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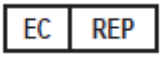
Lockable Intramedullary Nails

INSTRUCTION FOR USE

CE
0123

GRAPHICAL SYMBOLS	
	Manufacturer
	LOT number
	Do not re-use
	Non sterile
	Consult instructions before use
	Catalog number
QTY	Quantity
	Date of Manufacture

	Do not use if package is damaged
	Humidity limitation
	European Community Representative
	Material
	Caution, consult accompanying documents

DESCRIPTION

The intramedullary nail system is designed for use in the fixation of bone fractures to provide stabilization. It is supplied non sterile and available in numerous sizes.

It is supplied non sterile and available in numerous sizes. The intramedullary nails are made of stainless steel conforming to ISO 5832-1 or titanium alloy conforming to ISO 5832-3.

INTENDED USE

The Intramedullary nail system is indicated for use in the intramedullary canal of femur, tibia, humerus, ulna/radius, fibular, etc. For the treatment of bone fractures happened in those bones, which may achieve the function of alignment, stabilization, until the bone's healing.

INDICATIONS FOR USE

The intramedullary nail system is intended to perform as a fixation and stabilization unit of bone fractures including:

1. Acute fractures
2. Osteotomy.
3. Nonunions and malunions.
4. Bone reconstruction following tumor resection, grafting and prophylactic nailing of impending pathological fractures.
5. Revision procedures where other treatments and devices have failed.
6. It is indicated for shaft fractures and peri-articular fractures.

The Recon Nail is indicated for: Subtrochanteric fractures, intertrochanteric and pertrochanteric fractures associated with shaft fractures, pathological fractures (including prophylactic use) in both trochanteric and diaphysal areas, non-unions and mal-unions.

The Hip Fracture Nail is indicated for: treat stable and unstable proximal fractures of the femur including pertrochanteric fractures, intertrochanteric fractures, high subtrochanteric fractures and combinations of these fractures, including non-union, malunion and tumor resections.

The Retrograde Humeral Nail is indicated for: Fractures of the humeral shaft, non-unions, malalignments, pathological humeral fractures, and impending pathological fractures.

The Retrograde Femoral Nail is indicated for: Open and closed femoral fractures, pseudarthrosis and correction osteotomy, pathologic fractures, impending pathologic fractures, and tumor resections, supracondylar fractures, including those with intra-articular extension, fractures distal to a Total Hip Prosthesis and non-unions and mal-unions.

The Femoral Nail is indicated for: Open and closed femoral shaft fractures, ipsilateral shaft fractures, segmental fractures, comminuted fractures with or without bone loss, fractures proximal to a total knee arthroplasty, pathologic and impending pathologic fractures, tumor resections, non-unions, pseudarthrosis, mal-unions and corrective osteotomies.

The Tibial Nail System is indicated for: Open or closed tibia shaft fractures with a very proximal and very distal extent in which locking screw fixation can be obtained, multi-fragment fractures, segmental fractures, proximal or distal non-unions, proximal or distal mal-unions, pseudarthrosis, corrective osteotomies, pathologic and impending pathologic fractures, tumor resections and comminuted fractures with or without bone loss.

The Universal Retrograde Nail is intended for: the fixation of fractures where flexibility of the implant is desired. This includes fractures of: Lower extremity diaphyseal fractures of children and small statured adults, upper extremity diaphyseal fractures in both, adults and children as well as some metaphyseal fractures, such as radial neck, proximal humerus and supracondylar humerus fractures.

CONTRAINDICATIONS

The physician’s education, training and professional judgment must be relied upon to choose the most appropriate device and treatment.

Contraindications include but are not limited to:

1. Any active or suspected latent infection or marked local inflammation in or about the affected area.
2. Compromised vascularity that would inhibit adequate blood supply to the fracture or the operative site.
3. Bone stock compromised by disease, infection or prior implantation that cannot provide adequate support and/or fixation of the devices.
4. Material sensitivity, documented or suspected.
5. Patients having inadequate tissue coverage over the operative site.
6. Implant utilization that would interfere with anatomical structures or physiological performance.
7. Any mental or neuromuscular disorder which would create an unacceptable risk of fixation failure or complications in postoperative care.
8. Pregnant women or nursing mothers.
9. Major physical activities, adherent with intense percussion, on which the nails are exposed to excessive pressure.

10. Other medical or surgical conditions which would preclude the potential benefit of surgery.
11. Patients who are unwilling to restrict activities or follow medical advice.
12. Use with components of other systems.
13. Reusable or multiple uses.
14. Very proximal or distal fractures.
15. Highly comminuted fractures.
16. Longitudinal splits or longitudinal fractures.

WARNINGS AND CAUTIONS

WARNINGS

1. **NON-STERILE PRODUCTS**: The intramedullary nails and the instruments to be used must be cleaned carefully in a clean environment and sterilized thoroughly with appropriate temperature and pressure before they are used.
2. **STERILIZED PRODUCTS:** For the products provided sterile, the contents are sterile unless the package is damaged, opened, or the expiration date on the device label has passed. The integrity of the packaging should be checked to ensure that the sterility of the contents is not compromised. Remove implants from packaging, using aseptic technique, only after the correct size has been determined. For components provided sterile, ensure that the package is not damaged prior to use.

   PRECAUTION: Do not use implants if the condition of the package and/or labeling indicates a chance that the devices may not be sterile.
3. It is indicated for shaft fractures 5cm below the surgical neck, and 5cm proximal to the distal end of the medullary canal.
4. Unless stated otherwise, this system is not to be combined with the components of another system.
5. The methods of use of instruments are to be determined by the user's experience and training in surgical procedures.
6. This product can be used only by well-trained surgeons perfectly familiar with relevant surgical operations. Hospital must provide detailed medical orders to the patients.
7. All parts must be cleaned and sterilized before use.
8. Single use devices should not be reused, as they are not designed to perform as intended after the initial use. Never reuse the nail system. Although the nails may appear undamaged, previous stresses may have created non-visible damage that could result in nail failure.
9. **PATIENT EDUCATION:** Preoperative instructions to the patient are essential. The patient should be made aware of the limitations of the implant and potential risks of the surgery. The patient should be instructed to limit postoperative activity, as this will reduce the risk of bent, broken or loose implant components. The patient must be made aware that implant

components may bend, break or loosen even though restrictions in activity are followed.

10. **MAGNETIC RESONANCE (MR) SAFETY:** The product has not been evaluated for safety and compatibility in the MR environment. The product has not been tested for heating or migration in the MR environment.
11. The subject device is intended for use only as indicated.
12. Correct selection of the implant is extremely important. The potential for success is increased by the selection of the proper size of the implant. While proper selection can minimize risks, the size and shape of human bones present limitations on the size and strength of implants.
13. During the postoperative phase, in addition to mobility and muscle training, it is of particular importance that the physician keeps the patient well informed about post-surgical behavioral requirements.
14. Damage to the weight-bearing structures can give rise to loosening, dislocation and migration, as well as other complications. To ensure the earliest possible detection of such catalysts of nail dysfunction, the nail(s) must be checked periodically post operatively using appropriate techniques.
15. **POSTOPERATIVE MOBILIZATION:** Postoperative external immobilization is recommended, at the surgeon's discretion. Instructions to the patient to reduce stress on the implants are an equally important part of the attempt to avoid the occurrence of clinical problems that may accompany fixation failure.
16. Implant removal should be followed by adequate post-operative management to avoid fracture or refracture of the bone.
17. For optimal results, the same type of instruments used for implantation should be used for implant removal.
18. Trauson does not and cannot warrant the use of instruments nor any of the component parts upon which repairs have been made or attempted except as performed by Trauson or an authorized Trauson repair representative. The use of an Instrument for tasks other than those for which they are intended may result in damaged/broken instruments and/or patient injury.
19. If there is any doubt or uncertainty concerning the proper use of instruments please contact Trauson Customer Service. Any available operation brochure will be provided upon request.

CAUTION

1. Before using this product, the users must read carefully Surgical Technique published by Trauson and are skilled in the operation process of this product.

2. It is not recommended to use Trauson products together with other brands, as it is not verified or validated.

POTENTIAL ADVERSE EVENTS AND COMPLICATIONS

This list may not include all complications caused by the surgical procedure itself.

- Clinical failure (i.e. pain or injury) due to loosening, wear and tear, fracture, loss of fixation, dislocation and/or migration
- Pain and/or abnormal sensations due to the presence of the nail
- Primary and/or secondary infections
- Allergic reactions to nail material
- Injury to vessels, nerves and organs
- Hematoma and/or impaired wound healing; hemorrhage.
- Loosening, bending cracking or fracture of the nail with subsequent loss of fixation in bone attributable to nonunion, osteoporosis, markedly unstable comminuted fractures, or one or more of the factors listed in contraindications above and/or warnings and precautions below.
- Loss of anatomic position with nonunion or malunion with rotation or angulation.
- Supracondylar fractures from retrograde nailing.
- Nail migration.

PACKAGING

Packages for each of the components should be intact upon receipt. All instrument sets should be carefully examined for completeness, and for lack of damage, prior to use. Damaged packages or products should not be used, and should be returned to Trauson.

CLEANING AND DECONTAMINATION

Products delivered in non-sterile condition, must be cleaned, disinfected, and sterilized prior to use. For cleaning and sterilization, remove the product from its packaging before cleaning, disinfecting and sterilizing the product. A suitable cleaning, disinfection and sterilization process must be applied by the user. Only pH-neutral cleaning agents should be used. The preparation instructions of the respective cleaning and disinfection agent manufacturer must be considered.

All instruments must first be cleaned using established hospital methods before sterilization and introduction into a sterile surgical field. Cleaning and decontamination can include the use of neutral cleaners followed by a deionized water rinse.

All instrument moving parts should be well lubricated. Be careful to use surgical lubricants and not industrial oils.

Note: Certain cleaning solutions such as those containing bleach or formalin may damage some devices and must not be used.

STERILIZATION

The following sterilization process parameters are validated by Trauson and recommended for sterilization:

Method	Moist heat sterilization according to ISO 17665
Cycle	Saturated steam with fractional forced air removal
Temperature	132-137°C (270-277°F)
Exposure Time	4 minutes (minimum)
Drying Time	30 minutes (minimum, in chamber)

Additionally, the method of sterilization utilized by end users should be validated, as suggested by Trauson.

TRANSPORTATION AND STORAGE CONDITIONS

The relative humidity of transportation and storage is no more than 80%. Keep products in draughty room without corrosive gas.

INFORMATION

To obtain Operation Technique or should any information regarding the products or their uses be required, please contact your local representative or Trauson directly at +86-519-86387075. You may also email: info@trauson.com .