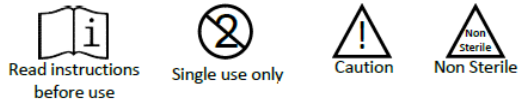
INSTRUCTIONS FOR USE (IFU)

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



Kentrospine TLIF Lumbar interbody fusion cage system

Device Description:

The Kentrospine TLIF are designed for **transforminal lumbar approach.** These are available in both PEEK and titanium material.

The Kentrospine TLIF Lumbar interbody fusion cage which provides mechanical stability whilst facilitating optimized conditions for fusion in patients with degenerative Disc Diseases (DDD). These are available in numerous footprints, heights, and sagittal profiles to accommodate various patient anatomies.

The Kentrospine TLIF Lumbar interbody fusion cage system will allow surgeons to build a spinal implant construct to stabilize and promote inter-body spinal fusion. TLIF cage system implant 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. & PEEK (Polyetheretherketone) according to ASTM F 2026. Various sizes of these implants are available.

Specialized instruments are available for the application and removal of the Kentrospine TLIF Lumbar interbody fusion cage. 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.

Indications, contraindications and possible adverse events:

Indications for use:

Kentrospine Lumbar interbody fusion cage is indicated for use in posterior lumbar interbody fusion in patients with degenerative Disc Diseases (DDD) at one or two levels from L2 to S1.These DDD patients may also have up to Grade 1 Spondylolisthesis or retrolisthesis at the involved levels.

DDD is defined as disco genic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of Non-operative treatment. Additionally, the lumbar cage is indicated to assist in the setting of spinal deformity as a supplement to pedicle screw fixation in patents diagnosed with degenerative scoliosis.

The Kentrospine TLIF implants are designed for **transforminal lumbar approach.** These are available in both PEEK and titanium material.

Contraindications:

- Use of the Kentrospine TLIF cage implant is contraindicated when there is 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 may prevent adequate fixation and thus preclude the use of this or any other orthopaedic implant.
- 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 patients with such conditions must be made by the physician, taking into account the risks versus the benefits to the patient.
- Use of these implants is relatively contraindicated in patients whose activity, mental capacity, mental illness, alcoholism, drug abuse, occupation, or lifestyle may interfere with their ability to follow postoperative instructions. The patients may place undue stresses on the implant during bony healing and may be at higher risk of implant failure.
- Prior fusion at the level(s) to be treated.
- Any condition not described in the indications for use.

Potential adverse events:

As with all major surgical procedures, risks, side effects and adverse events can occur. While many possible reactions may occur, some of the most common may include:

Problems resulting from anesthesia and patient positioning (e.g. nausea, vomiting, dental injuries, neurological impairments, etc.), thrombosis, embolism, infection, excessive bleeding, iatrogenic neural and vascular injury, damage to soft tissues incl. swelling, abnormal scar formation, functional impairment of the musculoskeletal system, Sudeck's disease, allergy/hypersensitivity reactions, side effects associated with implant or hardware prominence, malunion, non-union, ongoing pain; damage to adjacent bones, discs, or soft tissue, dural tear or spinal fluid leak; spinal cord compression and/or contusion, partial displacement of the graft, vertebral angulation.

Warning and precautions:

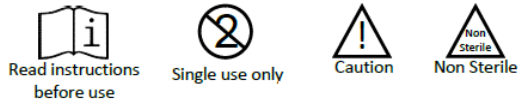
Warning:

Preoperative:

- Emphasis on the qualifications of the surgeon who should perform the TLIF implantation, highlighting the need for familiarity with spinal

INSTRUCTIONS FOR USE (IFU)

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



surgery challenges and mastery of specific surgical techniques.
- Recommendation that implantation should strictly adhere to the recommended surgical procedure instructions to mitigate risks.
- The responsibility lies with the surgeon to ensure the procedure is conducted correctly, underscoring the importance of preoperative planning and adherence to surgical protocols.
- Importance of surgeon qualifications, adherence to surgical protocols, and responsibility for ensuring proper implantation planning to mitigate risks.

Intraoperative:
- The surgeon's role in executing the procedure correctly according to specified guidelines, with a disclaimer from the manufacturer regarding liability for certain complications.
- Instructions for surgeons to implant TLIF according to the recommended surgical procedure.
- The manufacturer explicitly states their non-responsibility for complications arising from factors such as incorrect diagnosis, inappropriate implant choice, mismatched implant components, errors in surgical technique, limitations in treatment methods, or inadequate sterile techniques.
- Focus on precise execution of the surgical procedure by the surgeon to minimize risks associated with these factors during implantation.

Postoperative:
- There is no specific postoperative information provided in the excerpt. Typically, postoperative care would involve monitoring the patient's recovery, managing pain, assessing for complications related to the surgery, and ensuring proper healing and fusion if applicable.
- postoperative care would involve monitoring recovery and managing any complications that may arise after surgery.

PRECAUTION:

Precautions for the TLIF cages implant involve ensuring that only experienced spinal surgeons familiar with its specific techniques perform the procedure. Adherence to the manufacturer's recommended surgical instructions is essential to minimize risks such as incorrect implantation, surgical errors, or inadequate sterilization, for which the manufacturer disclaims responsibility. The implant must always be used in conjunction with posterior fixation to ensure spinal stability. Careful patient selection based on the device's indications (e.g., lumbar pathologies requiring fusion) and contraindications (e.g., vertebral fractures, spinal tumors) is crucial to mitigate potential complications. General surgical risks, including anesthesia-related issues, infection, bleeding, and neural or vascular injuries, should also be considered and managed appropriately during TLIF implantation procedures.

“The implantation of Kentrospine TLIF Cage System should be performed only by experienced spinal surgeons with specific training in the use of this cage 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.

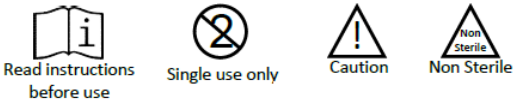
MRI Safety Information:

The Kentrospine TLIF Cage System is manufactured from Titanium alloy (Ti6Al4V ELI), hence it do not pose any safety risk.

“The Kentrospine TLIF Cage System System has not been evaluated for safety in the MR environment. It has not been tested for heating or unwanted movement in the MR environment. The safety of Kentrospine DGEN Pedicle Screw System in the MR environment is unknown. Performing an MR exam on a person who has this medical device may result in injury or device malfunction”.
On the basis of literature study, The minimum recommended time after the implantation that allows patients to safely undergo MRI examination or allowing the patient or an individual to enter the MRI environment is 6 (six) weeks.

INSTRUCTIONS FOR USE (IFU)

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



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

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.

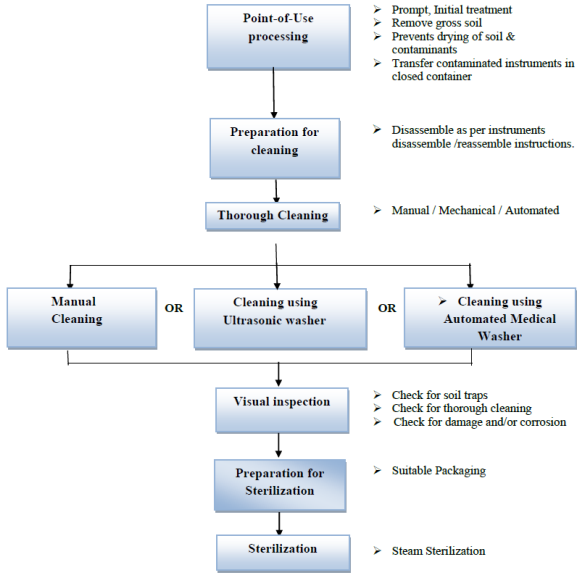
Packaging:
Packages for each of the components should be intact upon receipt. If a loaner or consignment system is used, all sets should be carefully checked for completeness and all components including instruments should be carefully checked to ensure that there is no damage prior to use. Damaged packages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

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.

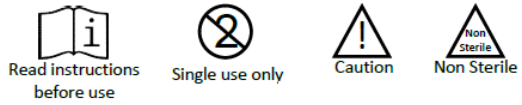


Cleaning Instructions:

- The Kentrospine TLIF Cage System 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.

INSTRUCTIONS FOR USE (IFU)

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



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

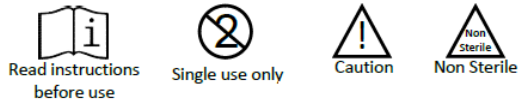
- Multi-component instruments should be disassembled for cleaning. Disassembly, where necessary, is generally self-evident. More specific instructions can be found in below section, 'Instruments Disassemble & Reassemble instructions for Cleaning'.

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).

INSTRUCTIONS FOR USE (IFU)

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



- 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.

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

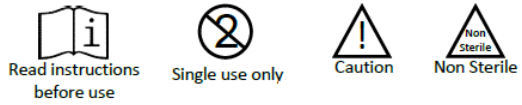
Visual Inspection:

- 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 labelling 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.

INSTRUCTIONS FOR USE (IFU)

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



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

Sterilization:

- The Kentrospine TLIF Cage System implants & instruments are provided non-sterile and must be sterilized before use.
- Rivarp medical recommends that, Kentrospine TLIF Cage 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 TLIF Cage 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.

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 TLIF Cage System 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 TLIF Cage System 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.

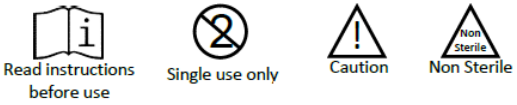
INSTRUCTIONS FOR USE (IFU)

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

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 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.
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