Kentrospine

Dgen Pedicle Screw System

Surgical Technique Manual:

Contents

Product Overview

Introduction

Pedicle screw surgery is a procedure commonly performed in spinal surgery to stabilize the spine. Here's an overview of the process:

1. Preoperative Evaluation: Before surgery, the patient undergoes a thorough evaluation, including a physical examination and diagnostic imaging such as X-rays, CT scans, or MRI scans. This helps the surgeon assess the spinal condition and plan the surgical approach.

2. Anesthesia: The surgery is performed under general anesthesia to ensure the patient remains unconscious and pain-free throughout the procedure.

3. Incision: A surgical incision is made over the affected area of the spine. The size and location of the incision depend on the specific procedure being performed and whether minimally invasive techniques are used.

4. Exposure: The surgeon carefully moves aside muscles and tissues to expose the vertebrae and the target area for pedicle screw placement.

5. Pedicle Screw Insertion: Using surgical tools and guidance techniques such as fluoroscopy or navigation systems, the surgeon drills small holes into the pedicles, which are small bony protrusions on the back of each vertebra. Pedicle screws are then inserted into these holes and anchored firmly into the vertebral body.

6. Rod Placement: Once all the pedicle screws are in place, a metal rod or rods are attached to the screws. The rod serves to stabilize the spine and maintain proper alignment.

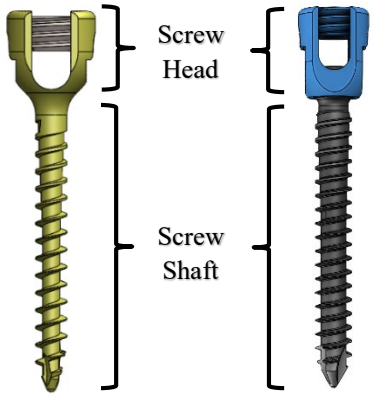
7. Compression and Fusion: In some cases, additional procedures may be performed to decompress nerves or to promote spinal fusion. Spinal fusion involves fusing together two or more vertebrae using bone grafts or synthetic materials. This promotes the growth of new bone and helps stabilize the spine further.

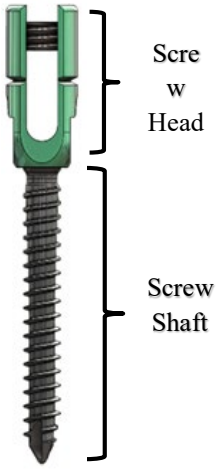
8. Closure: After all surgical steps are completed, the incision is closed with sutures or surgical staples. A sterile dressing is applied to the wound.

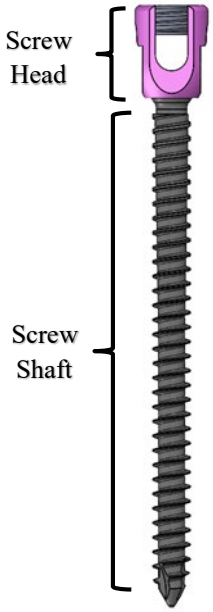
9. Postoperative Care: Following surgery, the patient is monitored closely in the recovery area. Pain management, physical therapy, and instructions for postoperative care are provided to promote healing and recovery.

Features

Kentrospine Dgen







- Screw Length: 25 to 55mm, for iliac screws 65 to 100mm
- Screw Diameter: 4.5 to 7.2mm
- Semi conical shaft with cortico cancellous threading.
- Flutes at proximal tip.
- Tulip design accommodates easy engagement of persuader at 2-point contact.
- Set Screws: Reverse buttress threading and hexagonal slot prevents splaying.
- Extended angle of 60 degree which is specifically useful to accommodate from T1 to S1.

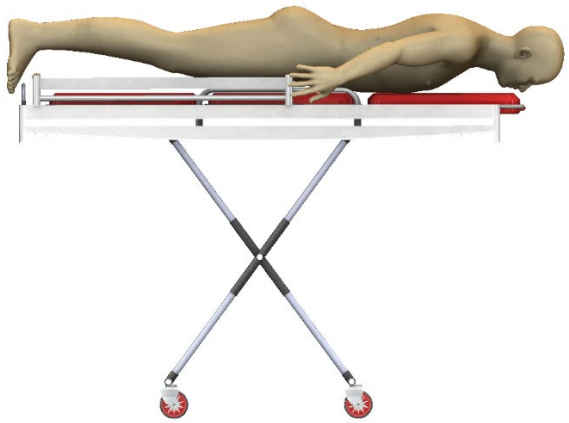
Surgical Technique

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 Dgen Screws and Rods as supplemental fixation without repositioning the patient.



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.

- **Screw Size Selection:**

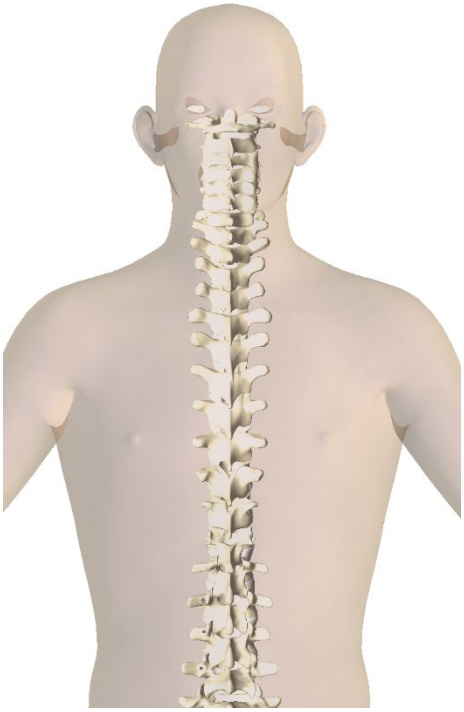
  Based on the preoperative imaging, select the appropriate screw diameter, length, and type (e.g., polyaxial or monoaxial) based on the patient's pedicle anatomy and the intended spinal construct.

  Take into account factors like bone quality (e.g., osteoporotic or hard bone), anatomical variations, and any existing deformities that might affect screw placement.

- **Rod Selection:**

  Select the correct rod length and curvature based on the rod template and the desired spinal alignment or correction (e.g., restoring lordosis).

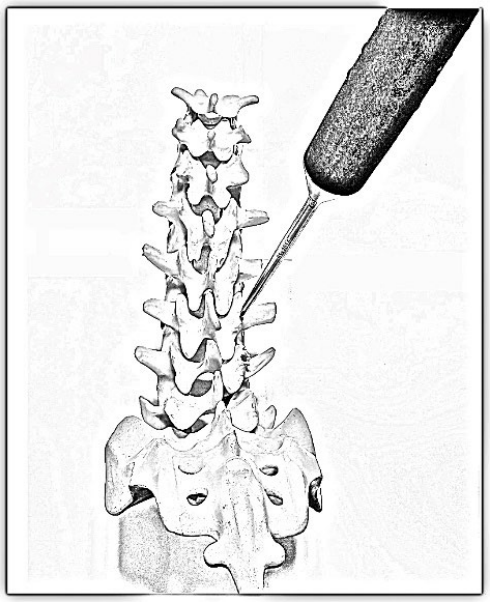
- General anaesthesia or regional anaesthesia (e.g., epidural or spinal aesthesia) is administered to ensure the patient's comfort and safety during the procedure.



Step 2

Prepare the Pedicle

- **Facet Joint Cleaning**:
  The facet joints in the spine are synovial joints that help with movement and stability. Cleaning the facet joints involves removing any fibrous tissue, debris, or any bone spurs that could interfere with the surgical procedure or the final spinal alignment.
- **Removing the Inferior Facet and Articular Cartilage of the Superior Facet**:
- The inferior facet (located on the bottom part of the vertebra) is removed, which helps in gaining better access to the pedicle and the surrounding bony structures.
- The articular cartilage of the superior facet (on the vertebra above) is removed to expose the underlying bone, which facilitates proper screw placement and avoids interference with the screw path.
- **Identifying the Intersection of the Transverse Process and Pars Interarticularis:**
- The transverse process is a bony protrusion on either side of the vertebra that provides attachment points for muscles and ligaments. The pars interarticularis is the bony segment connecting the superior and inferior facets of the vertebra, and it's where the pedicle screw will typically be inserted.
- The intersection of these two structures marks an important anatomical landmark to begin the placement of the pedicle screw. Accurately identifying this intersection ensures proper screw alignment, reducing the risk of errors such as nerve injury or screw misplacement.

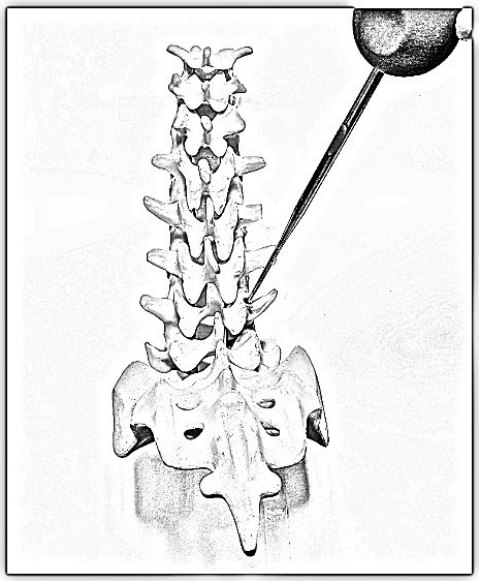


- **Breaching the Cortical Exterior of the Vertebra (Using a High-Speed Burr or Bone Awl)**
- **Starting Point for Pedicle Screw Insertion**:
  The intersection of the transverse process and the pars interarticularis serves as the starting point for drilling into the pedicle. Correct identification is crucial to ensure that the screw path is aligned properly and avoids damaging the spinal cord or nerve roots.
- **High-Speed Burr or Bone Awl**:
- High-speed burr is used to precisely remove bone in a controlled manner. It's typically used to create an initial hole in the cortical bone (the outer dense layer of the vertebra).
- Bone awl is used to puncture the cortex of the bone and create a small dimple or entry point. The awl helps in breaching the cortical bone and providing a guide for subsequent drilling to prepare the pedicle for screw insertion.
- **Breaching the Cortical Bone**:
  This is the critical first step in the actual insertion of the pedicle screw. The goal is to create an entry point without damaging the surrounding structures. The cortical bone is dense, so the use of a burr or bone awl is necessary to ensure the controlled way of breaching the bone to advance the drill for screw placement.

Step 3

Create Interpedicular Path

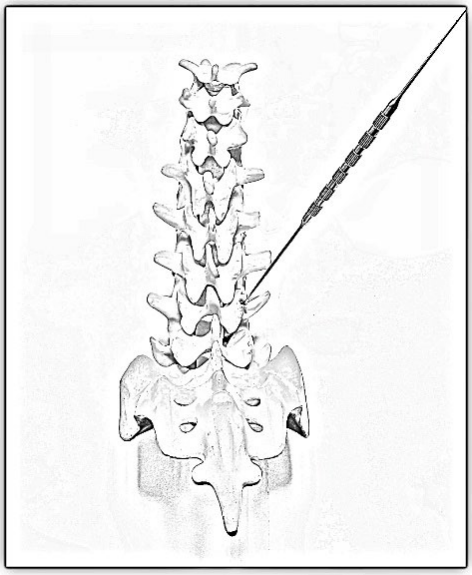
- Pedicle Probe is used to Create a Path through Interpedicular Cancellous Bone.
- **Pedicle Probe**:
  Pedicle probe is designed specifically for exploring and probing the pedicle, which is the bony structure that connects the vertebral body to the transverse process. It helps to create a precise channel through which a pedicle screw can later be inserted.
- **Interpedicular Cancellous Bone**:
  The cancellous (spongy) bone in the pedicle is softer than the cortical (dense) bone, so the probe will pass through this region to create a smooth path for the screw.
- **Initial Insertion**:
  The pedicle probe is first inserted into the entry point created earlier (after breaching the cortical bone with a burr or awl). It is then carefully advanced through the cancellous bone of the pedicle toward the vertebral body.
- **Lateral Orientation**:
  If a curved pedicle probe is selected, it should initially be oriented laterally (away from the spinal canal) when it is inserted into the pedicle. This helps avoid potential damage to the spinal cord or nerve roots, which are located near the midline of the vertebral body and could be at risk if the probe is directed medially too soon.
- **Advancing the Probe**:
  The curved probe is advanced through the pedicle, aiming to create a path that avoids critical structures. Since the curve is directed laterally at first, this ensures that the probe moves away from the spinal canal during the initial phase of insertion.
- **Clearing the Pedicle**:
  Once the tip of the curved probe has passed through the pedicle and entered the vertebral body, it is important to reorient the probe so that the curve points medially, toward the centre of the vertebral body.



- **Reorientation of the Curve**:
  The probe is removed, it reorients so the curve points inward (medially), and then carefully reinserts it back into the same entry point. This reorientation is done to ensure that the probe follows the optimal trajectory for screw placement, avoiding misplacement or interference with the spinal cord, nerve roots, or surrounding vessels.
- **Inserting the Probe to Desired Depth**:
  After the probe has been reoriented, the probe is advanced to the desired depth. The depth is critical because it determines how far the screw will penetrate into the vertebral body. Too shallow a path could lead to inadequate screw purchase, while too deep a path could risk injury to surrounding structures, such as the spinal cord or blood vessels.
- **Confirming the Path**:
  As the probe advances, it is important to regularly check its position using fluoroscopy or navigation systems to ensure that the path is being created in the correct direction and depth.
- **Soft Bone Tissue**:
  The cancellous bone in the pedicle is softer than cortical bone, so advancing the probe requires controlled, steady force to avoid overpenetration or deviation from the desired trajectory.

Step 4

Confirm Pedicle Integrity



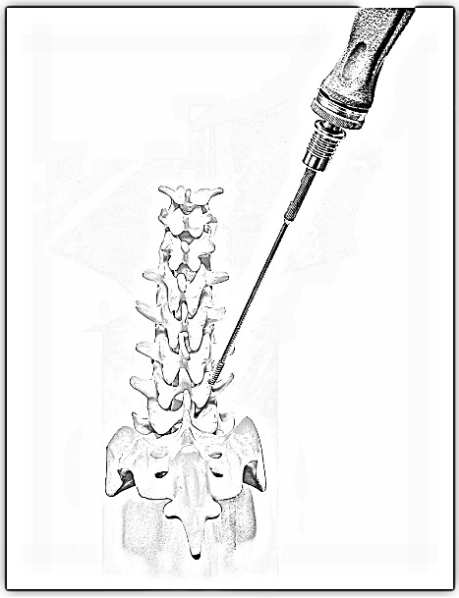
- **Remove the Pedicle Probe and Use the Flexible Ball-Tipped Pedicle Sounder:**
  The pedicle probe is initially used to create the entry point into the pedicle (the bony segment connecting the vertebrae to the spinal column). Once the hole is created, the flexible ball-tipped Pedicle Sounder is inserted to assess the integrity of the pedicle's anatomy.
  The ball-tipped sounder is flexible and smooth, which allows it to move gently within the hole without causing damage to the surrounding bony structures.
- **Determine the Integrity of the Medial, Lateral, Anterior, Posterior Walls, and the Base of the Hole:**
  The ball-tipped sounder is used to explore the pedicle hole carefully, checking the medial (inside), lateral (outside), anterior (front), posterior (back) walls, as well as the base (bottom) of the hole.
  These areas are critical because a breached pedicle (where the wall of the hole is compromised) can increase the risk of injury to nearby structures, such as nerves or blood vessels, and can lead to improper screw placement, which might affect spinal stability.
- **If Observation Reveals a Breached Pedicle, Use the Probe Again with a Different Trajectory:**
  If any wall or area of the pedicle is breached during the initial probe, this indicates that the pedicle has been compromised. Then adjust the trajectory of the probe (and later, the screw) to minimize further cortical breach.
  This step is essential because breaching the pedicle wall (especially posteriorly) could result in the screw misdirecting into nearby nerves or vessels, potentially causing significant complications. Altering the trajectory helps ensure that the screw path avoids these risks.

- **Confirm the Integrity of the Planned Pedicle Screw Path:**
  Once the ball-tipped sounder has been used to confirm the integrity of the pedicle and walls, it helps to verify the path that the pedicle screw will follow.
  Pedicle screws are a primary method for stabilizing the spine in surgeries such as spinal fusion or fracture fixation. Ensuring the planned screw path is clear and intact is crucial for proper screw placement.
- **Clamp Forceps to the Exposed Shaft of the Sounder to Determine the Length of the Hole:**
  After confirming the integrity of the pedicle and screw path, clamp forceps to the exposed shaft of the sounder. This allows them to measure the exact depth (length) of the pedicle hole.
  Accurate measurement is key to selecting the correct pedicle screw size and length. If the screw is too short, it may not anchor properly into the vertebrae. If it's too long, it could breach the opposite side of the pedicle, potentially causing damage to surrounding structures.
  The length measurement ensures the screw is appropriately sized to secure the vertebrae without penetrating too far.

Step 5

Tap the Pedicle

- **Preoperative Planning & Measurement:**
  Before surgery, imaging studies such as X-rays or CT scans are used to assess the anatomy of the patient's pedicles and determine the appropriate screw size. This helps in selecting the right diameter and length of the screw.
  During the surgical procedure, the screw choice is based on intraoperative findings, such as bone quality, pedicle diameter, and any abnormalities in the pedicle shape.
- **Tapping the Pedicle:**
  The tap is used to create threads in the pedicle bone for the screw to anchor into. Under-tapping by 0.75 mm ensures that the tap does not enlarge the hole excessively and allows for a tighter fit for the screw. The tap is rotated clockwise to create the threads, and the depth is monitored carefully. This helps to ensure that the screw will sit properly within the pedicle.
- **Maintaining Track Integrity:**
  After tapping, it's crucial to remove the tap in a counter-clockwise direction to preserve the integrity of the threads created in the pedicle. Any damage to the thread during this process could result in screw instability.
- **Confirming the Tapped Pedicle:**
  The pedicle sounder is used to verify the integrity and accuracy of the tapped hole. This tool helps to ensure that the hole is properly prepared, and the thread structure is intact before proceeding with screw insertion.

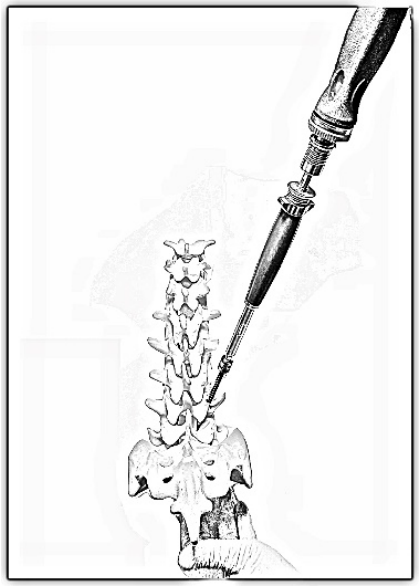


- **Selecting the Proper Screw Length:**
  Once the pedicle hole has been tapped, the length of the screw is selected based on the size of the prepared hole. This ensures the screw will engage the bone adequately without penetrating through the opposite side of the pedicle.
- **Importance of Tapping in Hard Bone or Larger Screws:**
  When using larger diameter screws or when operating on hard bone, tapping becomes even more crucial. The tapping process creates a secure, stable channel for the screw to engage with, reducing the risk of screw loosening or misplacement. Hard bone, in particular, requires careful tapping to avoid excessive force that could cause fractures or damage to the pedicle.

Step 6

Place the Pedicle Screw

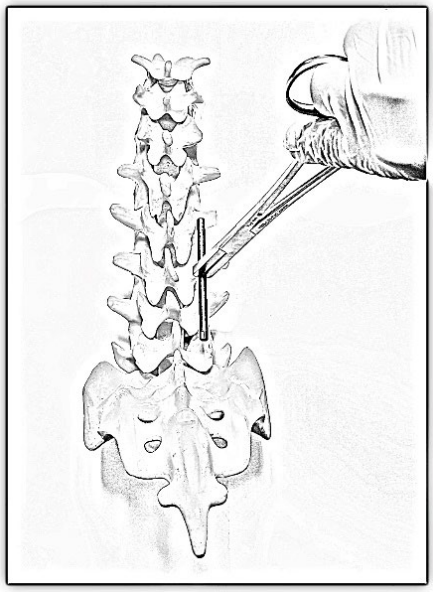
- **Aligning the Polyaxial Screw with the Driver:**
  Begin by aligning the male hex of the polyaxial screw with the female hex of the polyaxial screwdriver. This alignment ensures that the screw can be securely attached to the driver for controlled insertion. The male hex of the screw fits into the female hex of the driver, creating a stable connection that allows for precise control during screw insertion.
- **Threading the Retention Shaft:**
  Next, thread the retention shaft of the polyaxial screwdriver into the screw head. This action secures the screw onto the driver and eliminates any play or "toggle" of the screw. This ensures that the screw will stay firmly in place as it is advanced into the pedicle.
- **Locking the Retention Shaft:**
  To further secure the connection, tighten the collet by turning it clockwise. The collet locks the retention shaft in place, ensuring the screw remains stable and won't accidentally detach during the procedure. The screw should be fully attached and ready for insertion once the retention shaft is locked.
- **Advancing the Screw into the Pedicle:**
  With the screw securely attached, advance the screw down the prepared pedicle, making sure to carefully monitor the depth and angle. The goal is to seat the screw at the correct dorsal height within the pedicle, ensuring proper fixation. The polyaxial screw's ability to tilt allows for adjustments to the screw angle, making it easier to optimize screw positioning relative to the surrounding bone and anatomy.
- **Releasing the Driver from the Screw:**
  Once the screw is fully seated, it’s time to release the driver. First, turn the collet counterclockwise to unlock the retention shaft. This action disengages the retention mechanism, allowing the driver to be removed. Then, turn the retention shaft counterclockwise to fully release the driver from the screw. The driver can now be removed from the screw, leaving the polyaxial screw securely placed in the pedicle.



Step 7

Prepare & Insert the Rod

- **Verifying Screw Positions Radiographically:**
  After placing all the screws, it's crucial to perform a radiographic verification (usually using X-rays or fluoroscopy) to ensure that the screws are correctly positioned in the pedicles. This step confirms that each screw is properly aligned and seated, which is essential for the stability and safety of the spinal construct.
- **Using the Rod Template to Determine Lordosis and Rod Length:**
  The next step involves using the rod template, a tool designed to assist in determining the correct amount of lordosis (the natural curve of the lumbar spine) and the appropriate rod length for the patient's spine.
  The template is aligned with the screws, and how much curve (lordosis) is needed is to be checked to optimize the spinal correction. This ensures that the rod will match the patient's natural curve or the desired correction angle, helping to restore proper alignment to the spine.
- **Cutting the Rod to Length:**
  Once the appropriate rod length has been determined using the template, the rod is cut to the necessary size using a rod cutter. The rod must be the right length to span the screw heads at the correct distance, ensuring secure fixation across the vertebrae.
  This step is critical because the rod length must match the distance between the screw heads to ensure a stable and effective construct.
- **Bending the Rod to Achieve Lordosis:**
  After cutting the rod, it must be shaped to match the desired lordosis. This is done using the French Benders, a tool used to apply controlled bends to the rod. The rod is bend to the correct curvature, matching the lordosis determined with the rod template.

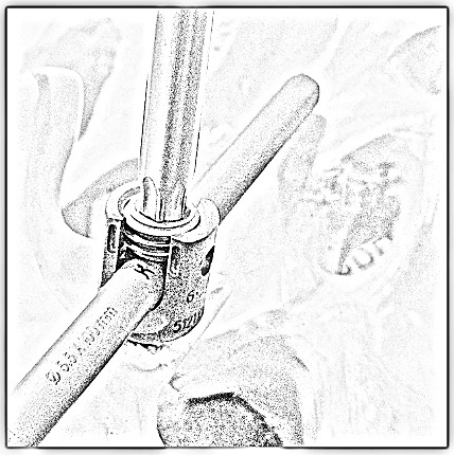


- Achieving the correct lordosis is important for ensuring the rod fits appropriately and restores the spine's natural curvature. The bending process should be done gradually to avoid compromising the integrity of the rod.
- **Rod Options Available in the Kentrospine Dgen Tray:** It's worth noting that the Kentrospine Dgen Pedicle Screw System tray includes straight rods, pre-cut rods, and pre-bent rods. These options can be used depending on the surgeon's preference or the patient's anatomy. Pre-cut and pre-bent rods save time in the procedure and may be preferable if the necessary curvature and length are already determined in advance.

Step 8

Place Closure Tops

- **Contouring the Rod:**
  After cutting and bending the rod to the desired length and lordosis, the rod is ready to be placed. The contouring process ensures that the rod matches the natural curve of the patient's spine and is the correct length for the screw heads.
- **Using the Screw Head Adjuster:**
  The Screw Head Adjuster is used to ensure that all the screw heads are properly aligned. It's important that the screw heads are positioned in such a way that they are parallel to one another and oriented in the correct direction to receive the rod.
  The adjuster helps fine-tune the screw angles and ensure they are all facing the correct way, creating a stable and symmetrical foundation for the rod to be inserted. Proper alignment is key to achieving optimal spinal stability and avoiding complications such as screw loosening or misalignment.
- **Placing the Rod into the Aligned Screw Heads:**
  Once the screw heads are aligned, the rod is carefully placed into the screw heads using the Rod Holder Forceps. The forceps provide a controlled grip to handle the rod and position it accurately into the screw heads without disturbing the alignment or causing damage to the rod or screws.
  The rod is gently seated into the screw heads, ensuring that it rests securely and comfortably in position.

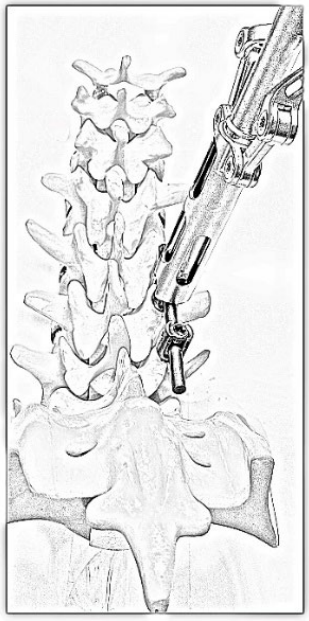


- **Introducing Closure Tops into the Screw Heads:**
  After the rod is properly placed, the Closure Top Starter is used to introduce the closure tops into the screw heads. These closure tops are the components that will ultimately secure the rod in place within the screws.
  The Closure Top Starter is turned clockwise to start the insertion of the closure tops. The goal here is to ensure that each closure top engages properly with its corresponding screw head, providing initial provisional fixation of the rod.
- **Provisionally Tightening the Closure Tops:**
  Once the closure tops are inserted into the screw heads, they should be provisionally tightened. This means the closure tops are tightened enough to hold the rod securely in place but not so tight as to finalize the fixation.
  Provisional tightening allows the surgeon to ensure everything is aligned correctly before proceeding with final tightening. It also gives the surgeon the opportunity to make any last-minute adjustments to rod placement, alignment, or screw head orientation if necessary.

Step 9

Rod Reduction

- **Using the Rod Persuade:**
  The Rod Persuade is a tool designed to help gently guide or "persuade" the rod into place within the screw heads. Sometimes, due to slight variations in screw head positioning or the rigidity of the rod, manual force may be needed to ensure the rod fits properly into the pedicle screws.
  To use the Rod, Persuade, the surgeon applies force by pressing the handle of the tool, which then pushes the rod into the screw heads. This ensures that the rod is fully seated within the screws, particularly if the rod is slightly off from the screw head or if there's resistance due to rod rigidity.
  The Rod Persuade helps avoid excessive force that could damage the screws or the rod while still achieving proper rod alignment and seating.
- **Introducing the Closure Tops with the Closure Top Starter:**
  Once the rod has been properly seated into the screw heads, closure tops need to be introduced into the screw heads to lock the rod in place and complete the spinal fixation. The Closure Top Starter is used to insert the closure tops into the screw heads. The closure tops are placed over the screw heads to secure the rod and prevent any movement or slippage. By turning the Closure Top Starter clockwise, the closure tops are introduced into each screw head. This step helps ensure that the rod is held in place securely, preventing it from shifting during the final tightening process.



- **Provisionally Tightening**
  At this stage, the closure tops are typically provisionally tightened. This ensures that the rod stays in place while giving the surgeon an opportunity to check the final alignment of the rod, screws, and closure tops before performing the final tightening. The closure tops should be tightened enough to hold the rod in position, but not too tight, as the final tightening will be done later to secure everything in place.

- **Using the sequential tower reducer:**
  Secure the Sequential Tower Reducer to the spinal rod and pedicle screw heads. This tool attaches to the screws via a tower-like structure, which holds the rod in place at each vertebral level.
  The sequential tower is usually adjusted for each vertebra to begin the gradual reduction of the rod into the screws.
- **Gradual Reduction of the Rod**
  Begin at the proximal end (the top of the spine) and start sequentially reducing the rod into the first set of pedicle screws, progressively working towards the distal end (lower spine).
  The Sequential Tower Reducer applies controlled force to the rod, bringing it closer to the screw heads in a step-by-step manner.
  Ensure that each screw is progressively tightened as the rod is reduced, which helps prevent any misalignment. This is done carefully to avoid overstressing the pedicle screws and to ensure that the screws are not dislodged or compromised.
- **Tighten Screws**
  Once the rod is sequentially reduced to each pedicle screw, tighten the screws to secure the rod in place. This step should be done after each individual reduction to ensure the alignment is maintained.
  If necessary, check the alignment with fluoroscopy to confirm the rod is properly reduced into the screw heads.

- **Using rocker:**
  If the rod does not align properly with the pedicle screw heads or if there is resistance in the reduction due to severe spinal deformity (e.g., scoliosis or kyphosis), the Rocker Tool is used to assist.
  The Rocker is attached to the rod near the screw heads that are difficult to reduce. The tool uses a levering action to push and "rock" the rod into position.
- **Apply Rocking Motion**
  With the Rocker Tool, apply a rocking or leveraging motion, beginning at the area of greatest resistance (this is often at a more distal or curved part of the spine).
  The tool applies pressure to the rod at a specific point, creating a downward force that helps it "rock" into the pedicle screw heads.
  This technique is particularly useful for overcoming any resistance due to curvature or any misalignment between the rod and screws.
- **Fine-tune Alignment**
  Use the Rocker Tool as necessary to realign the rod. This might involve repeated rocking at different vertebral levels until the rod is positioned properly over the screw heads.
- **Tighten Screws Again**
  Once the rod is aligned using the Rocker, begin tightening the pedicle screws again in the reduced positions. Double-check that each screw is firmly in place and that the rod is securely seated in all the screw heads.
  This step ensures the rod will maintain its position once fully tightened.

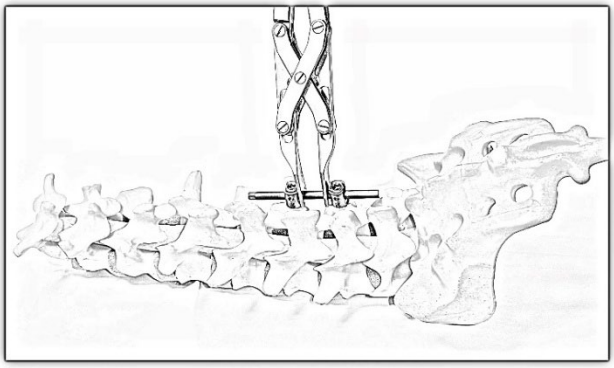
Step 10

Compression and distraction

- **Using the Compressor:**

  The Compressor is placed against the outer body of the two implants. The handles of the Compressor are then squeezed to apply compressive force between the implants. This action reduces the distance between the two implants, which is particularly useful in achieving spinal alignment, correcting deformities, or ensuring adequate spacing between the implants.

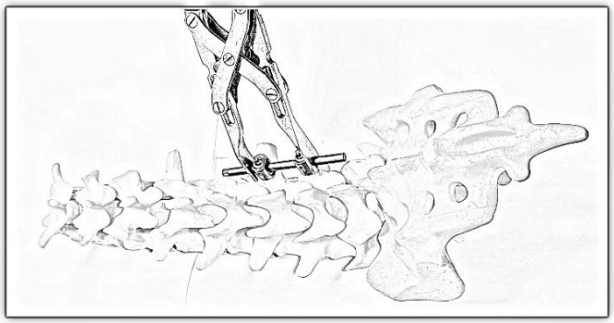
  Compression is commonly performed to stabilize the vertebrae or to help with spinal reduction by bringing the vertebrae closer together.



- **Serial Compression:**

  Compression can also be performed serially by first provisionally locking one implant using the Final Driver. Once one implant is locked, the implant is compressed off the provisionally locked implant, which helps achieve controlled compression without affecting the already locked implant.

  This step allows for a more controlled and gradual adjustment of the implants, especially when fine-tuning the positioning.



- **Provisionally Locking the Compressed Implants:**

  After the desired compression is achieved, the surgeon should provisionally lock the implants by using the Final Driver. This ensures that the implants remain in their compressed position while the surgeon prepares to move on to the next steps.

  Once the implants are provisionally locked, the Compressor can be safely released, maintaining the compression until final fixation.

- **Using the Distractor:**

  The Distractor is used to apply distracting force between two implants by placing it against the interior body of the implants (the part of the implant facing inward toward the center of the spine). By squeezing the handles of the Distractor, the surgeon applies a force that moves the implants apart, creating more space between them.

  This distraction is useful for decompressing neural structures, adjusting spinal alignment, or increasing the distance between the implants for better fixation or correction.

- **Serial Distraction:**

  Like compression, distraction can also be done serially. First, the surgeon provisionally locks one implant using the Final Driver. Then, the Distractor can be used to distract the other implant, adjusting the position while the locked implant remains stable.

  Serial distraction allows for controlled movement of the implants, particularly in complex cases where gradual adjustments are necessary.

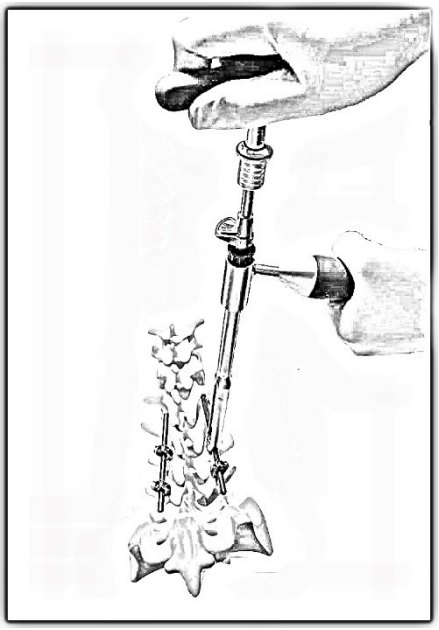
- **Provisionally Locking the Distracted Implants:**

  Once the desired distraction is achieved, the surgeon should provisionally lock the implants with the Final Driver. This ensures that the implants remain in the distracted position while further adjustments or steps are completed. After locking the implants, the Distractor can be released.

Step 11

Final Tightening

- **Final Tightening Setup:**
  After all implants are placed and provisionally tightened, it's time to perform final tightening to securely lock them in place. This is done using the Final Driver, Torque Limiting Handle, and Counter Torque Tube.
- **Connecting the Final Driver to the Torque Limiting Handle:**
  The Final Driver is connected to the Torque Limiting Handle. This assembly allows for precise control of the torque applied during tightening, preventing over-tightening or under-tightening of the closure tops, which could affect the stability of the construct.
- **Passing Through the Counter Torque Tube:**
  Next, the entire assembly (Final Driver and Torque Limiting Handle) is passed through the Counter Torque Tube. The Counter Torque Tube serves to stabilize the screw and prevent any unwanted torsion or movement in the construct as you tighten the closure tops.
  The Counter Torque Tube is positioned over the screw head, aligning the recesses in the tube with the axis of the rod to maintain proper alignment during tightening.
- **Interfacing the Final Driver with the Closure Top:**
  The Final Driver's hex is then aligned with the hex of the closure top. This ensures a secure and stable connection between the driver and the closure top so that the final tightening can proceed effectively without slippage or misalignment.
- **Avoiding Construct Torsion:**
  One of the key elements of this step is avoiding torsion in the construct, as any unwanted rotational force could destabilize the alignment of the screws and rod. The Counter Torque Tube helps maintain the integrity of the construct while tightening.



- **Tightening to the Correct Torque:**

  Torque Limiting Handle is used to tighten the closure top. The Torque Indicating Shaft on the handle indicates the precise amount of torque being applied. The closure top is tightened until the handle reaches the indicated mark on the final tightening shaft.

  This ensures that the appropriate amount of torque is applied to the closure top, locking the screw in place without damaging the screw or the rod. It also prevents over-tightening, which could lead to screw or rod failure.

- **Locking the Implant:**

  Once the proper torque is applied and the Torque Indicating Shaft reaches the indicated mark, the implant is considered locked. This means the screw is securely anchored in the pedicle and the rod is firmly held in place.

- **Repeat for All Implants:**

  This process is repeated for each implant in the construct. Each screw is tightened sequentially, ensuring all implants are securely locked and the spinal construct is stable.

Instruments

Open Awl

Pedicle Probe

Tap

Polyaxial Screwdrivers

Template Rod

Rod Bender

Rod Pusher

Wrench for Rods

Rod Holder

Persuader

Ratchet Handle

Tab Breaking Forceps

Power Gripper

Pin Holder

Cylindrical Pin

Screw Removal Driver 3.5mm

Tab Breaker

Star Locking Cap Holder

Auto Rotation Sleeve for Reduction

Quick Coupling T Handle

Probe-Straight

Probe-Curved

Rocker

Compression Forceps

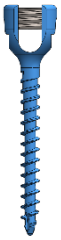
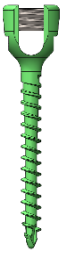
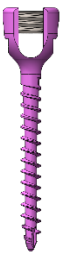
Distractor Forceps

Torque Limiting Handle

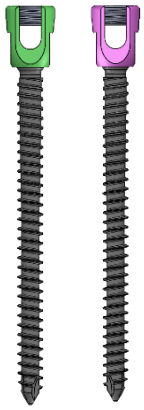
Counter Torque

Implants

Kentrospine Dgen Mono Screw - Ø4.5mm X 25mm	RODMS4525
Kentrospine Dgen Mono Screw - Ø4.5mm X 30mm	RODMS4530
Kentrospine Dgen Mono Screw - Ø4.5mm X 35mm	RODMS4535
Kentrospine Dgen Mono Screw - Ø4.5mm X 40mm	RODMS4540
Kentrospine Dgen Mono Screw - Ø5.5mm X 30mm	RODMS5530
Kentrospine Dgen Mono Screw - Ø5.5mm X 35mm	RODMS5535
Kentrospine Dgen Mono Screw - Ø5.5mm X 40mm	RODMS5540
Kentrospine Dgen Mono Screw - Ø5.5mm X 45mm	RODMS5545
Kentrospine Dgen Mono Screw - Ø5.5mm X 50mm	RODMS5550
Kentrospine Dgen Mono Screw - Ø6.5mm X 30mm	RODMS6530
Kentrospine Dgen Mono Screw - Ø6.5mm X 35mm	RODMS6535
Kentrospine Dgen Mono Screw - Ø6.5mm X 40mm	RODMS6540
Kentrospine Dgen Mono Screw - Ø6.5mm X 45mm	RODMS6545
Kentrospine Dgen Mono Screw - Ø6.5mm X 50mm	RODMS6550
Kentrospine Dgen Mono Screw - Ø6.5mm X 55mm	RODMS6555
Kentrospine Dgen Mono Screw - Ø6.5mm X 60mm	RODMS6560
Kentrospine Dgen Mono Screw - Ø7.2mm X 30mm	RODMS7530
Kentrospine Dgen Mono Screw - Ø7.2mm X 35mm	RODMS7535
Kentrospine Dgen Mono Screw - Ø7.2mm X 40mm	RODMS7540
Kentrospine Dgen Mono Screw - Ø7.2mm X 45mm	RODMS7545
Kentrospine Dgen Mono Screw - Ø7.2mm X 50mm	RODMS7550
Kentrospine Dgen Mono Screw - Ø7.2mm X 55mm	RODMS7555
Kentrospine Dgen Mono Screw - Ø7.2mm X 60mm	RODMS7560

Kentrospine Dgen Poly Iliac Screw - Ø6.5mm X 65mm	RODPSI6565
Kentrospine Dgen Poly Iliac Screw - Ø6.5mm X 75mm	RODPSI6575
Kentrospine Dgen Poly Iliac Screw - Ø6.5mm X 85mm	RODPSI6585
Kentrospine Dgen Poly Iliac Screw - Ø7.2mm X 65mm	RODPSI7265
Kentrospine Dgen Poly Iliac Screw - Ø7.2mm X 75mm	RODPSI7275
Kentrospine Dgen Poly Iliac Screw - Ø7.2mm X 85mm	RODPSI7285



Kentrospine Dgen Poly Reduction Screw - Ø5.5mm X 35mm	RODRPS5535
Kentrospine Dgen Poly Reduction Screw - Ø5.5mm X 40mm	RODRPS5540
Kentrospine Dgen Poly Reduction Screw - Ø5.5mm X 45mm	RODRPS5545
Kentrospine Dgen Poly Reduction Screw - Ø5.5mm X 50mm	RODRPS5550
Kentrospine Dgen Poly Reduction Screw - Ø6.5mm X 35mm	RODRPS6535
Kentrospine Dgen Poly Reduction Screw - Ø6.5mm X 40mm	RODRPS6540
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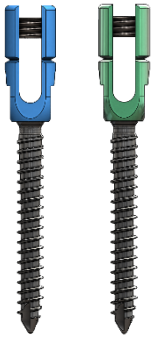

Kentrospine Dgen Poly Screw - Ø4.5mm X 25mm	RODPS4525
Kentrospine Dgen Poly Screw - Ø4.5mm X 30mm	RODPS4530
Kentrospine Dgen Poly Screw - Ø4.5mm X 35mm	RODPS4535
Kentrospine Dgen Poly Screw - Ø4.5mm X 40mm	RODPS4540
Kentrospine Dgen Poly Screw - Ø5.5mm X 30mm	RODPS5530
Kentrospine Dgen Poly Screw - Ø5.5mm X 35mm	RODPS5535
Kentrospine Dgen Poly Screw - Ø5.5mm X 40mm	RODPS5540
Kentrospine Dgen Poly Screw - Ø5.5mm X 45mm	RODPS5545
Kentrospine Dgen Poly Screw - Ø5.5mm X 50mm	RODPS5550
Kentrospine Dgen Poly Screw - Ø5.5mm X 55mm	RODPS5555
Kentrospine Dgen Poly Screw - Ø6.5mm X 30mm	RODPS6530
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Kentrospine Dgen Poly Screw - Ø6.5mm X 40mm	RODPS6540
Kentrospine Dgen Poly Screw - Ø6.5mm X 45mm	RODPS6545
Kentrospine Dgen Poly Screw - Ø6.5mm X 50mm	RODPS6550
Kentrospine Dgen Poly Screw - Ø6.5mm X 55mm	RODPS6555
Kentrospine Dgen Poly Screw - Ø6.5mm X 60mm	RODPS6560
Kentrospine Dgen Poly Screw - Ø7.2mm X 30mm	RODPS7230
Kentrospine Dgen Poly Screw - Ø7.2mm X 35mm	RODPS7235
Kentrospine Dgen Poly Screw - Ø7.2mm X 40mm	RODPS7240
Kentrospine Dgen Poly Screw - Ø7.2mm X 45mm	RODPS7245
Kentrospine Dgen Poly Screw - Ø7.2mm X 50mm	RODPS7250
Kentrospine Dgen Poly Screw - Ø7.2mm X 55mm	RODPS7255
Kentrospine Dgen Poly Screw - Ø7.2mm X 60mm	RODPS7260

Indications and Contraindications

Indications, contraindications and possible adverse events:

Indications for use:
The Kentrospine DGEN 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 DGEN 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 DGEN 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 DGEN 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 DGEN Pedicle Screw System is manufactured from Titanium alloy (Ti6Al4V ELI), hence it do not pose any safety risk.

"The Kentrospine DGEN 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 DGEN 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:

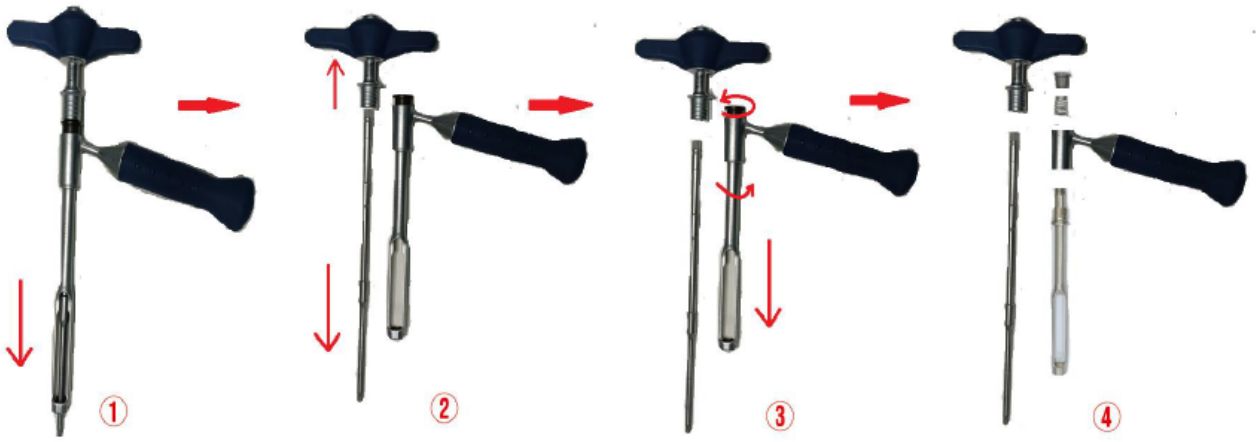
The sequence of steps required to prepare non-sterile instruments for use are summarized in the chart below. More detailed instructions for each step are given on the following pages.

Instruments disassemble & reassemble instructions for Cleaning:

Instruments disassemble & reassemble instructions for cleaning:

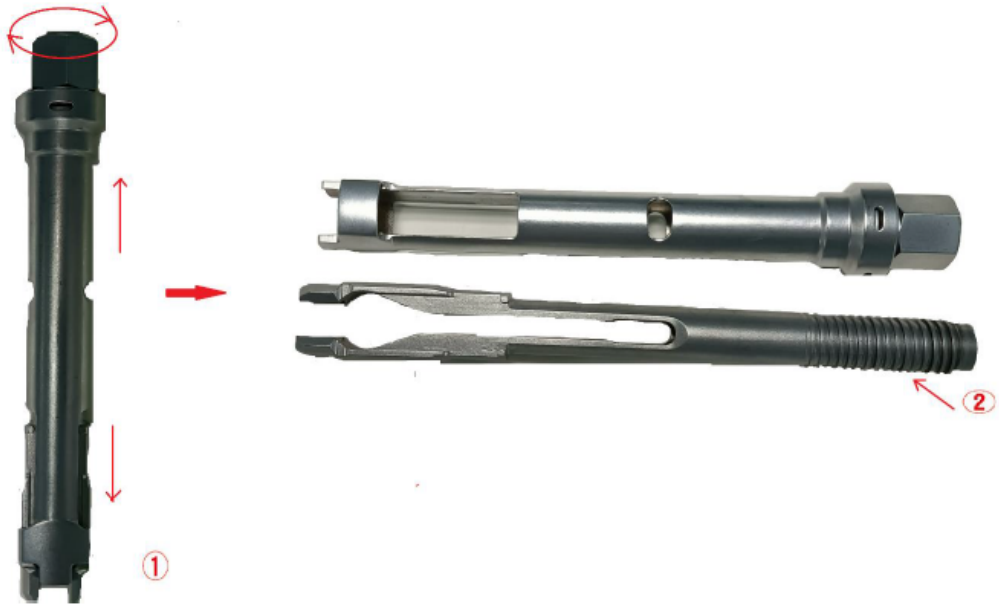
- Multi-component instruments should be disassembled for cleaning. Disassembly, where necessary, is generally self-evident. More specific instructions are given below.
- Disassemble the instruments at point of use area.
- After thorough cleaning, reassemble the small components / parts of the instruments 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.

Instruments	Steps	Instructions
• Final plug holder /counter torque, • Torque handle • T- handle	1	Final tightening Assembly
	2	Hold the Final plug holder /counter torque and T-Handle and slide them in opposite direction
	3	Pull the spring loaded bush upward and simultaneously pull the torque handle shaft downward to separate from each other.
	4	Rotate the knob to release the spring and dismantle the final plug holder.
	5.	Follow steps (Steps 4 to 2) in reverse order to reassemble the instruments as Final tightening Assembly.



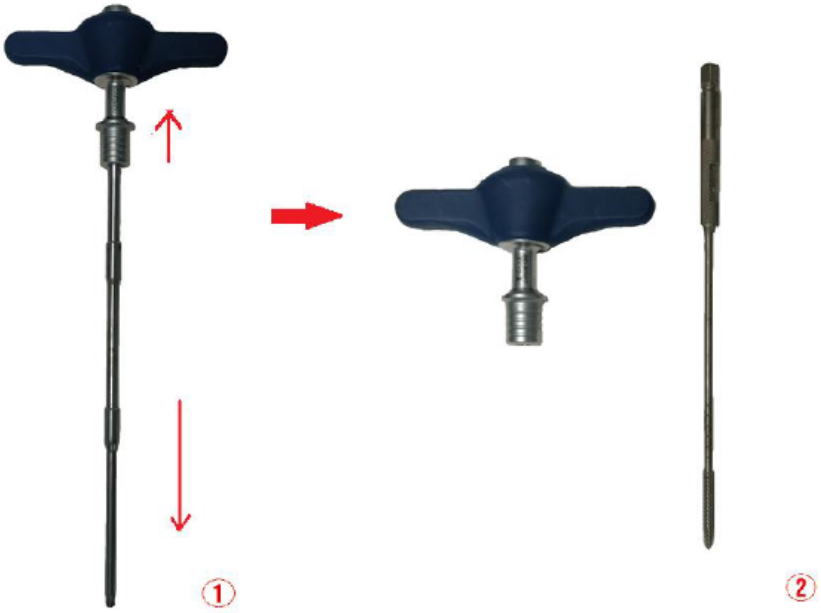
Instruments	Steps	Instructions
• Screw driver • Ratchet handle	1	Polydrive with ratchet handle assembly
	2	Release the polydrive by pulling the spring loaded bush of ratchet handle and polydrive in opposite direction Follow this step in reverse order to reassemble as Polydrive with ratchet handle assembly.
	3	Press the button on polydrive and pull in opposite direction to release the polydrive inner shaft from the polydrive outer shaft. Hold the button and insert the polydrive inner shaft into the polydrive outer shaft to reassemble as complete polydrive

Instruments	Steps	Instructions
• Tower reducer	1	Tower reducer assembly
	2	Rotate/unthread the hexagonal knob of outer sleeve to release inner sleeve. Put the inner sleeve into the outer sleeve and rotate the knob to reassemble the Tower reducer.



Instruments	Steps	Instructions
• Revision Driver and T-Handle	1	Revision Driver assembly
	2	Release the revision driver by pulling the spring loaded bush of T-handle and revision driver in opposite direction Follow this step in reverse order to reassemble as Revision Driver assembly with T-Handle.

Instruments	Steps	Instructions
• Pedicle tap and T-Handle	1	Pedicle tap assembly
	2	Release the pedicle tap by pulling the spring loaded bush of T-handle and revision driver in opposite direction Follow this step in reverse order to reassemble as pedicle tap assembly with T-Handle.




-Dgen
-Dgen
Instruments