Instructions for Use

Screw For Ligamentous Fixation

Legend of symbols adopted in the product labeling

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	Non-Sterile		Keep out of the sun
	Fragile, handle with care		Keep dry

Description

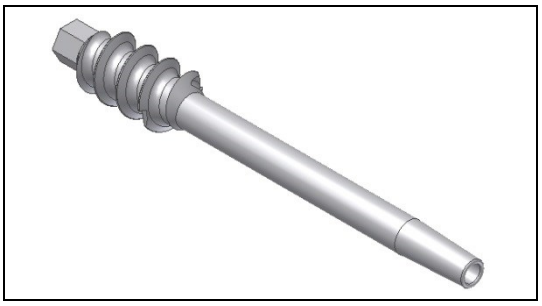
The trade models that make up the Screw for Ligamentous Fixation Family consist of surgically implantable components of long-term use indicated for ligamentoplasty surgical procedures for the reconstruction of the anterior and posterior cruciate ligaments of the knee.

The Screw for Ligamentous Fixation is indicated for fixing bone-tendon-bone grafting or soft tissue in the bone tunnel of the tibia and femur in the reconstruction treatment of the anterior and posterior ligaments of the knee.

The principle of the Interference Screw operation is to maintain normal the biomechanics joint and provide greater strength gain and linear load support.

The Screw for Ligamentous Fixation has parallel thread which allows the fixation of soft tissue and the graft during the restoration of the cruciate ligament through arthroscopy. It is cannulated, which its use along with the guide wire and has hexagonal head which makes insertion and removal easier. It has external thread developed to reduce the possibility of migration during deployment. It also has a smooth body that remains in contact with the graft without causing decidual damage.

An illustrative image of the Screw for Ligamentous Fixation can be seen below:



Composition

The materials selected for the composition of the product have the required properties to achieve the desired performance for the trade models that make up the Screw for Ligamentous Fixation Family. This selection took into account factors such as biocompatibility and physical, chemical and mechanical properties required for the product.

The Screw for Ligamentous Fixation is made from Titanium Alloy (Ti-6Al-4V) due to its properties which make it the ideal material for the production of implantable medical devices. Its main properties are biocompatibility, mechanical resistance, and resistance to wear when properly processed.

The Titanium Alloy (Ti-6Al-4V) used for the production of the trade models which make up the Screw for Ligamentous Fixation Family 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).

Characterized as an Alloy of mechanical and metallurgical properties which are favorable for this purpose, the Titanium Alloy (Ti-6Al-4V) specified by the ASTM F- 136 Norm, provides high biocompatibility proven by a vast historical widely described in literature all over the world.

Indication and Purpose

The Screw for Ligamentous Fixation is indicated for fixing bone-tendon-bone grafting or soft tissue in the bone tunnel of the tibia and femur in the reconstruction treatment of the anterior and posterior ligaments of the knee.

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 Screw for Ligamentous Fixation Family are wrapped in double polypropylene plastic packaging.

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 Screw for Ligamentous Fixation is available in the trade models showed below, and each one of these models is available for commercialization in the following dimensions:

Illustrative Image	Code	Description	Dimensions (Diameter/ Legth)	Made of	Qtty Packed
	04.24.45.65040 04.24.45.65045 04.24.45.65050 04.24.45.65055 04.24.45.65060 04.24.45.65065 04.24.45.65070 04.24.45.65075 04.24.45.65080 04.24.45.65085 04.24.45.65090 04.24.45.65095 04.24.45.65100	Ligfix Screw	Ø6,5 – 40, 45, 50, 55, 60, 65, 70, 75, 80, 85, 90, 95, 100 mm	Titanium Alloy (Ti-6Al-4V)	01

Ancillary Components

The ancillary implants to the Screw for Ligamentous Fixation are:

- Interference Screw;
- Cancellous Screw Ti Ø 6,5 mm;
- Cortical Screw Ti Ø 4,5 mm;
- Toothed Washer;
- Smooth Washer;

Such instruments are made of Titanium Alloy (Ti-6Al-4V) which meets the requirements specified by ASTM F-136 Norm - Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401).

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.

Illustrative Image	Code	Description	Dimensions (Length/ Diameter)	Made of	Qtty Packed
	04.24.16.0XXXX	Interference Screw Ti	Ø 07, 08, 09, 10 mm – 20, 25, 30, 35, 40, 45, 50 mm;	Titanium Alloy (Ti-6Al-4V)	01

	04.24.44.65XXX	Cancellous Screw Thread 16 mm Ø 6.5 mm Ti	Ø 6,5 mm – 30, 35, 40, 45, 50 mm;	Titanium Alloy (Ti-6Al-4V)	01
	04.24.43.45XXX	Cortical Screw Ti Ø 4.5 mm;	Ø 4.5 mm – 30, 35, 40, 45, 50, 60, 65 mm	Titanium Alloy (Ti-6Al-4V)	01
	04.02.05.00XXX	Toothed Washer Ti	Diameters 14 and 17 mm;	Titanium Alloy (Ti-6Al-4V)	01
	04.02.06.00XXX	Smooth Washer Ti	Diameters 14 and 17 mm;	Titanium Alloy (Ti-6Al-4V)	01

The surgeon in charge of the technique to be applied is also responsible for the right choice of the sizes and models of the Screw for Ligamentous Fixation 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 fixation of the devices 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 Screw for Ligamentous Fixation 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 Screw for Ligamentous Fixation and its respective ancillaries:

- OJ.04 Instruments of Ligamentous Fixation

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 Screw for Ligamentous Fixation 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 Screw for Ligamentous Fixation 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;
- 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 some common risks and complication possibilities such as 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 (pseudarthrosis) 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 Screw for Ligamentous Fixation 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 Screw for Ligamentous Fixation 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 (pseudarthrosis) 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 Screw for Ligamentous Fixation 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 Screw for Ligamentous Fixation 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 to 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 Screw for Ligamentous Fixation, 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 Screw for Ligamentous Fixation, there are risks of biologic contamination and viral disease transmission.

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

Product Discard

The Screw for Ligamentous Fixation 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;
- Product 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.

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

ANVISA Registration #: 10417940051
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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.