# Instructions for Use

## Locked Universal Intramedullary Nail

**Subtitles of the symbols used on the packaging**

| | | | |
|---|---|---|---|
| REF | Catalogue Number | LOT | Batch Code |
|  | Date of Manufacture |  | Consult instructions for use |
|  | Single-Use Product |  | Do not use if package is damaged |
|  | Non-Sterile |  | Keep out of the sun |
|  | Fragile, handle with care |  | Keep dry |

**Features and technical specifications of the product**

**Technical Name:** Implantable Material

**Trade Name:** Locked Universal Intramedullary Nail

**Trade Models:**

- Femoral Rigifix Intramedullary Nail;
- Tibial Rigifix Intramedullary Nail;
- Humeral Rigifix Intramedullary Nail;
- Left Humeral Rigifix Intramedullary Nail;
- Right Humeral Rigifix Intramedullary Nail;
- Locked Femoral Rigifix Nail II;
- Tibial Locked Rigifix Nail II;

**Accessories:**

- Cap for Femoral Rigifix Intramedullary Nail;
- Cap for Tibial Rigifix Intramedularry Nail;
- Cap for Tibial Intramedullary Nail II;

**Raw Material:** Stainless Steel Alloy (18Cr-14Ni-2.5Mo)

**Non-Sterile Product**

**Sterilization Method:** Moist Heat (autoclave)

**Shelf Life:** Undetermined

**Description**

The trade models which make the Locked Universal Intramedullary Nail family, consist of implantable devices surgically invasive. They are for long term utilization and are used in surgical procedures applicable to intramedullary segments of the femur, tibia and humerus for treating simple or exposed fractures, without affecting the articulation.

The nails are made of stainless steel alloy (18Cr-14Ni-2.5Mo) which provides resistance to high alternating loads despite of their slim profile, and were developed for a roughly trimmed technique.

Through a design that allows a perfect adaptation of the nail to the bone anatomy, associated to a simplified surgical instrumentation, the product comes to be a good option for the treatment of fractures of the femur, tibia and humerus, in their proximal or distal portions.

The nails are available in elongated and cannulated cylindrical shape, and their proximal and distal ends have holes for the locking screw insertion.

The holes were designed and strategically located at the ends of the nail, in order to propitiate the maximum harnessing during the surgery procedures for stabilizing fractures in the proximal and/or distal of the femur, tibia or humerus.

The trade models which make the Locked Universal Intramedullary Nail family are available in diameters of 07 and 08 mm and lengths varying from 210 mm to 310 mm for the humerus; diameters of 09 mm and 10 mm and lengths varying from 260 mm and 400 mm for the tibia; diameters 10 mm and 12 mm and lengths varying from 320 mm to 480 mm for the femur.

Illustrative images of the trade models which make the Locked Universal Intramedullary Nail family are shown below:

| | | | | | |
|---|---|---|---|---|---|
|  |  |  |  |  |  |
| Femoral Rigifix Intramedullary Nail | Tibial Rigifix Intramedullary Nail | Humeral Rigifix Intramedullary Nail | (Right/ Left) Humeral Rigifix Intramedullary Nail | Femoral II Rigifix Intramedullary Nail | Tibial II Rigifix Intramedullary Nail |

Below are the caps - accessories (integrant pieces) of the femoral and tibial nails – which are specifically for sealing the thread hole seated in the center of the nail, and is used for coupling the surgical instrument needed to the implanting or explanting of the implant after the fracture consolidation. The screw is available in only one size, and is also made of stainless steel alloy (18Cr-14Ni-2.5Mo) just like the nails.

| | | |
|---|---|---|
|  |  |  |
| **Cap for Femoral** Rigifix Intramedullary Nail | **Cap for Tibial** Rigifix Intramedullary Nail | **Cap for Tibial** II Rigifix Intramedullary Nail |

Featured as a material of physical, chemical and mechanical properties which is favorable for this purpose, for having biocompatibility proven by a vast clinical historic widely described in literature all over the world.

**Indication and Purpose**

The Locked Universal Intramedullary Nail is indicated as a structural element in the medullary canal of long bones of upper and lower limbs – femur, tibia and humerus – to stabilize fractures or their simple or complex pseudoarthrosis, in order to propitiate osseous consolidation in the most physiological way possible.

The Locked Universal Intramedullary Nails are indicated in surgical procedures which adopt reamed technique of the fractured bone intramedullary canal.

The products described herein were developed for use as described above. So, any other different use is considered contraindicated or with no scientific support.

**Contraindication**

Contraindications for the use of this device are listed below. After a thorough study of the case, the surgeon in charge will be able to indicate the procedures:

- Patients with general active infections or specific ones that may lead to fixation complications;
- Patients in general impaired health status and/or immunosuppressed who are unable to undergo a surgical procedure;
- Patients who have sensitivity to foreign bodies. In these specific cases, testing should be performed;
- Patients who developed advanced osteoporosis and/or other osseous disorders which may difficult the fixation stability;
- Patients who use narcotic, alcoholic beverages or tobacco;
- Patients whose fractured bone presents a very narrow intramedullary canal;
- The use of the nails associated with a non-reamed technique of the intramedullary canal.

**Forms of Presentation**

The components that make the Locked Universal Intramedullary Nail family are available in non-sterile condition, wrapped in double polypropylene plastic packaging.

Inside the second package you may find a pamphlet which brings the instructions for use. It shows this non-sterile condition, as well as the directions for handling and utilization of the product.

Outside the package there is a label which shows all information needed to identify the product.

The Locked Universal Intramedullary Nail family is formed by the following trade models, and each of these models is available in the following dimensions:

**List of the trade models that form the Locked Universal Intramedullary Nail family**

| Illustrative Image | Code | Description | Dimensions (Diameter/Length) | Made of | Quantity Packed |
|---|---|---|---|---|---|
|  | 04.11.04.XXXXX | Rigifix Femoral Intramedullary Nail | **Ø 10 mm –** 320, 340, 360, 380, 400, 420, 440, 460, 480 mm;<br><br>**Ø 12 mm –** 320, 340, 360, 380, 400, 420, 440, 460 mm; | Stainless Steel Alloy (18Cr-14Ni-2.5Mo) | 01 |
|  | 04.11.06.XXXXX | Rigifix Tibial Intramedullary Nail | **Ø 09 mm** – 260, 280, 300, 320, 340, 360, 380, 400 mm;<br><br>**Ø 10 mm** – 260, 280, 300, 320, 340, 360, 380 mm; | Stainless Steel Alloy (18Cr-14Ni-2.5Mo) | 01 |
|  | 04.11.07.XXXXX | Rigifix Humeral Intramedullary Nail | **Ø 07 mm** – 210, 220, 230, 240, 250, 260, 270 mm;<br><br>**Ø 08 mm** – 220, 230, 240, 250, 260, 270, 280, 290 mm; | Stainless Steel Alloy (18Cr-14Ni-2.5Mo) | 01 |

| | | | | | |
|---|---|---|---|---|---|
|  | 04.11.07.17XXX | Rigifix Humeral Intramedullary Nail Left | **Ø 07 mm** – 250, 260, 270, 280, 290, 300, 310 mm | Stainless Steel Alloy (18Cr-14Ni-2.5Mo) | 01 |
| | 04.11.07.27XXX | Rigifix Humeral Intramedullary Nail Right | **Ø 07 mm** – 250, 260, 270, 280, 290, 300, 310 mm | Stainless Steel Alloy (18Cr-14Ni-2.5Mo) | 01 |
|  | 04.11.14.XXXXX | Rigifix II Femoral Intramedullary Nail | **Ø 10 mm –** 320, 340, 360, 380, 400, 420, 440, 460, 480;<br><br>**Ø 12 mm** – 320, 340, 360, 380, 400, 420, 440, 460, 480 mm | Stainless Steel Alloy (18Cr-14Ni-2.5Mo) | 01 |
|  | 04.11.15.XXXXX | Rigifix II Tibial Intramedullary Nail | **Ø 09 mm –** 260, 280. 300, 320, 340, 360, 380, 400 mm;<br><br>**Ø 10 mm** – 260, 280. 300, 320, 340, 360, 380, 400 mm; | Stainless Steel Alloy (18Cr-14Ni-2.5Mo) | 01 |
| **Accessories (Integrant pieces)** | | | | | |
|  | 04.34.02.00000 | Cap for Rigifix Femoral Intramedullary Nail | ------ | Stainless Steel Alloy (18Cr-14Ni-2.5Mo) | 01 |
|  | 04.34.03.00000 | Cap for Rigifix Tibial Intramedullary Nail | ------ | Stainless Steel Alloy (18Cr-14Ni-2.5Mo) | 01 |
|  | 04.34.05.00000 | Cap for Rigifix II Tibial Intramedullary Nail | ------ | Stainless Steel Alloy (18Cr-14Ni-2.5Mo) | 01 |

**Ancillary Components**

The Ancillary Implants to the Locked Universal Intramedullary Nail are:

- Rigifix Screw Ø 5,0 mm;
- Rigifix Screw Ø 6,2 mm;

The ancillary implants to the trade models that make the Locked Universal Intramedullary Nail family are made of stainless steel alloy (18Cr-14Ni-2.5Mo) which meets the requirements specified by the ASTM F-138 Standard Specification for Wrought 18 Chromium-14 Nickel-2.5 Molybdenum Stainless Steel Bar and Wire for Surgical Implants (UNS S31673).

The ancillaries below are not subject of this registration process, and should, therefore, be always purchased separately from the same manufacturer of the implant or from another one the company indicates.

**List of the Ancillary Implants that form the Locked Universal Intramedullary Nail family**

| Illustrative Image | Code | Description of the Ancillary | Dimensions (Diameter/ Length) | Made Of | Qtty Packed | Matching with Trade models (subject of registration) |
|---|---|---|---|---|---|---|
|  | 04.24.08.35XXX | Cortical Screw Pitch 1,75 mm | **Ø 3,5 mm** – 10, 12, 14, 16, 18, 20, 22, 24, 26, 28, 30, 32, 34, 35, 36, 38, 40, 42, 44, 45, 46, 48, 50 mm; | Stainless Steel Alloy (18Cr-14Ni-2.5Mo) | 01 | 04.11.07.0XXXX Rigifix Humeral Intramedullary Nail<br><br>04.11.07.17XXX Rigifix Humeral Intramedullary Nail Left<br><br>04.11.07.27XXX Rigifix Humeral Intramedullary Nail Right |
|  | 04.24.39.5XXXX | Rigifix Locking Screw | **Ø 5,0 mm** – 24, 25, 30, 35, 40, 45, 50, 55, 60, 65, 70, 75, 80, 85 e 90 mm; | Stainless Steel Alloy (18Cr-14Ni-2.5Mo) | 01 | 04.11.04.XXXXX Rigifix Femoral Intramedullary Nail<br><br>04.11.06.XXXXX Rigifix Tibial Intramedullary Nail<br><br>04.11.14.XXXXX Rigifix II Femoral Intramedullary Nail<br><br>04.11.15.XXXXX Rigifix II Tibial Locking Nail |

| | | | | | | |
|---|---|---|---|---|---|---|
|  | 04.24.10.XXXXX | Rigifix Locking Screw | **Ø 6,2 mm –** 20, 25, 30, 35, 40, 45, 50, 55, 60, 65, 70, 75, 80, 85 e 90 mm; | Stainless Steel Alloy (18Cr-14Ni-2.5Mo) | 01 | 04.11.04.XXXXX Rigifix Femoral Intramedullary Nail<br><br>04.11.06.XXXXX Rigifix Tibial Intramedullary Nail<br><br>04.11.14.XXXXX Rigifix II Femoral Intramedullary Nail<br><br>04.11.15.XXXXX Rigifix II Tibial Locking Nail |

The surgeon in charge of the technique to be applied is also responsible for the right choice of the size of the implants which make the Locked Universal Intramedullary Nail to be implanted. He must be familiar with the material, the application method and the adopted surgical procedures.

The consolidation success is linked to the right choice, positioning, and the implants selection and fixation. It is responsibility of the physician who evaluates the patient and decides which implants are to be used. Also, it is linked to the strict compliance with postoperative care recommended by the surgeon in charge.

**Support Materials**

The supporting materials are all the instruments designated solely for the Locked Universal Intramedullary Nail implanting according to the above models and sizes.

Such instruments are made of stainless steel that meets the requirements specified by the ASTM F899 - Standard Specification for Stainless Steel for Surgical Instruments, and gives them high resistance and durability.

The instruments below are not subject of this registration process, and should, therefore, be always purchased separately from the same manufacturer of the implant or from another one the company indicates.

See below a list of the instruments available and provided by the manufacturer or their indication for implanting the Locked Universal Intramedullary Nail and its respective ancillaries:

- 0H.03 – Instrument – Femoral Rigid Locking Nail;
- 0H.05 – Instrument – Tibial Rigid Locking Nail;
- 0H.07 – Instrument – Humeral Rigid Locking Nail;
- 0H.08 – Instrument – Rigifix II Femoral Nail;
- 0H.12 – Instrument – Rigifix II Tibial Locking Nail;

The instruments are provided decontaminated, but not sterilized. Inappropriate sterilization of the surgical instrument might cause infection.

Surgical instruments are subject to wear and tear during their regular use. Therefore breaking may occur. The instruments should only be used for the purpose they were designed to and should be inspected regularly for possible wear and damage.

For further information concerning the instruments, please consult the dealer.

**Warning and Precautions**

For the product use, the medical team in charge of the implant must consider the following warning and precautions:

- The Locked Universal Intramedullary Nail must only be used after a thorough analysis of the surgical procedure to be adopted and complete reading of these instructions for use;
- The product should only be handled by specialized surgical teams with specific knowledge and capacity building concerning osteosynthesis techniques. The choice and dominance of the adopted technique to be applied are under the responsibility of the surgeon in charge;
- Inappropriate choice and selection of the implants to be used, as well as mistakes concerning the indication, handling and application technique might cause excessive stress and tractions on the implant leading to failure due to fatigue, fracture and even looseness;
- Clinical results and the durability of the implants are totally dependent upon a precise surgical technique;
- The use of bone graft may be needed, but it is under medical criteria;
- A greater risk of the implant failure is its use in patients who are predisposed to disobey medical guidelines and postoperative restrictions, such as children, elderly, individuals with neurological changes, or addicted;
- Implant failure risks are greater in patients who practice physical exertion activities or those who practice sports during the postoperative period, contradicting the medical restrictions;
- Postoperative complications represent a greater risk when the product is used in patients with morbid obesity;
- The Locked Universal Intramedullary Nail should not be used whether there is not an appropriate osseous support that can guarantee the implant stability;
- The patient must be submitted to periodic medical monitoring to check the implant, the bone and the adjacent tissues conditions;
- The pre and perioperative prophylactic antibiotic therapy as well as antibiotic therapy - in cases there is a local and/or systemic predisposition or infections occur – are under medical criteria;

- The implant should not be used with components from other manufacturers or purpose. The combination of implants from different manufacturers or purposes can result incongruity among the components;
- Use only screws which are indicated for the nail locking. DO NOT use screws made by other manufacturers;
- The Distal Locking Screw should NOT be used alone for the nail locking for there is a risk of failure of the screw.
- Care of this material is of responsibility of skilled staff, who should follow the normalization and/or any applicable local regulations;
- Falls or crushing on hard surfaces might damage the product. So, it is necessary the handler to perform inspection of the product to check its integrity while it is unpacked and if there is any abnormality, the product SHOULD NOT be used.
- Only skilled staff for the surgical procedure may open the package;
- Do not use the product if the packaging is violated.
- Handle with care;
- Single use product – Do not reuse;
- The implants must NEVER be reused. Although they may seem undamaged, prior tensions they have been submitted may cause imperfections that would reduce the lifetime of the product in a re-implantation;
- Non-sterile Product – must be sterilized before use and handled properly to avoid contamination;
- Inappropriate sterilization of implants might cause infections;
- REPROCESSING PROHIBITED;
- Manufacturing date and batch number: see label.

**Adverse Effects**

Every surgical procedure presents complication risks and possibilities, and some common risks are infections, bleeding, allergic drug reactions and anesthetic risks, among others. The following complications and adverse effects can still be associated with the implantation of the product:

- Risks of vascular injury, visceral and neural;
- Absence or delay of bone fusion (pseudoarthrosis) resulting in the implant breaking;
- Loosening, dismemberment, displacement, twisting or break of the implant;
- Deformation or fracture of the implant;
- Pains, discomfort or abnormal sensations due to the product;
- Reaction to foreign body;
- Bone necrosis or adjacent soft tissues;
- Device breaking may make removal difficult or impossible.

The decision for the removal due to one of the above adverse effects is made by the surgeon in charge.

**Use Instructions**

For the correct use of product, the following instructions should be adopted:

- The care of this material is responsibility of the skilled staff, which should follow the standards and/or other local regulations applied;
- The product should be handled with appropriate care in adequate locations (materials center and operating rooms);
- The product should only be used by specialized surgical teams, with specific knowledge and training on techniques for vertebral column stabilization, and the surgeon in charge is responsible for the choice and dominance of the surgical technique to be performed;

- The implant useful life is characterized by the time required for effective bone healing, limited to a maximum period of 01 (one) year. After this period, in case of absence or problems with bone healing, these conditions can represent a risk of implant failure by excessive mechanic stress;
- A revision surgery may be necessary in the case mentioned right above or if loosening of the components is observed.
- For implanting the Locked Universal Intramedullary Nail and its respective ancillaries, specific instruments – indicated in the "Supporting Material" - are necessary. Due to the possibility of dimensional and/or functional incompatibility it MUST NOT be used with any other instruments different from the ones indicated by the manufacturer.
- The correct matching of the Locked Universal Intramedullary Nail and its respective ancillary components is indicated in the "Ancillary Components". Due to the possibility of dimensional and/or functional incompatibility it MUST NOT be used with any other components different from the ones indicated by the manufacturer.

**Guidance to the Patient and/or Legal Representative**

The responsible surgical team should guide the patient or his legal representative about:

- The suitable care and restrictions during the postoperative period. The capacity and willingness of patient to follow these guidelines are one of the most important aspects in a surgical procedure;
- The fact that the risks are greater when using in patients with predisposition to disobey the medical guidelines, care and postoperative restrictions, such as children, elderly, individuals with neurological disorders or addicted;
- The fact that the product does not substitute nor does have the same performance of normal bone and therefore can break, deform or loosening due to excessive effort or activities of early load and other situations;
- The need to restrict the effort activities or sportive practice during the postoperative period, whose extension is defined by the surgeon in charge;
- The increase of the postoperative complications risk in patients' with morbid obesity;
- The necessity of use of external supports, aid to ambulate and orthopedic appliances, designed to limit the movement and/or load is under exclusive medical criteria;
- designed to limit the movement and/or load is under exclusive medical criteria;
- The necessity of periodic medical monitoring to check the conditions of the implant, the bone and the adjacent tissues;
- The fact that the non-performing of the revision surgery in a period longer than 01 (one) year, in cases in which bone fusion (pseudoarthrosis) does not occur, can lead the mechanical failure of the implant;
- The need of review surgery in cases of components loosening;
- The fact that implants can interfere with results of imaging examinations. So, implant users should report this fact when submitted to such examinations;;
- The listed information in this topic "Guidance to the patient and/or the Legal Representative" and in the topic "Adverse Effects".

**Sterilization**

The Locked Universal Intramedullary Nail is supplied in non-sterile condition and should be removed from its original packaging and packed in proper recipient for sterilization (provided by the manufacturer) before use.

The indicated sterilization method for sterilization of components that make the Locked Universal Intramedullary Nail is the sterilization by moist heat (autoclave);

The implants are provided decontaminated by manufacturer, but should be properly handled and sterilized, as instructions below, to avoid implant contamination and consequent infection to the patient.

**Sterilization Parameter**

The sterilization of the Locked Femoral Nail – HBF-2 should be done as parameters described in the table below:

| Method | Cycle | Temperature | Exposure Times |
|---|---|---|---|
| Moist Heat (autoclave) | Pre-Vacuum<br>Sterilization (vacuum)<br>Drying | 134º à 137º | 10 minutes |

The sterilization process must meet the theoretical probability of the presence of vitals microorganisms to a maximum of $1x10^{6}$ (S.A.L. [Sterility Assurance Level] = $10^{-6}$).

The equipment conditions (autoclave) used during the sterilization process (maintenance, calibration program, etc) as well as the guarantee of use of a proper sterilization process and the product sterility proof is responsibility of qualified personal (material center) of the health service.

**Cleaning**

The cleaning procedures described as follow are applied to the implants and their respective surgical instruments.

For using the Locked Universal Intramedullary Nail, it has to be removed from its packaging and cleaned with alcohol for medical aims at 70% + distillate water 30%.

After cleaning the product must be rinsed with sterile distillate water and dried with cleaning cloth that does not release fibers.

If the cleaning process is made by thermo disinfectors' equipment with the help of descaling substances, the manufacturer guidelines should be adopted.

**Contamination Risk**

As this is an implantable product, in cases in which there is need of components explantation of the Locked universal Intramedullary Nail, there are risks of biologic contamination and viral disease transmission.

For minimizing these risks, the explanted Locked Universal Intramedullary Nail should be treated as potentially contaminant material and should be adopted the standardization and/or other local regulations applied.

**Product Discard**

The implants that make the Locked Universal Intramedullary Nail explanted or regarded as inappropriate for use must be discarded. It's highly recommended that before discarding, the product is mischaracterized, and so its parts can be cut, bent or sanded.

The implants should be discarded in proper locals, to avoid the environmental contamination and other individuals. It is recommended adoption of local legal regulations for potentially contaminant products.

Single use product – do not reuse.

**Traceability**

To ensure the traceability of the implanted product, and comply with the requirements for sanitary surveillance, the surgeon or his team must register in the patient's medical record the information about the product. Furthermore, such information must also be passed to the distributor of the product and to the patient in order to complete the cycle of the product traceability established. The information necessary for traceability are relatives to the product used, surgery and patient, as below:

- Name of patient who received the implant;

- Surgeon’s name;
- Hospital’s name;
- Manufacturer’s name;
- Supplier’s name;
- Surgery date;
- Code of product;
- Number of batch of the product;
- Quantity used;
- Registration product at ANVISA;

The following Information needed for the product traceability is engraved on the piece or may be acquired from the label of the product package:

- Company logotype;
- Manufacturing Batch;
- Piece Code.

Traceability information is required for notifying the Sanitary Surveillance Agency ANVISA, either by the health service or by the patient him/herself, when serious adverse events occur, so that it helps to drive appropriate investigations.

**Storage and Transport**

For the storage it is recommended dry and airy place, without exposure to light incidence, humidity or contaminants substances.

The implants cannot be stored directly on the floor. It is recommended the use of shelves with minimal height of 20 cm.

The product should be kept in its original packaging until the moment of its use, being that the surgical packaging opening and handling should be done by trained personal for this procedure.

The product should be transported properly, avoiding falls and friction that can damage the structure and surface of the part.

For information about manufacturing date and batch number: see label.

**Other Information**

**Manufactured and distributed by:**
**MDT – Indústria Comércio Importação e Exportação de Implantes SA**
**CNPJ:** 01.025.974/0001-92
**Address:** Av. Brasil, nº. 2983 – Distrito Industrial – Rio Claro/SP – Brasil
**CEP:** 13505-600
**Phone/ Fax** (55-19) 2111-6500
**Technician Responsible:** Miguel Lopes Monte Júnior – CREA 0601150192

**ANVISA Registration #:** 10417940037
**Review:** 03
**Issue**: January, 28th 2013

# ALERT
# INSTRUCTIONS FOR USE

These INSTRUCTIONS FOR USE are not available in printed form, they are available at the website of the manufacturer www.mdt.com.br.

The INSTRUCTIONS FOR USE on the website are indexed by REGISTRATION/ CADASTRE ANVISA´s NUMBER and its TRADE NAME of the product, informed at the label of the product purchased.

All the INSTRUCTIONS FOR USE provided on the website have the identification of the revision and date of emission of the document. The user must pay attention to the correct version (revision and date of emission) of the document regarding the MANUFACTURING DATE informed at the label of the product purchased.

If it is interest to the user, the INSTRUCTIONS FOR USE may be provided in printed form, with no extra cost and the request of the same shall be held by the SAC (Customer Service Department) manufacturer, as following:

**Customer Service Department:**
**Telephone:** +55 19 2111.6500
**FAX:** +55 19 2111.6500
http://www.mdt.com.br
Avenida Brasil, 2983 – Distrito Industrial CEP: 13505-600 | Rio Claro – São Paulo – Brasil

**Opening Hours:** 8 AM to 5 PM, from Monday to Friday, except holidays.

MDTImplantes

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