the Blocker Inserter for Blocker introduction or adjustment.

Note: The Compression and Distraction Shaft and Hinge are designed to be used over one level. If an adjacent level to the corrected level also needs to be compressed or distracted, move either the shaft or hinge to the next level. Only one of the instruments needs to be moved as the eyelets on both instruments rotate. With the shaft and hinge in place to address the next level, rotate the eyelets to face outward so that the necessary compression or distraction can be applied.

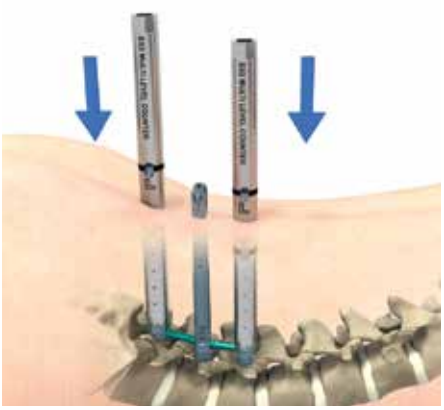
Note: The Compression and Distraction Shaft and Hinge are not designed to be used with the Torque Wrench for final tightening. Please refer to pages 34 or 35 for acceptable counter torque options to be used in conjunction with the Torque Wrench.

Note: The laser markings and windows on the Compression and Distraction Shafts correspond to the blade lengths to indicate when the shafts are fully seated.

Note: The outer diameter of the Multi-Level Compression and Distraction Shafts is 16mm.

Multi-level compression and distraction

Insert the Multi-Level Compression and Distraction Shafts over the blades of the two screws at the selected levels.



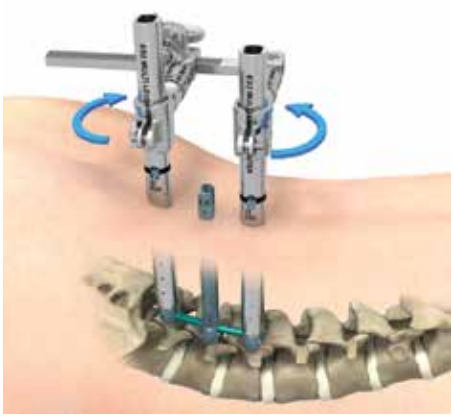
Multi-level compression and distraction assembly

Step 1: Insert the Ratchet Knob into the compression/distraction mechanism housing on the Adjustable Arm

Step 2: Put the latch on the compression/distraction mechanism into the "unlock" position.

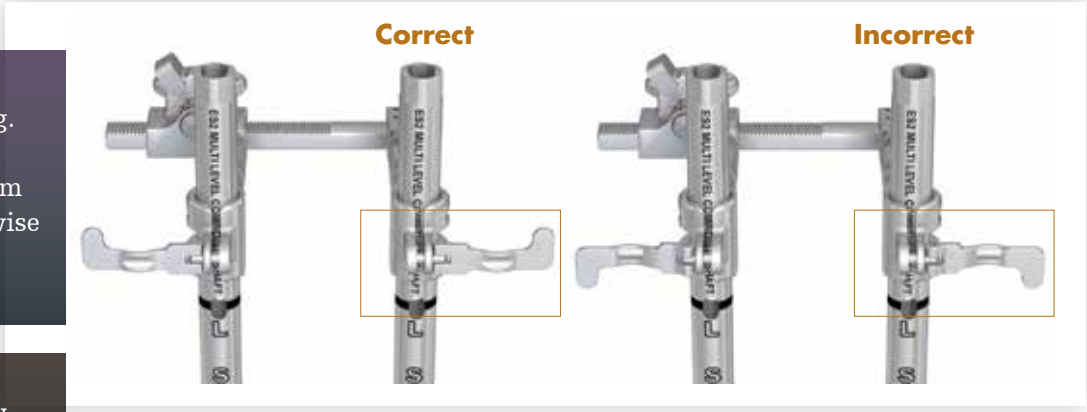
Step 3: To assemble the Fixed Arm onto the 2-Level or 4-Level rack, slide the arm into position on the end of the rack featuring the groove and lock the rack within the Fixed Arm.

Step 4: Slide the Ratchet Knob and Adjustable Arm assembly onto the opposite end of the rack with the arm facing the same direction as the Fixed Arm.

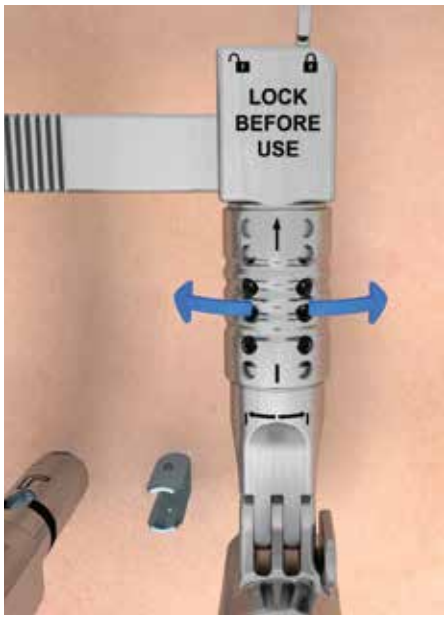


With the Multi-Level Compression and Distraction Shafts in place, release the clamping levers on the end of each of the arms and slide the arms/rack assembly down over the shafts. When the arm/rack assembly is in the desired position along the length of the shafts, press the levers back into position, locking the arm/rack assembly in place.

Note: The levers must be in the correct orientation before closing. Forcing the levers shut from an incorrect position may cause them to snap off of the arms or otherwise damage the functionality of the device.



Tip: If interference between the lever and an adjacent level screw blade occurs, rotate the lever 180° from the original position to lock the shaft.

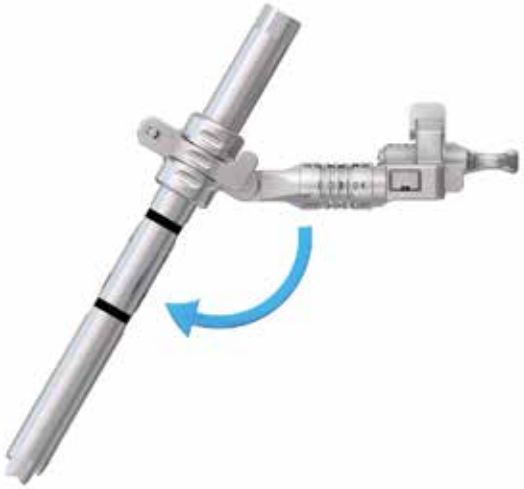


Note: The rotational position of each arm can be adjusted to account for variance in screw positioning by pushing the outer sleeve of the arm forward and rotating to the desired angle: ±50°. Pull the outer sleeve back into the "lock" position to maintain desired angle.

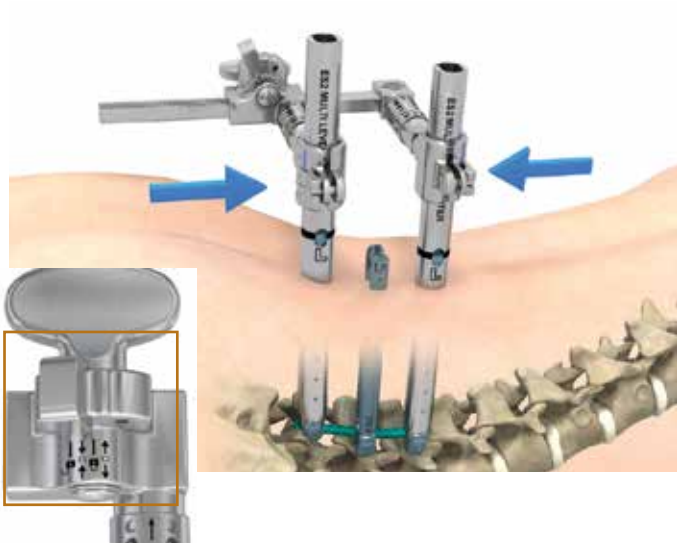
The angle of each arm can be adjusted to account for variance in the position of the blades. Adjust the joints located at the interface of the arms and shafts to reach the desired position.

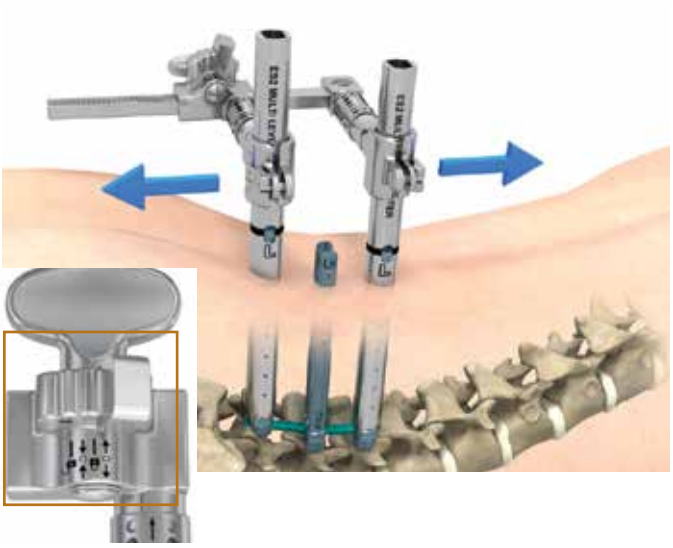
Note: The outer sleeve of the arms should be in the locked, neutral position for cleaning.

Note: Before applying force, ensure the levers on the arm/rack assembly are locked and the sleeves on the rotational components of the arms are in the locked position to maintain desired positioning along the shafts and desired angulation.



Put the latch on the compression/distraction mechanism into either the "compress" or "distract" position. Turn the Ratchet Knob to apply the desired force.

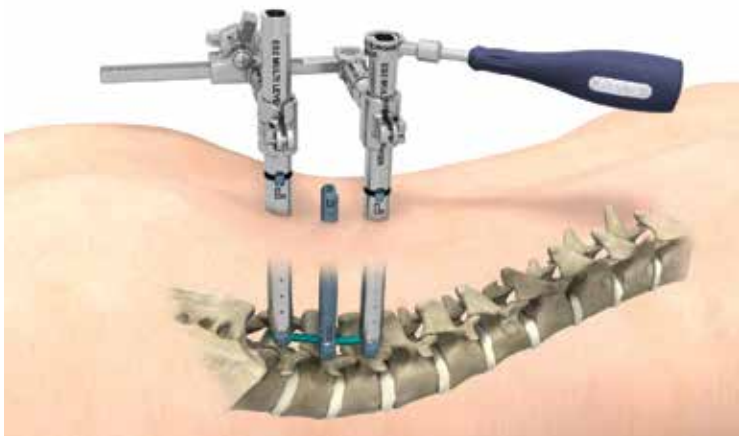




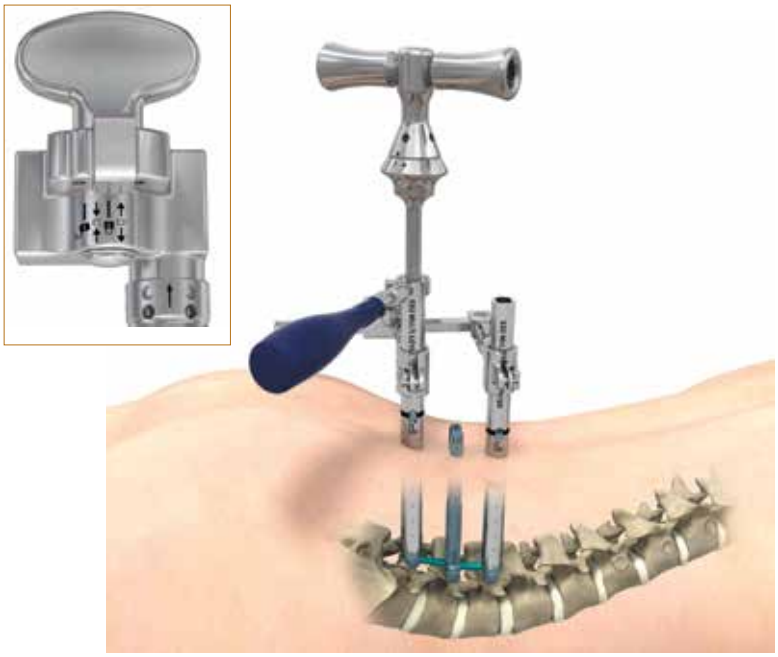
Note: The Multi-Level Compression and Distraction Shafts are cannulated to allow for Blocker introductions or adjustment. Put the latch on the compression/distraction mechanism into the "lock" position to maintain the desired position. It is recommended to use the Hex-End T-Handle with the Blocker Inserter for Blocker introduction or adjustment.

Note: The top of the shafts interface with the Anti-Torque Handle. The Anti-Torque Handle can be used, if needed, to apply a downward force on the shafts during application of compression or distraction forces to secure the shafts in the fully seated position.

Note: The Anti-Torque Handle can be used for final tightening of the Blockers with the Multi-Level Compressor/Distractor in place. The Torque Wrench must be used for final tightening of the construct.



Once the necessary compression or distraction is applied and secured by the Blockers, the arm/rack assembly can be released from the shafts and removed. The shafts can then be removed from the blades.



Multi-level compression and distraction disassembly

Step 1: Put the latch on the compression/distraction mechanism in the "unlock" position.

Step 2: Slide the Adjustable Arm off of the rack.

Step 3: Remove the Ratchet Knob from the compression/distraction mechanism by firmly pulling on the knob straight back and away from the instrument.

Step 4: Press the lever on the Fixed Arm into the "unlock" position and slide the Fixed Arm off of the rack.

Note: The Multi-Level Compressor/Distractor must be disassembled for cleaning and sterilization.

Caution: Extra caution is advised in the following cases:

- The rod is not horizontally placed into the screw head.
- The rod is high in the screw head.
- An acute convex or concave bend is contoured into the rod.

Note: The Ring must be removed prior to using the Counter Torque Tube.

Torque Wrench **48280081**

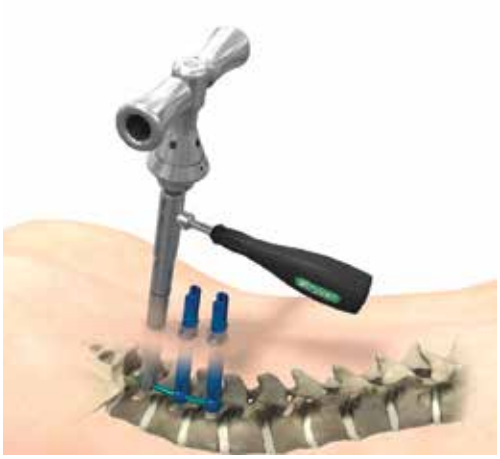
Note: The laser markings and windows on the Counter Torque Tube correspond to the blade lengths to indicate when the Counter Torque Tube is fully seated.

Note: The Counter Torque Tube must be used for final tightening. The Counter Torque Tube performs two important functions:
1) It allows the Torque Wrench to align with the tightening axis.
2) It allows the optimal torque needed to lock each Blocker without applying the torque to the rest of the construct.

Caution: Extra caution is advised in the following cases:
- The rod is not horizontally placed into the screw head.
- The rod is high in the screw head.
- An acute convex or concave bend is contoured into the rod.

Final tightening of the construct

Once the necessary correction procedures have been performed and the spine is fixed in a satisfactory position, the final tightening of the Blockers is performed using the Counter Torque Tube and the **Torque Wrench**.

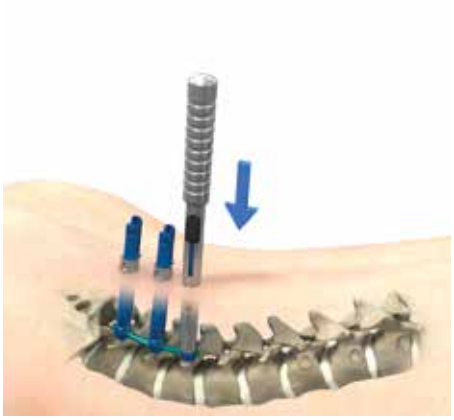


Place the Counter Torque Tube down over the blades.

Insert the Torque Wrench through the Counter Torque Tube to engage the Blocker.

Turn the handle of the Torque Wrench clockwise to align the two arrows on the Torque Wrench to achieve the 12Nm of torque required to secure the implant construct.

Repeat the process for each Blocker.

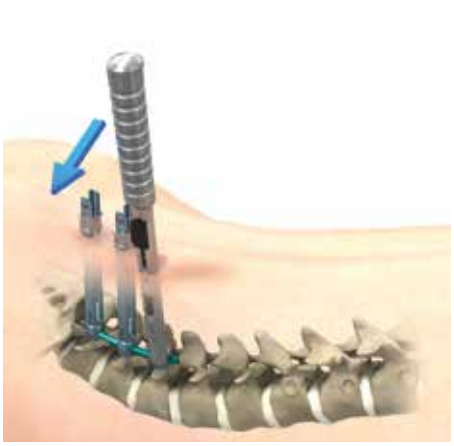


Note: In addition to the positive stop, the laser markings and windows on the Blade Remover correspond to the blade lengths to indicate when the Blade Remover is fully seated.

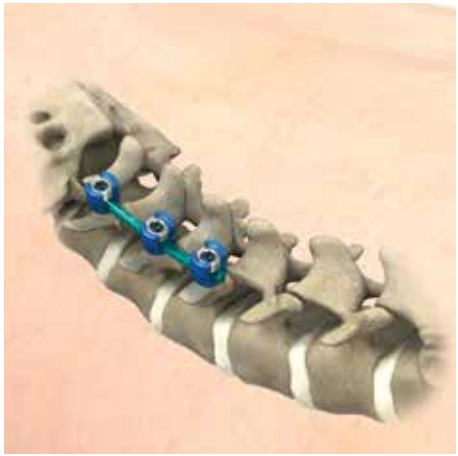
Blade removal

Once the construct is finally tightened, the blades can be removed. Slide the **Blade Remover**, with the arrow on the Blade Remover pointing away from the center of the blades, down over one of the blades.

Blade Remover **48280084**



In the direction of the arrow, apply a force to break the blade off of the screw head. The Blade Remover will retain the blade within the instrument. With the Blade Remover outside of the wound, slide the button down to eject the blade. Repeat for the remaining blades.



Important note: In the event the ES2 blade becomes disengaged prematurely, simply remove the screw and replace with a similarly sized ES2 screw or use the blade recovery system.

Important note: This instrument is not intended to be used for direct vertebral rotation.

Blade recovery

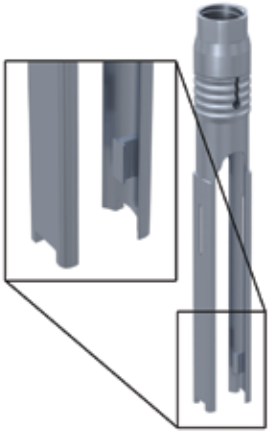
If one or both of the blades disassociates from the screw head, the Recovery System can be used.

Recovery Outer Sleeve **48280096**

Recovery Inner Shaft **48280095**

Recovery System assembly

Place one component on top of the other component so that the pegs on **Recovery Outer Sleeve** lie just past the threads on top portion of **Recovery Inner Shaft**. At the same time, push down to insert inner shaft into the outer sleeve.



Push inner shaft into outer sleeve.

With the distal end of the inner shaft on a table or flat surface, press down on outer sleeve until the components snap into place.

Note: Do not insert axially from the bottom of the outer sleeve.

Important note: Make sure the inner shaft does not accidentally rotate 90 degrees with respect to the outer sleeve. If this occurs, begin the process again at step 1.

Note: Take care to avoid damage to surgical gloves.

Final assembly

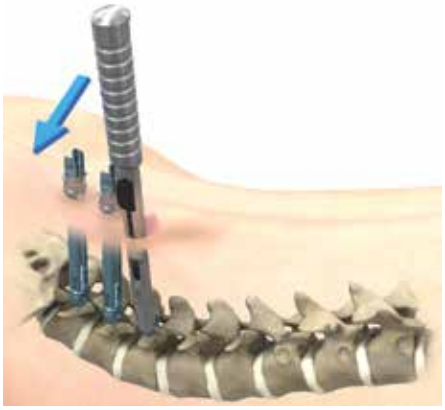
Note: A handle can be assembled to the Recovery Guide and lightly impacted if additional force is needed to ensure that the Recovery Guide is fully engaged within the screw head.

Recovery Guide **48280093**

Caution: When removing the remaining blade from the screw head, note that the entire blade will not be captured in the Blade Remover.

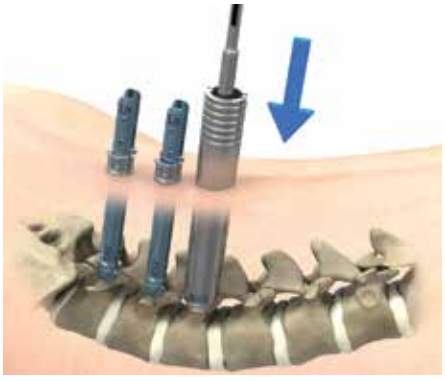
No rod in screw head

If one blade detaches from the screw head, use the remaining blade to help guide the **Recovery Guide** down into the screw head.

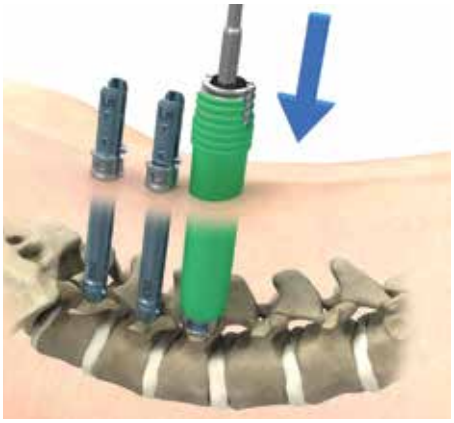


With the Recovery Guide engaged in the screw head, remove the handle from the Recovery Guide if used, and slide the Blade Remover down over the remaining blade as far as it will go. Detach the remaining blade from the screw head. With the Recovery Guide in place and the remaining blade removed, slide **Recovery Dilator 1** over the Recovery Guide.

If both blades are detached from the screw head, position the Recovery Dilator 1 over the screw head. Using imaging, verify the screw head is within the dilator. Insert the Recovery Guide through the dilator and into the screw head. A handle can be assembled to the Recovery Guide and impacted if additional force is needed to ensure that the Recovery Guide is fully engaged within the screw head. Disassemble the handle from the Recovery Guide if used.



Note: The openings on the tip of the dilator will allow the user to visually confirm that the screw head is within the dilator during imaging.



Sequentially dilate with Recovery Dilator 2 sliding over Recovery Dilator 1. Remove Recovery Dilator 1 when Recovery Dilator 2 is in place.

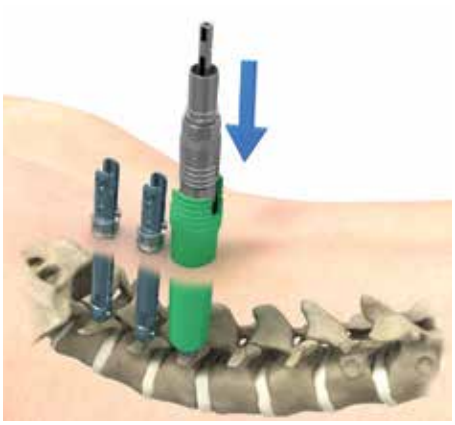
Recovery Dilator 1 **48280092**

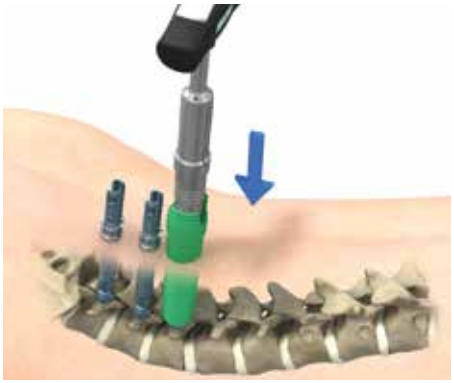
Recovery Dilator 2 **48280098**

Align the arrow on the Recovery System with the arrow on the Recovery Guide to ensure the Recovery System is inserted in line with the screw head. Slide the Recovery System over the Recovery Guide until the Recovery System engages fully with the screw head. If necessary, the Hex End T-Handle can be placed on the hex of the Recovery System and over the Recovery Guide for impaction if additional force is required in order to fully engage the Recovery System with the screw head.

Note: The recovery instrument has an outer diameter of 17.5mm so the incision may need to be extended to accommodate this instrument. The Recovery Dilator 1 has an outer diameter of 21.2mm and Dilator 2 has an outer diameter of 24mm.

Note: The surgeon will have tactile feedback upon engagement of the Recovery System with the screw head.



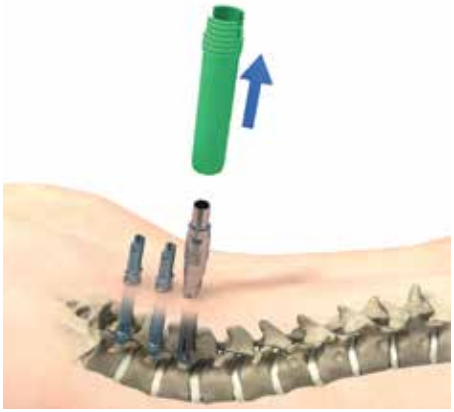


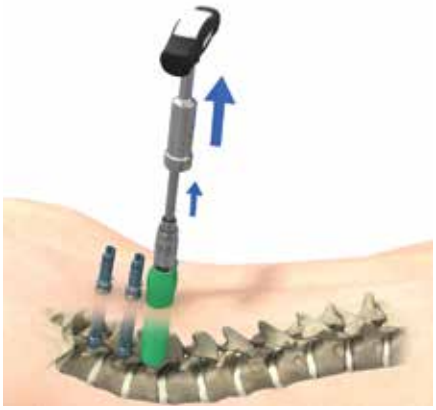
While holding the ribbed proximal portion of the Recovery System, use the Hex End T-Handle to tighten the Recovery System to the screw head. Remove the Hex End T-Handle, Recovery Guide and Recovery Dilator 2.

Continue the procedure as necessary performing rod and Blocker insertion (as seen in picture on left) and as outlined in the steps above. The Recovery System is cannulated to work with the Polyadjustment Driver, Blocker Inserter and the Torque Wrench and has slits to allow for rod passage.

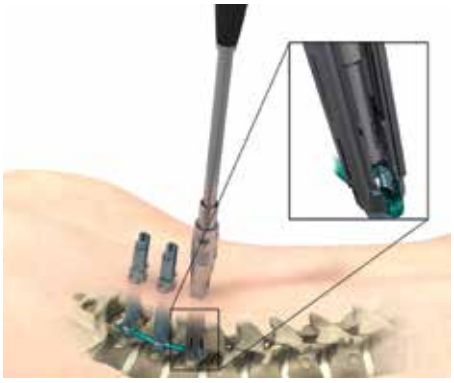
To final tighten the Blocker with the Recovery System in place, use the Counter Torque Tube on an adjacent level screw to provide the necessary counter torque.

Once the procedure is complete, use the Hex-End T-Handle to loosen the Recovery System from the screw head by turning the Recovery Outer Sleeve in a counterclockwise direction. Remove the Recovery System from the screw head by twisting the Recovery System off of the screw head.

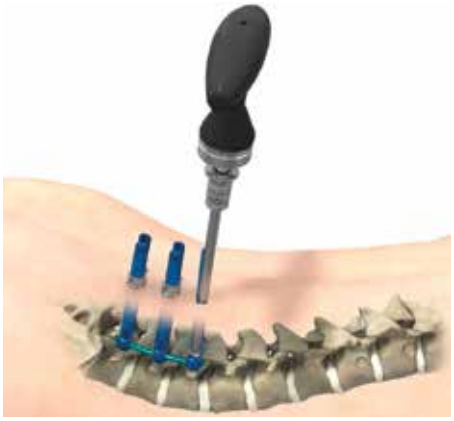




Note: The Recovery System is not compatible with the Compression and Distraction Shaft and Hinge or the Counter Torque Tube or the Polyaxial Screwdriver.



Note: If a Blocker is in place, it must be removed before using the Threaded Recovery Guide. The Blocker Inserter can be used to remove the Blocker.



Note: A handle can be assembled to the Threaded Recovery Guide for added mechanical advantage and control if needed. Once the Threaded Recovery Guide is fully engaged, disassemble the handle if used.

Rod in screw head

If one blade detaches from the screw head, use the remaining blade to help guide the **Threaded Recovery Guide** down to the top of the screw head.

Threaded Recovery Guide **48280099**

Note: Do not impact the handle when using the Threaded Recovery Guide. When the Threaded Recovery Guide can no longer advance by pushing, turn the Threaded Recovery Guide clockwise to engage the threads on the Threaded Recovery Guide with the threads in the screw head. Thread the Threaded Recovery Guide until it is fully seated on the rod within the screw head. With the Threaded Recovery Guide engaged in the screw head, remove the handle if used, and slide the Blade Remover down over the remaining blade as far as it will go. Detach the remaining blade from the screw head. With the Threaded Recovery Guide in place and the remaining blade removed, slide Recovery Dilator 1 over the Threaded Recovery Guide. Care should be taken to orient the rod cut-outs on the distal end of Recovery Dilator 1 with the rod position. These distal cut-outs allow Recovery Dilator 1 to fully engage with the rod and can be used to help push the rod down into the screw head if the rod is slightly proud.

Note: The cuts on the top surface of the Recovery Dilator 1 indicate the orientation of the rod cut-outs on the distal end of the Recovery Dilator 1.

Note: The openings on the tip of the Recovery Dilator 1 will allow the user to visually confirm that the screw head is within the Recovery Dilator 1 during imaging.

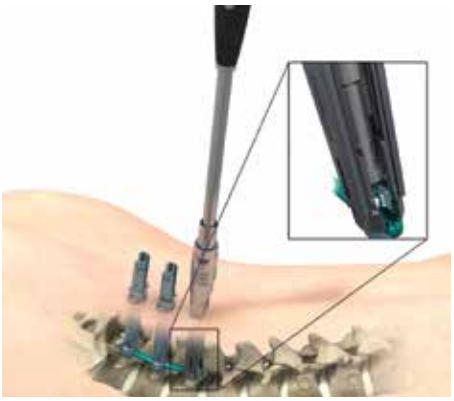
If both blades are detached from the screw head, position Recovery Dilator 1 over the screw head. Using imaging, verify the screw head is within Recovery Dilator 1 and the rod is within the cut-outs on the distal tip. Insert the Threaded Recovery Guide through Recovery Dilator 1 and into the screw head.

Sequentially dilate with Recovery Dilator 2 sliding over Recovery Dilator 1. Remove Recovery Dilator 1 when Recovery Dilator 2 is in place.

When inserting the Recovery System over the Threaded Recovery Guide use the blades on the other construct screws to orient the Recovery System to ensure proper alignment and engagement with the screw head. Slide the Recovery System over the Threaded Recovery Guide until the Recovery System engages fully with the screw head. If necessary, the Hex End T-Handle can be placed on the hex of the Recovery System and over the Threaded Recovery Guide for impaction if additional force is required in order to fully engage the Recovery System with the screw head.

While holding the ribbed proximal portion of the Recovery System, use the Hex End T-Handle to tighten the Recovery System to the screw head. Remove the Hex End T-Handle. Remove the Threaded Recovery Guide by turning counterclockwise to disengage the threads with the threads of the screw head.

Note: A handle can be assembled to Threaded Recovery Guide for added control during removal.



Remove Recovery Dilator 2.

Continue the procedure as necessary performing Blocker insertion as outlined in the steps above and as seen in the picture on the left.

To final tighten the Blocker with the Recovery System in place, use the Counter Torque Tube on an adjacent level screw to provide the necessary counter torque.

Once the procedure is complete, use the Hex-End T-Handle to loosen the Recovery System from the screw head by turning the Recovery Outer Sleeve in a counterclockwise direction. Remove the Recovery System from the screw head by twisting the Recovery System off of the screw head.

Note: The Recovery System is not compatible with the Compression and Distraction Shaft and Hinge, the Multi-Level Compression and Distraction Shafts, the Counter Torque Tube and the Polyaxial Screwdriver.

Note: The Recovery System is compatible with Xia II, Xia 3 and Mantis Redux screws.

Recovery system disassembly

To disassemble the instrument for cleaning and sterilization

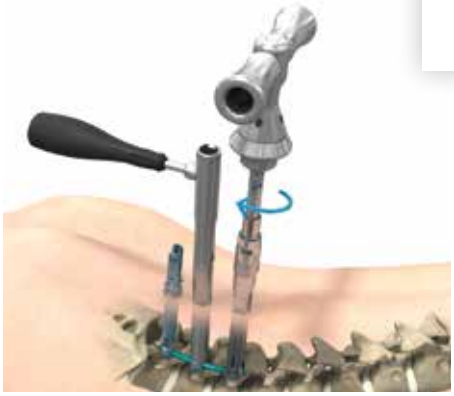
Fully loosen the instrument components by rotating the hex on top of Recovery Outer Sleeve in a counterclockwise direction. This will disengage the threads.

While squeezing the tips of the inner shaft and expanding the arms of the outer sleeve with your other hand, rotate the outer sleeve 90 degrees in either direction.

Note: Use T-Handle provided if necessary.

Note: Take care not to damage surgical gloves during this maneuver.

Pull inner shaft and outer seeve apart as shown.



Final tightening should be done with the Recovery System in place and Counter Torque Tube on adjacent screw.

Revision of the ES2 Spinal System

A surgical revision may be indicated for many reasons including new or unresolved pain or neurological symptoms, changes in device positioning, etc. If necessary, the ES2 implants can be removed with the use of the Blocker Inserter and the Polyadjustment Driver or Polyaxial Screwdriver. The surgeon user must use his/her professional judgment to determine the appropriate revision strategy taking into consideration the patient's health, the nature of the problem and/or device failure, the patient's bone quality and the surgeon's expertise with other spinal treatments and instrumentation.

Implants

	Reference number	Description
	482802425	Ø4.5x25mm Short Blade Cannulated Screw
	482802430	Ø4.5x30mm Short Blade Cannulated Screw
	482802435	Ø4.5x35mm Short Blade Cannulated Screw
	482802440	Ø4.5x40mm Short Blade Cannulated Screw
	482802445	Ø4.5x45mm Short Blade Cannulated Screw
	482802530	Ø5.5x30mm Short Blade Cannulated Screw
	482802535	Ø5.5x35mm Short Blade Cannulated Screw
	482802540	Ø5.5x40mm Short Blade Cannulated Screw
	482802545	Ø5.5x45mm Short Blade Cannulated Screw
	482802550	Ø5.5x50mm Short Blade Cannulated Screw
	482802555	Ø5.5x55mm Short Blade Cannulated Screw
	482802630	Ø6.5x30mm Short Blade Cannulated Screw
	482802635	Ø6.5x35mm Short Blade Cannulated Screw
	482802640	Ø6.5x40mm Short Blade Cannulated Screw
	482802645	Ø6.5x45mm Short Blade Cannulated Screw
	482802650	Ø6.5x50mm Short Blade Cannulated Screw
	482802655	Ø6.5x55mm Short Blade Cannulated Screw
	482802660	Ø6.5x60mm Short Blade Cannulated Screw
	482802730	Ø7.5x30mm Short Blade Cannulated Screw
	482802735	Ø7.5x35mm Short Blade Cannulated Screw
	482802740	Ø7.5x40mm Short Blade Cannulated Screw
	482802745	Ø7.5x45mm Short Blade Cannulated Screw
	482802750	Ø7.5x50mm Short Blade Cannulated Screw
	482802755	Ø7.5x55mm Short Blade Cannulated Screw
	482802760	Ø7.5x60mm Short Blade Cannulated Screw
	482802770	Ø7.5x70mm Short Blade Cannulated Screw
	482802780	Ø7.5x80mm Short Blade Cannulated Screw
	482802790	Ø7.5x90mm Short Blade Cannulated Screw
	482802830	Ø8.5x30mm Short Blade Cannulated Screw
	482802835	Ø8.5x35mm Short Blade Cannulated Screw
	482802840	Ø8.5x40mm Short Blade Cannulated Screw
	482802845	Ø8.5x45mm Short Blade Cannulated Screw
	482802850	Ø8.5x50mm Short Blade Cannulated Screw
	482802855	Ø8.5x55mm Short Blade Cannulated Screw
	482802860	Ø8.5x60mm Short Blade Cannulated Screw
	482802870	Ø8.5x70mm Short Blade Cannulated Screw
	482802880	Ø8.5x80mm Short Blade Cannulated Screw
	482802890	Ø8.5x90mm Short Blade Cannulated Screw

	Reference number	Description
	482804425	Ø4.5x25mm Long Blade Cannulated Screw
	482804430	Ø4.5x30mm Long Blade Cannulated Screw
	482804435	Ø4.5x35mm Long Blade Cannulated Screw
	482804440	Ø4.5x40mm Long Blade Cannulated Screw
	482804445	Ø4.5x45mm Long Blade Cannulated Screw
	482804530	Ø5.5x30mm Long Blade Cannulated Screw
	482804535	Ø5.5x35mm Long Blade Cannulated Screw
	482804540	Ø5.5x40mm Long Blade Cannulated Screw
	482804545	Ø5.5x45mm Long Blade Cannulated Screw
	482804550	Ø5.5x50mm Long Blade Cannulated Screw
	482804555	Ø5.5x55mm Long Blade Cannulated Screw
	482804630	Ø6.5x30mm Long Blade Cannulated Screw
	482804635	Ø6.5x35mm Long Blade Cannulated Screw
	482804640	Ø6.5x40mm Long Blade Cannulated Screw
	482804645	Ø6.5x45mm Long Blade Cannulated Screw
	482804650	Ø6.5x50mm Long Blade Cannulated Screw
	482804655	Ø6.5x55mm Long Blade Cannulated Screw
	482804660	Ø6.5x60mm Long Blade Cannulated Screw
	482804730	Ø7.5x30mm Long Blade Cannulated Screw
	482804735	Ø7.5x35mm Long Blade Cannulated Screw
	482804740	Ø7.5x40mm Long Blade Cannulated Screw
	482804745	Ø7.5x45mm Long Blade Cannulated Screw
	482804750	Ø7.5x50mm Long Blade Cannulated Screw
	482804755	Ø7.5x55mm Long Blade Cannulated Screw
	482804760	Ø7.5x60mm Long Blade Cannulated Screw
	482804770	Ø7.5x70mm Long Blade Cannulated Screw
	482804780	Ø7.5x80mm Long Blade Cannulated Screw
	482804790	Ø7.5x90mm Long Blade Cannulated Screw
	482804830	Ø8.5x30mm Long Blade Cannulated Screw
	482804835	Ø8.5x35mm Long Blade Cannulated Screw
	482804840	Ø8.5x40mm Long Blade Cannulated Screw
	482804845	Ø8.5x45mm Long Blade Cannulated Screw
	482804850	Ø8.5x50mm Long Blade Cannulated Screw
	482804855	Ø8.5x55mm Long Blade Cannulated Screw
	482804860	Ø8.5x60mm Long Blade Cannulated Screw
	482804870	Ø8.5x70mm Long Blade Cannulated Screw
	482804880	Ø8.5x80mm Long Blade Cannulated Screw
	482804890	Ø8.5x90mm Long Blade Cannulated Screw

	Reference number	Description
	**48289999**	**LITe Blocker**
	482807020	Ø5.5x20mm Straight Rod
	482807025	Ø5.5x25mm Straight Rod
	482807030	Ø5.5x30mm Straight Rod
	482807035	Ø5.5x35mm Straight Rod
	482807040	Ø5.5x40mm Straight Rod
	482807045	Ø5.5x45mm Straight Rod
	482807050	Ø5.5x50mm Straight Rod
	482807055	Ø5.5x55mm Straight Rod
	482807060	Ø5.5x60mm Straight Rod
	482807065	Ø5.5x65mm Straight Rod
	482807070	Ø5.5x70mm Straight Rod
	482807080	Ø5.5x80mm Straight Rod
	482807090	Ø5.5x90mm Straight Rod
	482807100	Ø5.5x100mm Straight Rod
	482807110	Ø5.5x110mm Straight Rod
	482807120	Ø5.5x120mm Straight Rod
	482807130	Ø5.5x130mm Straight Rod
	482807140	Ø5.5x140mm Straight Rod
	482807150	Ø5.5x150mm Straight Rod
	482807160	Ø5.5x160mm Straight Rod
	482807170	Ø5.5x170mm Straight Rod
	482807180	Ø5.5x180mm Straight Rod
	482807190	Ø5.5x190mm Straight Rod
	482807480	Ø5.5x480mm Straight Rod
	482807600	Ø5.5x600mm Straight Rod
	482806030	Ø5.5x30mm Rad Rod
	482806035	Ø5.5x35mm Rad Rod
	482806040	Ø5.5x40mm Rad Rod
	482806045	Ø5.5x45mm Rad Rod
	482806050	Ø5.5x50mm Rad Rod
	482806055	Ø5.5x55mm Rad Rod
	482806060	Ø5.5x60mm Rad Rod
	482806065	Ø5.5x65mm Rad Rod
	482806070	Ø5.5x70mm Rad Rod

Reference number	Description
482806075	Ø5.5x75mm Rad Rod
482806080	Ø5.5x80mm Rad Rod
482806090	Ø5.5x90mm Rad Rod
482806100	Ø5.5x100mm Rad Rod
482806110	Ø5.5x110mm Rad Rod
482806120	Ø5.5x120mm Rad Rod
482806130	Ø5.5x130mm Rad Rod
482808020	Ø5.5x20mm Vitallium Straight Rod
482808025	Ø5.5x25mm Vitallium Straight Rod
482808030	Ø5.5x30mm Vitallium Straight Rod
482808035	Ø5.5x35mm Vitallium Straight Rod
482808040	Ø5.5x40mm Vitallium Straight Rod
482808045	Ø5.5x45mm Vitallium Straight Rod
482808050	Ø5.5x50mm Vitallium Straight Rod
482808055	Ø5.5x55mm Vitallium Straight Rod
482808060	Ø5.5x60mm Vitallium Straight Rod
482808065	Ø5.5x65mm Vitallium Straight Rod
482808070	Ø5.5x70mm Vitallium Straight Rod
482808075	Ø5.5x75mm Vitallium Straight Rod
482808080	Ø5.5x80mm Vitallium Straight Rod
482808090	Ø5.5x90mm Vitallium Straight Rod
482808100	Ø5.5x100mm Vitallium Straight Rod
182808110	Ø5.5x110mm Vitallium Straight Rod
482808120	Ø5.5x120mm Vitallium Straight Rod
482808130	Ø5.5x130mm Vitallium Straight Rod
482808140	Ø5.5x140mm Vitallium Straight Rod
482808150	Ø5.5x150mm Vitallium Straight Rod
482808160	Ø5.5x160mm Vitallium Straight Rod
482808170	Ø5.5x170mm Vitallium Straight Rod
482808180	Ø5.5x180mm Vitallium Straight Rod
482808190	Ø5.5x190mm Vitallium Straight Rod
482808480	Ø5.5x480mm Vitallium Straight Rod
482808600	Ø5.5x600mm Vitallium Straight Rod

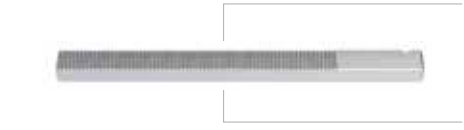
Reference number	Description
48487030	Ø6.0x30mm Straight Rod
48487035	Ø6.0x35mm Straight Rod
48487040	Ø6.0x40mm Straight Rod
48487045	Ø6.0x45mm Straight Rod
48487050	Ø6.0x50mm Straight Rod
48487055	Ø6.0x55mm Straight Rod
48487060	Ø6.0x60mm Straight Rod
48487065	Ø6.0x65mm Straight Rod
48487070	Ø6.0x70mm Straight Rod
48487075	Ø6.0x75mm Straight Rod
48487080	Ø6.0x80mm Straight Rod
48487090	Ø6.0x90mm Straight Rod
48487100	Ø6.0x100mm Straight Rod
48487110	Ø6.0x110mm Straight Rod
48487120	Ø6.0x120mm Straight Rod
48487130	Ø6.0x130mm Straight Rod
48487140	Ø6.0x140mm Straight Rod
48487150	Ø6.0x150mm Straight Rod
48487160	Ø6.0x160mm Straight Rod
48487170	Ø6.0x170mm Straight Rod
48487180	Ø6.0x180mm Straight Rod
48487190	Ø6.0x190mm Straight Rod
48487200	Ø6.0x200mm Straight Rod
48487480	Ø6.0x480mm Straight Rod
48487600	Ø6.0x600mm Straight Rod

48486030	Ø6.0x30mm Rad Rod
48486035	Ø6.0x35mm Rad Rod
48486040	Ø6.0x40mm Rad Rod
48486045	Ø6.0x45mm Rad Rod
48486050	Ø6.0x50mm Rad Rod
48486055	Ø6.0x55mm Rad Rod
48486060	Ø6.0x60mm Rad Rod
48486065	Ø6.0x65mm Rad Rod
48486070	Ø6.0x70mm Rad Rod
48486075	Ø6.0x75mm Rad Rod

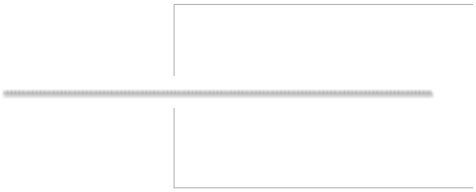
Reference number	Description
48486080	Ø6.0x80mm Rad Rod
48486090	Ø6.0x90mm Rad Rod
48486100	Ø6.0x100mm Rad Rod
48486110	Ø6.0x110mm Rad Rod
48486120	Ø6.0x120mm Rad Rod
48486130	Ø6.0x130mm Rad Rod
482805020	Ø6.0x20mm Vitallium Straight Rod
482805025	Ø6.0x25mm Vitallium Straight Rod
482805030	Ø6.0x30mm Vitallium Straight Rod
482805035	Ø6.0x35mm Vitallium Straight Rod
482805040	Ø6.0x40mm Vitallium Straight Rod
482805045	Ø6.0x45mm Vitallium Straight Rod
482805050	Ø6.0x50mm Vitallium Straight Rod
482805055	Ø6.0x55mm Vitallium Straight Rod
482805060	Ø6.0x60mm Vitallium Straight Rod
482805065	Ø6.0x65mm Vitallium Straight Rod
482805070	Ø6.0x70mm Vitallium Straight Rod
482805075	Ø6.0x75mm Vitallium Straight Rod
482805080	Ø6.0x80mm Vitallium Straight Rod
482805090	Ø6.0x90mm Vitallium Straight Rod
482805100	Ø6.0x100mm Vitallium Straight Rod
482805110	Ø6.0x110mm Vitallium Straight Rod
482805120	Ø6.0x120mm Vitallium Straight Rod
482805130	Ø6.0x130mm Vitallium Straight Rod
482805140	Ø6.0x140mm Vitallium Straight Rod
482805150	Ø6.0x150mm Vitallium Straight Rod
482805160	Ø6.0x160mm Vitallium Straight Rod
482805170	Ø6.0x170mm Vitallium Straight Rod
482805180	Ø6.0x180mm Vitallium Straight Rod
482805190	Ø6.0x190mm Vitallium Straight Rod
482805480	Ø6.0x480mm Vitallium Straight Rod
482805600	Ø6.0x600mm Vitallium Straight Rod

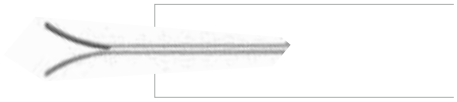
Instruments

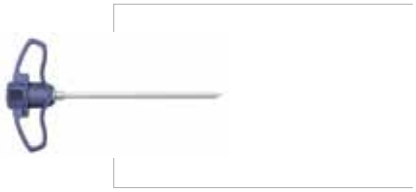
	Reference number	Description
	48281202	Ring
	48281000	Dilator 1
	48282000	Dilator 2
	48280091	Dilator 3
	48280092	Recovery Dilator 1
	48280098	Recovery Dilator 2
	48280200	Cannulated Modular Awl
	48280145	Ø4.5mm Cannulated Modular Tap
	48280155	Ø5.5mm Cannulated Modular Tap
	48280165	Ø6.5mm Cannulated Modular Tap
	48280175	Ø7.5mm Cannulated Modular Tap
	48280185	Ø8.5mm Cannulated Modular Tap (not in standard set)
	48280100	Tap Sleeve (Ø8.5mm)
	48280310	Polyaxial Screwdriver

	Reference number	Description
	48280311	Polyaxial Screwdriver Inner Shaft
	48280090	90° Rod Inserter
	48280110	110° Rod Inserter
	48480112	Rod Inserter Inner Shaft
	48280080	Counter Torque Tube
	48280081	Torque Wrench
	48280082	Compression/Distraction Shaft
	48280083	Compression/Distraction Hinge
	48280178	Multi-Level Compression/Distraction Ratchet Knob
	48280179	Multi-Level Compression/Distraction Adjustable Arm
	48280180	Multi-Level Compression/Distraction Shaft
	48280181	Multi-Level Compression/Distraction 2-Level Rack
	48280182	Multi-Level Compression/Distraction 4-Level Rack
	48280183	Multi-Level Compression/Distraction Fixed Arm

	Reference number	Description
	48280184	Multi-Level Compression/Distraction Anti-Torque Handle
	48280084	Blade Remover
	48282100	Rod Template, 100mm
	48282200	Rod Template, 200mm
	48280186	Rod Length/Passage Indicator
	48280085	Blocker Inserter
	48280187	Modular Blocker Inserter
	48280086	Polyadjustment Driver
	48280087	French Bender
	48280096	Recovery Outer Sleeve
	48280095	Recovery Inner Shaft
	48280097	Hex-End T-Handle
	48280093	Recovery Guide
	48280099	Threaded Recovery Guide







Reference number	Description
48280120	Slap Hammer
48237005	K-Wire Container
48230230	Stainless Steel K-Wire Sharp
48230231	Stainless Steel K-Wire Blunt
48280233	Nitinol K-Wire Sharp
48280232	Nitinol K-Wire Blunt
FC-128-22-B-2	Y-Wire (5 sets of 2: 1.28mm diameter x 559mm)
FC-128-22-B-4	Y-Wire (5 sets of 4: 1.28mm diameter x 559mm)
GEN2-125B-6	Funnel (package of 6)
48237110	Jam Shidi 10 Gauge 9 Inch
48237105	Jam Shidi 10 Gauge 5 Inch
48237115	Jam Shidi 11 Gauge 5 Inch
48237135	Jam Shidi 13 Gauge 5 Inch
TN-100	Tiger Cub - Jam Shidi Needle
TN-200	Tiger Needle Express - Jam Shidi Needle
TN-300	Tiger Needle Express with Broach - Jam Shidi Needle
TN-400	Tiger Needle - Jam Shidi Needle

Reference number	Description
2090-9051	Needle 11 Gauge 6 Inch
2090-9052	Needle 8 Gauge 6 Inch
2090-9053	Fenestrated Needle 8 Gauge 6 Inch
2090-9027	Needle 11 Gauge 4 Inch
2090-9028	Needle 11 Gauge 6 Inch
2090-9029	Needle 8 Gauge 6 Inch
2090-9030	Fenestrated Needle 8 Gauge 6 Inch
2090-9047	Needle 8 Gauge 8 Inch
48284070	Distractor
48284075	Compressor
48289200	T-Handle Ratchet
48289300	Round Handle Ratchet
48280006	Implant Tray
48280006A	Implant Tray Lid
48280006B	Implant Tray Top Insert
48280006C	Implant Tray Middle Insert
48280006D	Straight Rod Caddy
48280006E	Implant Tray Base
48280006F	Short Blade Screw Caddy
48280006G	Long Blade Screw Caddy

Reference number	Description
48280006H	Ring Caddy with Lid
48280006I	Blocker Caddy with Lid
48280006J	Screw Caddy Stand
48280006K	Rad Rod Caddy
48280007	Instrument Tray 1
48280007A	Instrument Tray 1 Lid
48280007B	Instrument Tray 1 Top Insert
48280007C	Instrument Tray 1 Middle Insert
48280007D	Instrument Tray 1 Base
48280008	Instrument Tray 2
48280008A	Instrument Tray 2 Lid
48280008B	Instrument Tray 2 Insert
48280008C	Instrument Tray 2 Base
48280009	Outlier Implant Tray
48280009A	Outlier Implant Tray Lid
48280009B	Outlier Implant Tray Base
48280010	Instrument Tray 3

Reference number	Description
48280010C	Instrument Tray 3 Lid
48280010A	Instrument Tray 3 Top Insert
48280010B	Instrument Tray 3 Base
48287005	K-Wire Container

Compatible instruments (Not included in set)

Reference number	Description
48480001	Adjustable Rod Inserter
48230235	K-Wire Guide Tube
48289205	T-Handle Non-Ratchet
48289305	Round Handle Non-Ratchet
48769210	Short T-Handle, Ratchet, Cannulated (Navigated MANTIS)
48250310	Screw Head Adjuster
48237065	Double-Ended Universal Tightener
48287008	Blocker Inserter (MANTIS Redux)
03710620	Xia 3 Rod Template

ES2 instructions for use

Indications

ES2 Spinal System

The ES2 Spinal System is intended for percutaneous, posterior, non-cervical pedicle fixation of the spine to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion for the following indications:

- Degenerative Disc Disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies),
- Spondylolisthesis,
- Trauma (i.e. fracture or dislocation),
- Spinal stenosis,
- Curvatures (i.e. scoliosis, kyphosis, and/or lordosis),
- Tumor,
- Pseudoarthrosis, and
- Failed previous fusion.

The Titanium and Vitallium rods from the Stryker Spine RADIUS, MANTIS and MANTIS Redux Spinal Systems are intended to be used with the other components of the ES2 Spinal System.

The ES2 Awls, Taps, and Screwdriver can be used by the surgeon to assist in location of the spinal nerves by providing proximity information before, during or after bone preparation and placement of bone screws in open and percutaneous minimally invasive posterior surgical approaches of the non-cervical spine.

Contraindications

Contraindications may be relative or absolute. The choice of a particular device must be carefully weighed against the patient's overall evaluation. Circumstances listed below may reduce the chances of a successful outcome:

- Any abnormality present which affects the normal process of bone remodeling including, but not limited to, severe osteoporosis involving the spine, bone absorption, osteopenia, primary or metastatic tumors involving the spine, active infection at the site or certain metabolic disorders affecting osteogenesis.
- Insufficient quality or quantity of bone which would inhibit rigid device fixation.
- Previous history of infection.
- Excessive local inflammation.
- Open wounds.
- Any neuromuscular deficit which places an unusually heavy load on the device during the healing period.
- Obesity. An overweight or obese patient can produce loads on the spinal system which can lead to failure of the fixation of the device or to failure of the device itself.
- Patients having inadequate tissue coverage of the operative site.
- Pregnancy.
- A condition of senility, mental illness, or substance abuse. These conditions, among others, may cause the patient to ignore certain necessary limitations and precautions in the use of the implant, leading to failure or other complications.
- Foreign body sensitivity. Where material sensitivity is suspected, appropriate tests should be made prior to material selection or implantation.
- Other medical or surgical conditions which would preclude the potential benefit of spinal implant surgery, such as the presence of tumors, congenital abnormalities, elevation of sedimentation rate unexplained by other diseases, elevation of white blood cell count (WBC), or marked left shift in the WBC differential count.
- These contraindications can be relative or absolute and must be taken into account by the physician when making his decision. The above list is not exhaustive.
- Surgeons should warn patients of the above listed potential adverse effects, including the finite service life of the device and the need for post-operative protection of the implant.

General conditions of Use

The implantation of pedicle screw spinal systems must be performed only by experienced spinal surgeons having undergone the necessary specific training in the use of such systems because this is a technically demanding procedure presenting a risk of serious injury to the patient.
The information contained in the Package Insert is necessary but not sufficient for the use of this device. This information is in no sense intended as a substitute for the professional judgment, skill and experience of the surgeon in careful patient selection, preoperative planning and device selection, knowledge of the anatomy and biomechanics of the spine, understanding of the materials and the mechanical characteristics of the implants used, training and skill in spinal surgery and the use of associated instruments for implantation, securing the patient's cooperation in following an appropriately defined post-operative management program and conducting scheduled post-operative follow-up examinations.

Information for patients

The surgeon must discuss all physical and psychological limitations inherent to the use of the device with the patient. This includes the rehabilitation regimen, physical therapy, and wearing an appropriate orthosis as prescribed by the physician. Particular discussion must be directed to the issues of premature weight bearing, activity levels, and the necessity for periodic medical follow-up.

The surgeon must warn the patient of the surgical risks and made aware of possible adverse effects. The surgeon must warn the patient that the device cannot and does not replicate the flexibility, strength, reliability or durability of normal healthy bone, that the implant can break or become damaged as a result of strenuous activity or trauma, and that the device may need to be replaced in the future. If the patient is involved in an occupation or activity which applies inordinate stress upon the implant (e.g., substantial walking, running, lifting, or muscle strain) the surgeon must advise the patient that resultant forces can cause failure of the device. Patients who smoke have been shown to have an increased incidence of non-unions. Surgeons must advise patients of this fact and warn of the potential consequences. For diseased patients with degenerative disease, 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. In such cases, orthopaedic devices may be considered only as a delaying technique or to provide temporary relief.

Infection

Transient bacteremia can occur in daily life. Dental manipulation, endoscopic examination and other minor surgical procedures have been associated with transient bacteremia. To help prevent infection at the implant site, it is advisable to use antibiotic prophylaxis before and after such procedures.

Implant selection and use

The choice of proper shape, size and design of the implant for each patient is crucial to the success of the surgery. The surgeon is responsible for this choice which depends on each patient.

Patients who are overweight may be responsible for additional stresses and strains on the device which can speed up metal fatigue and/or lead to deformation or failure of the implants.

The size and shape of the bone structures determine the size, shape and type of the implants. Once implanted, the implants are subjected to stresses and strains. These repeated stresses on the implants should be taken into consideration by the surgeon at the time of the choice of the implant,

during implantation as well as in the post-operative follow-up period. Indeed, the stresses and strains on the implants may cause metal fatigue or fracture or deformation of the implants, before the bone graft has become completely consolidated. This may result in further side effects or necessitate the early removal of the osteosynthesis device.

Improper selection, placement, positioning and fixation of these devices may result in unusual stress conditions reducing the service life of the implant. Contouring or bending of rods or plates is recommended only if necessary according to the surgical technique of each system. Rods or plates should only be contoured with the proper contouring instruments. Incorrectly contoured rods/plates, or rods/plates which have been repeatedly or excessively contoured must not be implanted. The surgeon is to be thoroughly familiar with the surgical procedure, instruments and implant characteristics prior to performing surgery. Refer to the Stryker Spine surgical protocols for additional procedural information. Periodic follow-up is recommended to monitor the position and state of the implants, as well as the condition of the adjoining bone.

Post-operative care

Prior to adequate maturation of the fusion mass, implanted spinal instrumentation may need additional help to accommodate full load bearing. External support may be recommended by the physician from two to four months postoperatively or until x-rays or other procedures confirm adequate maturation of the fusion mass; external immobilization by bracing or casting be employed. Surgeons must instruct patients regarding appropriate and restricted activities during consolidation and maturation for the fusion mass in order to prevent placing excessive stress on the implants which may lead to fixation or implant failure and accompanying clinical problems. Surgeons must instruct patients to report any unusual changes of the operative site to his/her physician. The physician should closely monitor the patient if a change at the site has been detected.

Adverse effects

- While the expected life of spinal implant components is difficult to estimate, it is finite. These components are made of foreign materials which are placed within the body for the potential fusion of the spine and reduction of pain. However, due to the many biological, mechanical and physicochemical factors which affect these devices but cannot be evaluated in vivo, the components cannot be expected to indefinitely withstand the activity level and loads of normal healthy bone.
- Bending, disassembly or fracture of any or all implant components.
- Fatigue fracture of spinal fixation devices, including screws and rods, has occurred.
- Pain, discomfort, or abnormal sensations due to the presence of the device.
- Pressure on skin from components where inadequate tissue coverage exists over the implant, with the potential extrusion through the skin.
- Dural leak requiring surgical repair.
- Loss of proper spinal curvature, correction, height and/or reduction.
- Delayed Union or Nonunion: Internal fixation appliances are load sharing devices which are used to obtain alignment until normal healing occurs. In the event that healing is delayed, does not occur, or failure to immobilize the delayed/nonunion results, the implant will be subject to excessive and repeated stresses which can eventually cause loosening, bending or fatigue fracture. The degree or success of union, loads produced by weight bearing, and activity levels will, among other conditions, dictate the longevity of the implant. If a nonunion develops or if the implants loosen, bend or break, the device(s) should be revised or removed immediately before serious injury occurs.
- Loosening of spinal fixation implants can occur. Early mechanical loosening may result from inadequate initial fixation, latent infection, premature loading of the prosthesis or trauma. Late loosening may result from trauma, infection, biological complications or mechanical problems, with the subsequent possibility of bone erosion, migration and/or pain.
- Peripheral neuropathies, nerve damage, heterotopic bone formation and neurovascular compromise, including paralysis, loss of bowel or bladder function, or foot-drop may occur.
- Serious complications may be associated with any spinal surgery. These complications include, but are not limited to: genitourinary disorders; gastrointestinal disorders; vascular disorders, including thrombus; bronchopulmonary disorders, including emboli; bursitis, hemorrhage, myocardial infarction, infection, paralysis or death.
- Neurological, vascular, or soft tissue damage due directly to the unstable nature of the fracture, or to surgical trauma.
- Inappropriate or improper surgical placement of this device may cause distraction or stress shielding of the graft or fusion mass. This may contribute to failure of an adequate fusion mass to form.
- Decrease in bone density due to stress shielding.
- Intraoperative fissure, fracture, or perforation of the spine can occur due to implantation of the components. Postoperative fracture of bone graft, the intervertebral body, pedicle, and/or sacrum above and/or below the level of surgery can occur due to trauma, the presence of defects, or poor bone stock.

Adverse effects may necessitate reoperation or revision.

Removal of implants

These implants are temporary internal fixation devices designed to stabilize the operative site during the normal healing process. After healing occurs, these devices serve no functional purpose and can be removed. Removal may also be recommended in other cases, such as:

- Corrosion with a painful reaction
- Migration of the implant, with subsequent pain and/or neurological, articular or soft tissue lesions
- Pain or abnormal sensations due to the presence of the implants
- Infection or inflammatory reactions
- Reduction in bone density due to the different distribution of mechanical and physiological stresses and strains
- Failure or mobilization of the implant

Standard ancillaries provided by Stryker Spine can be used to remove the implants. Any decision by a physician to remove the internal fixation device must take into consideration such factors as the risk to the patient of the additional surgical procedure as well as the difficulty of removal. Removal of an unloosened spinal screw may require the use of special instruments to disrupt the interface at the implant surface. This technique may require practice in the laboratory before being attempted clinically. Implant removal should be followed by adequate postoperative management to avoid fracture or re-fracture. Removal of the implant after fracture healing is recommended. Metallic implants can loosen, bend, fracture, corrode, migrate, cause pain or stress shield bone.

Pre-operative precautions
Anyone using Stryker Spine products can obtain a Surgical Technique brochure by requesting one from a distributor or from Stryker Spine directly. Those using brochures published more than two years before the surgical intervention are advised to get an updated version.

Stryker Spine devices can only be used by doctors who are fully familiar with the surgical technique required and who have been trained to this end. The doctor operating must take care not to use the instruments to exert inappropriate stress on the spine or the implants and must scrupulously comply with any operating procedure described in the surgical technique provided by Stryker Spine. For example, the forces exerted when repositioning an instrument in-situ must not be excessive as this is likely to causes injury to the patient.

To reduce the risks of breakage, care must be taken not to distort the implants or nick, hit or score them with the instruments unless otherwise specified by the applicable Stryker Spine Surgical Technique.

Extreme care must be taken when the instruments are used near vital organs, nerves or vessels.

Unless otherwise specified on the label, the instruments can be reused after decontamination, cleaning and sterilization.

Caution
Federal law (U.S.A) restricts this device to sale by or on the order of a licensed physician.

Warning (U.S.A.)
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 spondylolisthesis (grades 3 and 4) of the L5-S1 vertebrae, 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.

The ES2 Spinal System has not been tested for heating or migration in the MR environment.

Precautions (U.S.A.)
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.

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A surgeon must always rely on his or her own professional clinical judgment when deciding whether to use a particular product when treating a particular patient. Stryker does not dispense medical advice and recommends that surgeons be trained in the use of any particular product before using it in surgery.

The information presented is intended to demonstrate the breadth of Stryker product offerings. A surgeon must always refer to the package insert, product label and/or instructions for use before using any Stryker product. Products may not be available in all markets because product availability is subject to the regulatory and/or medical practices in individual markets. Please contact your Stryker representative if you have questions about the availability of Stryker products in your area.

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