RETROPSOAS

EARP Nerve Cuff Electrode and EARP Interbody System

Instructions For Use

Electrodes and Implants are for Single Use Only
Instruments are Reusable

STERILE ELECTRODE
Implants and instruments are provided NON-STERILE

℞ Only CAUTION: FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN

IMPORTANT INFORMATION FOR PHYSICIANS, SURGEONS, AND/OR STAFF

The ***EARP Nerve Cuff Electrode*** conducts electrical signal as a component of intraoperative neuromonitoring. The EARP Nerve Cuff Electrode is used with commercially available neuromonitoring systems and does not stimulate or record signal itself. The standard connectors at the proximal end of the EARP Nerve Cuff Electrode interface with the neuromonitoring equipment and the distal cuff contacts the target tissue. The EARP Nerve Cuff Electrode is provided sterile packaged and is for single use only.

The ***EARP Interbody System*** is an intervertebral body fusion device used in the lumbar spine following discectomy. All devices are manufactured from PEEK OPTIMA® LT1 per ASTM F2026 and include tantalum markers per ASTM F560 for radio-graphic visualization. The devices have multiple footprints to adapt to the general shape of the vertebral endplates and have a hollow center to accommodate bone graft. Each footprint is available in multiple heights to accommodate patient variability and there are anti-migration features on the superior and inferior surfaces designed to improve fixation, stability, and prevent back out and migration.

INDICATIONS FOR USE:

The ***EARP Nerve Cuff Electrode*** is used to perform localized stimulation of neural tissue and to locate, identify, and monitor spinal nerve roots during surgery.

The ***EARP Interbody System*** is intended for intervertebral body fusion in the lumbar spine in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1 of the lumbosacral spine. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. These patients should have had six months of non-operative treatment prior to treatment with an intervertebral cage. DDD patients may also have Grade 1 spondylolisthesis or retrolisthesis at the involved levels. The device system must be used with supplemental fixation and autograft and/or allogeneic bone graft composed of cancellous, cortical, and/or corticocancellous bone to facilitate fusion and are implanted via a posterolateral approach.

CONTRAINDICATIONS:

Contraindications for the ***EARP Interbody System*** include, but are not limited to:

1. Use in the cervical spine
2. Suspected or documented material allergy or intolerance.
3. Patients with infection, inflammation, fever, leukocytosis, obesity, pregnancy, mental illness and other medical conditions which would prohibit beneficial surgical outcomes (such as the presence of tumors, fracture local to the operating site, elevation of sedimentation rate unexplained by other diseases, elevation of white blood count (WBC), or a marked shift in the WBC differential count.)
4. Grossly distorted anatomy caused by congenital abnormalities.
5. Rapid joint disease, bone absorption, osteopenia. Osteoporosis is a relative contraindication since this condition may limit the degree of obtainable correction, stabilization, and/or the amount of mechanical fixation.
6. Any patient not described in the indications.
7. Any patient unwilling to follow postoperative instructions.
8. Any patient/case in which implant utilization would interfere with anatomical structures or expected physiological performance.
9. Any patient having inadequate tissue coverage over the operative site or inadequate bone stock or quality.
10. Any case where the implant components selected for use would be too large or too small to achieve a successful result.
11. Prior successful fusion at the level(s) to be treated.
12. Reuse or multiple use.

DEVICE MATERIALS:

Patient contacting components of the ***EARP Nerve Cuff Electrode*** are manufactured from medical grade silicone rubber and high purity platinum foil. Other non-patient contacting components are manufactured from nitinol, stainless steel, polyimide, FEP polymer, and polypropylene.

The ***EARP Interbody System*** implants are manufactured from PEEK OPTIMA® LT1 per ASTM F2026 and include tantalum markers per ASTM F560 for radio-graphic visualization.

POTENTIAL ADVERSE EFFECTS:

The potential for complications and adverse reactions exists in any surgical procedure. The following do not include all adverse effects which can occur with surgery but are important considerations particular to neuromonitoring electrodes:

- Infection
- Nerve injury
- Tissue damage
- Pain and loss of function
- Electrical shock and/or burns
- Tissue reactions due to tissue allergy

Possible adverse effects or complications for interbody fusion devices include, but are not limited to:

- Implant device migration and/or subsidence
- Breakage of implant device
- Foreign body (allergic) reaction to the implant devices
- Post-operative change in spinal curvature, loss of correction, height, and/or reduction
- Infection
- Loss of neurological function including paralysis (partial or complete), radiculopathy, and/or the development or continuation of pain, numbness, spasms, or sensory loss
- Non-union (pseudarthrosis), delayed union, mal-union
- Physiological reaction to implant devices due to foreign body intolerance including inflammation, local tissue reaction, and possible tumor formation.
- Inability to perform the activities of daily living
- Fracture, micro-fracture, resorption, damage or penetration of any spinal bone
- Loss or increase in spinal mobility or function
- Cessation of growth of the fused portion of the spine
- Pain, discomfort, or abnormal sensations due to the presence of the device.
- Hemorrhage of blood vessels and/or hematomas
- Herniated nucleus pulposus, disc disruption or degeneration at, above or below the level of surgery
- Post-operative change in spinal curvature, loss of correction, height and/or reduction
- Scar tissue formation possibly causing neurological and/or vascular compromise
- Death.

WARNINGS AND PRECAUTIONS:

The ***EARP Nerve Cuff Electrode*** must be used by an experienced surgeon with specific training in the use of neuromonitoring systems because these are technically demanding procedures presenting risks of serious injury to the patient. Preoperative planning, including knowledge of the surgical technique, proper selection of device size, and proper placement of the device is critical for the achievement of successful results.

- For safe and effective use of the EARP Nerve Cuff Electrode, the surgeon should be familiar with the procedure and devices and must exercise reasonable judgment in use of the device.
- Inform the patient of the precautions necessary for the success of the procedure.
- Carefully inspect the EARP Nerve Cuff Electrode, accessory instruments, and packaging prior to use to assure they are in proper operational condition. Any device that appears faulty, damaged, or suspect should not be used.
- The EARP Nerve Cuff Electrode is provided sterile packaged for single use only. Do not re-use or re-sterilize the EARP Nerve Cuff Electrode.
- The EARP Nerve Cuff Electrode:
  - is intended for intraoperative use only for less than two hours,
  - is not to be implanted,
  - is not intended to contact the central nervous system (CNS) or cerebrospinal fluid (CSF).
- The EARP Nerve Cuff Electrode is not intended for use in the MR environment. It 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 the device in the MR environment is unknown. Performing an MR exam on a person while this device is in use may result in injury or device malfunction.
- Accessory instruments are provided non-sterile and must be sterilized prior to use. Recommended sterilization instructions are provided in this insert.

The ***EARP Interbody System*** implant devices must be implanted by an experienced spinal surgeon with specific training in the use of spinal system(s) because these are technically demanding procedures presenting risks of serious injury to the patient. Preoperative planning, including knowledge of the surgical technique, proper selection of device size, proper placement of the device is critical for the achievement of successful results. Conditions such as levels of implantation, patient weight, patient activity level and other patient conditions may impact the performance of the system and should be taken into consideration during patient selection.

- The EARP Interbody System implants and instruments are provided non-sterile and must be sterilized prior to use. Recommended sterilization instructions are noted in this insert. The EARP devices should never be reused under any circumstances.
- Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without a previous surgery.
- Care must be taken to protect implant device surfaces from being scratched, nicked or damaged during handling and storage of the implant devices as these could become focal points for failure or breakage of the implant device.
- Due to the presence of implants, interference with CT and/or MR imaging may result. The EARP Interbody System devices have not been evaluated for safety and compatibility in the MR environment. The EARP Interbody System devices have not been tested for heating, migration or image artifact in the MR environment. The safety of the system in the MR environment is unknown. Scanning a patient who has the device may result in injury.
- Some degree of corrosion occurs on all metal and alloy devices. Contact of dis-similar metals, however, may accelerate the corrosion process. Ensure that the supplemental fixation is not positioned in contact with the implant, including the tantalum markers.
- 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 the performance of the system.

HANDLING, CLEANING, AND REPROCESSING:

Unused Components: ***The EARP Interbody System*** instruments, cases and caddies must be cleaned prior to sterilization. If there are any visual signs of contaminants, soil or debris, the cleaning steps below must be taken prior to sterilization. Implant devices are single-use, thus do not clean or re-sterilize an implant device that has been in contact with or contaminated by blood or other infectious substances.

Special pre-processing handling of used instruments: The instruments, cases, and caddies are reusable and must be cleaned as soon as possible after use. If cleaning must be delayed for more than 30 minutes, immerse the components in a compatible detergent solution to prevent drying and encrustation of surgical soil.

The implantable devices, instruments, cases, and caddies are supplied non-sterile and must be cleaned and sterilized prior to use. In the event that an unused implant device or instrument has visual signs of contaminants, soil or debris, the implant device or instrument should not be used until cleaned and sterilized in accordance with the recommended parameters below. The implant devices are single-use only, therefore do not clean or re-sterilize a device that has been in contact with or contaminated by blood or other infectious substances. These implant devices must be disposed of in accordance with facility protocol.

The EARP Interbody System inserter instruments must be disassembled for proper cleaning.

Inserter Disassembly:

Grip the proximal knob and gently pull the inner shaft until you feel it engage the retention stop. Rotate the knob counterclockwise to thread the inner shaft threads past the stop and fully remove the inner shaft from the handle.

The accessory instruments must be cleaned after use as part of reprocessing prior to sterilization in accordance with the recommended parameters below. The accessory instruments are reusable and must be cleaned as soon as possible after use. If cleaning must be delayed for more than 30 minutes, immerse the components in a compatible detergent solution to prevent drying and encrustation of surgical soil.

Manual Cleaning Instructions

1. Prepare Enzol® or other neutral cleaning detergent according to the manufacturer's recommendation at 1 oz/gal using warm tap water (27-49°C).

2. Fully immerse instruments in the detergent and allow soaking for 2-3 minutes.

3. Thoroughly scrub items with an appropriately sized soft bristled brush, paying additional attention to threads, lumens or other internal channels, where applicable.

4. Rinse the items with lukewarm tap water (27-49°C) for approximately 2-3 minutes, followed by a final rinse using deionized water for a minimum of 1 minute.

5. Allow the items to dry for a minimum of 20 minutes or until no condensation or moisture is visible.

6. Dry the exterior with a clean, lint free cloth to remove condensation, if necessary.

Automated Cleaning Instructions

1. Prepare Enzol® or other neutral cleaning detergent per manufacturer's recommendations at 1 oz/gal using warm tap water (27-49°C).

2. Fully immerse instruments in the detergent and allow soaking for 2 - 3 minutes.

3. Use a soft bristled brush to remove soil. Pay close attention to crevices and hard to reach areas.

4. Remove inst0ruments from the detergent and rinse with tap water for 1 minute.

5. Prepare Enzol® per manufacturer's recommendations at 1 oz/gal using warm tap water (27-49°C) in an ultrasonic cleaner.

6. Place instruments in ultrasonic cleaner and sonicate for 10 minutes.

7. Transfer instruments into an automated washer for processing.

8. Select the cycle and ensure the following set of cycle parameters are properly programmed as defined in the subsequent table (using Motor Speed: High).

Phase	**Recirculation Time** (Minutes)	**Temperature**	**Detergent Type and Concentration**
Pre-wash 1	01:00	Cold tap water	N/A
Enzyme Wash	01:00	Hot tap water	Enzol® (1 oz/gal)
Wash 1	02:00	60°C (Set point)	Prolystica™ 2X Concentrate Neutral 1/8 oz/gal
Rinse 1	01:00	Hot tap water	N/A
Drying	07:00	115°C	N/A

9.) Remove instruments from the washer.

After cleaning/decontamination, each item must be visually inspected to ensure that there are no visual contaminants or debris on the instrument. If contaminants or debris are visible, repeat the cleaning steps listed above. If contaminants are still not removed, dispose of the items in accordance with facility protocol.

Once all components of the EARP Interbody System inserters are thoroughly dry, reassemble the instrument by gripping the proximal knob and gently inserting the inner shaft into the handle until you feel it engage the retention stop. Rotate the knob clockwise to thread the inner shaft threads past the stop until it is fully seated.

STERILIZATION:

The *EARP Nerve Cuff Electrode* is provided sterile by exposure to gamma irradiation. Do not re-sterilize. Do not use the EARP Nerve Cuff Electrode after the expiration date. The EARP Nerve Cuff Electrode is for single use; do not clean, re-sterilize, or re-use an EARP Nerve Cuff Electrode that has been previously used. EARP Nerve Cuff Electrodes must be disposed of in accordance with facility protocol.

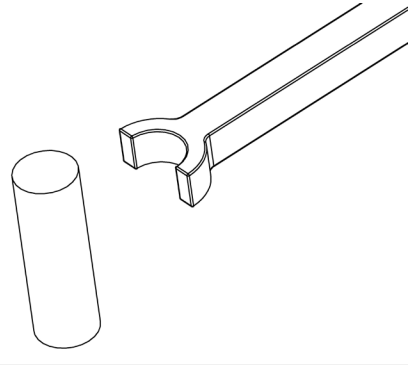
The EARP Nerve Cuff Electrode sterile packaging should be inspected to ensure that packaging has not been damaged or previously opened. If the outer package integrity has been compromised, do not use the electrode as this may indicate a breach of the sterile barrier. Contact the manufacturer for further instructions. The electrode should be opened using an aseptic technique. The EARP Nerve Cuff Electrode should only be opened after the correct size has been determined.

The *EARP Nerve Cuff Electrode* accessory instruments and the *EARP Interbody System* implant devices, instruments, cases, and caddies are supplied non-sterile and must be sterilized prior to use. The recommended sterilization method and parameters are listed in the table below. Sterilization must be conducted with an FDA cleared wrap. These recommendations are in accordance with ANSI/AAMI ST79. Do not stack trays during sterilization.

Method	**Cycle**	**Temperature**	**Exposure Time**	**Dry Time**
Steam	Pre-Vacuum	270°F (132°C)	4 Minutes	40 Minutes

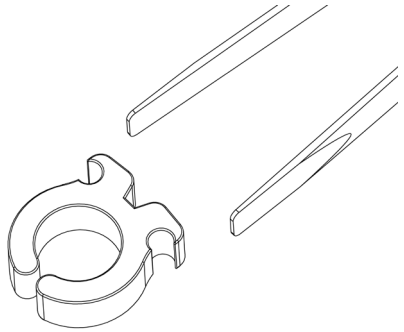
***EARP NERVE CUFF ELECTRODE* DEVICE USE:**

1. Use the trial sizers to help determine the desired EARP Nerve Cuff Electrode size for the targeted nerve.

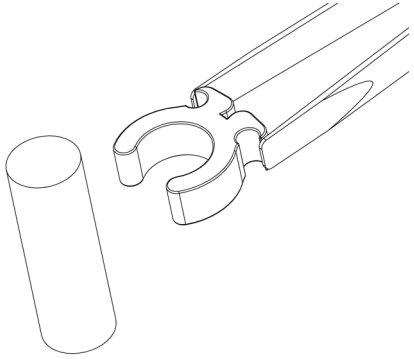


2. Insert the EARP Nerve Cuff Electrode proximal connectors into the receiving sockets of the neuromonitoring equipment. Note that the blue connector corresponds to the side of the distal cuff that is color coded with a blue band.

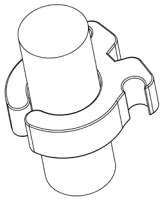
3. The distal cuff of the EARP Nerve Cuff Electrode can be applied by using common forceps to grip the protrusions on the proximal side of the cuff.



4. Spread the mouth of the distal cuff open by squeezing the forceps and compressing the tips on the cuff protrusions, and then carefully apply the cuff to the targeted nerve.



5. After the cuff has been positioned around the targeted nerve, disengage the forceps to close the cuff in place, and remove the forceps from the cuff, as appropriate. The cuff will encircle most of the nerve while leaving a small gap between the cuff tips.



6. To remove the cuff, re-engage the forceps on the cuff protrusions, squeeze to spread the cuff open, and carefully withdraw the cuff.

STORAGE PRECAUTIONS:

The sterile packaged ***EARP Nerve Cuff Electrode*** must be stored in the original unopened packaging, away from moisture and must not be used after the expiration date. Keep away from extreme temperature and direct sunlight.

INSPECTION, ROUTINE MAINTENANCE AND OTHER IMPORTANT INFORMATION:

- Visually inspect all instruments and check for damage, wear, and/orcorrosion.
- Cutting edges should be free nicks and have a continuous sharp edge.
- Moveable parts should have smooth movement without excessive play
- Ensure a tight fit between the handles and components.
- Confirm appropriate fit between the thread on the inserter and the thread on the implant device.
- The cases are supplied to the end user with the recommended instruments required for the EARP systems.
- A complete case with devices and instruments should not exceed 25 lbs and cases should not be stacked at any time.
- Inspection of the cases should be performed after each use. If there are any excessive dents, scrapes, corrosion or discoloration, the cases must bereplaced
- All handling, inspection, and maintenance must be performed by trained personnel only.

If any of the items do not meet acceptable inspection criteria, they must be sent to Retropsoas Technologies, LLC for replacement.

FURTHER INFORMATION:

Recommended surgical technique is available at no charge upon request. If further information is needed or required, please contact Retropsoas Technologies, LLC at Frontenac, MO 63131. Phone: (480) 360-0000.

PRODUCT COMPLAINTS:

Any healthcare professional who has a complaint or who has experienced any dissatisfaction in the product quality, durability, reliability, safety, effectiveness, and/or performance should notify Retropsoas Technologies, LLC at Frontenac, MO 63131. Phone: (480) 360-0000.

Disclaimer of Warranty and Limited Remedies:

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SYMBOLS GLOSSARY:

REF	Catalog number
LOT	Batch code
	Use by
	Consult Instructions for Use
	Do not reuse
	Do not resterilize
	Do not use if package is damaged
STERILE R	Sterilized using irradiation
R_x Only	Prescription only
	Manufacturer

Reference EN 980, Symbols for use in the labelling of medical devices

Manufactured for:
Retropsoas Technologies, LLC
Frontenac, MO 63131