Instructions for Use

MI 360° Trans-facet Trans-laminar Cannulated Screw

Symbols used in packaging

REF	Reference Code		Keep Dry
NON STERILE	Non Sterile	LOT	Lot Code
	Manufacturing Date	CE XXXX	Product Certified in accordance to 93/42/CEE Directive. If applicable
	Consult Instructions for use		Single Use Product
	Do not use if package is damaged		Fragile – Handle with care
	Keep away from the sun		

Characteristics and Technical specifications of the Product

Technical Name: Non Absorbable screw for Osteosynthesis

Trade Name: MI 360° Trans-facet Trans-laminar Cannulated Screw

Trade Models: 360º Cannulated Screw MI

Raw Material: Titanium Alloy (Ti-6Al-4V – ASTM F136)

Non Sterile Product

Sterilization Method: Sterilization by humid heat (autoclave)

Validity: Indeterminate

Description

The MI 360° Trans-facet Trans-laminar Cannulated Screw family is formed by cortical cannulated screws used for segmental stabilization of the lumbar spine and lumbosacral, via posterior approach.

The purpose of the cannulated channel is the passage of the guide wire to guide the surgeon during the surgical procedure. The screws have spherical head, fully threaded body with Asymmetrical thread of a nominal diameter of 4.5 mm.

Screws are fixed via trans-facet trans-laminar through a small incision (about 1 cm), in arthrodesis procedures.

The operating principle of the Trans-facet Trans-laminar cannulated screw MI 360 is to provide stability to the instrumented segment, promoting surgical arthrodesis of the posterior lumbar facet joints.

The screws have connection for hex drive of 3.5 mm and are available for sale with a diameter of 4.5 mm and lengths ranging from 40 mm to 55 mm.

Composition

The screws that make up the family of the MI 360° Trans-facet Trans-laminar Cannulated Screw are manufactured from titanium alloy Ti-6Al-4V, specified by ASTM F136 "Standard Specification for Wrought Titanium-6Aluminum 4Vanadium-ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401) '.

The selected materials for manufacturing the family of the MI 360° Trans-facet Trans-laminar Cannulated Screw gathers the required physico-chemical and mechanical properties to achieve the desired performance for the product. This selection considered factors such as manufacturing effects, handling, sterilization, storage, as well as possible reactions of the material when in contact with human tissues and body fluids.

The manufacturing material is compatible with biological tissues, cells and body tissues with which it comes in contact in implantable state, evidenced by the historical usage in similar applications available in the world scientific and clinical literature. Such confirmation also applies to possible wear products and wear of the material at acceptable levels throughout its use.

Indication and Purpose

The screws of the family of the MI 360° Trans-facet Trans-laminar Cannulated Screw are indicated for minimally invasive surgical procedures mono and bi lumbosacral segmental stabilization of the lumbar spine, and posterior approach in cases of:

- Deformity in the sagittal axis - Grade I Spondilolistesis
- Degenerative diseases - Reviews of surgeries, stenosis, Degeneration of intervertebral disc, pseudarthrosis and degenerative Spondilolistesis.

The product is designed to be used in lumbar contralateral trans-laminar and trans-facet arthrodesis through minimally invasive percutaneous surgery with 360 degrees with unilateral approach via trans-muscular Para-spinal.

This minimally invasive technique minimizes extensive dissection in the muscle tissue with consequent ischemic injury and denervation, present in conventional surgery.

The procedure for trans-laminar and trans-facet fixation and stabilization, in certain clinical situations and under the physician's discretion, can be associated to the stabilization and complement fixation with the use of intersomatic devices, spacers and / or pedicular systems, however, these components do not interact among each other.

The product described herein was developed to be used in the above conditions, so that any other uses are considered contraindicated or with no scientific substratum to support its use.

Contraindication

Contraindications for the use of the product are listed below. Indication of the surgical procedure is done by the surgeon in charge, after a thorough 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, being that 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 trade models that make up the MI 360° Trans-facet Trans-laminar Cannulated Screw family are available for commercialization unitarily packed in double polypropylene plastic packing.

The trade models that make up the MI 360° Trans-facet Trans-laminar Cannulated Screw family are available for commercialization in non-sterile condition product.

Inside of second packaging are five copies of the traceability label and a flyer with the use instructions, which presents this condition of non-sterile product, such as the instructions for handling and product use.

A label containing the necessary information for the product identification is glued on the packaging.

The MI 360° Trans-facet Trans-laminar Cannulated Screw implants family is available in the following trade models and dimensions:

Illustrative image	Code	Description	Made of	Qtty Packed
	04.43.17.45040	MI 360º Cannulated Screw Ø 4,5 x 40 mm	Titanium Alloy (Ti-6Al-4V)	01
	04.43.17.45045	MI 360º Cannulated Screw Ø 4,5 x 45 mm		
	04.43.17.45050	MI 360º Cannulated Screw Ø 4,5 x 50 mm		
	04.43.17.45055	MI 360º Cannulated Screw Ø 4,5 x 55 mm		

The correct selection of models and sizes of screws to be implanted is responsibility of the surgeon, as well as the surgical technique used and knowledge of the material, the method of application and the surgical procedure to be performed.

The success of the procedure is linked to correct selection, positioning and fixation of the devices, which are the responsibility of the surgeon that assesses the patient and decides which implants to be

used. It is also bound to strict compliance with postoperative care recommended by the surgeon in charge.

Support Material

The supporting materials are instruments designed solely for the implantation of the MI 360° Trans-facet Trans-laminar Cannulated Screw.

These instruments are made in stainless steel which gives them high resistance and durability in accordance with the specified requirements by standard ASTM F-899 – "Standard Specification for Stainless Steel for Surgical Instruments".

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

The instruments available by the manufacturer or by them indicated, for the implanting of the family of screws of the MI 360° Trans-facet Trans-laminar Cannulated Screw are listed below:

Description
MI 360 Handling Knob with Quick Coupling
MI 360 Reducing Cannula for Guide Wire
MI 360 cannulated Driver
MI 360 Dilator nº1
MI 360 Dilator nº2
MI 360 Dilator nº3
MI 360 Guide Wire Ø1,5x300mm
MI 360 Guide Wire Ø3,0x230mm
MI 360 Guide
Cannulated Screw Ø 4,5 x 40 mm
Cannulated Screw Ø 4,5 x 45 mm
Cannulated Screw Ø 4,5 x 50 mm
Cannulated Screw Ø 4,5 x 55 mm
MI 360 Depth Gauge
Soft Parts Protector

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

The surgical instruments 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 for possible wear and damage.

For more information on the instrumental, see the representative.

Warning and Precautions

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

- The MI 360° Trans-facet Trans-laminar Cannulated 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 only be used by specialized surgical team, with specific knowledge and capacity on the vertebral column stabilization techniques, being the responsibility of the surgeon the choice and dominion of the 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 surgical procedure for Intersomatic bone fusion presents risks of vascular injuries, visceral, neural, pseudarthrosis, among others;
- 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 product must not be used if an adequate bone support does not exist to ensure the implant stability;
- The screw implantation in improper positions can cause vascular damage, nerves or injuries in organs;
- The patient must be submitted to periodic medical monitoring to check the conditions of the implant, the bone and adjacent tissues;
- Antibiotic therapy prophylactic pre and perioperative, and the antibiotic therapy in cases where there is a local predisposition and/or systemic or where there is occurrence of infections can be used under medical criteria;
- 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 this material is responsibility of qualified staff, 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 the packaging is damaged;
- 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;
- Non Sterile Product – must be sterilized before use and handled properly to avoid contamination;
- Improper sterilization of implants can cause infection;
- REPROCESSING PROHIBITED;
- Manufacturing date and lot 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, visceral and neural injuries;
- Absence or delay of bony fusion (pseudarthrosis) resulting in implant breaking;
- Loosening, dismemberment, displacement, twisting or break of the implant;
- Deformation or fracture of the implant;
- Fracture of vertebrae parts;
- 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 column fixation in any level is a surgical procedure of universal recognition, however, the bone fusion of one or more vertebral-motors segments can cause overload over the adjacent levels.

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 due care in appropriate locations (Material Center and surgical rooms);
- The product should only be used by specialized surgical teams, with specific knowledge and training on techniques for vertebral column stabilization, being the surgeon in charge by the choice and dominion of the surgical technique to be performed;
- The torque to be applied on screw during the bone insertion depends on its characteristics and conditions. Only the surgeon in charge must decide which torque to be applied;
- The implant useful life is characterized by required time to bone fusion, limiting to the maximum term of 01 (one) year. After this period in case of absence or problems with the bone consolidation (pseudarthrosis), these can represents a risk of implant failure by excessive mechanical stress;
- Review surgery may be necessary in the above cited case or if is observed the release of components;
- It is necessary the use of specified instruments for the application of MI 360° Trans-facet Trans-laminar Cannulated Screw according to the "Support Material" topic. They should be not used with other instruments than those indicated by the manufacturer, due to dimensional and/or functional possibility of 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 in the vertebral column;
- 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 to use external supports, aid to ambulate and orthopedic appliances, designed to limit the movement and/or load, under exclusive medical criteria;
- 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 fusion (pseudarthrosis) 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. 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 product is provided 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 the MI 360° Trans-facet Trans-laminar Cannulated Screw 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

Sterilization of the product should be done as parameters described in the table below:

Method	Cycle	Temperature	Exposure Time
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 (materials central) of the health service.

Cleaning

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

When using the screws and their respective ancillary, these should be removed of its 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' equipment 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 the implant, there are risks of biologic contamination and viral disease transmission.

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

Product Discard

The explanted screws 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 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;
- ANVISA product Registration;

The surgeon in charge and his team should make use of the traceability labels provided in five (05) copies inside the product packaging, sticking them onto the patient's chart for the implanted product traceability maintenance. In addition, one of these labels should be provided to the patient for it has information about the product implanted on their surgical procedure.

The label contains the following information necessary for product traceability:

- Manufacturer Identification.
- Component Code.
- Component Lot Number.
- Component description (in three languages – Portuguese, English and Spanish).
- Quantity.
- ANVISA Registration Number.
- Technical Name.
- Product Trade Name.

The traceability information is necessary to notification of adverse events involving failure of implant. These cases should be notified to the Sanitary surveillance Agency – ANVISA and the manufacturer, 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 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
Address: Av. Brasil, nº. 2983 – Distrito Industrial – Rio Claro/SP
CEP: 13.505-600
Phone/Fax: (55-19) 2111-6500
CNPJ: 01.025.974/0001-92
Responsible Technician: Miguel Lopes Monte Junior – CREA: 0601150192
CE(according to Directive 93/42/CEE) if applicable.

ANVISA Registration nº.: 10417940099
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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 CAP (Customer Service Department) manufacturer, as following:

Customer Service Department – CAP:

Telephone: +55 19 2111.6500

FAX: +55 19 2111.6500

http://www.mdt.com.br/contato

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.