Instructions for Use

Interference Screw

Legends of the symbols used on packaging

REF	Number in the catalogue	LOT	Batch code
NON STERILE	Non sterile product		Manufacturing date
	Single use product		Consult instructions for use
	Keep away from the sun		Do not use if the package is damaged
	Keep dry		Fragile, handling with care

Product technical specifications and Characteristics

Technical Name: Implant

Commercial Name: Interference Screw

Business models:

- Interference Screw Ti Ø 07 mm;
- Interference Screw Ti Ø 08 mm;
- Interference Screw Ti Ø 09 mm;
- Interference Screw Ti Ø 10 mm.

Raw Material: Titanium Alloy (Ti-6Al-4V)

Non Sterile Product

Sterilization Method: Humid heat (autoclave)

Description

The business models that compose the Interference Screw family consist of surgically implantable components of long term use indicated for surgical procedures of ligamentoplasty for reconstruction of the cruciate ligaments, anterior and posterior of knee.

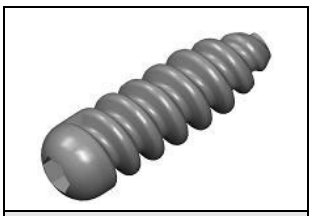
The interference screw is indicated for use in the fixation of graft bone-tendon-bone or soft tissues in bone tunnel of the tibia and femur in treatment of reconstruction of the anterior and posterior ligaments of the knee.

The functioning principle of Interference Screw is keep the articular biomechanics normal and provide greater strength gains and support of linear load.

The business models that compose the Interference Screw family have parallel thread that permit the soft tissues fixation or tendon/bone without risk of disruption during the restoring of the crossed ligaments, whether through traditional technique or by arthroscopy technique.

The external thread was developed to reduce possibility of migration during the implantation while the smooth body stays in contact with the bone grafting, without cause tissue damage. The screw has cannulated body that allows its use in association to the guide wire. It has round head with hexagonal crack and total thread, to facilitate its insertion and removal. The product design provides distribution of torque strengths proportional over its length, reducing the possibility of breaking or wear and greater rigidity in the fixation.

The Interference Screw is available for marketing in the diameters 07, 08 and 09 mm with lengths varying of 20 to 50 mm. It follows below a illustrative image of the Interference Screw:



Interference Screw

Composition

The selected materials for product composition present the required properties to achieve the desired performance for the product. This selection considered factors as biocompatibility and mechanical, chemical, physical properties required for the product.

The Interference Screw is manufactured from titanium alloy (Ti-6Al-4V) due to its properties that it makes an ideal material to producing of implantable medical devices. Its main properties are the biocompatibility and mechanical resistance.

The titanium alloy (Ti-6Al-4V) used to manufacturing of the business models that compose the Interference Screw family meets specified requirements by standard ASTM F-136 - Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) for Surgical Implant Applications (UNS R56401).

Characterized as an alloy with mechanical and metallurgic properties favorable for this aim, the titanium alloy (Ti-6Al-4V) specified by standard ASTM F-136 presents biocompatibility proven by a vast historic widely described in the worldwide literature.

Indication and Purpose

The Interference Screw is indicated for ligament reconstruction procedures of the cruciate ligaments anterior and posterior of knee, for graft fixation bone-tendon-bone or graft of soft tissues in the bone tunnel of the tibia and femur.

The products described here were developed for use in the circumstances above described, so that other use is considered contra indicated or without scientific substrate.

Contra indication

The relative contra indications for use of the device are listed below, leaving to the surgeon in charge the surgical procedure indication, after a detailed study of the case:

- Patients with general active infections or specific that can lead to complications with the fixation;
- Patients with impaired general state and/or immune compromised, unable to be submitted to a surgical procedure;
- Patients with sensibility to foreign bodies, and in these cases, tests should be performed;
- Patients with osteoporosis and/or bone affections that may compromise the fixation stability;
- Patients who use narcotic substance, alcohol or smoke;

Forms of Presentation

The business models that compose the Interference Screw family are available for marketing unitarily packed in the non sterile product condition in plastic packaging double of polypropylene.

Inside the second packaging is a leaflet with instructions for use, which shows the condition of non-sterile product, as well as instructions for handling and use of the product.

There is a label with further information about the product pasted on each package.

The Interference Screw is presented in the following business models, being that each one of these models is commercially available in the following dimensions:

Illustrative Images	Code	Description	Dimensions (Diameter/Length)	Manufacturing Material	Packaged Quantity
	04.24.16.07XXX	Interference Screw	**Ø 07 mm –** 20, 25, 30, 35, 40, 45, 50 mm;	Titanium Alloy (Ti-6Al-4V)	01
	04.24.16.08XXX		**Ø 08 mm –** 20, 25, 30, 35, 40, 45, 50 mm;	Titanium Alloy (Ti-6Al-4V)	01
	04.24.16.09XXX		**Ø 09 mm –** 20, 25, 30, 35, 40, 45, 50 mm;	Titanium Alloy (Ti-6Al-4V)	01
	04.24.16.10XXX		**Ø10 mm** – 20, 25, 30, 35, 40, 45, 50 mm.	Titanium Alloy (Ti-6Al-4V)	01

Ancillaries List

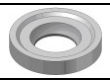
The ancillary implants to the Interference Screw are:

- Ligfix Screw Ø 6,5 mm;
- Cancellous Screw Ti Ø 6,5 mm;
- Cortical Screw Ti Ø 4,5 mm;
- Serrated Washer;
- Smooth Washer;

The ancillary implants are manufactured from titanium alloy (Ti-6Al-4V) that meets specified requirements by standard ASTM F-136 - Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) for Surgical Implant Applications (UNS R56401).

The following ancillary are not objects of this registration process and should therefore be purchased separately and always from the same manufacturer or indicated by the manufacturer.

List of ancillaries Implants to the Interference Screw

Illustrative Images	Code	Description	Dimensions (Length / diameter)	Manufacturing Material	Packaged Quantity	Combination with business models (registry objects)
	04.24.45.650XX	Ligfix Screw Ø 6.5 mm	**Ø 6,5 mm –** 40, 45, 50, 55, 60 mm	Titanium Alloy (Ti-6Al-4V)	01	 Interference Screw 04.24.16.XXXXX
	04.24.44.65XXX	Cancellous Screw Thread 160 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	Serrated 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 is responsible for the correct selection of models and measures of the Interference Screw and by the adopted technique, as well as their ancillary that will be implanted. He should be familiar with the material, method of application and surgical procedure to be adopted.

The success of the procedure is linked to correct selection, positioning and fixation of the devices, which is the responsibility of the surgeon that assesses the patient and decides which implants to use. It is also bound to strict compliance of postoperative care recommended by the surgeon in charge.

List of Support Material

The support materials are the instrumentals designed solely for business models implantation of the Interference Screw and their respective ancillaries aforementioned.

These instrumentals are made in stainless steel that provides high resistance and durability, according to specified requirements by standard ASTM F-899 – Standard Specification for Stainless Steel for Surgical Instruments.

The instrumentals below are not object of this registry and must, therefore, be purchased separately and always from the same manufacturer of the implant or indicated by them.

See list of instrumentals below, available by manufacturer or other by them indicated to implantation of the Interference Screw Ti and its respective ancillaries:

- OJ.04 – Instrumental of Ligament Fixation

The instrumentals are provided decontaminated, but not sterilized. Inadequate sterilization of surgical instruments can cause infection.

The surgical instrumentals are subject to wear and tear during the normal use, and it can therefore break. The instruments should be used only for its purpose and should be inspected regularly to check possible wear and damage.

For more information about the instrumental, consult the representative.

Warning and Precautions

For use of the product, the responsible team must consider the following warning and precautions:

- The Interference Screw must be only used after a detailed analysis of the surgical procedure to be adopted and complete reading of this use instruction;
- The product must be only used by specialized surgical team, with specific knowledge and training on the techniques of ligamentoplasty, and it is the responsibility of the surgeon the choice and domain of technique to be applied;
- The selection and inadequate choice of the implants to be used, as well as the mistakes in the indication, handling and surgical technique can cause excessive tensions and tractions on the implant, leading to failure by fatigue, fracture and to release them;
- The clinical results and the durability of the implants are extremely dependents on an accurate surgical technique;
- The use in patients with predisposing to disobey the medical guidelines and postoperative restrictions, as children, elderly, individuals with neurological disorders or dependent in narcotic substances, represent a greater risk for failure of the implant;
- The risk of failure of the implant are greater in patients engaged in efforts activities or practice sports activities, during the postoperative period, contrary to the medical restriction;
- The postoperative complications represent a greater risk when the product is used in patients with morbid obesity;
- The Interference Screw and their respective ancillary should not be used if it do not have an adequate bone support to ensure the implant stability;
- The patient must make a periodic medical monitoring to check the conditions of the implant, of the bone and adjacent tissues;
- The medical criteria, can be use an antibioticterapy prophylactic pre and perioperative, and the antibioticterapy in cases where there is a local predisposition and/or systemic or where there is occurrence of infections;
- The implant should not be used with components from other manufacturers or purpose. The combination of implant of manufacturers or different purpose can result in incongruence between the components;
- The care of these materials are the responsibility of qualified personnel, which should follow the standards and/or other local regulations applied;

- Fall and crushing on hard surfaces can cause damage to the product. Thus, it is necessary the user perform an inspection of the product integrity, when the packaging is opened, and if any abnormality is observed the product should not be used;
- The opening of the packaging for surgical use should only be performed by qualified personnel for this procedure;
- Do not use the product if its validity is expired or its packaging is violated.
- Handle with care;
- Single use product – Do not reuse;
- The implants must NEVER be reused. Although they may seem undamaged, tensions previous that they have been submitted can cause imperfections that would reduce the lifetime of the product in a re-implantation;
- Improper sterilization of implants can cause infection;
- PROHIBITED REPROCESS;
- Manufacturing date and batch number: see label.

Adverse Effects

Every surgical procedure presents risks and possibility of complications, being that any common risks are infection, bleeding, drug allergic reaction 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 bony consolidation resulting in implant disruption;
- 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;
- Break of the device that can make its removal difficult or impractical.

The surgeon is responsible to make the decision of implant removal due to adverse effects aforementioned.

Use Instructions

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

- The care of this material is the responsibility of the qualified personnel, which should follow the standards and/or other local regulations applied;
- The product should be handled with appropriate care in adequate locations (materials central and operating rooms);
- The product should only be used by specialized surgical teams, with specific knowledge and specific training on techniques for osteosynthesis, being the surgeon in charge by the choice and dominion of the surgical technique to be applied;
- The implant useful life is characterized by required time to bone consolidation, limiting to the maximum term of 01 (one) year. After this period in case of absence or problems with the bone consolidation, these conditions can represents a risk of implant failure by excessive mechanical stress;
- May be necessary the review surgery, in the above cited case or if is observed the release of components;
- For the application of Interference Screw and its ancillary components respective is necessary the use of specific instrumental, indicated in topic: “Support Material”. They should be not used with other instruments than those indicated by the manufacturer, due to possibility of dimensional incompatibility and/or functional;
- For application of the Interference Screw and their respective ancillary components needs the use of specific instrumental, indicated in the topic “Support Material”. Should not be used with instruments other than those indicated by manufacturer, due to possibility of dimensional/functional incompatibility;

- The correct combination of the Interference Screw and their respective ancillary components is indicated in the topic “Ancillary Components”. Should not be used with components other than those indicated by manufacturer, due to possibility of dimensional/functional incompatibility;

Guidance to the patient and/or the Legal Representative

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

- The adequate 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 higher when using in patients with predisposition to disobey the guidelines medical, care and postoperative restrictions, such as children, elderly, individuals with neurological disorders or chemical dependents;
- The fact that the product does not substitute and does not have the same performance of normal bone and therefore can break, deform or loosen 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, the medical criteria exclusively of external supports, aid to ambulate and orthopedic appliances, designed to limit the movement and/or load;
- The necessity for periodic medical monitoring to check the conditions of the implant, the bone and the adjacent tissues;
- The fact that the non-performing of the review surgery in a superior term the 01 (one) year, in cases in which not occurred bone consolidation can lead the mechanical failure of the implant ;
- The needs of review surgery in cases of components loosening;
- The fact that implants can interfere with results of imaging examinations. Thus, implant users should report this fact when carrying out 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 Interference Screw Ti is supplied in the 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 Interference Screw Ti and their respective ancillary is 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 Interference Screw Ti sterilization 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 (materials central) of the health service.

Cleaning

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

When to use the Interference Screw Ti and their respective ancillary, they should be removed from their packaging and washed 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' equipments with the help of descaling substances, the manufacturer guidelines should be adopted.

Contamination Risk

As this is an implantable product, in cases where there is need the explantation of Interference Screw, there are risks of biologic contamination and viral disease transmission.

For minimize these risks, the explanted Interference screw should be treated as contaminant potentially material and should be adopted the standardization and/or other local regulations applicable.

Product Discard

The explanted Interference screw or considered improper for use should be discarded. It is recommended before discard that the product be mischaracterized, for this the parts can be cut, bent or polished.

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 contaminants potentially 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. The necessary information 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;

The necessary information to traceability of the product, to follow, is engraved in the part or may be obtained by label inside its packaging:

- Company logo;
- Manufacturing batch;
- Part code.

The surgeon in charge and his team must use of the labels for traceability supplied in the product packaging, pasting them into the patient's medical record to maintenance of the traceability of the implanted product. In addition, one of these labels should be supplied to the patient for that has information about the product implanted in his surgery.

The labels contain the product data as: code, description and lot number, among other information.

The traceability information is necessary for notification by the service of health and/or by the patient to the Sanitary surveillance Agency – ANVISA and to the manufacturer in cases of serious adverse events to conduct the 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 of the product 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

Av. Brasil, nº. 2983 – Distrito Industrial

Rio Claro/SP – CEP 13.505-600

Phone/ Fax: (55-19) 2111-6500

Technical Responsible: Miguel Lopes Monte Junior – CREA 0601150192

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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.