Rivarp MEDICAL

Kentrospine - PCF

RVP/PCFSTM/02

Kentrospine

PCF Screw System

Surgical Technique Manual

Contents

Product Overview

Introduction

PCF is a surgical procedure commonly used to treat conditions such as cervical spondylosis, degenerative disc disease, or cervical spinal stenosis. Here's an overview of the surgical techniques involved:

1. Patient Positioning: The patient is typically placed in a prone (face down) position on the operating table.

2. Incision: The surgeon makes an incision in the midline of the posterior neck, exposing the cervical vertebrae.

3. Decompression: If there is any spinal cord or nerve compression due to bone spurs or herniated discs, the surgeon may perform a laminectomy or laminotomy to decompress the affected nerves.

4. Discectomy: If there are herniated or degenerated discs causing compression, the surgeon may remove part or all of the affected discs.

5. Bone Grafting: To promote fusion between the vertebrae, the surgeon may use bone grafts. These grafts can be sourced from the patient's own bone (autograft), a donor bone (allograft), or synthetic materials. The bone graft material is typically placed between the vertebrae.

6. Fixation: Hardware such as screws, plates, or rods may be used to stabilize the spine and promote fusion. The screws are typically inserted into the vertebrae above and below the fusion site, and rods or plates are used to connect the screws.

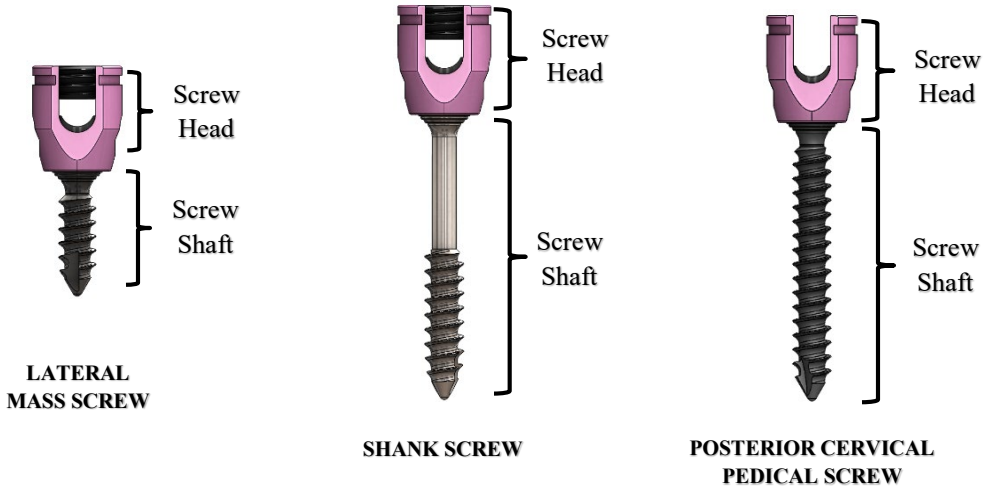
7. Closure: Once the bone graft and hardware are in place, the incision is closed with sutures or staples.

8. Recovery: After surgery, the patient will be monitored in the recovery room and then moved to a hospital room for further observation. Physical therapy and rehabilitation may be required to aid in recovery and improve mobility.

It's essential to note that surgical techniques may vary depending on the specific condition being treated, the patient's anatomy, and the surgeon's preferences and expertise. Therefore, it's crucial for patients to discuss the details of their surgery with their healthcare provider

Features

Kentrospine PCF



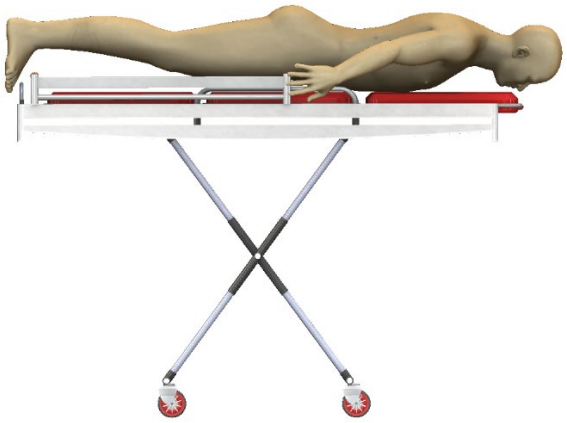
- Screw Lengths: 10mm to 32mm
- Screw Diameters: 3.5 and 4mm
- Polyaxial screws with upto 40 degree
- Low Profile tulip Self-tapping Screws for easy and rapid insertion.
- Locking cap has reverse buttress thread.
- Dual option for 2-point reduction. It has two different options for reduction. One at the top-notch grove of tulip and other at the mid of tulip.
- Chances of slippage during reduction is less due to the presence of reduction point at various location in tulip.

Surgical Technique

Step 1

- **Preoperative Preparation**

Position the patient prone on the operating table with the neck in a neutral position.
Place the head in a stereotactic frame or use a Mayfield headrest to ensure stability.

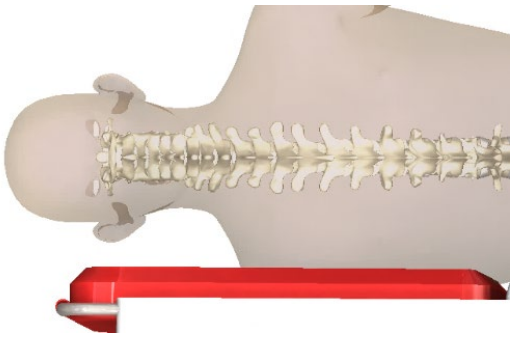


Precautions:
It is recommended to use a Jackson Table to assist in achieving the proper patient positioning and an unrestricted fluoroscopic view. Confirm the C-Arm will allow for easy rotation in the lateral, oblique, and A/P positions around the table.

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:**

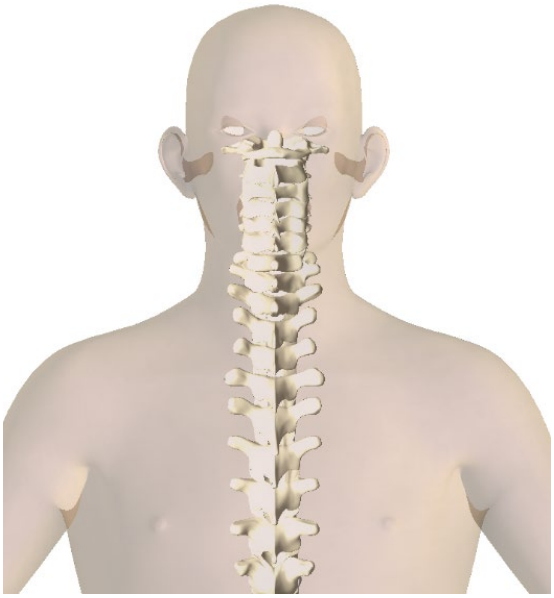
  Based on the preoperative imaging, select the appropriate screw diameter, length, and type (e.g., polyaxial or monoaxial) based on the patient's pedicle anatomy and the intended spinal construct.

  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.

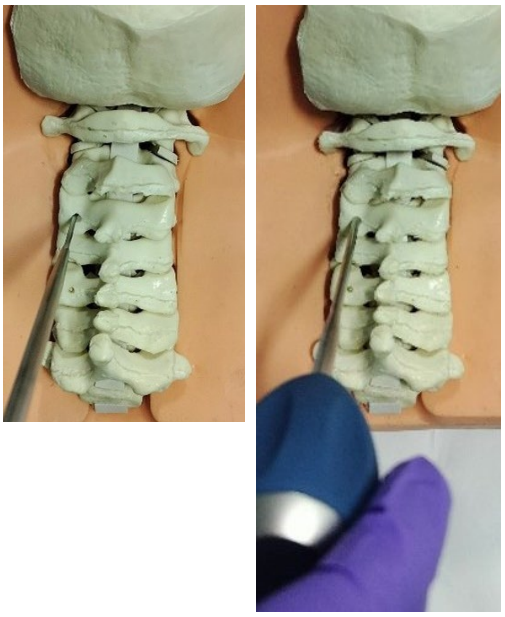


Step 2

Make the Entry

- **Using awl and gear shift**:

- **Marking the Entry Point with the Awl**
  Begin by placing the awl at the planned entry point for the spinal screw, typically at the pedicle of the targeted vertebra.
  Gently tap the awl with a mallet to create a small indentation in the bone. This indentation will serve as a precise starting point for screw placement.
  The awl not only marks the spot but also helps define the trajectory (direction and angle) of the screw. The surgeon should ensure that the angle is correct to avoid damage to surrounding structures (e.g., nerves or vessels).



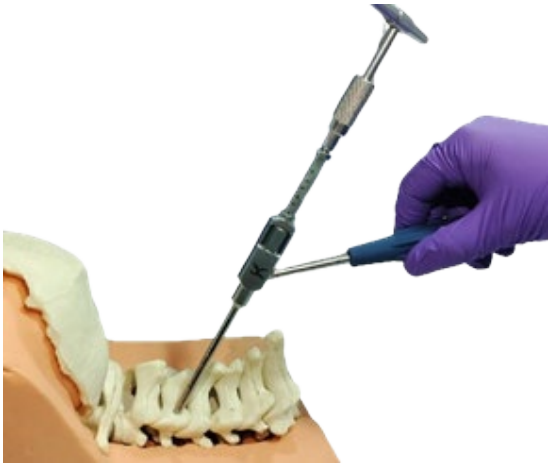
- **Advancing the Hole with the Gear Shift**
  After the indentation is made, the next step is to advance the hole along the defined path. This is done using a gear shift (drill or reamer).
  The gear shift is placed into the indentation created by the awl and is rotated to enlarge and deepen the hole. The gear shift will follow the trajectory defined by the awl, ensuring the hole remains on the correct path.
  The gear shift helps to refine the size and depth of the hole to accommodate the spinal screw, allowing for precise screw insertion later.

- **Using the drill guide**:

- **Positioning the Drill Guide:**
  Once the initial skin incision and exposure of the targeted vertebra are completed, carefully position the drill guide over the pedicle entry point. The guide should align with the intended trajectory of the screw, as planned.
  The drill guide is typically a cylindrical instrument that contains a guide sleeve through which the drill shaft will pass. The guide is designed to ensure that the drill remains on the correct angle and trajectory for accurate screw placement

- **Adjusting the Drill Guide:**
  The drill guide features a dial and a rotating knob for precise adjustment of the guide's position.
  Adjust the angle of the drill guide using the rotating knob to match the planned trajectory for screw insertion. This knob allows the surgeon to make fine adjustments to the angle of the guide to ensure correct screw alignment.
  Once the desired angle is set, the surgeon can lock the guide into place, ensuring stability during drilling.

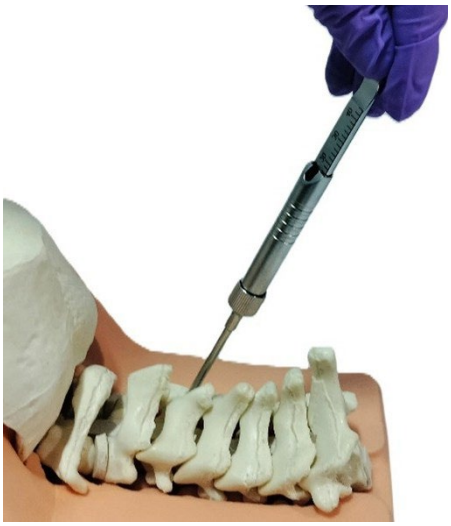
- **Insertion of the Drill Shaft:**
  Select the appropriate drill shaft that corresponds to the screw size to be used. The drill shaft should be compatible with the quick coupling T-handle.
  Couple the drill shaft with the quick coupling T-handle. This T-handle allows for easy and controlled manual rotation of the drill.
  Insert the drill shaft assembly (T-handle and drill shaft) into the guide sleeve of the drill guide, ensuring it is securely seated.
- **Drilling the Entry Hole:**
  Begin rotating the T-handle to advance the drill through the guide sleeve. As you rotate the T-handle, the drill will follow the trajectory set by the guide and will begin to create the entry hole in the bone.
  Monitor the progress of the drilling. The dial on the drill guide will display the distance the drill has advanced, allowing the surgeon to track the drilling depth and ensure it stays within the desired limits.
  The surgeon should carefully control the speed of drilling and ensure the drill stays aligned with the trajectory defined by the guide. The guide sleeve prevents any deviation or misalignment, ensuring the hole remains precise and true to the planned path.



Step 3

Measure the drill depth with Depth Gauge

- **Position the Depth Gauge:**
  After drilling to the approximate depth, select the depth gauge to confirm the exact depth of the hole.
  The depth gauge typically consists of an inside sleeve with a probe end that is designed to slide within the drilled hole. The probe end is tapered and designed to move smoothly through the drilled path.
- **Insert the Depth Gauge:**
  Insert the probe end of the depth gauge into the drilled hole. The probe should fit snugly inside the hole to ensure accurate measurements.
  Advance the depth gauge gently into the hole by allowing the inside sleeve to move through the hole. The probe will travel through the hole as it slides within the bone's structure, measuring the depth.
- **Read the Depth on the Gauge:**
  The opposite end of the depth gauge features a dial that will display how far the probe has advanced inside the hole. The reading on the dial shows the exact depth of the drilled hole.
  Confirm that the depth reading matches the planned depth for screw insertion (usually about 1–2 mm past the pedicle). This ensures the screw will fit correctly without breaching the cortical bone or causing damage to surrounding structures.
- **Record and Adjust if Necessary:**
  If the depth measurement indicates that the hole is not deep enough, the drill can be advanced further, or the depth gauge can be used to ensure that the hole is drilled precisely.
  If the hole is too deep, a more appropriate screw size may be selected or further adjustments made to prevent any complications.



Measure the drill depth with Feelers:

- **Position the Feeler:**

  Select the appropriate feeler tool. Feelers are typically used for more tactile measurements of the hole depth.

  Insert the feeler into the drilled hole. The feeler tool consists of a rod or shaft with a scale marked along its length, and the probe end contains a dial that corresponds to the depth of penetration.

- **Advance the Feeler Tool:**

  Insert the feeler tool into the hole and gradually advance the shaft. The shaft is marked with depth scales, while the dial on the probe end shows the depth as the tool moves into the hole.

  Observe the dial reading at the probe end. This reading corresponds to the depth of the hole and provides an accurate measurement of how far the feeler has penetrated.

- **Confirm Depth:**

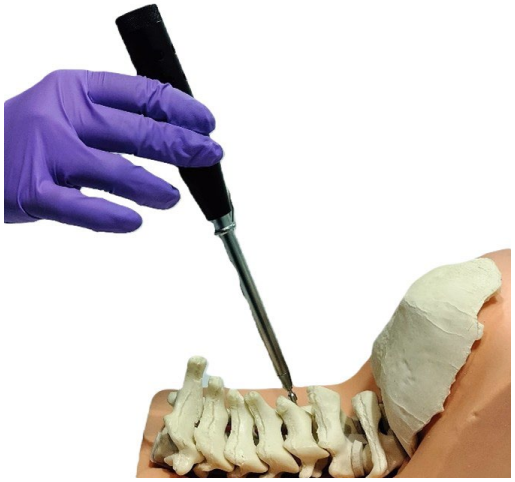
  Ensure that the measurement matches the desired depth for screw placement. The dial on the feeler will provide a precise reading, helping to verify that the hole is adequately prepared.

  If necessary, adjust the drilling depth by further advancing or retracting the drill.

STEP 4

Positioning / Marking

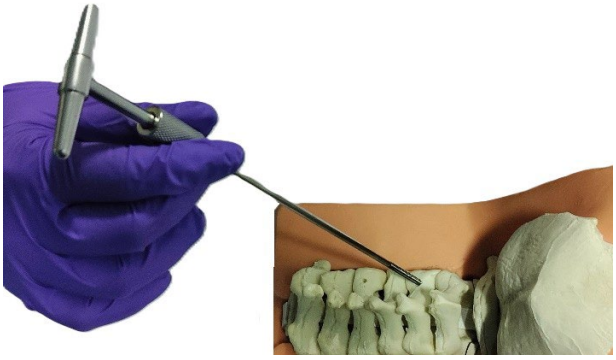
- **Clearance and Widening of the Trajectory:**
  After the initial drilling with the drill shafts, the trajectory is confirmed and widened to ensure an adequate pathway for screw insertion. This is facilitated by the use of taps, which help to clear any debris and widen the drilled hole, ensuring the screw can be placed securely and without resistance.
- **Removal of Guide Sleeve and Drill:**
  Following the use of taps, the guide sleeve and drill are carefully removed. The guide sleeve is withdrawn first, followed by the drill, leaving a clearly defined pathway in the bone.
- **Marking the Pathway:**
  To ensure precise screw placement, markers are introduced. These markers are placed in the drilled path and serve to highlight the trajectory created by the previous steps. This step ensures that the path for screw insertion is easily identifiable and accessible, which aids in optimal screw alignment and placement during the final stages of the surgery.



STEP 5

Tapping

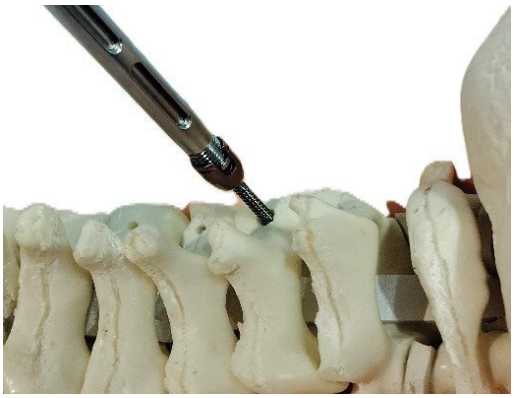
- **Assembly of the Tap with the Quick Coupling T-Handle:**
  The tap is securely assembled onto the quick coupling T-handle. The quick coupling mechanism ensures a firm connection between the tap and the handle, providing ease of use and stability during the procedure.
- **Insertion of the Tap:**
  Once assembled, the tap is advanced into the entry hole created by the drill. The surgeon carefully positions the tap in the prepared path, ensuring proper alignment with the trajectory established for screw insertion.
- **Utilizing the T-Handle for Advancement:**
  The T-handle, equipped with knurling, provides a secure grip for the surgeon. By rotating the handle, the tap is advanced into the bone along the pre-established trajectory. The knurling on the handle ensures that the surgeon maintains a firm hold while applying controlled rotational pressure.
- **Progression of the Tap:**
  As the handle is rotated, the tap progresses into the entry hole, cutting threads into the bone along the drilled path. This creates a stable and precise pathway for the insertion of the spinal screw, allowing for optimal screw placement and ensuring proper fixation. The controlled advancement of the tap is critical to achieving a stable and accurate screw trajectory.

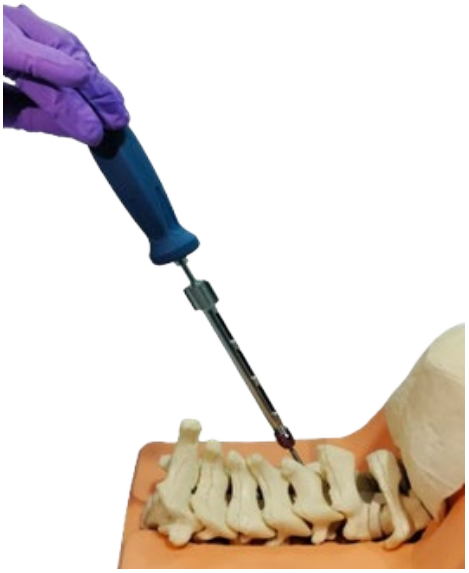


STEP 6

Screw Insertion.

- **Attach the Screw to the Screwdriver**:
  Secure the PCF polyaxial screw to the poly screw driver by threading the screw onto the driver. The external thread of the driver should mate with the internal thread of the screw.
- **Check for Wobbling**:
  Gently rotate the screwdriver to check for any wobbling of the screw. Ensure that the screw is stable and does not exhibit excessive movement. This ensures the screw is properly seated on the driver and will insert in a controlled manner.
- **Align the Screw**:
  Position the polyaxial screw at the entry hole created for insertion, ensuring it is aligned with the planned trajectory.
- **Insert the Screw**:
  Begin to slowly rotate the screwdriver to advance the screw into the bone. Maintain steady, controlled pressure to ensure the screw follows the pre-established path.
- **Monitor Screw Progression**:
  As the screw is advanced, ensure it moves smoothly without resistance or misalignment. Adjust the angle if necessary (for polyaxial screws) to ensure proper insertion and screw positioning.
- **Confirm Seating**:
  Once the screw has reached the desired depth and position, ensure it is fully seated within the bone. Confirm that the screw is properly locked in place, without any wobble.

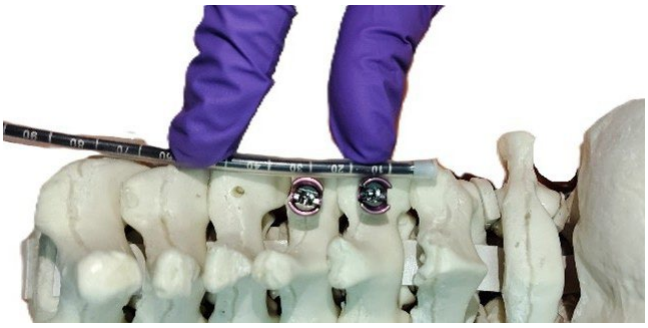




STEP 7

Measuring the Screw Distance

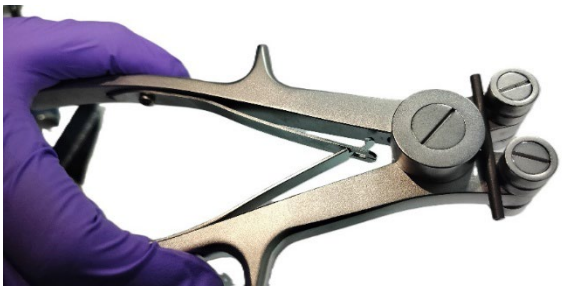
- **Measuring the Distance Between the Screws:**
  A template rod is used to measure the appropriate distance between the two planned screw insertion points. The rod is carefully positioned along the spinal segment where the screws are to be placed, ensuring that the distances correspond to the desired placement for optimal fixation.
- **Marking the Template Rod:**
  After the distance between the two screws is measured, the template rod is marked. These markings serve as a visual guide for the surgeon, indicating the precise placement and alignment of the screws relative to each other. The markings help ensure consistency in screw positioning, especially when working with multiple screw insertion sites.
- **Alignment and Verification:**
  Once the template rod is marked, the surgeon verifies the placement against the spinal anatomy, confirming that the distance between screws is accurate and suitable for achieving optimal fixation. This verification step helps in guiding the correct trajectory for screw insertion, minimizing the risk of misplacement and enhancing the overall stability of the construct.



STEP 8

Making the Rod ready.

- **Cut the Template Rod to Desired Length**:
  Using a surgical saw or appropriate cutting tool, cut the template rod to the measured length between the two screw entry points. Ensure the rod is cut accurately, as this will define the proper spacing for the screws.
- **Assess the Angulation**:
  Evaluate the anatomy of the spine and any necessary screw angulation, taking into account the desired screw trajectory and positioning. Ensure that the rod will align with the natural curve or angle required for optimal screw placement.
- **Bend the Rod (If Necessary)**:
  If the rod requires bending to conform to the specific anatomical angle, carefully apply gentle pressure to the rod to achieve the necessary curvature. Use a bending jig or manual force to bend the rod while ensuring the rod maintains its integrity and does not become deformed.
- **Check Fit in Screw Tulips**:
  After cutting and bending, place the template rod on the screw tulips (if applicable). Ensure that the rod sits properly and securely in the tulip of each screw, allowing for accurate alignment and correct screw positioning.
- **Final Adjustments**:
  Make any final adjustments to the rod's length or bend to ensure it fits perfectly between the screw tulips. Verify that the rod aligns with the anatomical requirements and screw trajectory.
- **Confirm Alignment and Spacing**:
  Once the rod is cut and bent, confirm the spacing between the screws and the angulation. This ensures the template rod reflects the correct screw trajectory and positioning before proceeding with screw insertion.



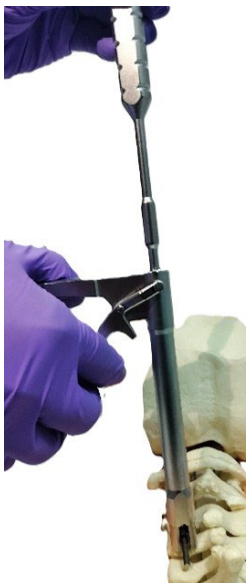
STEP 9

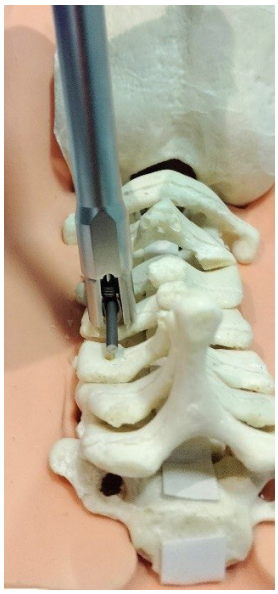
Innie Insertion using Counter Torque

- **Prepare the Counter Torque**:
  Select the appropriate counter torque device with the tip profile that matches the screw head. The counter torque is designed to securely hold the screw head in place and prevent any unwanted movement during the insertion of the Innie.
- **Position the Counter Torque**:
  Carefully place the counter torque onto the screw head. Ensure that the profile of the counter torque tip fully engages with the screw head to prevent any slipping or wobbling. The counter torque should be firmly secured in place to provide stabilization for the screw.
- **Introduce the Innie Holder**:
  With the counter torque properly positioned, take the Innie holder and attach the Innie (the rod or driver) securely into the holder. The holder is designed to stabilize the Innie during insertion.
- **Insert the Innie through the Counter Torque Sleeve**:
  Carefully insert the Innie through the inner sleeve of the counter torque. This setup ensures that the Innie is guided accurately into the screw mechanism, with the screw head stabilized by the counter torque.
- **Insert the Innie into the Screw**:
  Once the Innie is through the counter torque sleeve, gently advance the Innie into the screw mechanism. The screw will now be held in place, and the Innie will engage with the screw for precise advancement.
- **Monitor Insertion**:
  As you rotate or advance the Innie, keep a close watch on the screw's progression. The counter torque should prevent any movement of the screw head, ensuring that the screw insertion remains controlled and accurate.

Innie Insertion using rod introduction instrument

- **Preparation of the Instrument:**
  Select the rod introduction instrument with a head that matches the profile of the screw head. Ensure the instrument is properly sterilized and all parts
  are available for the procedure, including the guide sleeve and the Innie holder.
- **Insertion of the Rod Introduction Instrument:**
  Insert the rod introduction instrument into the pedicle screw system, aligning it with the screw trajectory.
  Use the guide sleeve to ensure smooth and precise placement of the instrument along the screw path.
  Tighten the instrument carefully to secure it in place, ensuring that the screw is properly aligned within the pedicle.
- **Inserting the Innie:**
  Once the rod introduction instrument is tightened and secured, the next step is the insertion of the Innie.
  Using the Innie holder, carefully insert the Innie through the inside sleeve of the guide setup.
  The Innie should be positioned precisely in the screw hole, ensuring it is fully seated and engaged within the screw profile.
- **Verification and Final Adjustments:**
  Verify the position of the Innie under fluoroscopy or radiographic imaging to ensure correct placement.
  Make any necessary adjustments to confirm proper alignment before moving on to the next step of screw tightening or rod insertion.

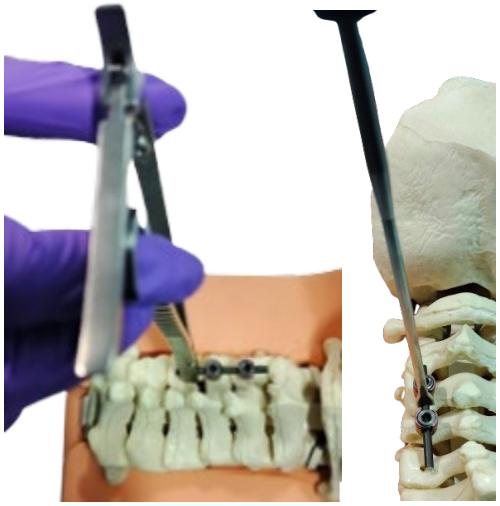




STEP 10

Rod Reduction

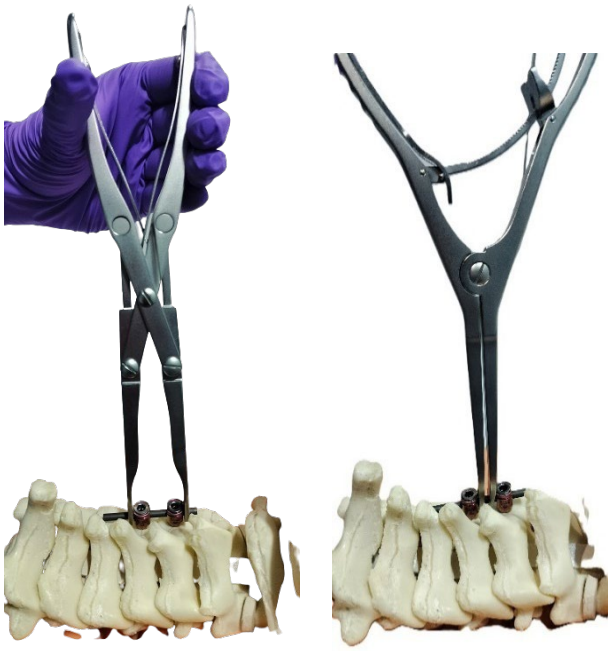
- **Rod Reduction for Proper Seating:**
  After the template rod has been cut and bent to the appropriate length and angle, it is necessary to reduce the rod to ensure it sits correctly in the rod slot of the screw tulips. This step ensures proper alignment and secure fixation of the rod within the screw mechanism.
- **Instruments for Rod Reduction:**
  Various instruments can be used to achieve this reduction, depending on the surgeon's preference and the specific requirements of the procedure. These instruments include:
- **Rod Pusher with Rocker:**
  A rod pusher, often equipped with a rocker, is used to push the rod into the slot of the screw tulip. The rocker allows controlled pressure to be applied, ensuring that the rod sits firmly in place without causing excessive force that could risk damage to the surrounding anatomy or screws.
- **Rod Holder:**
  A rod holder may be used to stabilize and control the rod as it is reduced into the screw slot. It provides a firm grip and allows the surgeon to manipulate the rod while ensuring precise placement within the screw tulip.
- **Rod Gripper:**
  Alternatively, a rod gripper can be employed to firmly grip the rod while assisting in the precise reduction and seating within the screw tulip. This tool provides added stability and control during the reduction process.
- **Ensuring Proper Fit and Reduction:**
  Regardless of the instrument chosen, the goal is to carefully reduce the rod into the screw slot, ensuring that it is securely seated with proper alignment. The rod should fit snugly within the slot without any gaps, and the screw tulips should be appropriately engaged to maintain the rod's position during final tightening.



STEP 11

Compression and Distraction

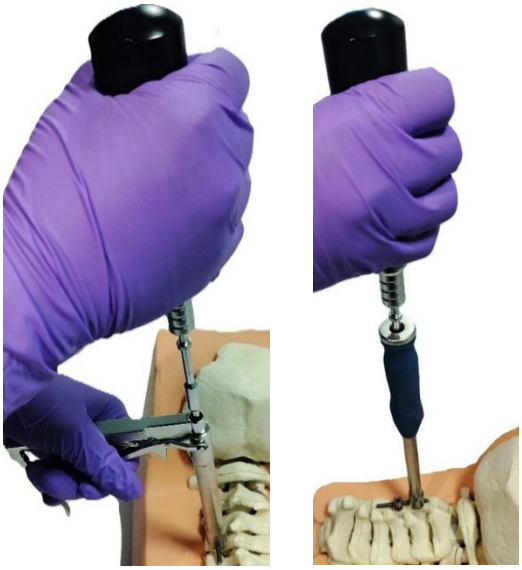
- **Assess Screw Alignment:**
  After seating the rod in the screw tulips, assess the alignment of the screws to determine if compression, distraction, or both are needed to achieve the desired spinal alignment and stability.
- **Apply Compression (If needed):**
  Use the compression instrument to move the screws closer together. Position the compression instrument between the screws and apply gradual pressure to bring the screws and the vertebral segments closer. Monitor the alignment as you compress to ensure the desired reduction or spinal correction is achieved.
- **Apply Distraction (If needed):**
  Alternatively, use the distractor instrument to move the screws apart. Place the distractor between the screws and gently pull the screws away from each other, creating space in the disc or correcting spinal alignment. Ensure that the distraction is applied carefully to avoid damaging any surrounding structures, and monitor the segment's alignment during the process.
- **Simultaneous Compression and Distraction (If Necessary):**
  In cases where both compression and distraction are required, apply them simultaneously or sequentially, adjusting the screws to fine-tune the alignment. This may involve alternating the use of the compression and distraction instruments until the desired spinal alignment is achieved.
- **Final Adjustment and Stabilization:**
  Once the correct alignment is achieved, tighten the screws to secure the rod in place. Ensure that the screws are firmly locked into the desired position, maintaining the compression or distraction forces as required for the final stabilization of the spine.



STEP 12

Final Tightening

- **Preparation for Final Tightening:**
  Ensure that the rod is properly seated in the screw tulips and the alignment is optimal. The final tightening step is critical to securing the screw and rod in place.
- **Assembly of the Final Tightening Instrument:**
  Attach the final tightening shaft to the 3 Nm torque handle. The torque handle is specifically calibrated to apply a controlled and validated force of 3 Nm, which is the recommended torque to ensure proper tightening of the screw and rod connection.
- **Insertion of the Torque Handle:**
  Insert the torque handle, with the attached tightening shaft, through a counter torque instrument or rod introduction instrument. This counter torque instrument is used to stabilize the rod and prevent any movement while the screw is being tightened.
- **Applying Controlled Torque:**
  Rotate the torque handle clockwise, applying gradual and controlled pressure. The handle will engage with the screw and rod, causing them to tighten and lock in place.
- **Confirmation of Proper Tightening:**
  As the torque reaches 3 Nm, the torque handle will release the applied pressure, signalling that the correct amount of torque has been achieved. A distinct mechanical sound will be heard, indicating that the screw has been properly tightened and the connection between the screw and rod is secure.
- **Final Inspection:**
  After the torque handle releases, inspect the screws to ensure they are fully tightened and the rod is securely locked into the screw tulips. Verify that there is no movement in the construct and that the desired spinal alignment is maintained.



Instruments

Adjustable Drill Sleeve

Rodpusher/ Headaligner

Open Awl

Pedicle Probe

Anti Rotation Sleeve

Screw Driver with Sleeve

Cylinderical Markers

Poly Screw Driver

Distractor Foreceps

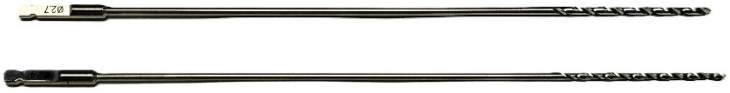
Quick Coupling T Handle

Holding Forceps for
Rods/ Power Gripper

Depth Limiter

Tap

Drill bit



Tap Guide

Ball pin probe curved and straight

Innie Holder

Instive Bender Left

Template Rod

Hex Screwdriver Shaft

Lift Hook

Holding Forceps for Rocker

Holding Foreceps for Rods

Quick Coupling Straight Handle

Bending Iron for Rod

Parallel Comprerssion Forceps

Torque Limiting Handle

Rod Introduction Instrument

Rod Cutter

Positione
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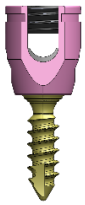
Implants

Kentrospine PCF Lateral Mass Screw - Ø3.5mm X 10mm	ROPCF3510
Kentrospine PCF Lateral Mass Screw - Ø3.5mm X 12mm	ROPCF3512
Kentrospine PCF Lateral Mass Screw - Ø3.5mm X 14mm	ROPCF3514
Kentrospine PCF Lateral Mass Screw - Ø3.5mm X 16mm	ROPCF3516
Kentrospine PCF Lateral Mass Screw - Ø3.5mm X 18mm	ROPCF3518
Kentrospine PCF Lateral Mass Screw - Ø3.5mm X 20mm	ROPCF3520
Kentrospine PCF Lateral Mass Screw - Ø4.0mm X 10mm	ROPCF4010
Kentrospine PCF Lateral Mass Screw - Ø4.0mm X 12mm	ROPCF4012
Kentrospine PCF Lateral Mass Screw - Ø4.0mm X 14mm	ROPCF4014
Kentrospine PCF Lateral Mass Screw - Ø4.0mm X 16mm	ROPCF4016
Kentrospine PCF Lateral Mass Screw - Ø4.0mm X 18mm	ROPCF4018
Kentrospine PCF Lateral Mass Screw - Ø4.0mm X 20mm	ROPCF4020



Kentrospine PCF Shank Screw - Ø3.5 X 24mm	ROPCFSK3524
Kentrospine PCF Shank Screw - Ø3.5 X 26mm	ROPCFSK3526
Kentrospine PCF Shank Screw - Ø3.5 X 28mm	ROPCFSK3528
Kentrospine PCF Shank Screw - Ø3.5 X 30mm	ROPCFSK3530
Kentrospine PCF Shank Screw - Ø3.5 X 32mm	ROPCFSK3532
Kentrospine PCF Shank Screw - Ø3.5 X 34mm	ROPCFSK3534
Kentrospine PCF Shank Screw - Ø3.5 X 36mm	ROPCFSK3536
Kentrospine PCF Shank Screw - Ø3.5 X 38mm	ROPCFSK3538

Kentrospine PCF Posterior Cervical Pedicle Screw - Ø3.5mm X 22mm	ROPCF3522
Kentrospine PCF Posterior Cervical Pedicle Screw - Ø3.5mm X 24mm	ROPCF3524
Kentrospine PCF Posterior Cervical Pedicle Screw - Ø3.5mm X 26mm	ROPCF3526
Kentrospine PCF Posterior Cervical Pedicle Screw - Ø3.5mm X 28mm	ROPCF3528
Kentrospine PCF Posterior Cervical Pedicle Screw - Ø3.5mm X 30mm	ROPCF3530
Kentrospine PCF Posterior Cervical Pedicle Screw - Ø3.5mm X 32mm	ROPCF3532
Kentrospine PCF Posterior Cervical Pedicle Screw - Ø4.0mm X 22mm	ROPCF4022
Kentrospine PCF Posterior Cervical Pedicle Screw - Ø4.0mm X 24mm	ROPCF4024
Kentrospine PCF Posterior Cervical Pedicle Screw - Ø4.0mm X 26mm	ROPCF4026
Kentrospine PCF Posterior Cervical Pedicle Screw - Ø4.0mm X 28mm	ROPCF4028
Kentrospine PCF Posterior Cervical Pedicle Screw - Ø4.0mm X 30mm	ROPCF4030
Kentrospine PCF Posterior Cervical Pedicle Screw - Ø4.0mm X 32mm	ROPCF4032

Indications and Contraindications

Indications for use:
The Kentrospine PCF Screw System is intended for posterior, 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:
PCF screw system which is indicated for cervical fixation only, the safety and effectiveness of Kentrospine PCF Screw System 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 tumour, 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 PCF Screw System 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 PCF Screw System should be performed only by experienced spinal surgeons with specific training in the use of this cervical 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 PCF Screw System is manufactured from Titanium alloy (Ti6Al4V ELI), hence it do not pose any safety risk.

"The Kentrospine PCF 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 PCF 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 is 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.

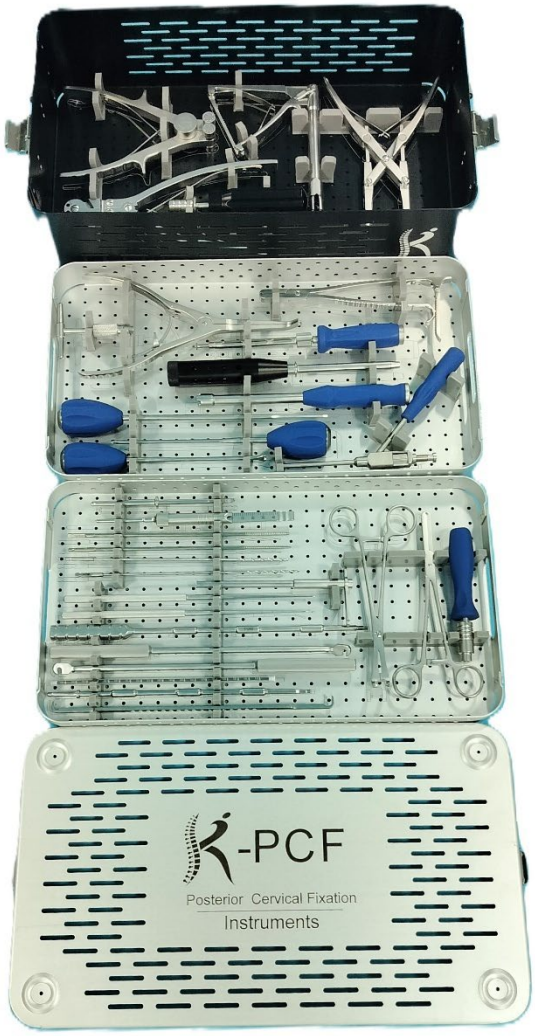
Reprocessing Overview:

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.


K-PCF
Posterior Cervical Fixation
Instruments