INSTRUCTIONS FOR USE (IFU)

Rivarp Medical Pvt.Ltd
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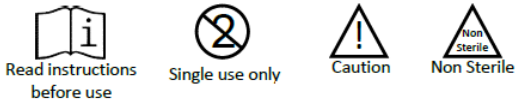

Kentrospine PCF screw system

Device description:
The Kentrospine PCF Screw System is a top-loading multiple component, posterior spinal fixation system which consists of PCF Screw.
The Kentrospine PCF Screw System will allow surgeons to build a spinal implant construct to stabilize and promote spinal fusion. Kentrospine PCF Screw System components are supplied non-sterile and to be sterilized by end user, single use and are made from medical grade, biocompatible Titanium alloy (Ti6Al4V ELI) conforming to ASTM F136-13(2021)- Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications. Various sizes of these implants are available.
Specialized instruments are available for the application and removal of the Kentrospine PCF Screw System. The instruments are made from SAE 316L stainless steel which is complies to ASTM F899 – 20 Standard Specification for Wrought Stainless Steels for Surgical Instruments.

The PCF Screws are available in diameters from Ø4.25 , 4.5 , 4.75 , 5.5 , 6.5 , 7.0 , 7.20 & Ø7.50mm lengths –25mm , 30 , 35 , 40 , 45 , 50 & 55mm Kentrospine- PCF Polyaxial Shank screw available in diameters from Ø 3.5 & 4.0 mm lengths –22 , 24 , 26 , 28 , 30 , 32 , 34 , 36, 38mm.

Indications, contraindications and possible adverse events:

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,

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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 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 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 imp lants 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.

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All Rivarp's system is
manufactured in metallic material and does not emit any io nizing radioactive radiation.

Other preoperative, intraoperative, and postoperative warnings and precautions are as follows:
Implant selection:
The selection of the proper size, shape and design of the implant for each patient is crucial to the success of the procedure. Metallic surgical implants are subject to repeated stresses in use, and their strength is limited by the need to adapt the design to the size and shape of human bones. Unless great care is taken in patient selection, proper placement of the implant, and postoperative management to minimize stresses on the implant, such stresses may cause metal fatigue and consequent breakage, bending or loosening of the device before the healing process is complete, which may result in further injury or the need to remove the device prematurely.

Preoperative:

1. Only patients that meet the criteria described in the indications should be selected.
2. Patient conditions and/or pre dispositions such as those addressed in the aforementioned contraindications should be avoided.
3. Care should be used in the handling and storage of the implant components. The implants should not be scratched or otherwise damaged. Implants and instruments should be protected during storage, especially from corrosive environments.

An adequate inventory of implants should be available at the time of surgery, normally a quantity in excess of what is expected to be used.

5. Since mechanical parts are involved, the surgeon should be familiar with the various components before using the equipment and should personally assemble the devices to verify that all parts and necessary instruments are present before the surgery begins.
6. The Kentrospine PCF Screw System components (described in the DEVICE DESCRIPTION section) are not to be combined with the components from another manufacturer.
7. All components and instruments should be cleaned and sterilized before use. Additional sterile components should be available in case of an unexpected need.

Intraoperative:

1. Extreme caution should be used around the spinal cord and nerve roots. Damage to the nerves will cause loss of neurological functions.
2. Breakage, slippage, or misuse of instruments or implant components may cause injury to the patient or operative personnel.
3. The rods should not be repeatedly or excessively bent. The rods should not be reverse bent in the same location. Use great care to insure that the implant surfaces are not scratched or notched, since such actions may reduce the functional strength of the construct. If the rods are cut to length, they should be cut in such a way as to create a flat, non-sharp surface perpendicular to the midline of the rod. Cut the rods outside the operative field. Whenever possible, use pre-cut rods of the length needed.
4. Utilize an imaging system to facilitate surgery.
5. To insert a Screw properly, a guide wire should first be used, followed by a sharp tap. Caution: Be careful that the guide-wire, if used, is not inserted too deep, becomes bent, and/or breaks. Ensure that the guide-wire does not advance during tapping or Screw insertion. Remove the guide-wire and make sure it is intact. Failure to do so may cause the guide wire or part of it to advance through the bone and into a location that may cause damage to underlying structures.

Caution: Do not over tap or use a Screw /bolt that is either too long or too large. Over tapping, using an incorrectly sized Screw /bolt, or accidentally advancing the guidewire during tap or Screw /bolt insertion, may cause nerve damage, hemorrhage, or the other possible adverse events listed elsewhere in this package insert.

8. Bone graft must be placed in the area to be fused.
9. Before closing the soft tissues, provisionally tighten (finger tighten) all of the nuts or Screw s, especially Screw s or nuts that have a break-off feature. Once this is completed go back and firmly tighten all of the Screw s and nuts. Recheck the tightness of all nuts or Screw s after finishing to make sure that none loosened during the tightening of the other nuts or Screw s. Failure to do so may cause loosening of the other components.

Postoperative:

1. The physician's postoperative directions and warnings to the patient, and the corresponding patient compliance, are extremely important.
2. Detailed instructions on the use and limitations of the device should be given to the patient. If partial weight-bearing is recommended or required prior to firm bony union, the patient must be warned that bending, loosening and/or breakage of the device(s) are complications which may occur as a result of excessive or early weight-bearing or muscular activity. The risk of bending, loosening, or breakage of a temporary internal fixation device during postoperative rehabilitation may be increased if the patient is active, or if the patient is debilitate demented. The patient should be warned to avoid falls or sudden jolts in spinal position.
3. To allow the maximum chances for a successful surgical result, the patient or devices should not be exposed to mechanical vibrations or shock that may loosen the device construct. The patient should be warned of this possibility and instructed to limit and restrict physical activities, especially lifting and twisting motions and any type of sport participation. The patient should be advised not to smoke tobacco or utilize nicotine products, or to consume alcohol or non-steroidals or anti-inflammatory medications such as aspirin during the bone graft healing process.

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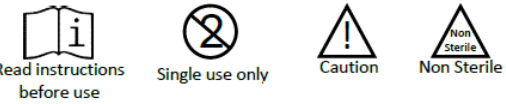

4. The patient should be advised of their inability to bend or rotate at the point of spinal fusion and taught to compensate for this permanent physical restriction in body motion.

5. Failure to immobilize a delayed or non-union of bone will result in excessive and repeated stresses on the implant. By the mechanism of fatigue, these stresses can cause the eventual bending, loosening, or breakage of the device(s). It is important that immobilization of the spinal surgical site be maintained until firm bony union is established and confirmed by roentgenographic examination. If a state of nonunion persists or if the components loosen, bend, and/or break, the device(s) should be revised and/or removed immediately before serious injury occurs. The patient must be adequately warned of these hazards and closely supervised to insure cooperation until bony union is confirmed.

6. As a precaution, before patients with implants receive any subsequent surgery (such as dental procedures), prophylactic antibiotics may be considered, especially for high-risk patients.

7. The Kentrospine PCF Screw System implants are temporary internal fixation devices. Internal fixation devices are designed to stabilize the operative site during the normal healing process. After the spine is fused, these devices serve no functional purpose and may be removed. While the final decision on implant removal is, of course, up to the surgeon and patient, in most patients, removal is indicated because the implants are not intended to transfer or support forces developed during normal activities. If the device is not removed following completion of its intended use, one or more of the following complications may occur: (1) Corrosion, with localized tissue reaction or pain; (2) Migration of implant position, possibly resulting in injury; (3) Risk of additional injury from postoperative trauma; (4) Bending, loosening and breakage, which could make removal impractical or difficult; (5) Pain, discomfort, or abnormal sensations due to the presence of the device; (6) Possible. increased risk of infection; (7) Bone loss due to stress shielding; and (8) Potential unknown and/or unexpected long term effects such as carcinogenesis. Implant removal should be followed by adequate postoperative management to avoid fracture, re-fracture, or other complications.

8. Any retrieved devices should be treated in such a manner that reuse in another surgical procedure is not possible. As with all orthopedic implants, the Kentrospine PCF Screw System components should never be reused under any circumstances.

Packaging:
Packages for each of the components should be intact upon receipt. If a loaner or consignment system is used, all sets should be carefully checked for completeness and all components including instruments should be carefully checked to ensure that there is no damage prior to use. Damaged packages or products should not be used, and should be returned to Rivarp Medical Private Limited.

Disposal:
Please note that using a single use device (SUD) which comes into contact with human blood or tissue constitutes, it is a biohazard. Dispose it in a safe manner by hospital or disposed by authorize disposer having Pollution control board clearance.

Clinical Evaluation of Spinal Implants
The Rivarp Medical Pvt. Ltd. Spinal Implant is clinically safe, and effective in use as discussed and proved up to the mark in the clinical evaluation of the device.

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.

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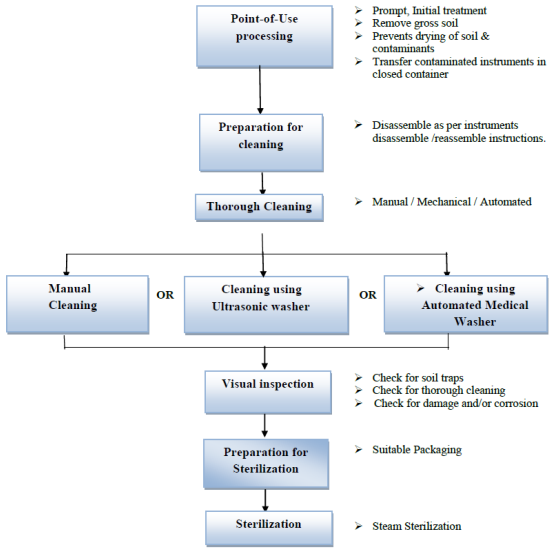
Reprocessing Overview:
The sequence of steps required to prepare non-sterile instruments for use are summarized in the chart below. More detailed instructions for each step are given on the following pages.



Cleaning Instructions:

- The Kentrospine PCF Screw instruments must be cleaned thoroughly prior to sterilization.
- The cleaning process is the first step in effectively reprocessing devices. Adequate sterilization depends on thoroughness of cleaning.
- Any unused, single-use device that has been exposed to blood, bone, tissue, or body fluids must not be reprocessed and must be discarded.

- Multi-component instruments should be disassembled for cleaning. Disassembly, where necessary, is generally self-evident. More specific instructions can be found in below section. (Instruments disassemble & reassemble instructions for cleaning) care must be taken to avoid losing small parts. If a part is lost, notify your Rivarp Medical representative when the instrument set is returned.
- Complex instruments, such as those with, cannulas, hinges, retractable features, mated surfaces, and textured surface finishes, require special attention during cleaning. Brush tight tolerance areas with an appropriately sized brush and flush using a water jet or syringe where debris could become trapped.
- Ensure all moving parts of instruments are cleaned at both extents of travel.
- Handle all products with care. Mishandling may lead to damage and possible improper functioning.
- Use of caustic solutions (caustic soda) will damage the devices.
- Visually inspect each instrument for deterioration such as corrosion and worn components; ensure that the laser markings are legible and verify that all actuating parts move freely.
- Visual inspection must be performed at each cleaning to determine if an instrument is acceptable for use. If an instrument is not acceptable for use, return to the manufacturer.
- Visually inspect the instrument after each cleaning step to ensure the instrument is clean. If not clean, repeat the steps until clean.

Note:

- The information on cleaning agent concentration, temperature, exposure time and cycles used in the equipments, follow the instructions for use and labels according to products manufacturer.
- The cleaning agents should be prepared at the use-dilution and temperature recommended by the manufacturer. Use of recommended temperatures is important for optimal performance of cleaning agents.
- The cleaning and sterilization processes mentioned in this IFU have been validated and demonstrate that soil and contaminants have been removed leaving the devices effectively free of viable microorganisms.
- As not all cleaning agents may be available around the globe, Rivarp Medical does not recommend any specific cleaning agent. The end user should verify the selected cleaning agent is appropriate for use on surgical instruments designed for reprocessing.

5. Cleaning Agent used during the validation of these reprocessing instructions is Neodisher® MediClean forte (CE certified).

6. Reusable cleaning tools, as the bristles wear from constant use, the efficacy of these tools can greatly diminish, so the tools will need to be inspected and replaced on a regular basis. If possible use the single-use disposable cleaning tools.

Cleaning steps:
1. Point-of-Use Processing:

- At point of use, soiled instruments must be removed from trays and moistened to prevent debris from drying before transportation to the reprocessing area for cleaning procedures. Do not clean soiled instruments while in trays.
- Remove excess body fluids and tissue from instruments with a disposable, non-shedding wipe. Place devices in a basin of distilled water or in a tray covered with damp towels. Do not allow saline, blood, body fluids, tissue, bone fragments

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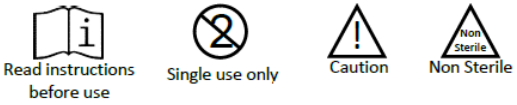

or other organic debris to dry on devices prior to cleaning.
- For optimal results, instruments should be cleaned within 20 minutes of use or after removal from solution to minimize the potential for drying prior to cleaning.
- Used instruments must be transported to the designated cleaning area in closed or covered containers to prevent unnecessary contamination risk.

2. Thorough Cleaning:

- The device should be thoroughly cleaned after the point-of-use processing. Generally, thorough cleaning is done in a designated cleaning area.

3. Preparation for cleaning:

- Multi-component instruments should be disassembled for cleaning. Disassembly, where necessary, is generally self-evident. More specific instructions can be found in below section, 'Instruments Disassemble & Reassemble instructions for Cleaning'.

4. Method of cleaning:
Manual cleaning:

- Rinse soiled instruments under running cold tap water for a minimum of one minute. Remove gross soil and debris using a soft bristled, nylon brush.
- Completely submerge the instruments in enzymatic cleaning solution (1% neodisher® MediClean forte for example) at temperature range of 30°C to 40°C and allow to soak

- for 15 minutes. (**Note**: The cleaning agents should be prepared at the use-dilution and temperature recommended by the manufacturer, hence refer to the cleaning agent labeling for preparation and use instructions).
- Use a soft nylon-bristled brush to gently scrub the devices for a minimum of two minutes and until all visible soil has been removed. Particular attention must be given to crevices, lumens, mated surfaces, connectors and other hard-to-clean areas. Lumens should be cleaned with a long, narrow, soft nylon-bristled brush (i.e. Pipe cleaner).
- Rinse in deionized water until all traces of cleaning solution are removed.
- Visually inspect for any remaining soil and repeat the steps above if necessary.
- Allow to drain on absorbent paper and dry with a clean soft lint free cloth or with filtered-compressed air.

Note:

- Instruments must be removed from the trays or cases and place them in a suitable basket during the cleaning.
- Use of a syringe or water jet will improve flushing of difficult to reach areas and closely mated surfaces.

Caution: Never use metal brushes or steel wool for cleaning.

Cleaning using Ultrasonic washer:

- Rinse soiled instruments under running cold tap water for a minimum of one minute to remove excess soil.
- Completely submerge the instruments in enzymatic cleaning solution (1% neodisher® MediClean forte for example) in ultrasonic washer and sonicate for 15 minutes at 40+/-5 kHz using ultrasonic bath large enough to allow complete immersion of the device. Instruments must be removed from the trays or cases during the cleaning.
- Remove instruments from the cleaning solution and rinse in deionized water for a minimum of 5 minute.
- Thoroughly and aggressively flush lumens, blind holes and other difficult-to-reach areas with deionized water and dry with a clean soft lint free cloth or with filtered-compressed air.

Note: Visually inspect for any remaining soil. If, after completion of the cleaning step in the ultrasonic bath, encrusted soil remains on the device, the cleaning step must be repeated as described above.

Automated cleaning using Medical Washer:

- Rinse soiled instruments under running cold tap water for a minimum of one minute to remove excess soil.
- Load the instruments into the medical washer as per required loading configuration and maximum load size as specified by machine manufacturer.

- (**Note:** Operate the Medical Washer cycle as per machine manufacturer instructions and refer to the cleaning agent labeling for preparation and use instructions).

Steps	Time	Temperature	Cleaning agent
Pre Wash	2 minutes	45°C	Tap water
Cleaning	10 minutes	55°C	Enzymatic cleaner (0.5% neodisher® MediClean forte for example)
Neutralization	2 minutes	45°C	Tap water
Rinsing	5 minutes	45°C	Deionized water
Drying	25 minutes	80°C	N/A

- Upon completion, unload the medical washer.
- Visually inspect each device for remaining soil and dryness. If soil remains, repeat the cleaning process.
- Remaining wetness may be removed with filtered, compressed air or clean, lint-free wipes.

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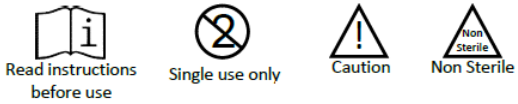


Note: The Medical washer manufacturer's instructions should be strictly adhered to.

Visual Inspection:

- Before preparing for sterilization, all devices should be inspected carefully. Generally un-magnified visual inspection under good light conditions is sufficient to ensure that all visible contamination has been removed. If contamination is noted repeat the cleaning process.
- Visually inspect for completeness, damage and/or excessive wear and tear of components. **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.
- If necessary, hinged, rotating, or articulating instruments can be lubricated with a water soluble, biocompatible, medical grade , steam sterilizable lubricant intended for surgical instruments (neodisher IP Spray for example). The implants should not be lubricated.

Note: Refer to the lubricating agent labeling for preparation and use instructions.Lubricants not specifically designed for compatibility with steam sterilization should not be used because they may: 1) coat microorganisms; 2) prevent direct contact of the surface with steam; and 3) are difficult to remove.

Sterilization:

- The Kentrospine PCF Screw System implants & instruments are provided non-sterile and must be sterilized before use.
- Rivarp medical recommends that, Kentrospine PCF Screw System implants & instruments must be sterilized by the moist heat/steam sterilization, using below mentioned validated parameters.
- The hospital is responsible for sterilization before surgery. The sterilization procedures as well as the quality and the training of staff involved in this process is sole responsibility of the health service

Packaging for sterilization:

- Before sterilization, the devices (Instruments/Implants) should be placed in the Kentrospine PCF Screw System instruments trays/ implant trays respectively. The tray must be packaged in a standard medical grade, steam sterilization wrap using the AAMI double wrap method or equivalent and sterilize as per given validated steam sterilization parameters.
- Note: Instruments can be packed individually and can sterilize using above mentioned packaging & sterilization method.
- Ensure that the wrap is large enough to contain the implant / instrument tray without stressing or tearing the wrap.
- The sterilization wrap used should be FDA cleared and compliant to ISO 11607-1.

Steam Sterilization Cycle:

- See below table for recommended validated sterilization parameters.

Method	Cycle	Temperature	Exposure time	Minimum drying time[1]
Steam	Gravity displacement	250°F (121°C)	30 minutes	15-30 minutes

The product must be wrapped with a Medical grade steam sterilization compatible wrap that is FDA cleared and compliant to ISO 11607-1.

- Because of the many variables involved in sterilization, each medical facility should calibrate and verify the sterilization process (e.g. temperatures, times) used for their equipment.
- Sterilizer manufacturer recommendations should always be followed. When sterilizing multiple instrument sets in one sterilization cycle, ensure that the manufacturer's maximum load is not exceeded. Instrument cases should not be stacked during steam sterilization.
- Additional information regarding sterilization are described in ISO 17665-1-"Sterilization of health care products -- Moist heat -- Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices".
- Instruments / implants should be properly prepared and packaged in trays that will allow steam to penetrate and make direct contact with all surfaces.
- 1Drying times vary according to load size and should be increased for larger loads.

Note:

- Kentrospine PCF Screw instruments generally have a long service life; however, mishandling or inadequate protection can quickly diminish their life expectancy. Great care must be taken of the instruments to ensure that they remain in good working order.
- Devices which no longer perform properly because of long use, mishandling, or improper care should be returned to Rivarp Medical to be discarded. Notify your Rivarp Medical representative of any instrument problems.
- Kentrospine PCF Screw instruments should be examined for wear or damage by physicians and staff in operating centres prior to surgery.
- The examination shall include a visual and functional inspection of the working surfaces, articulation points, rotating features, hinges,

springs, connection mechanisms, mating parts, cutting features, threads, and working tip of all instruments.

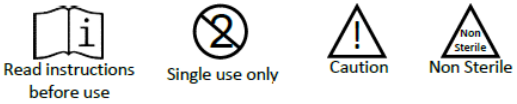
Instruments disassemble & reassemble instructions for cleaning:

- 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.

Product complaints:

Any Health Care Professional (e.g., customer or user of this system of products), who has any complaints or who has experienced any dissatisfaction in the product quality, identity, durability, reliability, safety, effectiveness and/or performance, should notify the distributor and Rivarp Medical Private Limited. Further, if any of the implanted

INSTRUCTIONS FOR USE (IFU)



spinal system component(s) ever “malfunctions,” (i.e., does not meet any of its performance specifications or otherwise does not perform as intended), or is suspected of doing so, the manufacturer / distributor should be notified immediately. **If any Rivarp Medical’s product ever “malfunctions” and may have caused or contributed to the death or serious injury of a patient, same should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established by telephone, or written correspondence.** When filing a complaint, please provide the component(s) name and number, lot number(s), your name and address, the nature of the complaint and notification of whether a written report from the distributor is requested.

Summary of Safety and Clinical Performance:

The link to Summary of Safety and Clinical Performance (S SCP) will be updated in this Instructionsfor Use when the S SCP will be made available to the EUDAMED Database.

For Further Information:

Please contact Rivarp Medical Pvt.Ltd., in case of any Query, Complain or Adverse Effect Email: info@rivarpmedical.pvt.ltd , Tel (+91) 9739735550

NON STERILE	**Non-Sterile** Indicating that the device has not been sterilized.
	Consult Instructions For Use Note: This symbol advises the reader to consult the operating instructions for information needed for the proper use of the device.
	Do not re-use Single use or use only once
REF	**Catalogue Number** Note: This symbol be accompanied by the catalogue number relevant to the device bearing the symbol.

Rivarp Medical Pvt.Ltd
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Email: info@rivarpmedical.com
Website: www.rivarpmedical.com

LOT	**Batch Code** Note: This symbol should be accompanied by the batch code relevant to the device bearing the symbol.
	Caution This symbol is to denote that there some warning or precautions associated with device, which are not otherwise found on labels
Material	Raw Material used for manufacturing
CE XXXX	CE marking with Notified Body Number (This symbol shall be used only after completion of conformity assessment & availability of valid CE certificate)
MD	Medical device Indicates the item is a **medical device**
Rx	Rx is the symbol for a medical prescription.

EC REP	**Advena Ltd. Tower Business Centre, 2nd Flr., Tower Street, Swatar, BKR 4013 Malta**
	Manufacturer: Rivarp Medical Pvt.Ltd No:34, Azeez Sait Industrial town, 6th mile, Mysore Road, Nayandahalli, Bangalore -560039 Karnataka.Tel: +91 973 973 5550 Email: info@rivarpmedical.com Website: www.rivarpmedical.com