Instructions for Use

Intramedullary Nail Locking Screw

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 Screws

Trade Name: Intramedullary Nail Locking Screw

Trade Model:

- Rigifix Locking Screw;
- HBF-2 Locking Screw;
- Locking Screw for Solid Nail Ti;

Raw Material:

- Stainless Steel Alloy (18Cr-14Ni-2.5Mo) –Rigifix Locking Screw / HBF-2 Locking Screw;
- Titanium Alloy (Ti-6Al-4V) – Locking Screw for Solid Nail Ti;

Non Sterile Product

Sterilization Method: Moist Heat (autoclave)

Shelf Life: Undetermined

Description

The trade models which make up the Locking Screw family for Intramedullary Nail are classified as surgically invasive implants for long-term use and were developed to be applied in intramedullary osteosynthesis surgical procedures.

The product is intended for fixing the intramedullary nail to the cortical wall of the proximal and distal portions of the bone, after reduction and stabilization, so that the nail serves as structural element for the fracture healing.

The trade models that make up the Locking Screw family for Intramedullary Nail have symmetric thread and shallow profile, tapered at the tip, providing a self-drilling feature. The screw head has a hexagonal slit with a conical fitting type at the bottom.

The Rigifix Locking Screw is available for commercialization in diameters 5.0 mm and 6.2mm with length varying from 24 mm to 90 mm.

The HBF-2 Locking Screw is available for commercialization in diameters 4.5 mm and 6.0 mm with length varying from 20 mm to 88 mm.

The Locking Screw for Solid Nail Ti is available for commercialization in diameters 4.5 mm and 6.0 mm and length varying from 20 mm to 96 mm.

Below are illustrative images of the trade models which make the Locking Screw family for Intramedullary Nail:

		
Rigifix Locking Screw	**HBF-2 Locking Screw**	**Locking Screw for Solid Nail Ti**

Composition

The materials selected for the composition of the product have the required properties to achieve the desired performance for the product. This selection took into account factors such as biocompatibility and physical, chemical and mechanical properties required for the product.

Rigifix Locking Screw and HBF-2 Locking Screw trade models are made of stainless steel alloy (18Cr-14Ni-2.5Mo) that meets the requirements specified by ASTM F-138 - Standard Specification for Wrought 18 Chromium-14 Nickel-2.5 Molybdenum Stainless Steel Bar and Wire for Surgical Implants (UNS S31673).

In turn, the Locking Screw for Solid Nail Ti is made of titanium alloy (Ti-6Al-4V) that meets the requirements specified by ASTM F-136 - Standard Specification for Wrought Titanium-6Aluminum 4Vanadium ELI-(Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401).

Such materials are featured with physical, chemical and mechanical properties which are favorable for this purpose providing high biocompatibility proven by a vast historical widely described in literature all over the world.

Indication and Purpose

The intramedullary osteosynthesis is indicated for fractures and pseudoarthrosis simple or complex of long bones, in order to propitiate the osseous consolidation in the most physiological way possible.

The product is intended for fixing the intramedullary nail to the cortical wall of the bone proximal and distal portions, after reduction and stabilization, so that the nail serves as structural element to the fracture consolidation.

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;

Forms of Presentation

The trade models that make up the Locking Screw family for Intramedullary Nail are available for commercialization in unitary package, wrapped in double polypropylene plastic packaging and in non-sterile condition.

Inside the second package you may find five copies of the tracking label and 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 Locking Screw for Intramedullary Nail is presented in the following trade models, and each of these models is available for commercialization in the following dimensions:

List of trade models that make up the Locking Screw family for Intramedullary Nail

Illustrative Image	Code	Description	Dimensions (Diameter/Length)	Made of	Quantity Packed
	04.24.39.XXXXX	Rigifix Locking Screw	Ø 5,0 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
	04.24.10.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
	04.24.67.XXXXX	HBF-2 Locking Screw	Ø 4,5 mm: 20, 24, 28, 32, 36, 40, 44, 48, 52, 56, 60, 64, 68, 72, 76 e 80 mm; Ø 6,0 mm: 36, 40, 44, 48, 52, 56, 60, 64, 68, 72, 76, 80, 84 e 88 mm	Stainless Steel Alloy (18Cr-14Ni-2.5Mo)	01
	04.24.70.XXXXX	Locking Screw for Solid Nail Ti	Ø 4,5 mm: 20, 24, 28, 32, 36, 40, 44, 48, 52, 56 e 60 mm; Ø 6,0 mm: 36, 40, 44, 48, 52, 56, 60, 64, 68, 72, 76, 80, 84, 88, 92 e 96 mm	Titanium Alloy (Ti-6Al-4V)	01

Ancillary Components

The ancillary implants to the Locking Nail for Intramedullary Nail are:

- Rigifix Intramedullary Nail;
- HBF-2 Locked Femoral Nail;
- Solid Locked Intramedullary Nail Ti;

The ancillary compnents – Rigifix Intramedullary Nail and Locked Femoral Nail HBF-2 are made of stainless steel alloy (18Cr-14Ni-2.5Mo) which meets the requisite 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).

In turn, the component Solid Locked Intramedullary Nail is made of titanium alloy (Ti-6Al-4V) which meets the requisite specified by the ASTM F-136 – Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401).

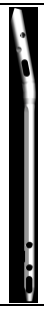
The surgeon in charge of the technique to be applied is also responsible for the right choice of the sizes and combination of the Locking Screw for Intramedullary Nail to be implanted. He must be familiar with the material, the application method and the adopted surgical procedures.

The consolidation success is linked to the right choice, combination, 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.

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 ancillary components to the trade models which make up the Locking Screw family for Intramedullary Nails

Illustrative Image	Code	Description of the Ancillary	Dimensions (Diameter/ Length)	Made Of	Qtty Packed	Matching with Trade models (subject of registration)
	04.11.04.XXXXX	Rigifix Femoral Intramedullary Nail	**Ø 10 mm –** 320, 340, 360, 380, 400, 420, 440, 460, 480 mm; **Ø 12 mm –** 320, 340, 360, 380, 400, 420, 440, 460 mm;	Stainless Steel Alloy (18Cr-14Ni-2.5Mo)	01	 **Rifigix Locking Screw**
	04.11.06.XXXXX	Rigifix Tibial Intramedullary Nail	**Ø 09 mm** – 260, 280, 300, 320, 340, 360, 380, 400 mm; **Ø 10 mm** – 260, 280, 300, 320, 340, 360, 380 mm;	Stainless Steel Alloy (18Cr-14Ni-2.5Mo)	01	
	04.11.14.XXXXX	Rigifix Femoral II Locked Nail	**Ø 10 mm –** 320, 340, 360, 380, 400, 420, 440, 460, 480 mm; **Ø 12 mm** – 320, 340, 360, 380, 400, 420, 440, 460, 480 mm	Stainless Steel Alloy (18Cr-14Ni-2.5Mo)	01	 **Rifigix Locking Screw**

	04.11.15.XXXXX	Rigifix Tibial II Locked Nail	**Ø 09 mm –** 260, 280. 300, 320, 340, 360, 380, 400 mm; **Ø 10 mm** – 260, 280. 300, 320, 340, 360, 380, 400 mm;	Stainless Steel Alloy (18Cr-14Ni-2.5Mo)	01	
	04.11.16.XXXXX	Locked Intramedullary Nail HBF-2 - Short 130º	**Ø 10 mm** – 220 mm; **Ø 12 mm** – 220 mm;	Stainless Steel Alloy (18Cr-14Ni-2.5Mo)	01	 **HBF-2 Locking Screw**
	04.11.17.XXXXX	Locked Intramedullary Nail HBF-2 Long - Left	**Ø 10 mm** – 260, 300, 340, 380, 420, 460 mm;	Stainless Steel Alloy (18Cr-14Ni-2.5Mo)	01	
	04.11.18.XXXXX	Locked Intramedullary Nail HBF-2 Long - Right	**Ø 10 mm** – 260, 300, 340, 380, 420, 460 mm;	Stainless Steel Alloy (18Cr-14Ni-2.5Mo)	01	
	04.11.19.XXXXX	Solid Blocked Femoral Nail Ti	**Ø 09 mm** – 260, 280, 300, 320, 340, 360, 380, 400, 420, 440, 460, 480 mm; **Ø 10 mm** – 300, 320, 340, 360, 380, 400, 420, 440, 460, 480 mm;	Titanium Alloy (Ti-6Al-4V)	01	 **Locking Screw for Solid Nail Ti**

	04.11.20.XXXXX	Solid Locked Tibial Nail Ti	**Ø 08 mm** – 240, 255, 270, 285, 300, 315, 330, 345, 360, 375, 390, 405 mm; **Ø 08 mm** – 240, 255, 270, 285, 300, 315, 330, 345, 360, 375, 390, 405 mm;	Titanium Alloy (Ti-6Al-4V)	01	

Support Materials

The supporting materials are all the instruments designated solely for the Locking Screw for Intramedullary Nail implanting and its respective ancillaries mentioned above.

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 Locking Screw for Intramedullary Nail and its respective ancillaries:

- 0H.03 – Instrument – Femoral Rigid Locking Nail;
- 0H.05 – Instrument – Tibial Rigid Locking Nail;
- 0H.08 – Instrument – Rigifix II Femoral Nail;
- 0H.11 – Instrument – HBF-2 Femoral Locking Nail;
- 0H.12 – Instrument – Rigifix II Tibial Locking Nail;
- 0H.13 – Instrument – Femur/Tibia Solid 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 Locking Screw for 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 Locking Screw for Intramedullary Nail and its respective ancillaries 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 applying the Locking Screw for 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 Locking Screw for 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;
- 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 Locking Screw for 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 Locking Screw for 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 Locking Screws for Intramedullary Nails should be done as parameters described in the table below:

Method	Cycle	Temperature	Exposure Times
Moist Heat (autoclave)	Pre-Vacuum Sterilization (vacuum) 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 Locking Screw for 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 Locking Screw for Intramedullary Nail, there are risks of biologic contamination and viral disease transmission.

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

Product Discard

The Locking Screw for 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;
- Code (if applicable) or piece dimension.

The surgeon in charge and his team must use the traceability labels provided in five copies inside the product package. The labels are to be pasted onto the patient medical records for keeping the implanted product traceability. Besides that, one of those labels must have given the patient in order he or she can get information about the implanted product in his/her surgical procedure.

Below are listed the label information needed for theproduct traceability:

- Manufacturer Identification;
- Component Code;
- Component Batch N°;
- Component Description (in three languages – Portuguese – English and Spanish);
- Quantity;
- ANVISA Registration N°;
- Technical Name;
- Product Trade Name.

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.

Further Information

Manufactured and distributed by:

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

Registration ANVISA #: 10417940073
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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.