Kentrospine

Viktr-MIS Pedicle Screw System

Surgical Technique Manual

Contents

Product Overview

Introduction

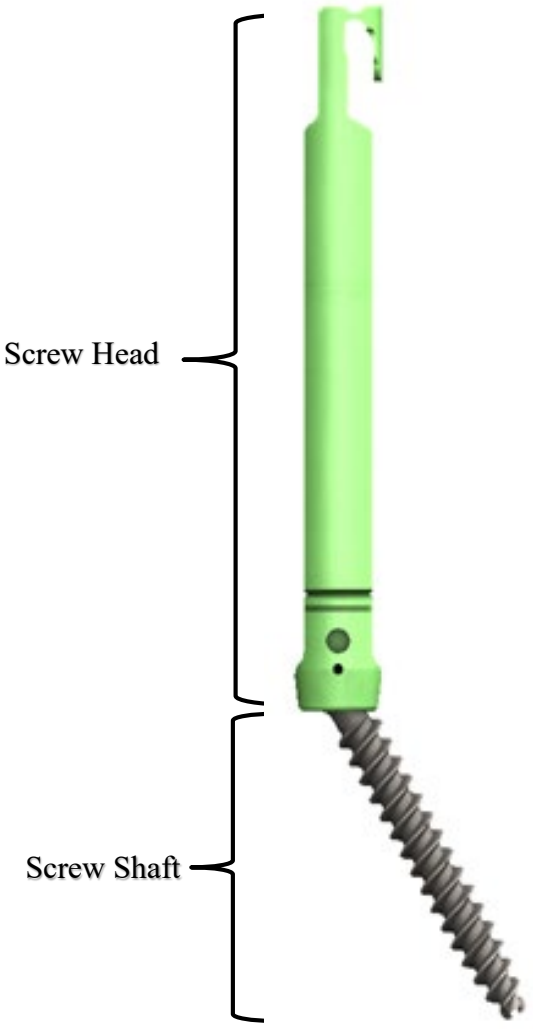
- MIS (Minimally Invasive Surgery) spine surgery is a type of surgical procedure performed on the spine using minimally invasive techniques. Traditional open spine surgery involves large incisions and significant disruption of muscles and tissues surrounding the spine. In contrast, MIS techniques use smaller incisions and specialized instruments to access the spine with minimal disruption to surrounding structures. Here are some key points about MIS spine surgery:

1. **Smaller Incisions**: Instead of large incisions, MIS spine surgery typically involves one or more small incisions, often less than an inch long.
2. **Reduced Muscle Damage**: Since the incisions are smaller, there's less disruption to the muscles and tissues surrounding the spine. This can lead to less postoperative pain and faster recovery times compared to traditional open surgery.
3. **Specialized Instruments**: MIS spine surgery often utilises specialised instruments such as tubular retractors, endoscopes, and miniature cameras to access and visualise the spine.
4. **Various Procedures**: MIS techniques can be used for a variety of spinal procedures including decompression (removing bone or tissue that's pressing on nerves), fusion (joining two or more vertebrae together), and disc replacement.
5. **Advantages**: Some of the potential advantages of MIS spine surgery include reduced blood loss, shorter hospital stays, quicker recovery times, and decreased risk of infection compared to traditional open surgery.

Features

Kentrospine Viktr MIS Poly Cannulated Screw

- Square threaded locking cap eliminate cross threading.
- MIS threaded screw have self-tapping flutes allowing for easy and quick screw insertion.
- Available in diameter 5.5, 6.5, 7.2.
- High angulation (60°) of the poly axial screw head makes it easier to adapt the other system components to the patient's individual anatomy.
- Long Sleeve- Sleeves length is around 100 mm & 120 mm which is useful in obese patient.
- Straight and pre lordosed 5.5 diameter rod Surgeon friendly, versatile Instrumentation.
- Screw lengths 30, 35, 40, 45, 50.



Kentrospine Viktr MIS Poly Cannulated Dualcore Fenestrated screw

- Square threaded locking cap eliminate cross threading.
- Due to dual step locking mechanism, it helps in parallel compression and distraction.
- MIS dual start threaded screw have self-tapping flutes allowing for easy and quick screw insertion. also available in dual core penetrated screw.
- Available in diameter 5.5, 6.5, 7.2.
- High angulation (60°) of the poly axial screw head makes it easier to adapt the other system components to the patient's individual anatomy.
- Long Sleeve- Sleeves length is around 100 mm & 120 mm which is useful in obese patient.
- Straight and pre lordosed 5.5 diameter rod Surgeon friendly, versatile Instrumentation.
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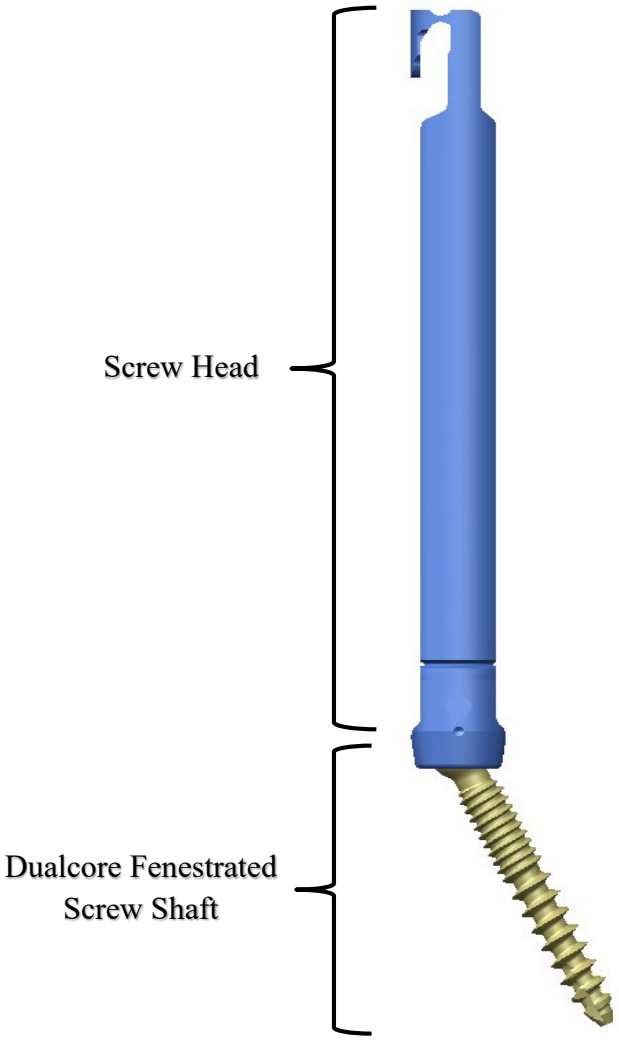
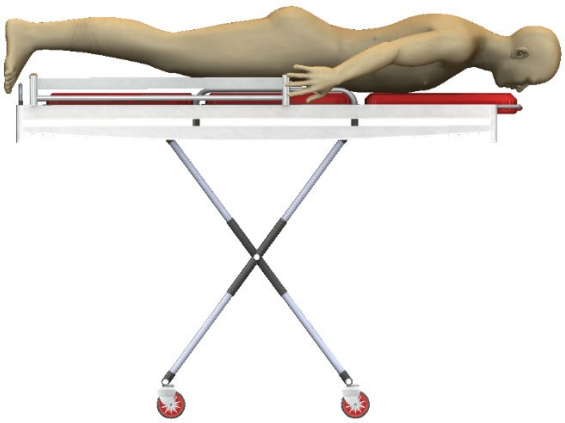


Surgical Technique

Step 1

Preoperative Preparation

- Patient positioning can be either prone or lateral decubitus.

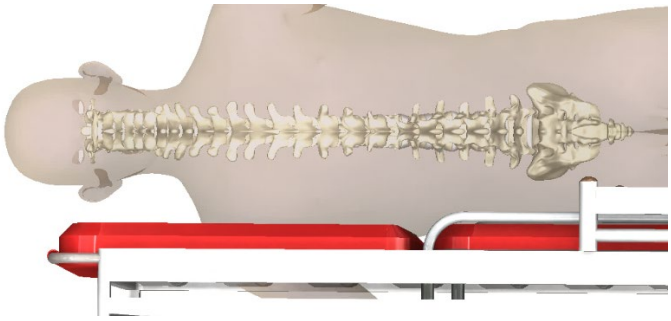


A patient may be in the lateral decubitus position from a lateral lumber interbody fusion procedure and it may be desired to insert Viktr-MIS Screws and Rods as supplemental fixation without repositioning the patient.

Warning: The lateral decubitus position is not intended for cement augmented procedures with fenestrated screws.

Precautions:
It is recommended to use a Jackson Table to assist in achieving the proper patient positioning and an unrestricted fluoroscopic view. Confirm the C-Arm will allow for easy rotation in the lateral, oblique, and A/P positions around the table.

Tables that prohibit unobstructed A/P and lateral images should not be used for this procedure.



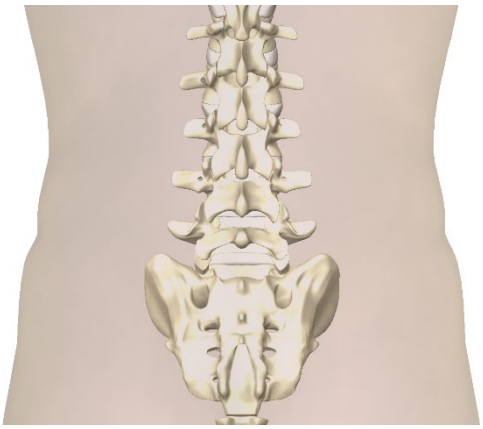
Fluoroscopic Planning

- Use A/P and lateral fluoroscopy to identify and target the appropriate level(s).

Ensure that the C-Arm is positioned correctly for each targeted level by adjusting the position of the C-Arm until both endplates are parallel and the spinous process is equidistant from the center of each pedicle when viewed on A-P fluoroscopy.

The C-Arm may need to be repositioned for each appropriate level.

Determine the Skin Incision Location

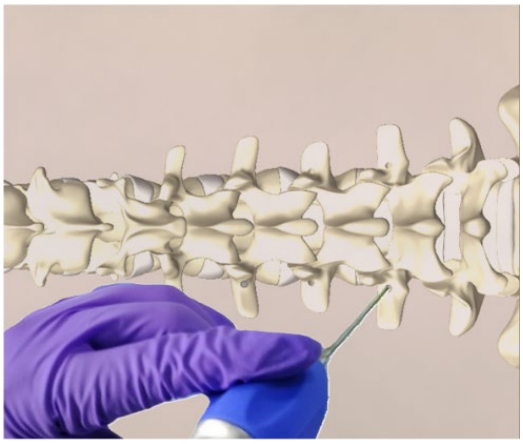


- Place a guidewire on the patient perpendicular to the axis of the spine at the targeted level. Using A-P fluoroscopy, position the guidewire such that its projection transects the center of both pedicles in the cephalad-caudal direction. Use a surgical marker to transfer that plane to the patient.
- Place guidewires on the patient parallel to the axis of the spine. Using A-P fluoroscopy, position the guidewire such that its projection aligns to the lateral pedicle wall of the targeted level and the adjacent levels. The lateral pedicle wall of adjacent levels may also be estimated at this time. Use a surgical marker to transfer this plane onto the patient.

The longitudinal skin incision for each level should be at least 1 cm lateral to the intersection of the two lines. This distance may vary depending on size of the patient.

General anaesthesia or regional anaesthesia (e.g., epidural or spinal aesthesia) is administered to ensure the patient's comfort and safety during the procedure.

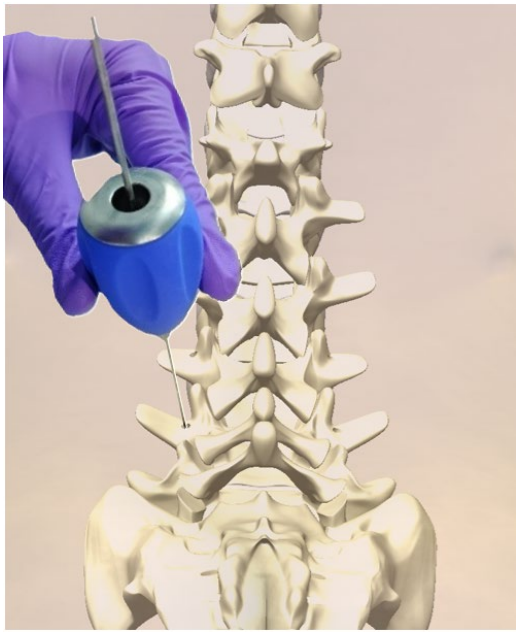
Step 2



- **Marking the Entry Point:** The awl is used to create a small indentation or mark at the precise location on the pedicle where the screw will be inserted. This mark helps guide the trajectory and ensures proper alignment with the planned screw placement.

- **Creating the Entry Hole:** After the mark is made, the awl is used to carefully create a small pilot hole or entry point in the pedicle. This initial hole serves as a guide for the subsequent screw insertion. The awl is typically held at a specific angle to align with the planned screw trajectory, ensuring that the screw will be placed accurately.

Step 3



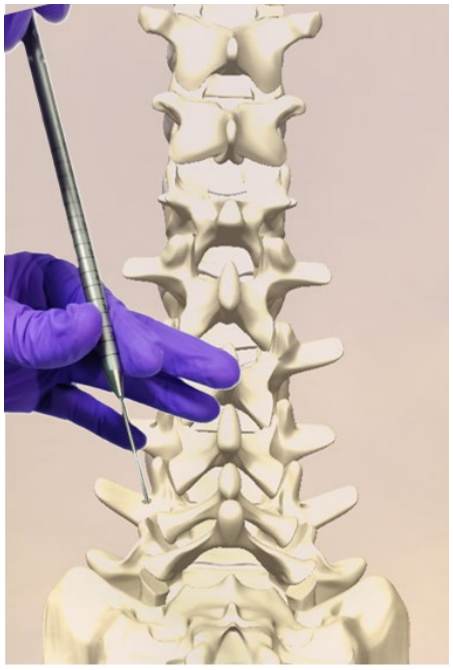
- **Removing the Trocar/ Jamshidi needle from the Awl**: The trocar is a sharp, pointed instrument used to make an initial
- puncture or entry into the bone. In this step, the trocar is removed from the awl after the initial entry hole has been created in the pedicle. The trocar's sharp tip can be dangerous if left in place during the next steps, so it is removed to prevent injury and allow for more controlled subsequent actions.
- **Inserting the Guidewire Through the Sleeve**: Once the trocar is removed, the sleeve remains in place. This sleeve acts as a guide for the next step. The guidewire is inserted through the sleeve into the pedicle. The guidewire is a thin, flexible wire that helps ensure the accurate trajectory for the screw. It serves as a reference for the screw's path, allowing the surgeon to ensure that the screw is placed at the correct angle and depth.
- **Purpose of the Guidewire**: The guidewire acts as a pathway for the pedicle screw insertion. Once the guidewire is in place, it helps to navigate and maintain the proper alignment of the screw. It also allows for confirmation of screw position under imaging guidance, typically fluoroscopy, before the screw itself is inserted.

Step 4

- **Removing the Inserter (Awl)**: The awl, which was initially used to create the entry hole in the pedicle, is removed from the guidewire. The purpose of removing the awl at this point is to clear the way for the screw inserter, which will now follow the guidewire to insert the pedicle screw.

Step 5

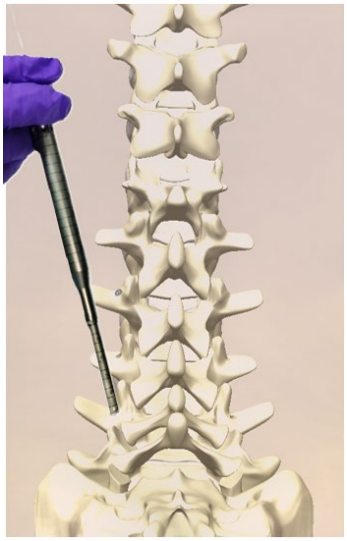
The dilator is a specialized instrument designed to gently enlarge the access pathway created by the initial entry, allowing to expand the tissue and bone around the guidewire in a controlled manner. This step is critical for preparing the pedicle for screw insertion while minimizing tissue trauma. It is typically used to progressively enlarge the path for the screw inserter and other instruments.



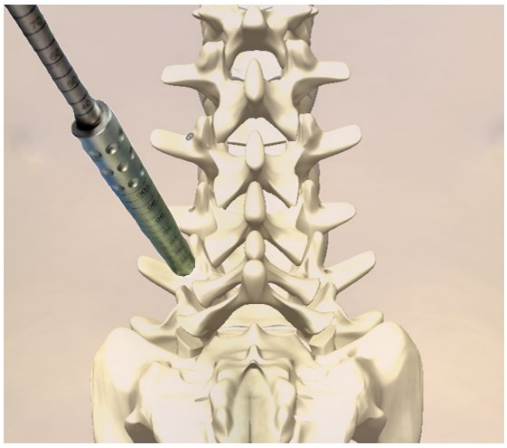
- **Inserting the First Dilator**: After confirming the guidewire is positioned correctly in the pedicle, the first dilator, which is usually a small, tapered instrument, is inserted over the guidewire. The dilator slides through the tissue and into the bone, following the trajectory set by the guidewire.
  The guidewire acts as a guide, ensuring that the dilator follows the correct angle and path for the screw insertion. The guidewire provides a stable, precise reference to maintain alignment.

Step 6

- **Inserting the Second Dilator**: the second, slightly larger dilator is carefully guided through the first dilator. The guidewire still provides a stable and accurate reference, ensuring that the second dilator follows the correct path toward the pedicle.
- The second dilator is designed to widen the access further, preparing the space for the final instruments (such as the screw inserter).
- As the second dilator is advanced, it follows the trajectory set by the guidewire and enters the pathway
- created by the first dilator. This step ensures the space is gradually and controlled, expanding to the required diameter without causing unnecessary damage to surrounding tissue.

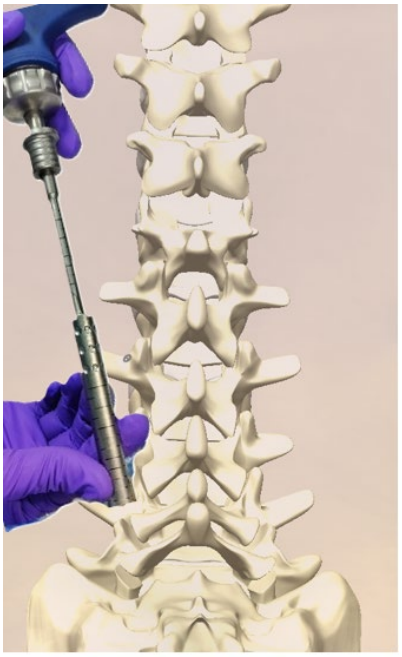


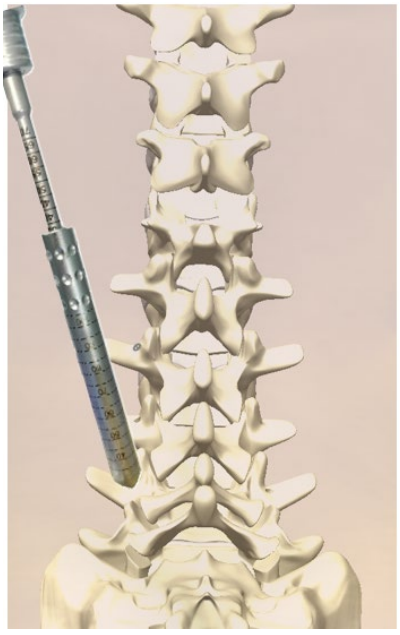
- **Removing the First Dilator**: After the second dilator is securely in place and properly positioned, the first dilator is no longer necessary. The first dilator is removed, leaving the second dilator in position.
- **Final Position of the Second Dilator**: The second dilator has expanded the access pathway further. It provides a larger working space for the screw inserter and other instruments, facilitating the next step in screw insertion.



Step 7

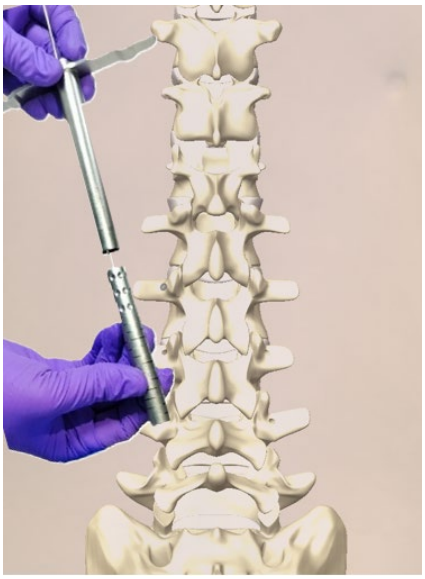
- **Tapping Instrument**: The tapping instrument, which is used to create threads in the bone for the screw to grip, has a central hole or channel through which the guidewire will pass. The tapping instrument typically has a "T-handle" that is used to rotate it, allowing the surgeon to control the tapping action and advance the instrument into the bone.
- **Guiding the Tap Through the Guidewire**: The guidewire is carefully inserted into the hole in the tapping instrument. This ensures that the tapping instrument follows the path of the guidewire as it moves toward the pedicle. The guidewire is essential here because it keeps the tapping instrument aligned with the planned screw trajectory, reducing the risk of deviation.
- **Advancing the Tapping Instrument**: The tapping instrument advances down the guidewire, so the instrument moves in a controlled fashion along the path created by the guidewire. The tapping instrument is carefully guided through the dilator, which has been previously placed in the pedicle. The dilator helps ensure that the tapping instrument can move smoothly and maintain its alignment as it reaches the pedicle.
- **Reaching the Pedicle**: As the tapping instrument
- moves through the dilator and reaches the pedicle, it begins to engage with the bone.
- **Rotating the T-Handle**: The T-handle is used to rotate the tapping instrument. It is rotated slowly to "tap" the bone, creating a thread in the bone that will accommodate the pedicle screw. The controlled rotation allows to gradually cut the threads without over-damaging the bone, ensuring the screw will be securely anchored.
- **Checking the Dial**: The tapping instrument has a dial or depth gauge that indicates how far the tap has advanced into the bone. This gauge helps to track the depth of the tapping process, ensuring that the hole is of the correct depth to receive the pedicle screw. The dial provides a visual reading, allowing to stop once the desired depth is reached, ensuring that the threads are appropriately created and that the screw will be properly sized.

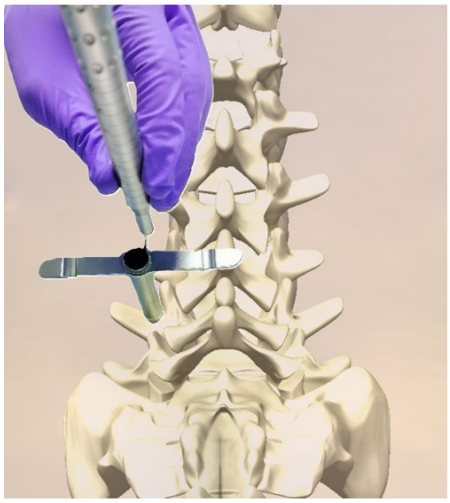




Step 8

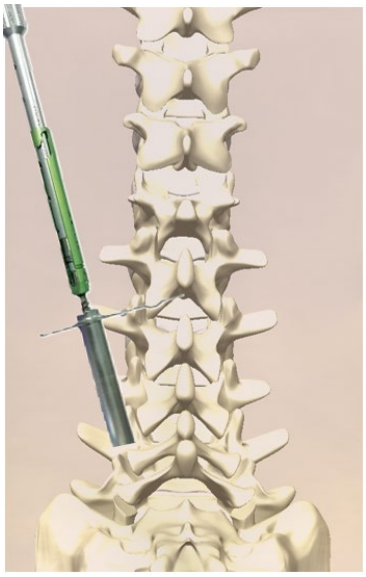
- **Guiding the Tissue Protector**: The tissue protector is a protective instrument used to shield the surrounding soft tissues, muscles, and other structures as the pedicle screw is inserted. It is typically a hollow tube that fits over the guidewire and serves to protect the tissues from the sharp instruments that follow.
- The tissue protector is guided over the guidewire and into the pathway created by the dilator.
- The tissue protector is advanced through the dilator, following the path the guidewire has created, and is positioned right above the pedicle entry site. Its purpose is to keep the surrounding soft tissues safe from being damaged by the screw insertion process.
- **Positioning the Tissue Protector**: Once the tissue protector reaches the appropriate depth, it should sit
- securely over the guidewire and in alignment with the pedicle entry. The protector provides a barrier between the instruments and the surrounding tissues, ensuring that they are not accidentally harmed while the screw is inserted. The tissue protector's position also provides a precise guide for the screw inserter.
- **Removing the Dilator**: Once the tissue protector is securely in place, the dilator is no longer needed. The dilator, having already done its job of creating space for the next instruments, is carefully removed, leaving the tissue protector in position.

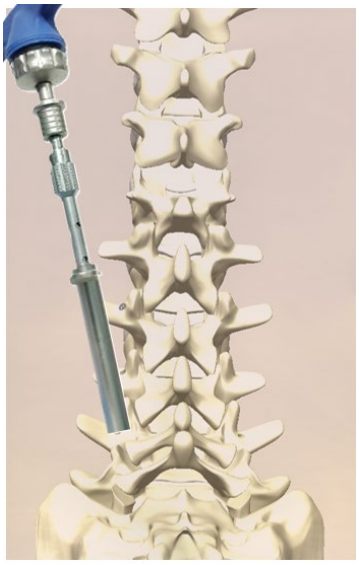




Step 9

- **Preparing the Pedicle Screw:** The pedicle screw, which is typically part of a spinal fixation system, is now ready for insertion. The screw is usually attached to a screw inserter or a driver, which helps in the control the placement of the screw.
- **Inserting the Screw:** The screw is inserted through the tissue protector, guiding it along the path established by the guidewire. The screw follows the precise trajectory set by the guidewire, which ensures that it enters the pedicle at the correct angle and depth. The tissue protector remains in place, protecting the muscles, nerves, and other soft tissues around the pedicle.
- The screw is typically advanced slowly and with gentle pressure to ensure it follows the guidewire's path and engages with the bone of the pedicle. This controlled insertion is crucial for maintaining the correct screw position and avoiding complications.
- **Role of the Tissue Protector:** As the screw is inserted, the tissue protector continues to shield the surrounding tissues from the screw's sharp threads and the pressure
- of the insertion process. The tissue protector helps ensure that the screw can be placed precisely and safely without damaging the muscles, soft tissues, or nerves near the spine.
- **Ensuring Proper Screw Position:** Once the screw has been advanced through the tissue protector and into the pedicle, the position can be checked under fluoroscopy (or other imaging techniques) to confirm that the screw is correctly placed. The guidewire serves as a reference to ensure the screw follows the correct path.



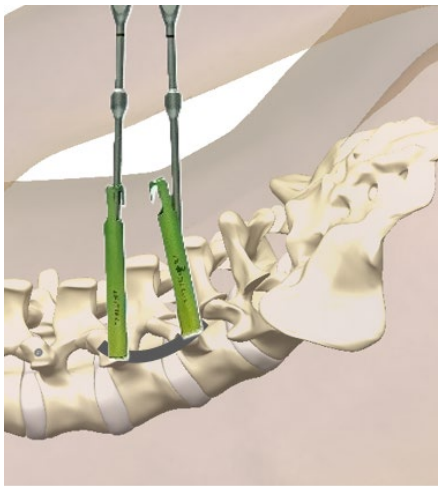


Step 10

- **Putting the Clip on the Guidewire:** After the pedicle screw has been properly inserted, the guidewire is no longer needed for that particular screw. To secure the guidewire and prevent any accidental movement, a small clip is placed on the guidewire. This clip helps to anchor the guidewire in place, preventing it from shifting.
- **Removing the Guidewire from the Screwdriver:** The guidewire is now detached from the screw inserter (or screwdriver). This is typically done by loosening the mechanism on the screwdriver that holds the guidewire. The guidewire is gently pulled out of the screw inserter through the ratchet handle, which leaves the screw securely in place in the pedicle.
- **Unthreading the Screwdriver:** Once the guidewire is removed, the screwdriver is unthreaded from the inserted screw. The screwdriver is carefully unscrewed in a counterclockwise motion, disengaging it from the screw. This unthreading is done slowly and deliberately to avoid disturbing the screw position.
- The screw should remain securely in the pedicle, even as the screwdriver is removed, as it is now firmly anchored within the bone.
- **Removing the Screwdriver:** After the screwdriver has been unthreaded and detached from the screw, the instrument is carefully removed from the surgical site. With the screwdriver removed, the screw is now securely in place in the pedicle.

Step 11

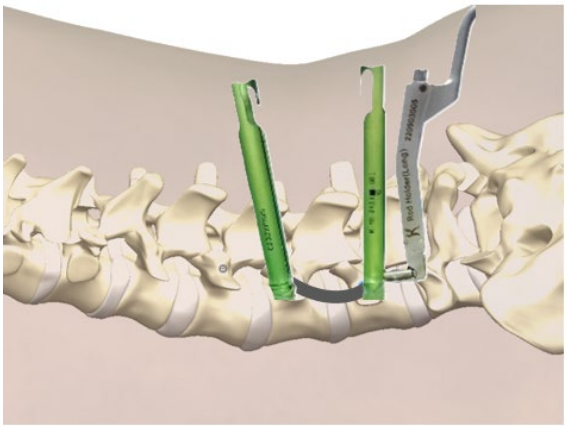
- **Using the Rod Measuring Device**: The surgeon uses a rod measuring device to measure the distance between the two pedicle screws (or the screws being connected). This device is typically a caliper or ruler-like instrument designed to measure the exact distance between the



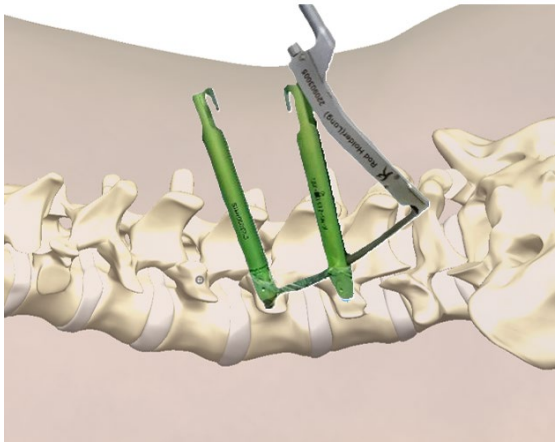
- screw heads. It ensures that the correct rod length is selected to provide proper stabilization and alignment of the spine.
- The device is carefully placed across the screw heads to measure the space between them. This measurement is critical because selecting the correct rod size ensures optimal spinal alignment, stability, and fixation.
- **Selecting the Desired Size Rod**: Based on the measurement provided by the rod measuring device, the rod is selected of the appropriate length and size. The rod must be long enough to span between the screws, but it must also be the right diameter to fit securely into the screw heads without causing undue tension or compression. The correct rod size ensures that the spine is stabilized and the screws are held in place effectively.
- The rod can be straight or with a slight curvature, depending on the alignment needs of the patient's spine.
- **Connecting the Rod to the Rod Holder**: Once the desired rod is selected, the surgeon connects the rod to the rod holder, which is a specialized instrument used to hold the rod in place during the insertion process. The rod holder typically has clamps or other mechanisms that securely grip the rod.
- The rod holder also helps to maintain the correct alignment of the rod with the screws, ensuring the rod is positioned accurately within the screw heads.

Step 12

- **Inserting the Rod into the Screws**: After the rod is selected and connected to the rod holder, the rod is guided into the screw heads. The rod is typically inserted at one end, and then gently fed into the screw slots, one screw at a time. The rod needs to be inserted into the screw heads so that it fits securely into the screw's rod mating slot. The screw's slot is specifically designed to accept the rod, ensuring that the rod will stay in place once the screws are tightened.
- **Aligning the Rod Properly**: As the rod is inserted, it should be aligned correctly with the screw heads. This means checking that the rod is positioned in a way that matches the natural curvature or alignment of the spine. Proper alignment is critical to prevent any unnecessary pressure or misalignment that could lead to complications post-surgery.



- **Placing the Rod in the Screw Rod Mating Slot**: Once the rod is in place, it must fit into the screw's mating slot. Each screw head is designed to accept the rod in such a way that it holds the rod securely and prevents any movement. The rod should sit flush within
- the mating slot, without any gaps or misalignments.



- The rod's position within the screw slots ensures that the screws are fixed in place, and that the rod is securely holding the spine in the desired alignment. If the rod is not properly seated, it could cause instability in the spinal fixation, which is why careful attention is given to this step.
- **Final Adjustments**: Once the rod is inserted and aligned, minor adjustments can be made to ensure that the rod fits perfectly into the screw heads, especially if the spine needs fine-tuning to achieve the desired alignment. The rod must be positioned in such a way that it supports the spine appropriately while maintaining the correct curvature and alignment.

Step 13

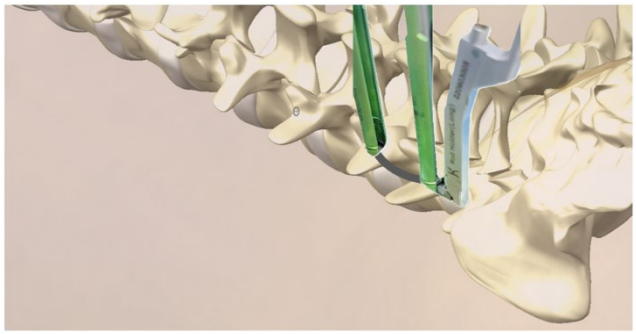
- **Selecting the Desired Innie**: The correct **innie** (also called a set screw or locking screw) is choose based on the screw system being used (single-step or dual-step). The "innie" is designed to fit into the screw head and lock the rod in place.

- **Holding the Innie with the Compatible Innie Holder**: Once the desired innie is selected, the surgeon places it into the corresponding innie holder. The holder is a tool designed to securely hold the innie while it is being inserted into the screw head. The innie holder allows to control and manipulate the innie during insertion, helping to prevent loss of the innie and ensuring it's properly placed.
- The innie holder typically has a locking or gripping mechanism that ensures the innie is securely held in place as the surgeon prepares to insert it.
- **Inserting the Innie into the Screw Head**: The innie holder is used to carefully insert the selected innie (set screw) into the screw head, locking the rod into place within the screw's mating slot. The holder helps to guide the innie smoothly into the correct position and ensures that the screw is engaged securely.

- **Single-step innie**: For the single-step system, once the innie is inserted, the screw automatically locks into place with a simple turn of the instrument.
- **Dual-step innie**: In dual-step systems, the first step involves placing the innie into the screw head to hold the rod. The second step is then performed, often involving a final turn to engage the second locking mechanism, providing additional security.
- **Securing the Rod with the Innie**: Once the innie is fully inserted and secured, it locks the rod firmly into the screw head, stabilizing the spine. The dual-step system typically provides additional stability, particularly in cases requiring extra security or for patients with high activity levels.

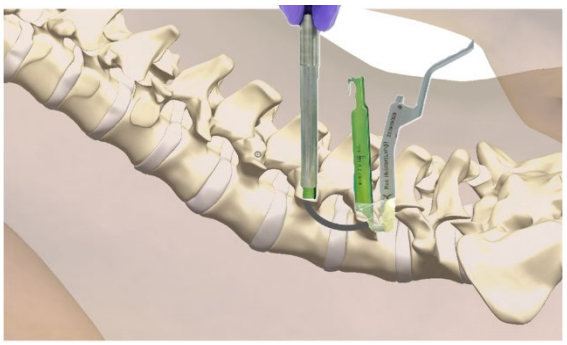
Step 14

- **Inserting the Innie Through the Screw Tulip:** The innie (set screw) is selected based on the screw system and is inserted into the screw tulip, which is the part of
- the screw that holds the rod in place. The screw tulip has a specific slot designed to fit the rod, and the innie is used to lock the rod inside the tulip.
- The innie is carefully guided through the screw tulip, ensuring it aligns correctly with the rod and screw head. It is typically inserted manually or with an instrument that helps guide the innie into place.
- **Placing the Counter-Torque Over the Screw:** To prevent the screw from rotating or loosening during the tightening process, a counter-torque device is applied. This instrument is placed over the screw head to apply
- stabilization and counterforce as the innie is tightened. The counter-torque device helps to ensure that the screw head does not rotate or shift, allowing the innie to lock the rod securely into place.
- The counter-torque is especially important in dual-step innie systems, where additional torque and security are required.
- **Tightening the Innie with the Final Tightening Shaft:** Once the innie is properly positioned in the screw tulip, the surgeon uses a final tightening shaft (or tool) to tighten the innie. This tool is typically a ratcheted or controlled torque device that ensures the innie is tightened to the appropriate level of force. The tightening should be done gradually and with controlled pressure, ensuring that the innie engages securely without over-tightening or under-tightening. The correct amount of torque is essential to ensure the screw and rod are securely locked in place, offering optimal spinal stability.

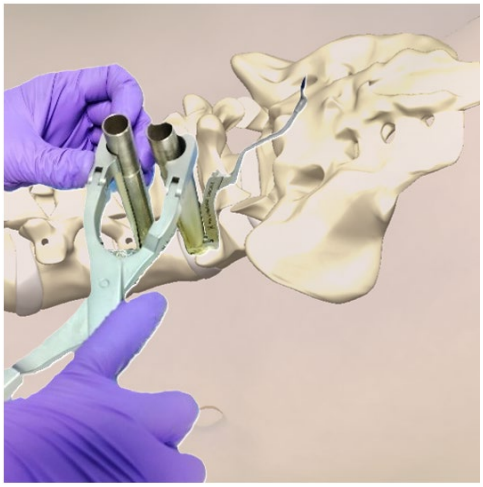


Step 15

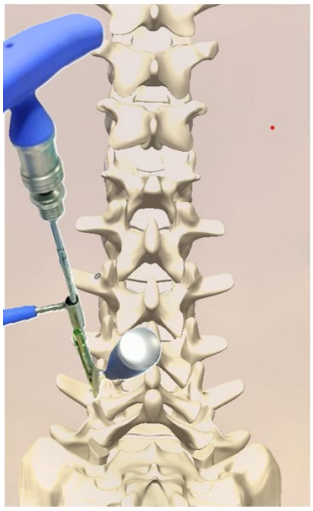
- **Inserting the Sleeve Over Both Screws:** After the first screw has been tightened, a **sleeve** is placed over both screws (the first and the second) to protect the surrounding tissues and to maintain alignment during the second tightening. The sleeve helps guide the alignment of the second screw relative to the first, ensuring that
- both screws are aligned in the correct position for optimal spinal stability.
- The sleeve typically has a guiding mechanism that ensures the second screw will align properly with the first screw in terms of both position and angle.

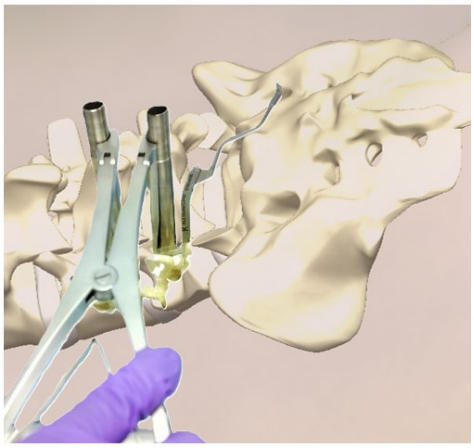


- **Adjusting the Second Screw According to the Required Alignment:** With the sleeve in place, the surgeon adjusts the second screw to match the required alignment. The first screw is already securely tightened, serving as a reference for the second screw's position.
- The surgeon will carefully rotate, adjust, or slightly shift the second screw until it is aligned with the first screw in terms of trajectory, depth, and angle. The alignment of the screws is crucial for the overall stability of the spine, ensuring the rod will fit securely and properly hold the vertebrae in place.
- This alignment is often confirmed using fluoroscopy or other imaging methods to ensure that the screws are positioned optimally before final tightening.

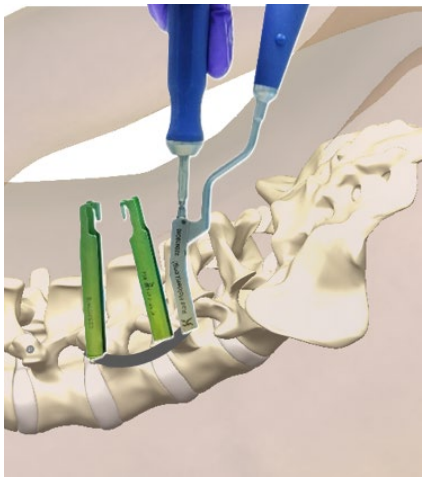


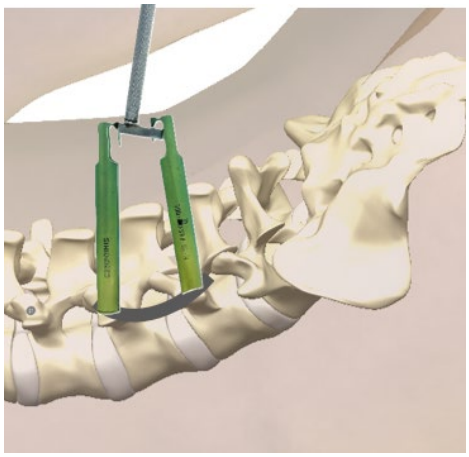
- **Performing the Final Tightening on the Second Screw:** Once the second screw is properly aligned with the first, the **final tightening** is performed using the final tightening shaft (similar to the process for the first screw). The surgeon uses a controlled torque tool to tighten the innie (set screw) on the second screw.
- The tightening should be done with precision, ensuring that the second screw is locked in place securely without over-tightening or under-tightening. The surgeon needs to apply the correct amount of torque to avoid damaging the screw or the bone while ensuring that the rod is held firmly in place.
- **Final Check and Confirmation:** After both screws are tightened, the surgeon will typically perform a final check, often using fluoroscopy, to confirm that both screws and the rod are properly aligned and securely fixed. The alignment and tightening of both screws should be evaluated to ensure the rod is in the correct position and that the spine is stable.





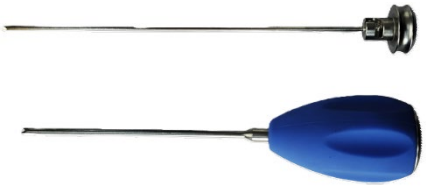
- **Removing the Rod Holder:** After both screws are tightened and the rod is securely locked into place, the rod holder is no longer needed. To remove it, the rod holder is twisted toward the direction of the rod.
- This twisting motion loosens the grip of the rod holder on the rod, allowing it to be removed without disturbing the position of the rod and screws.
- Once loosened, the instrument is carefully taken out of the surgical field.
- It's important to remove the rod holder carefully to avoid dislodging the rod or screws.
- **Placing the Tap Breaker Outside the Screw Tulip:** The tap breaker is a specialized instrument used to break the screw tulip, which is the part of the screw that holds the rod in place. The tulip must be broken to complete the locking mechanism for the rod.
- The tap breaker is placed outside of the screw tulip, positioning it around the screw head. The purpose of this step is to initiate the breaking of the tulip to fully secure the rod and screw in place.
- **Moving the Instrument Down to Break the Tulip:** Once the tap breaker is in place, the instrument is moved downward (toward the screw) in a controlled motion. The instrument applies force to the screw tulip, effectively breaking it and locking the rod into place.
- This breaking process ensures that the rod stays securely within the screw tulip and cannot move, creating a solid connection between the rod and screws for spinal stabilization.
- **Confirming the Break and Secure Fixation:** After the tulip has been broken, the stability of the fixation is checked to ensure that the rod is securely locked in place.
- Using fluoroscopy (or other imaging methods) can be used to confirm that the screw tulip has been properly broken and the rod is fully secured.





Instruments

Awl with Trokar



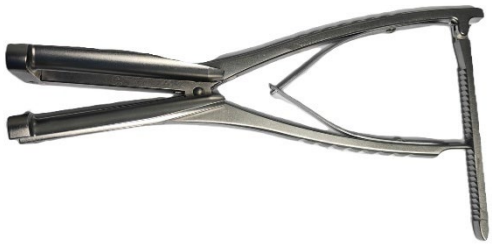
Dilator

Tap

Dual Innie Holder

Innier Sleeve

Distractor



Driver For Rod Inserter

Screw Removal Screw Driver

Dual Innie Final Tightner

Tap Breaker

Self-Holding Innie Driver for Removal

Ratchet T Handle

Quick Coupling T Handle

Torque Limiting Handle

Tissue Protector

Quick Coupling Handle

Guide Wire

Rod Measuring Device

Awl

Compressor

Poly Screw Driver

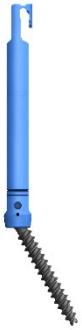
Head Aligner

Rod Inserter

Implants

Kentrospine Viktr MIS Poly Cannulated Screw - Ø4.5 X 25mm	ROMISPS4525
Kentrospine Viktr MIS Poly Cannulated Screw - Ø4.5 X 30mm	ROMISPS4530
Kentrospine Viktr MIS Poly Cannulated Screw - Ø4.5 X 35mm	ROMISPS4535
Kentrospine Viktr MIS Poly Cannulated Screw - Ø4.5 X 40mm	ROMISPS4540

Kentrospine Viktr MIS Poly Cannulated Screw - Ø5.5 X 30mm	ROMISPS5530
Kentrospine Viktr MIS Poly Cannulated Screw - Ø5.5 X 35mm	ROMISPS5535
Kentrospine Viktr MIS Poly Cannulated Screw - Ø5.5 X 40mm	ROMISPS5540
Kentrospine Viktr MIS Poly Cannulated Screw - Ø5.5 X 45mm	ROMISPS5545
Kentrospine Viktr MIS Poly Cannulated Screw - Ø5.5 X 50mm	ROMISPS5550
Kentrospine Viktr MIS Poly Cannulated Screw - Ø5.5 X 55mm	ROMISPS5555



Kentrospine Viktr MIS Poly Cannulated Screw - Ø6.5 X 30mm	ROMISPS6530
Kentrospine Viktr MIS Poly Cannulated Screw - Ø6.5 X 35mm	ROMISPS6535
Kentrospine Viktr MIS Poly Cannulated Screw - Ø6.5 X 40mm	ROMISPS6540
Kentrospine Viktr MIS Poly Cannulated Screw - Ø6.5 X 45mm	ROMISPS6545
Kentrospine Viktr MIS Poly Cannulated Screw - Ø6.5 X 50mm	ROMISPS6550
Kentrospine Viktr MIS Poly Cannulated Screw - Ø6.5 X 55mm	ROMISPS6555

Kentrospine Viktr MIS Poly Cannulated Screw - Ø7.2 X 35mm	ROMISPS7235
Kentrospine Viktr MIS Poly Cannulated Screw - Ø7.2 X 40mm	ROMISPS7240
Kentrospine Viktr MIS Poly Cannulated Screw - Ø7.2 X 45mm	ROMISPS7245
Kentrospine Viktr MIS Poly Cannulated Screw - Ø7.2 X 50mm	ROMISPS7250
Kentrospine Viktr MIS Poly Cannulated Screw - Ø7.2 X 55mm	ROMISPS7255

Kentrospine Viktr MIS Poly Cannulated Dualcore Fenestrated Screw - Ø4.5 X 25mm	ROMISPS4525
Kentrospine Viktr MIS Poly Cannulated Dualcore Fenestrated Screw - Ø4.5 X 30mm	ROMISPS4530
Kentrospine Viktr MIS Poly Cannulated Dualcore Fenestrated Screw - Ø4.5 X 35mm	ROMISPS4535
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Kentrospine Viktr MIS Poly Cannulated Dualcore Fenestrated Screw - Ø7.2 X 50mm	ROMISPS7250
Kentrospine Viktr MIS Poly Cannulated Dualcore Fenestrated Screw - Ø7.2 X 55mm	ROMISPS7255

Indications and Contraindications

Indications for use:
The Kentrospine Viktr MIS Pedicle Screw System is intended for posterior, non-cervical fixation as an adjunct to fusion for skeletally mature patients for rigid fixation and stability with 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; Pseudarthritis; and/or failed previous fusion.

Contraindications:
Contraindications include, but are not limited to:

1. Active infectious process or significant risk of infection (Immunocompromise)
2. Sign of local inflammation.
3. Fever or leukocytosis.
4. Morbid obesity.
5. Pregnancy.
6. Mental illness.
7. Grossly distorted anatomy caused by congenital abnormalities.
8. Any other medical or surgical condition which would preclude the potential benefit of spinal implant surgery, such as the presence of congenital abnormalities, elevation of sedimentation rate unexplained by other diseases, elevation of white blood count (WBC), or a marked left shift in the WBC differential count.
9. Rapid joint disease, bone absorption, osteopenia, osteomalacia and/or osteoporosis.
10. Suspected or documented metal allergy or intolerance.
11. Any case not needing a bone graft and fusion.
12. Any case where the implant components selected for use would be too large or too small to achieve a successful result.
13. Any patient having inadequate tissue coverage over the operative site or inadequate bone stock or quality.
14. Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance.
15. Any patient unwilling to follow postoperative instructions.
16. Any case not described in the indications.

Potential adverse events:
All of the possible adverse events associated with spinal fusion surgery without instrumentation
are possible. With instrumentation, a listing of potential adverse events includes, but is not limited to:

1. Early or late loosening of any or all of the components.
2. Disassembly, bending, and/or breakage of any or all of the components.
3. Foreign body (allergic) reaction to implants, debris, corrosion products (from crevice, fretting, and/or general corrosion), including metallosis, staining, tumor formation, and/or autoimmune disease.
4. Pressure on the skin from component parts in patients with inadequate tissue coverage over the implant possibly causing skin penetration, irritation, fibrosis, neurosis, and/or pain. Bursitis. Tissue or nerve damage caused by improper positioning and placement of implants or instruments.
5. Post-operative change in spinal curvature, loss of correction, height, and/or reduction.
6. Infection.
7. Dural tears, pseudomeningocele, fistula, persistent CSF leakage, meningitis.
8. Loss of neurological function (e.g., sensory and/or motor), including paralysis (complete or incomplete), dysesthesias, hyperesthesia, anesthesia, paresthesia, appearance of radiculopathy, and/or the

development or continuation of pain, numbness, neuroma, spasms, sensory loss, tingling sensation, and/or visual deficits.

9. Cauda equina syndrome, neuropathy, neurological deficits (transient or permanent), paraplegia, paraparesis, reflex deficits, irritation, arachnoiditis, and/or muscle loss.
10. Urinary retention or loss of bladder control or other types of urological system compromise.
11. Scar formation possibly causing neurological compromise or compression around nerves and/or pain.
12. Fracture, microfracture, resorption, damage, or penetration of any spinal bone (including the sacrum, Pedicles, and/or vertebral body) and/or bone graft or bone graft harvest site at, above, and/or below the level of surgery. Retropulsed graft.
13. Herniated nucleus pulposus, disc disruption or degeneration at, above, or below the level of surgery.
14. Non-union (or pseudarthrosis). Delayed union. Mal-union.
15. Cessation of any potential growth of the operated portion of the spine.
16. Loss of or increase in spinal mobility or function.
17. Inability to perform the activities of daily living.
18. Bone loss or decrease in bone density, possibly caused by stresses shielding.
19. Graft donor site complications including pain, fracture, or wound healing problems.
20. Ileus, gastritis, bowel obstruction or loss of bowel control or other types of gastrointestinal system compromise.
21. Hemorrhage, hematoma, occlusion, seroma, edema, hypertension, embolism, stroke, excessive bleeding, phlebitis, wound necrosis, wound dehiscence, damage to blood vessels, or other types of cardiovascular system compromise.
22. Reproductive system compromise, including sterility, loss of consortium, and sexual dysfunction.
23. Development of respiratory problems, e.g. pulmonary embolism, atelectasis, bronchitis, pneumonia, etc.
24. Change in mental status.
25. Death.

Note: Additional surgery may be necessary to correct some of these potential adverse events.

Warning and precautions:
WARNING:
The safety and effectiveness of Kentrospine Viktr MIS Pedicle Screw Systems have been established only for spinal conditions with significant mechanical instability or deformity requiring fusion with instrumentation. These conditions are significant mechanical instability or deformity of the thoracic, lumbar, and sacral spine secondary to severe spondylolisthesis (grades 3 and 4) of the L5-S1 vertebra, degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudoarthrosis). The safety and effectiveness of these devices for any other conditions are unknown. The implants are not prostheses. In the absence of fusion, the instrumentation and/or one or more of its components can be expected to pull out, bend or fracture as a result of exposure to every day mechanical stresses.

Kentrospine MIS Pedicle Screw Systems is for Single use only, do not Re-use. A device that has been implanted should never be reprocesses or reused under any circumstances. Reprocessing or reuse may compromise the structural integrity of these implants and create a risk of contamination
of the implants which could result in patient injury, illness, or death.

PRECAUTION:
"The implantation of Kentrospine Viktr MIS Pedicle Screw 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".
"Based on the fatigue testing results, the physician/surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc. which may impact on the performance of the system".

A successful result is not always achieved in every surgical case. This fact is especially true in spinal surgery where many extenuating circumstances may compromise the results. This device system is not intended to be the sole means of spinal support. Use of this product without a bone graft or in cases that develop into a non-union will not be successful. No spinal implant can withstand body loads without the support of bone. In this event, bending, loosening, disassembly and/or breakage of the device(s) will eventually occur. Preoperative and operating procedures, including knowledge of surgical techniques, good reduction, and proper selection and placement of the implants are important considerations in the successful utilization of the system by the surgeon. Further, the proper selection and compliance of the patient will greatly affect the results. Patients who smoke have been shown to have an increased incidence of non-unions.

These patients should be advised of this fact and warned of this consequence. Obese, malnourished, and/or alcohol abuse patients are also poor candidates for spine fusion. Patients with poor muscle and bone quality and/or nerve paralysis are also poor candidates for spine fusion.

PHYSICIAN NOTE: Although the physician is the learned intermediary between the company and the patient, the important medical information given in this document should be conveyed to the patient.

MRI Safety Information:
The Kentrospine Viktr MIS Pedicle Screw System is manufactured from Titanium alloy (Ti6Al4V ELI), hence it do not pose any safety risk.

"The Kentrospine Viktr MIS Pedicle Screw System has not been evaluated for safety in the MR environment. It has not been tested for heating or unwanted movement in the MR environment. The safety of Kentrospine Viktr MIS Pedicle Screw System in the MR environment is unknown.
Performing an MR exam on a person who has this medical device may result in injury or device malfunction".
On the basis of literature study, the minimum recommended time after the implantation that allows patients to safely undergo MRI examination or allowing the patient or an individual to enter the MRI environment is 6 (six) weeks.
All Rivarp's system manufactured in metallic material and does not emit any ionizing radioactive radiation.

Reprocessing Instructions:

Warnings and Precautions:

- Universal Precautions should be observed by all hospital personnel that work with contaminated or potentially contaminated medical devices.
- Caution should be exercised when handling devices with sharp points or cutting edges.
- Personal Protective Equipment (PPE) should be worn when handling or working with contaminated or potentially contaminated materials, devices and equipment. PPE includes gown, mask, goggles or face shield, gloves and shoe covers.
- Metal brushes or scouring pads must not be used during manual cleaning procedures. These materials will damage the surface and finish of instruments. Soft-bristled, nylon brushes and pipe cleaners should be used.
- Cleaning agents with low foaming surfactants should be used during manual cleaning procedures to ensure that instruments are visible in the cleaning solution. Manual scrubbing with brushes should always be performed with the instrument below the surface of the cleaning solution to prevent generation of aerosols and splashing which may spread contaminants. Cleaning agents must be completely rinsed from device surfaces to prevent accumulation of detergent residue.
- Do not stack instruments or place heavy instruments on top of delicate devices.
- Dry, soiled surgical instruments are more difficult to clean. Do not allow contaminated devices to dry prior to reprocessing. All subsequent cleaning and sterilization steps are facilitated by not allowing blood, body fluids, bone and tissue debris, saline, or disinfectants to dry on used instruments.
- The cleaning and sterilization instructions provided below have been validated by Rivarp Medical as being capable of preparing a medical device for reuse. The processor remains responsible for ensuring that the processing, as actually performed using equipment, materials and personnel at the processing facility, achieves the desired result. This requires verification and/or validation and routine process monitoring.

Reprocessing Overview:

The sequence of steps required to prepare non-sterile instruments for use are summarized in the chart below. More detailed instructions for each step are given on the following pages.

Instruments disassemble & reassemble instructions for Cleaning:

Instruments disassemble & reassemble instructions for cleaning:

- Multi-component instruments should be disassembled for cleaning. Disassembly, where necessary, is generally self-evident. More specific instructions are given below.
- Disassemble the instruments at point of use area.
- After thorough cleaning, reassemble the small components / parts of the instruments before sterilization and instruments which needs to assemble with other instruments for its desired functions, needs to be reassembled after sterilization by physicians and staff in operating centres prior to surgery.
- During disassembly and reassembly, visually inspect the device and components for wear and tear of components that cannot be assessed in the fully assembled configuration.
- **Note:** If damage or wear and tear (unacceptable deterioration such as corrosion, discoloration, and pitting, cracked seals) is noted that may compromise the function of the instrument, contact your Rivarp Medical Representative for a replacement.
- Mating devices should be checked for proper assembly. Instruments with moving parts (e.g. hinges, box-locks, connectors, sliding parts, etc.) should be operated to ensure smooth operation throughout the intended range of motion.


KentroSpine®
Viktr-MIS
Instruments