Instructions for Use

PEEK OPTIMA - Interference Screw

Legend of symbols adopted in the product packing

REF	Catalogue Number	LOT	Lot Code
STERILE R	Sterilized using irradiation	CE	Product Certified in accordance to 93/42/CEE Directive. If applicable
	Manufacturing Date		Validity
	*Consult instructions for use*		Single Use Product
	Do not use if package is damaged		DO NOT re-sterilize
	Keep out of the sunlight		Fragile – Handle with care
	Keep Dry		Maximum Temperature (40°C)

Characteristics and Technical specifications of the Product

Technical Name: Non Absorbable screw for Ligamentoplasty

Trade Name: PEEK OPTIMA Interference Screw

Trade Model:

- PEEK interference Screw;

Raw Material: Polyetheretherketone (PEEK) – ASTM F-2026;

Sterile Product

Sterilization Method: Gamma Radiation (Dosage 25 kGy)

Validity: 05 anos (após a data da esterilização)

Description

The PEEK OPTIMA Interference Screw consists of an implantable device, surgically invasive, of long-term use, mainly used in procedures of reconstruction of the cruciate ligaments of the knee.

The product is indicated for graft fixation in bone tunnels of the femur and tibia in conventional or arthroscopic reconstruction procedures of intra-articular of the cruciate ligaments of the knee.

The principle of fixation with interference screw is based on the wedge effect, in which the bolt compresses the graft against the bone tunnel wall of the cavity ("compression-loaded wedge to secure the bone graft Within the tunnel '), promoting insertion and fixation of soft tissue the femoral and tibial tunnels of the knee.

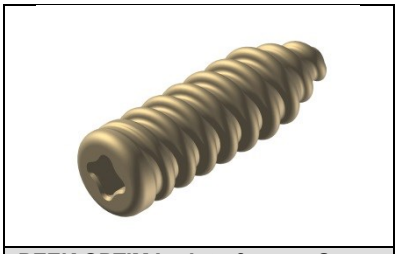
Surgical treatment with interference screws aims the reconstruction of the ligaments, in order to restore the stability of the knee joint, as well as prevent progression of instability of the joint and subsequent meniscal and cartilaginous injuries under this grievance which can trigger osteoarthritis of the knee.

The operating principle of the product is through the stiffness of the implant, promote stability and fixation of the graft used for reconstruction of the knee joint and provide resistance against slippage in cyclic loading conditions to prevent the gradual loss of the reconstruction of the cruciate ligaments during the postoperative period;

The PEEK OPTIMA - Interference Screw presents head with slightly round corners and hexagonal slot. The screw body is cannulated, for use in combination with the wire guide, and has parallel full thread of round profile, which facilitates insertion and removal. The product is designed, so that the external

screw thread provides the graft fixation during implantation, whereas the flat body of the screw promotes contact, without causing tissue damage to the graft. The product design allows the distribution of torque forces proportionally on the screw length, reducing the chance of breakage or wearing of the implant and providing more rigid fixation.

The PEEK OPTIMA - Interference Screw is manufactured from Polyetheretherketone (PEEK), of the OPTIMA family, polymer characterized by its high biocompatibility, strength and stability. The product is available for commercialization with diameters of 06, 07, 08, 09, 10 and 11 mm and lengths ranging from 20 mm to 40 mm, as illustrated below:



PEEK OPTIMA – Interference Screw

Composition

The selected material for the device manufacturing 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.

The product is manufactured from granules of the polymer named Polyetheretherketone (PEEK) from the OPTIMA Family, polymer characterized by high strength and stability. The chemical composition of PEEK-OPTIMA (Polyetheretherketone in medical grade) is -**C6H4**-**O**-**C6H4**-**O**-**C6H4**-**CO**-)**n**. The material has partially crystalline structure which gives excellent mechanical properties, extreme resistance to hydrolysis and to most solvents and of ionizing and radiation effects.

The polymer Polyetheretherketone (PEEK) from the OPTIMA family, used for manufacturing the trade models which make up the Non Expansive Intersomatic Cage – PEEK OPTIMA meets the requirements specified by the norm ASTM F-2026 Standard Specification for Polyetheretherketone (PEEK) Polymers for Surgical Implant Applications.

Extensively studied, these manufacturing materials have satisfactory results in long term segments. Characterized by their physical, chemical and mechanical properties which are favorable for this purpose, they have proven biocompatibility through a vast clinical historic widely described in the literature.

This material was selected and elected to manufacture the product due to its mechanical characteristics, sufficient and necessary efforts to receive to which the implants are subjected during his period in service and due to its characteristics of proven biocompatibility requirements as specified by ISO 10993-1 - 'Biological evaluation of medical devices - Part 1: Evaluation and testing Within the risk management process'.

The raw material used is provided in the form of granules, as specified below:

Property	ASTM F2026 Reference Value
Melting Temperature (Tm)	320ºC - 360ºC
Recrystalization Temperature (Tc)	260ºC - 320ºC
Vitrea Transition Temperature (Tg)	125ºC - 165ºC
Total of Heavy Metals. (% max.)	< 0,1
Dimensions of the Granule	Diameter: 2,0 mm – 3,5 mm Length: 2,0 mm – 4,0 mm

Indication and Purpose

The PEEK OPTIMA - Interference Screw is indicated for the fixation of soft tissue to bone tunnels of the femur and tibia procedures for conventional or arthroscopic reconstruction of the cruciate ligaments of the knee. It is also suitable for other surgical situations, in which reinsertion and fixation of soft tissue (autologous or homologous) in bone tunnels are needed.

The purposes of the product are the re-insertion, fixation and stabilization of graft in bone tunnels, in the reconstruction of the cruciate ligaments, aiming at restoring the joint biomechanics of the knee.

The ligament reconstruction procedure has by appointment various clinical situations, which according to the treatment strategies adopted by the surgeon, the most commonly treated are:

- Instabilities arising from the failure of the cruciate ligaments of the knee;
- Acute peripheral injury or laxity;
- Ruptures of the cruciate ligaments of the knee;
- Reconstruction of the medial patellofemoral ligament;
- Other surgical situations in which the re-insertion of the soft tissue (autologous or homologous) in bone tunnels is necessary;

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.

Contraindications

Contraindications related to the use of the implant are listed below, leaving the indication of the procedures under the responsibility of the surgeon in charge, after a detailed study of the case:

- Patients with general active infections or specific that can lead to fixation complications.
- 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 advanced osteoporosis and/or bone affections that may compromise the fixation stability;
- Patients who use narcotic substance, alcohol or smoke;

Presentation Form

The trade models that compose the PEEK OPTIMA – Interference Screw Family are unitarily packed in blister type (PET) double primary package system, sealed with surgical grade paper (Tyvec ® type). The screw is placed in a blister type cot, also sealed with surgical grade paper, which is put inside a second pack, sealed with surgical grade paper, too, forming the double sterilization shield.

The product is available for the market in sterile condition, and the adopted sterilization method is by Gamma Radiation (dosage of 25 kGy) performed by a certified outsource company.

After being sterilized, the product, in its primary package, duly labeled, is conditioned in an outer carton (secondary package), which contains 5 copies of the traceability label and a folder which has all the instructions for the correct use and handling of the product.

A label containing information needed for the product identification is glued on the carton and also on the primary package.

The PEEK OPTIMA Interference Screw is presented in the following trade models and each one of them are available for commercialization in the dimensions listed below:

List of the models that make up the PEEK OPTIMA Interference Screw Family

Illustrative Image	Code	Description	Dimensions (Diameter x Length)	Made of	Qtty Packed
	04.43.12.06020	PEEK Interference Screw Ø 06x20 mm	**Diameter :** 06 mm **Length :** 20, 25, 30, 35, 40 mm	Polyetheretherketone (PEEK) ASTM F-2026	01
	04.43.12.06025	PEEK Interference Screw Ø 06x25 mm			
	04.43.12.06030	PEEK Interference Screw Ø 06x30 mm			
	04.43.12.06035	PEEK Interference Screw Ø 06x35 mm			
	04.43.12.06040	PEEK Interference Screw Ø 06x40 mm			
	04.43.12.07020	PEEK Interference Screw Ø 07x20 mm	**Diameter :** 07 mm **Length :** 20, 25, 30, 35, 40 mm	Polyetheretherketone (PEEK) ASTM F-2026	01
	04.43.12.07025	PEEK Interference Screw Ø 07x25 mm			
	04.43.12.07030	PEEK Interference Screw Ø 07x30 mm			
	04.43.12.07035	PEEK Interference Screw Ø 07x35 mm			
	04.43.12.07040	PEEK Interference Screw Ø 07x40 mm			
	04.43.12.08020	PEEK Interference Screw Ø 08x20 mm	**Diameter :** 08 mm **Length :** 20, 25, 30, 35, 40 mm	Polyetheretherketone (PEEK) ASTM F-2026	01
	04.43.12.08025	PEEK Interference Screw Ø 08x25 mm			
	04.43.12.08030	PEEK Interference Screw Ø 08x30 mm			
	04.43.12.08035	PEEK Interference Screw Ø 08x35 mm			
	04.43.12.08040	PEEK Interference Screw Ø 08x40 mm			
	04.43.12.09020	PEEK Interference Screw Ø 09x20 mm	**Diameter :** 09 mm **Length :** 20, 25, 30, 35, 40 mm	Polyetheretherketone (PEEK) ASTM F-2026	01
	04.43.12.09025	PEEK Interference Screw Ø 09x25 mm			
	04.43.12.09030	PEEK Interference Screw Ø 09x30 mm			
	04.43.12.09035	PEEK Interference Screw Ø 09x35 mm			
	04.43.12.09040	PEEK Interference Screw Ø 09x40 mm			
	04.43.12.10020	PEEK Interference Screw Ø 10x20 mm	**Diameter :** 10 mm **Length :** 20, 25, 30, 35, 40 mm	Polyetheretherketone (PEEK) ASTM F-2026	01
	04.43.12.10025	PEEK Interference Screw Ø 10x25 mm			
	04.43.12.10030	PEEK Interference Screw Ø 10x30 mm			
	04.43.12.10035	PEEK Interference Screw Ø 10x35 mm			
	04.43.12.10040	PEEK Interference Screw Ø 10x40 mm			
	04.43.12.11020	PEEK Interference Screw Ø 11x20 mm	**Diameter :** 11 mm **Length :** 20, 25, 30, 35, 40 mm	Polyetheretherketone (PEEK) ASTM F-2026	01
	04.43.12.11025	PEEK Interference Screw Ø 11x25 mm			
	04.43.12.11030	PEEK Interference Screw Ø 11x30 mm			
	04.43.12.11035	PEEK Interference Screw Ø 11x35 mm			
	04.43.12.11040	PEEK Interference Screw Ø 11x40 mm			

Ancillary Components

The following are ancillary components compatible with the PEEK OPTIMA Interference Screw:

- Ligfix Screw Ø 6,5 mm;
- Cancellous Screw Ti Ø 6,5 mm;
- Cortical Screw Ti Ø 4,5 mm;
- Toothed Washer;
- Flat Washer;

Related Ancillary Components are manufactured from 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).

The Ancillary Components 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:

List of the Ancillary Components compatible with the PEEK OPTIMA Interference Screw

Illustrative Image	Code	Description	Dimensions (Diameter / Length)	Made of	Qtty Packed
	04.24.45.650XX	Ligfix Screw Ø 6.5 mm	**Diameter :** Ø 6,5 mm; **Length :** 40, 45, 50, 55, 60 mm	Titanium Alloy (Ti-6Al-4V) ASTM F-136	01
	04.24.44.65XXX	Cancellous Screw Thread 16 mm Ø 6.5 mm Ti	**Diameter :** Ø 6,5 mm; **Length :** 30, 35, 40, 45, 50 mm;	Titanium Alloy (Ti-6Al-4V) ASTM F-136	01
	04.24.43.45XXX	Cortical Screw Ti Ø 4.5 mm;	**Diameter :** Ø 4.5 mm; **Length :** 30, 35, 40, 45, 50, 60, 65 mm;	Titanium Alloy (Ti-6Al-4V) ASTM F-136	01
	04.02.05.00XXX	Toothed washer Ti	**Diameter** – 14 e 17 mm;	Titanium Alloy (Ti-6Al-4V) ASTM F-136	01
	04.02.06.00XXX	Flat washer Ti	**Diameter –** 14 e 17 mm;	Titanium Alloy (Ti-6Al-4V) ASTM F-136	01

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 trade models that make up the PEEK OPTIMA Interference Screw Family..

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 below 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.

See below the list of instruments provided by the manufacturer or other by them indicated for the product implantation:

- Instrument – Ligamentous Fixation
- Instrument – Anatomic Ligamentous Reconstruction

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 product must be only used after a detailed analysis of the surgical procedure to be adopted and complete reading of this use instruction;
- The must be only 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 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 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;
- REPROCESSING PROHIBITED;
- Sterile Product – DO NOT re-sterilize;
- 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 decision to implant removal due to the aforementioned adverse effects must be 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 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 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 product life is characterized by the time necessary for the re-insertion of the grafted tissue to bone, which usually takes from six (06) months to one (01) year, and must remain implanted after the consummation of ligament reconstruction, since the device performs the function of a passive permanent implant. However, after this period, failures caused by surgical procedure and metabolic problems of the patient may represent risk of implant failure by excessive mechanical stress;
- Thus, the likelihood of the need for revision surgery increases, in the above or other situations that can cause the failure or loosening of the implant and / or rupture when the graft is perceived.
- For the application of the product, it is necessary the use of specific instruments, indicated in topic: “Support Materials”. They should not be used with other instruments than those

indicated by the manufacturer, due to possibility of dimensional and/or 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 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 higher when using in patients with predisposition to disobey the medical guidelines, care and postoperative restrictions, such as children, elderly, individuals with neurological disorders or chemical dependence;
- The fact that the product does not substitute nor does 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 using, solely under medical criteria, external supports, aid for ambulating and orthopedic appliances, designed to limit movements and / or load, as well as physical therapy in the immediate postoperative;
- The necessity for periodic medical monitoring to check the conditions of the implant, the bone and the adjacent tissues
- The necessity of review surgery in cases of loosening of the product and / or graft failures;
- 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 available in sterile condition. It is adopted the Gamma Radiation (dosage of 25 kGy) Sterilization method.

The product manufacturing process is done with great care, in order to meet the intended performance for it. So, the surgical team and all the other who are involved with the procedure should handle the devices properly in order to minimize the infection risks.

STERILE Product – Do Not Re-sterilize.

Do NOT USE if the product if the package is damaged.

Contamination Risk

As this is an implantable product, there are risks of biologic contamination and viral disease transmission in cases in which it has to be explanted.

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

Product Discard

The devices which were 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

REPROCESSING PROHIBITED

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 surgeon in charge and his team should make use of the traceability labels which are supplied in 5 copies inside the product package, placing them onto the patient's medical record for the implanted product traceability. Besides that, one of these labels MUST BE GIVEN to the patient so that s/he has information about the product implanted in her/his surgical procedure.

The labels bring the following information necessary for the traceability of the product:

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

The traceability information are necessary to notifying by the health service and/or the patient to Sanitary Surveillance Agency - ANVISA and manufacturer, when there is occurrence of serious adverse events, for the conduct of appropriate investigations.

Storage and Transport

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

As it is a STERILE PRODUCT, the storage place temperature and humidity must be monitored and kept under 40° C.

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, and 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 lot number: see label.

Further Information

Manufactured and distributed by:
MDT – Indústria Comércio Importação e Exportação de Implantes SA
Address: Av. Brasil, nº. 2983 – Distrito Industrial – Rio Claro/SP – Brasil
CEP: 13.505-600
Phone/Fax: (55-19) 2111-6500
CNPJ: 01.025.974/0001-92
Technician Responsible: Miguel Lopes Monte Júnior – CREA: 0601150192
CE XXXX (according to Directive 93/42/CEE). If applicable).

ANVISA Registration nº.: 10417940100
Review: 00
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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/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.