Kentrospine

ACP Anterior Cervical Plate System

Surgical Technique

Contents

Product Overview

Introduction

The Anterior Cervical Discectomy and Fusion (ACDF) procedure is a well-established surgical approach used to treat various cervical spine disorders, including degenerative disc disease, herniated discs, and spinal instability. The procedure involves the removal of the damaged or degenerated intervertebral disc and the subsequent fusion of the vertebrae using a specialized implant. One of the most commonly used implants in cervical fusion surgery is the ACP plate, designed to restore spinal stability, maintain proper alignment, and facilitate the natural fusion process between the vertebrae.

The surgical technique for ACP plate insertion begins with the careful positioning of the patient, ensuring optimal access and alignment of the cervical spine. The anterior approach is chosen to provide direct access to the affected disc space. Once the disc material is removed, distraction is applied to create sufficient space for implant placement. The ACP plate is then carefully inserted into the disc space, where it serves as a spacer, allowing for proper vertebral alignment and promoting bone growth across the fusion site.

Throughout the procedure, it is critical to maintain the natural cervical lordosis, ensure proper positioning of the implant, and monitor for any potential complications. The success of this technique hinges on the precise execution of each step, with particular attention to the patient's safety, effective use of surgical instruments, and optimal implant placement to ensure a stable, long-term fusion outcome. This technique provides a reliable solution for patients with cervical spine pathology, allowing for pain relief, stabilization, and restoration of function.

Features

Kentrospine ACP Anterior Cervical Plate System

1 Level 2 Level 3 Level

- **Set Screws:** Dia 4mm & 4.35mm.
- Medial Angulation – 15^0 Range.
- Lateral Angulation – 6^0 Offset.
- Screws are colour coded to identify function and diameter.
- **Design:** Design of plate holder helps positioning plates precisely.
- Unique design of plate bender and other supporting instruments will make the surgery more Comfortable.
- **Instrumentation:** Reducing the number of instruments has the potential to reduce the amount of retraction and time to implant a cervical plate.
- Simple and ergonomic instruments for swift placement.

Surgical Technique

Step 1

Positioning the Patient

Positioning the Patient:

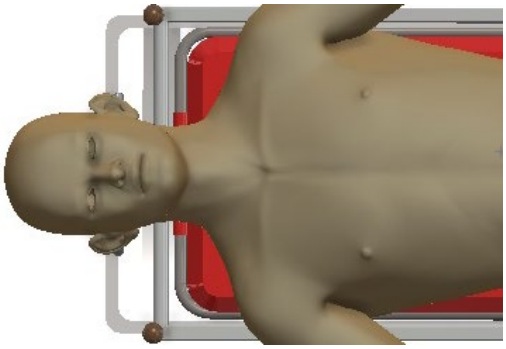
- The patient is placed in the supine position, meaning they lie on their back. This is the standard position for procedures involving the anterior (front) cervical spine because it allows the surgeon to approach the spine from the front of the neck.

Alignment of the Head and Neck:

- The patient's head should be aligned with the rest of the body to minimize the risk of nerve or vascular injury. The head is positioned in slight extension, which means it is slightly tilted backward. This is important because it helps open up the spaces between the cervical vertebrae, improving exposure for the surgery.

Cervical Spine Support:

- To maintain the normal cervical lordosis (the natural curve of the cervical spine), a support (often a soft cervical roll or cushion) is placed beneath the patient's shoulders or back.
- This support helps in creating an optimal position for surgery, maintaining the alignment of the cervical spine and ensuring that the vertebral bodies are spaced in such a way that it allows easy access to the intervertebral disc spaces.
- Maintaining this curvature is crucial because if the cervical spine is flattened or misaligned, it may cause complications or make it more difficult to access and work on the vertebrae. It must be considered that the intervertebral discs in the neck region are slightly inclined from a terocaudal to posterocranial. Screws should remain in the vertebral body and not penetrate the intervertebral discs.



Step 2

Plate Alignment and Bending:

Determining Plate Alignment:

- Align the plate with the cervical spine's natural lordosis. The plate should sit flush against the anterior vertebral bodies without causing undue pressure on surrounding soft tissues.

Bending the Plate for Lordotic Curvature:

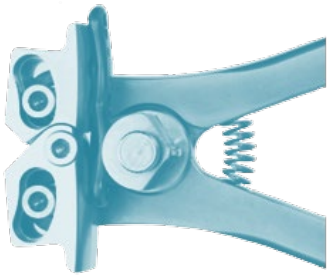
- Specialized surgical instruments called bending pliers are used to gently apply force to the plate, creating a controlled curve that mirrors the cervical spine's natural lordotic shape.

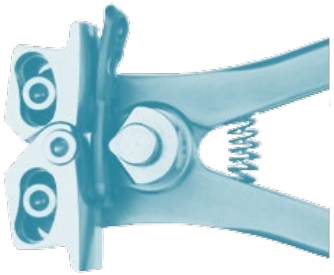
Bending Notches:

- The plate has specific bending notches—designated areas designed to tolerate stress without compromising the structural integrity of the plate. Notches provide a controlled zone where the metal can flex without distorting the screw holes.

Key Precautions During Bending:

- Only Bend at Notches: Applying force outside these notches can distort the screw holes, making it difficult to insert screws accurately and risking hardware failure.
- Avoid Repeated Bending: Repeated adjustments can cause metal fatigue, weakening the plate over time and increasing the risk of breakage.
- Do Not Bend at Screw Holes: Bending near the screw holes can misalign them, leading to:
- Improper screw placement.
- Compromised fixation strength.
- Potential hardware failure.





Step 3

Secure plate with temporary Fixation Pins

Initial Plate Positioning:

- Ensure the plate is correctly aligned with the vertebral bodies, maintaining proper lordosis and fit against the anterior spine.
- Verify the alignment with intraoperative imaging (fluoroscopy) to confirm accuracy.

Insertion of the First Temporary Fixation Pin:

- Use the Screwdriver for Insertion along with the Holding Sleeve to stabilize the plate while inserting the pin.

Pin Placement:

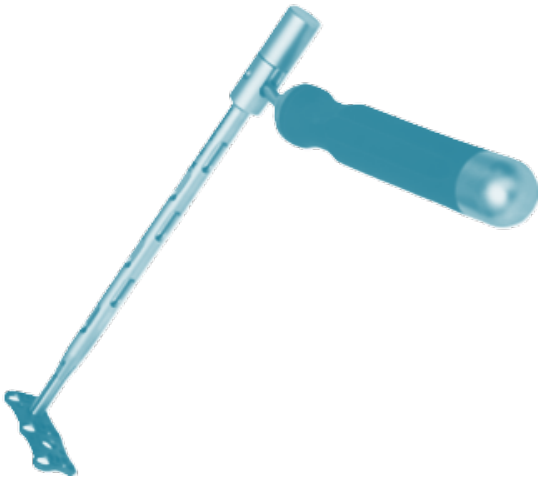
- Insert the first Fixation Pin through one of the plate's screw holes into the adjacent vertebral body.
- The pin should be directed perpendicular to the plate and securely anchored into the bone to prevent any shifting.
- The Holding Sleeve helps maintain the plate's position, providing additional control during pin insertion.

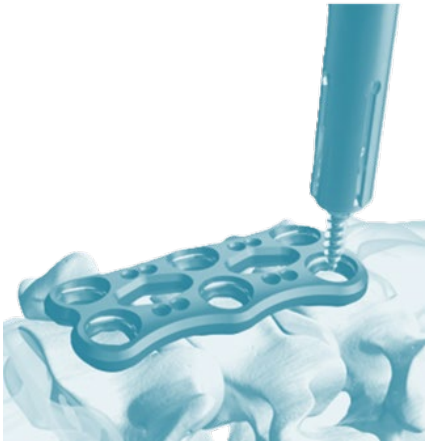
Insertion of the Second Temporary Fixation Pin:

- Insert the second Fixation Pin into the diagonally opposite hole of the plate to secure it in place.
- This diagonal placement enhances the plate's stability, reducing the risk of displacement during the final screw fixation.

Additional Temporary Fixation Pins (Optional):

- Additional Fixation Pins can be inserted into the remaining screw holes if the plate requires extra stabilization, especially in cases with challenging anatomy or poor bone quality.
- These pins act as temporary anchors, ensuring the plate remains in position until all permanent screws are secured.





Step 4

Break cortex

Identify the Correct Entry Point:

- After securing the ACP plate with temporary fixation pins, identify the screw hole directly beneath the plate, aligning with the target vertebral body.
- The entry point should be just above the anterior cortex of the vertebral body, ensuring the screw trajectory stays within the vertebral body and avoids the intervertebral disc.

Establish the Correct Screw Angle:

- The cervical vertebral bodies have a natural lordotic curvature, so the screw should follow this angle to maintain spinal alignment.
- The trajectory should be slightly antero-posterior, directed toward the posterior part of the vertebral body but avoiding the posterior cortical wall.
- Use the plate's design as a guide to maintain consistency with the cervical spine's natural curve.

Prepare the Awl:

- The awl is a sharp, pointed instrument designed to initiate the pilot hole.
- Hold the awl perpendicular to the ACP plate to maintain the correct angle relative to the vertebral body.

Positioning the Awl:

- Place the awl tip precisely at the entry point identified under the plate hole.
- Ensure the awl is aligned with the intended screw trajectory to avoid misplacement.

Breaking the Cortex:

- Apply gentle but firm downward pressure on the awl while simultaneously twisting the handle clockwise.
- The twisting motion helps the awl penetrate the dense outer cortical bone, creating an initial pilot hole.
- Key Technique: Rotate the awl slowly, maintaining steady pressure, to avoid damaging the underlying cancellous bone.

Awl Removal:

- Once the cortex is breached and the pilot hole is established, carefully remove the awl.
- Ensure the hole remains intact and aligned with the plate. The pilot hole should be clean, with minimal debris, and ready for the drill.

Fluoroscopic Check:

- Use intraoperative fluoroscopy (lateral view) to verify the awl's position within the vertebral body.
- Confirm that the pilot hole does not encroach on the intervertebral disc space or breach the posterior cortex.
- The trajectory should appear straight, with the awl tip well within the vertebral body boundaries.

Introducing the Drill Guide:

- The Drill and Screw Guide helps maintain precise alignment during drilling and screw insertion.
- Align the diamond-shaped window of the guide with the alignment post on the ACP plate. This ensures the guide is positioned correctly over the screw hole.

Engaging the Drill Guide:

- Insert the tip of the drill guide into the established pilot hole at the correct angle.
- Gently rotate the guide forward until the tip snaps into place within the clip of the plate hole.
- This "snap-in" mechanism ensures the guide is firmly engaged, preventing any slippage during drilling.

Verify Alignment:

- Use fluoroscopy again to confirm that the guide's trajectory matches the intended screw path.
- This step significantly reduces the risk of malpositioned screws, especially in cases of complex cervical anatomy.

Step 5

Drill Pilot Hole

Determine Screw Length:

- Choose a screw of appropriate length based on the thickness of the vertebral body and the intended depth of fixation.
- The screw should be long enough to provide stable fixation without breaching the posterior cortex.

Select the Drill Bit:

- Use a drill bit that matches the diameter of the selected screw to ensure a tight fit.
- The drill bit should be compatible with the drill guide for accurate alignment.

Position the Drill Guide:

- Insert the Drill Guide into the plate hole, ensuring it is aligned at the correct angle.
- The guide should be inclined appropriately, following the natural trajectory of the cervical spine and the planned screw path.
- The diamond-shaped window of the guide should be properly aligned with the alignment post on the ACP plate to maintain accuracy.

Secure the Guide:

- Confirm that the guide is stable and firmly seated in the plate hole.
- Check the alignment with fluoroscopy to ensure the guide's trajectory matches the intended screw path.

Insert the Drill Bit:

- Carefully insert the drill bit into the drill guide, ensuring it fits snugly within the guide channel.
- The drill bit should be positioned precisely at the entry point of the pilot hole.

Drill to Desired Depth:

- Gently activate the drill and advance the bit into the vertebral body.
- Drill slowly and steadily to maintain control and prevent overheating or damaging the bone.
- The drill will automatically stop when the depth stop on the drill contacts the top of the drill guide, ensuring consistent drilling depth.
- **Confirm Depth:**
- The depth stop on the drill is calibrated to the screw length, providing an accurate measure.
- If additional depth is needed, adjust the drill or use a longer bit cautiously.

Fluoroscopic Check:

- Use intraoperative fluoroscopy (lateral and AP views) to confirm the pilot hole's position and depth.
- Verify that the drill has not breached the posterior cortex or encroached on the intervertebral disc space.
- Ensure the trajectory aligns with the intended screw path.

Carefully Remove the Drill Bit:

- Gently retract the drill bit from the pilot hole, ensuring no disruption to the bone or guide alignment.

Remove the Drill Guide:

- Carefully detach the drill guide from the plate hole, maintaining the integrity of the pilot hole.
- Check that the pilot hole remains clean and well-defined, ready for screw insertion.

Precautions:

- Avoid Over-drilling: Do not drill beyond the stop mechanism, as this can cause posterior cortical breach.
- Monitor for Heat Generation: Continuous drilling can generate heat, potentially damaging the bone. Use intermittent drilling if necessary.
- Maintain Stable Position: Ensure the drill guide and plate remain stable during the procedure to prevent misalignment.
- Intraoperative Imaging: Regular fluoroscopic checks help verify proper placement and avoid complications.

Step 6

Preparation for Screw Insertion

Select the Appropriate Screw:

- Choose the correct length, based on the depth of the pilot hole and the thickness of the vertebral body.
- For long spans or cases with suboptimal bone quality, consider using longer screws or evaluating the need for posterior fixation to enhance stability.

Load the Screw:

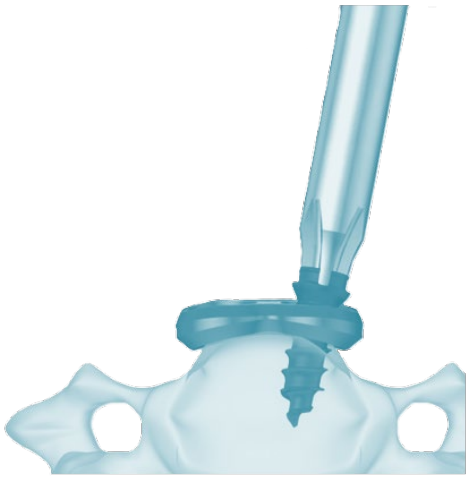
- Place the screw onto the Screwdriver for Insertion, ensuring it is securely seated in the screwdriver's tip.
- Confirm that the screw threads are clean and free from any debris that could affect insertion.

Align the Screwdriver:

- Position the screwdriver perpendicularly to the ACP plate, ensuring the screw is aligned with the pre-drilled pilot hole.
- Maintain proper alignment to prevent the screw from deviating into the intervertebral disc space or breaching the posterior cortex.

Advancing the Screw:

- Gently apply downward pressure while rotating the screwdriver to advance the screw into the vertebral body.
- The screw's self-tapping feature will allow it to cut into the bone as it advances, eliminating the need for pre-tapping in most cases.
- Continue advancing until the head of the screw is fully seated in the plate, ensuring the ACP plate is securely lagged to the bone.
- The screw should be snug, with no wobble or movement, indicating secure fixation.



- **Anatomical Considerations:**
- The cervical intervertebral discs are slightly inclined from anterocaudal to posterocranial.
- Ensure that the screw trajectory remains entirely within the vertebral body and does not penetrate the intervertebral disc space.
- There should be adequate space between the screw and the adjacent intervertebral discs to prevent complications.
- If a 4.0 mm screw strips the bone (commonly due to poor bone quality), consider switching to a 4.35 mm screw.
- The larger screw provides additional grip and stability in cases of compromised bone integrity.
- **Intraoperative Imaging:**
- Use fluoroscopic imaging to verify the screw's position in both lateral and AP views.
- Confirm that the screw is fully seated in the vertebral body, with the head flush against the plate and no cortical breach.

- **Repeat for Adjacent Screws:**
- If additional screws are required, repeat the same process for each, maintaining proper alignment and trajectory.
- **Check Plate Alignment:**
- After all screws are inserted, verify the ACP plate's alignment with fluoroscopy to ensure proper cervical lordosis and fusion setup.
- **Secure the Plate:**
- Tighten all screws uniformly to achieve balanced compression without over-tightening, which could damage the bone or plate.

Key Warnings:
- For Long Spans/Suboptimal Bone, Consider supplemental posterior fixation.
- Avoid Disc Penetration, always verify screw placement relative to the intervertebral disc.
- Bone Quality Concerns, use larger screws if necessary to enhance fixation.

Step 7

Preparation for Screw Removal

Assess the Need for Removal:

- Screw removal may be necessary if there is implant failure, misplacement, infection, or complications such as screw loosening.
- Confirm the need for removal with imaging and clinical evaluation.

Gather the Correct Instrument:

- Use the Screwdriver for Extraction, specifically designed for secure screw removal without causing damage.

Position the Driver:

- Insert the driver shaft into the screw head recess, ensuring it fits snugly without slipping.
- Confirm that the driver aligns correctly with the screw's drive mechanism

Secure the Driver:

- Tighten the knob on the handle to thread the threaded tip of the inner shaft into the mating thread of the screw.
- This action locks the driver securely into the screw head, creating a stable connection for extraction.

Advance the Sleeve:

- Turn the sleeve clockwise to advance it downward until it contacts the upper surface of the ACP plate.
- This ensures that the sleeve provides proper support and stabilization during screw removal.

- **Key Precaution:**
- Do NOT rotate the sleeve after it has made contact with the plate surface.
- This prevents undue stress on the plate and reduces the risk of damaging the implant.

Screw Extraction Process:

- Hold the Sleeve Steadily
- Maintain firm pressure on the sleeve to keep it in place while preventing any movement that could cause damage.

Rotate the Handle Counterclockwise:

- Turn the handle counterclockwise to extract the screw.
- Apply steady, controlled force to avoid stripping the screw head or damaging the driver.

Complete the Removal:

- Continue rotating until the screw is fully disengaged from the bone and can be easily removed.

Precautions and Warnings:

- A screw can typically be inserted and removed twice without compromising its integrity.
- If a screw is removed a third time, the plate must be replaced to ensure stability.
- Proper Tightening of the Knob:
- Ensure the inner shaft knob is fully tightened to the handle before attempting extraction.
- Failure to do so can result in driver breakage, posing a risk of injury to the patient.
- Avoid Misuse:
- The extraction screwdriver is for removal only.
- Using it for screw insertion can lead to driver or implant breakage.
- Intraoperative Imaging:
- Use fluoroscopy to confirm the screw's position and ensure there are no complications during extraction.

Step 8

Preparation for Plate Removal

Confirm All Screws Are Removed:

- Verify that all screws have been completely removed using the Screwdriver for Extraction.
- Check both AP and lateral fluoroscopic views to ensure no screws or fragments remain in the vertebral bodies.

Inspect the Plate:

- Confirm that the plate is not embedded in fibrous tissue or adhered to the bone.
- If there is any resistance during removal, reassess to ensure no hidden screws are still attached.

Grasp the Plate:

- Use a plate removal instrument or forceps to securely grasp the ACP plate.
- Ensure a firm grip to prevent the plate from slipping or causing unintended soft tissue injury.

Gently Lift the Plate:

- Apply gentle, controlled force to lift the plate away from the vertebral bodies.
- If the plate is resistant, avoid using excessive force, as this could damage the bone or soft tissues.

Use a Plate Removal Tool (if needed):

- If the plate is firmly adhered to the bone, a plate remover instrument with a prying edge can be used to gently dislodge it.
- Carefully insert the tool under the plate and lever it upward while maintaining support on the surrounding bone.

Minimize Soft Tissue Disruption:

- Carefully navigate around any adherent soft tissue, ensuring not to damage the prevertebral fascia, muscle attachments, or vascular structures.

Bone Surface Inspection:

- After plate removal, inspect the vertebral bodies for any damage, osteolysis, or residual hardware fragments.
- If bone integrity is compromised, consider additional stabilization or consult for posterior fixation if needed.

Check for Remaining Debris:

- Ensure no screws, fragments, or debris remain in the surgical field.
- Irrigate the area thoroughly with sterile saline to clear any residual material.

Inspect the Surgical Site:

- Verify that the cervical spine maintains proper alignment after plate removal.
- Assess for any hematoma formation or signs of vascular compromise.
- Close the prevertebral fascia, subcutaneous tissue, and skin in layers, following standard surgical closure techniques.

Precautions and Warnings

- Avoid Excessive Force:
- Never force the plate off if there is resistance—this may cause bone fractures or soft tissue damage.
- Monitor for Vascular Structures:
- Be cautious around the carotid artery, jugular vein, and recurrent laryngeal nerve during plate removal.
- Consider Post-Operative Imaging:
- Obtain post-removal X-rays to confirm that the cervical spine alignment is intact and that no hardware remnants remain.

Instruments

RVPACP01 - ACP - Awl

RVPACP02 - ACP - Adjustable
Drill Guide 13mm.

RVPACP03 – ACP Camlock Screw Driver.

RVPACP04 - ACP - Plate Bender

RVPACP05 - ACP - Plate Holder.

RVPACP06 - ACP - Quick Change Handle

RVPACP07 - ACP – Tap

RVPACP08 - ACP - 2.5mm Drill Shaft.

RVPACP10 - ACP - Locking Screwdriver.

RVPACP11 – ACP – Pin Holding Driver.

RVPACP12 - ACP - Pins SW 2.5

Implants

Kentrospine ACP 1 Level - 14.0mm	ROACP1140
Kentrospine ACP 1 Level - 16.5mm	ROACP1165
Kentrospine ACP 1 Level - 19.0mm	ROACP1190
Kentrospine ACP 1 Level - 21.5mm	ROACP1215
Kentrospine ACP 1 Level - 24.0mm	ROACP1240
Kentrospine ACP 2 Level - 26.5mm	ROACP2265
Kentrospine ACP 2 Level - 29.0mm	ROACP2290
Kentrospine ACP 2 Level - 31.5mm	ROACP2315
Kentrospine ACP 2 Level - 34.0mm	ROACP2340
Kentrospine ACP 2 Level - 36.5mm	ROACP2365
Kentrospine ACP 2 Level - 41.5mm	ROACP2415
Kentrospine ACP 3 Level - 45.5mm	ROACP3455
Kentrospine ACP 3 Level - 51.5mm	ROACP3515
Kentrospine ACP 3 Level - 57.5mm	ROACP3575
Kentrospine ACP 3 Level - 63.5mm	ROACP3635
Kentrospine ACP 3 Level - 69.5mm	ROACP3695
Kentrospine ACS Screw - Ø4.35mm X 12mm	ROACS4512
Kentrospine ACS Screw - Ø4.35mm X 14mm	ROACS4514
Kentrospine ACS Screw - Ø4.35mm X 16mm	ROACS4516
Kentrospine ACS Screw - Ø4.35mm X 18mm	ROACS4518
Kentrospine ACS Screw - Ø4mm X 12mm	ROACS4012
Kentrospine ACS Screw - Ø4mm X 14mm	ROACS4014
Kentrospine ACS Screw - Ø4mm X 16mm	ROACS4016
Kentrospine ACS Screw - Ø4mm X 18mm	ROACS4018

Indications and Contraindications

Indications, contraindications and possible adverse events:

Indications for use:
The Kentrospine Plate System (ACP Anterior cervical Plate with ACS screw) is intended for anterior fixation of the cervical spine C2-C7. The system is indicated for use in temporary stabilization of the anterior spine during the development of cervical spinal fusion in patients with the following indications:

- Degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies),
- trauma (including fractures),
- tumors,
- deformity (defined as kyphosis, lordosis, or scoliosis),
- pseudarthrosis,
- failed previous fusion,
- spondylolisthesis, and spinal stenosis.

Contraindications:
Use of this system is contraindicated in patients with the following conditions:

- Active systemic infection, infection localized to the site of the proposed implantation, or when the patient has demonstrated allergy or foreign body sensitivity to any of the implant materials.
- Severe osteoporosis, which may prevent adequate fixation.
- Conditions that may place excessive stresses on bone and implants, such as severe obesity or degenerative diseases, are relative contraindications. The decision whether to use these devices in such conditions must be made by the physician taking into account the risks versus the benefits to the patient.
- Patients whose activity, mental capacity, mental illness, alcoholism, drug abuse, occupation, or lifestyle may interfere with their ability to follow postoperative restrictions and who may place undue stresses on the implant during bony healing and may be at a higher risk of implant failure.
- Any condition not described in the indications for use

WARNINGS:

- One of the potential risks identified with this system is death. Other potential risks, which may require additional surgery, include device component fracture, loss of fixation, non-union, fracture of the vertebrae, neurological injury.
- This device is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.
- Certain degenerative diseases or underlying physiological conditions such as diabetes, rheumatoid arthritis, or osteoporosis may alter the healing process, thereby increasing the risk of implant breakage or spinal fracture.
- Possible adverse effects that may occur include: failed fusion or pseudarthosis leading to implant breakage; allergic reaction to implant materials; device fracture or failure; device migration or loosening; decrease in bone density; pain, discomfort, or abnormal sensations due to the presence of the device; injury to nerves, vessels, and organs; venous thrombosis, lung embolism and cardiac arrest; and death.
- The components of this system are manufactured from titanium alloy. Dissimilar metals in contact with each other can accelerate the corrosion process due to galvanic corrosion effects. Mixing of implant components with different materials is not recommended, for metallurgical, mechanical, and functional reasons.
- Plate contouring is not recommended due to the plate's translational components. These warnings do not include all adverse effects which could occur with surgery in general, but are important considerations particular to orthopedic implants.
- General surgical risks should be explained to the patient prior to surgery.

PRECAUTIONS

- The implantation of screw and plate systems should be performed only by experienced spinal surgeons with specific training in the use of this system because this is a technically demanding procedure presenting a risk of serious injury to the patient. Preoperative planning and patient anatomy should be considered when selecting implant size, screw diameter and length.
- Surgical implants must never be reused. An explanted implant must never be reimplanted. Even though the device appears undamaged, it may have small defects and internal stress patterns, which could lead to breakage.
- Metallic implants can loosen, fracture, corrode, migrate, cause pain, or stress shield bone even after a fracture has healed particularly in young, active patients. While the surgeon must have the final decision on implant removal, we recommend that
- Whenever possible and practical for the individual patient, fixation devices should be removed once their service as an aid to healing is accomplished. Implant removal should be followed by adequate postoperative management.
- Adequately instruct the patient. Mental or physical impairment that compromises or prevents a patient's ability to comply with necessary limitations or

precautions may place that patient at a particular risk during postoperative rehabilitation.

- Factors such as the patient's weight, activity level, and adherence to weight bearing or load bearing instructions have an effect on the stresses to which the implant is subjected.

- "The implantation of Kentrospine Plate System should be performed only by experienced spinal surgeons with specific training in the use of this plate 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.

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:

- 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 centers 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.