Instructions for Use

Non Expansive Intersomatic Cage – PEEK OPTIMA

Subtitles of the symbols used in the packaging

REF	Catalog Code	LOT	Batch Code
STERILE R	Sterile Product – Sterilized by Gamma Radiation		Valid Until
	Manufacturing Date		Single Use Product
	Consult Instructions for Use		DO NOT Sterilize
	Do not use if the package is damaged		Fragile – Handle with care
	Keep protected of the sun		Temperature Limit (40°C)
	Keep Dry		

Features and technical specifications of the product

Technical Name: Disc Replacement Intersomatic Spacing Device

Trade Name: Non Expansive Intersomatic Cage – PEEK OPTIMA

Trade Model:

- Fusimax ACP – Fusion Cage – PEEK OPTIMA;
- Fusimax BCP – Self-Locking Cervical Cage – PEEK OPTIMA;
- Fusimax ALP/ PLP – Posterior Intersomatic Cage – PEEK OPTIMA;
- Fusimax TLP – Transforaminal Intersomatic Cage – PEEK OPTIMA;

Raw Material:

- **Cages –** Polyetheretherketone (PEEK) – ASTM F-2026;
- **Reference Pins –** Tantalum – ASTM F-560;
- **Flip Lock –** Titanium Alloy (Ti-6Al-4V) – ASTM F-136;

Sterile Product

Sterilization Method: Gamma Radiation (Dose 25 kGy);

Shelf Life: 05 years (from sterilization date)

Description

The Family of the Non Expansive Intersomatic Cage – PEEK OPTIMA consists of long-term use surgically invasive implantable devices, used in spinal column fusion procedures.

The product has the purpose of stabilizing and maintaining the intervertebral space of the cervical and lumbar segments via anterior and posterior accessing in surgical procedures for spinal arthrodesis.

The product is designed to promote spacing without replacement of vertebral bodies, providing the appropriate environment so that one or more levels of the spine bone fusion occurs. Its action is keeping the spacing among the vertebral bodies and containing bone material which is essential for the rigid bone formation (arthrodesis) for the correction of pathologies.

The product operating principle is to serve as a bridge to drive the compressive stresses, give structure and contain bone material, maintaining the necessary spacing until fusion occurs among the vertebral bodies.

The implant body is a fenestrated rectangular module, to contain bone material. It has casting side walls and grooves in the lower and upper surfaces which come into contact with the vertebral body, in order to increase stability of the implant.

The trade models that make up the Family of the Non Expansive Intersomatic Cage – PEEK OPTIMA are made of Polyetheretherketone (PEEK) from the OPTIMA family. It is a polymer characterized by its high strength and stability. All trade models have tantalum pins which work as location markers, since PEEK OPTIMA is radio-transparent.

The trade models which make up the Family of the Non Expansive Intersomatic Cage – PEEK OPTIMA are available in specific shapes according to its finality and application, as illustrated bellow:

<table>
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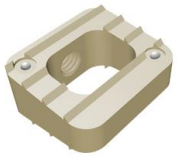
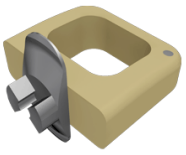
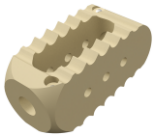
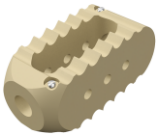
<td>  </td>
<td>  </td>
<td>  </td>
<td>  </td>
<td>  </td>
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<tr>
<td>Fusimax ACP
Fusion Cage
PEEK OPTIMA</td>
<td>Fusimax BCP
Self-blocking Cervical Cage
PEEK OPTIMA</td>
<td>Fusimax ALP</td>
<td>Fusimax PLP</td>
<td rowspan="2">Fusimax TLP
Transforaminal Intersomatic Cage
PEEK OPTIMA</td>
</tr>
<tr>
<td colspan="2">Posterior Intersomatic Cage
PEEK OPTIMA</td>
</tr>
</table>

Composition

The materials selected, for manufacturing the product, meet the required physicochemical and mechanical properties to achieve the desired performance for the product. The selection took into consideration factors such as the effects of fabrication, handling, sterilizing, storing, as well as possible reactions of the material with human tissues and body fluids.

The manufacturing materials are compatible to the biological tissue, cells and body tissues which come in contact with in implantable state, evidenced by historical usage in similar applications available in the worldwide scientific and clinical literature. This confirmation also applies to possible products of wear and degradation of materials at acceptable levels throughout its use.

The product is manufactured from the polymer known as Polyetheretherketone (PEEK) from the OPTIMA Family and such polymer is 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.

The reference pins contained in the trade models which make up the Non Expansive Intersomatic Cage – PEEK OPTIMA are made from tantalum, which meet the requirements specified by the norm ASTM F-560 Standard Specification for Unalloyed Tantalum for Surgical Implant Applications (UNS R05200, UNS R05400).

The locking flip contained in the trade model Fusimax BCP – Self-locking Cervical Cage – PEEK OPTIMA is made from titanium alloy (Ti-6Al-4V) which meets the requirements specified by the norm ASTM F-136 – Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy 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.

Indication and Finality

The trade models which make up the Non Expansive Intersomatic Cage – PEEK OPTIMA are indicated for the treatment of spine congenital, traumatic or degenerative origin pathologies. The product is intended to maintain the intervertebral space after discectomy procedure of cervical and lumbar segments via anterior or posterior access in surgical procedures for spinal arthrodesis.

The discectomy procedure is indicated for patients with herniated disc, deformities, tumors, fractures, disc replacement and need to restore the intervertebral space.

Each trade model of the Non Expansive Intersomatic Cage - PEEK OPTIMA family is designed specifically as follows:

- **Fusimax ACP – Fusion Cage – PEEK OPTIMA:** Applicable to the cervical segment of the spine with implantation via anterior access. It is most indicated for cervical segments C2 to C7, with no contraindication for high thoracic region T1 to T3; for cases of long neck to be used at T3 with approach by the low cervical. The product is contraindicated for use of the segments under T3.
- **Fusimax BCP – Self-locking Cervical Cage – PEEK OPTIMA:** Applicable to the cervical segment of the spine, with implantation via anterior access. It is indicated ONLY for cervical segments from C2 to C7 and in cases of herniated segment C7-T1, The product is contraindicated for use of the segments under T1.
- **Fusimax ALP/ PLP – Posterior Intersomatic Cage Fusimax – PEEK OPTIMA:** Applicable to the spine lumbar segment, with implantation via posterior access, but it may also be applicable via anterior access. It is indicated ONLY for lumbar segments from L1 to L5 and lumbosacral L5-S1. The product can be implanted either alone or in pairs, under medical criteria according to the pathology to be treated. The product is contraindicated for cervical, thoracic, sacral and coccygeal segments of the spine.
- **Fusimax TLP –Transforaminal Intersomatic Cage – PEEK OPTIMA:** Applicable to the spinal lumbar segment, with implantation via transforaminal access. It is indicated ONLY for the lumbar segments from L1 to L5 and lumbosacral transition L5-S1. The product is contraindicated for cervical, thoracic, sacral and coccygeal segments of the spine.

The product described herein was designed for use in the above circumstances, so that all other uses are considered contraindicated or with no scientific support.

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 Non Expansive Intersomatic Cage – PEEK OPTIMA are unitarily packed in blister type double primary package system, sealed with surgical grade paper (Tyvec ® type), which works as a shield for sterilization and oxygen. In such filling system the primary packaging consists of conditioning the product in a vacuum sealed plastic package for the removal of the oxygen from the packaging. The plastic bag duly sealed is conditioned in a blister type package sealed with Tyvec® type paper. The product can also be conditioned unitarily in Tyvec® type surgical package system, which works as shield for sterilization.

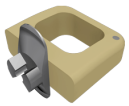
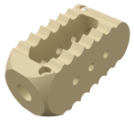
The product is available for the market in sterile condition, and the adopted sterilization method is by Gamma Radiation (dosage of 25 kGy) performed by a certified outsource company.

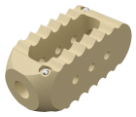
After being sterilized, the product, in its primary package, duly labeled, is conditioned in an outer carton (secondary package), which contains 5 copies of the traceability label and a folder which has all the instructions for the correct use and handling of the product.

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

The Non Expansive Intersomatic Cage – PEEK OPTIMA comes in the following trade models and each one of these trade models is available for the market in the following dimensions:

List of the trade models that make up the family of the Non Expansive Intersomatic Cage – PEEK OPTIMA

Illustrative Image	Code	Description	Dimensions (HxLxW)	Made of	Qty. Packed
	04.36.25.00005	Fusimax ACP – Fusion Cage 5.0x11x13 mm – PEEK OPTIMA;	5.0x11x13 mm	Polyetheretherketone (PEEK) ASTM F-2026/ Pure Tantalum ASTM F-560	01
	04.36.25.00055	Fusimax ACP – Fusion Cage 5.5x11x13 mm – PEEK OPTIMA;	5.5x11x13 mm		
	04.36.25.00006	Fusimax ACP – Fusion Cage 6.0x11x13 mm – PEEK OPTIMA;	6.0x11x13 mm		
	04.36.25.00065	Fusimax ACP – Fusion Cage 6.5x11x13 mm – PEEK OPTIMA;	6.5x11x13 mm		
	04.36.25.00007	Fusimax ACP – Fusion Cage 7.0x11x13 mm – PEEK OPTIMA;	7.0x11x13 mm		
	04.36.25.00008	Fusimax ACP – Fusion Cage 8.0x11x13 mm – PEEK OPTIMA;	8.0x11x13 mm		
	04.36.25.00010	Fusimax ACP – Fusion Cage 10x13x15 mm – PEEK OPTIMA;	10x13x15 mm		
	04.36.29.05009	Fusimax BCP – Self-Locking Cervical Cage 05x09x14 mm – PEEK OPTIMA;	05x09x14 mm	Polyetheretherketone (PEEK) ASTM F-2026/ Pure Tantalum ASTM F-560/ Titanium Alloy (Ti-6Al-4V) ASTM F-136	01
	04.36.29.05012	Fusimax BCP – Self-Locking Cervical Cage 05x12x14 mm – PEEK OPTIMA;	05x12x14 mm		
	04.36.29.05014	Fusimax BCP – Self-Locking Cervical Cage 05x14x14 mm – PEEK OPTIMA;	05x14x14 mm		
	04.36.29.06009	Fusimax BCP – Self-Locking Cervical Cage 06x09x14 mm – PEEK OPTIMA;	06x09x14 mm		
	04.36.29.06012	Fusimax BCP – Self-Locking Cervical Cage 06x12x14 mm – PEEK OPTIMA;	06x12x14 mm		
	04.36.29.06014	Fusimax BCP – Self-Locking Cervical Cage 06x14x14 mm – PEEK OPTIMA;	06x14x14 mm		
	04.36.29.07009	Fusimax BCP – Self-Locking Cervical Cage 07x09x14 mm – PEEK OPTIMA;	07x09x14 mm		
	04.36.29.07012	Fusimax BCP – Self-Locking Cervical Cage 07x12x14 mm – PEEK OPTIMA;	07x12x14 mm		
	04.36.29.07014	Fusimax BCP – Self-Locking Cervical Cage 07x14x14 mm – PEEK OPTIMA;	07x14x14 mm		
	04.36.30.10085	Fusimax ALP – Posterior Intersomatic Cage 08.5 mm – PEEK OPTIMA	08.5x22x10 mm	Polyetheretherketone (PEEK) ASTM F-2026/ Pure Tantalum ASTM F-560	01
	04.36.30.10095	Fusimax ALP – Posterior Intersomatic Cage 09.5 mm – PEEK OPTIMA	09.5 x22x10 mm		
	04.36.30.10105	Fusimax ALP – Posterior Intersomatic Cage 10.5 mm – PEEK OPTIMA	10.5 x22x10 mm		
	04.36.30.10115	Fusimax ALP – Posterior Intersomatic Cage 11.5 mm – PEEK OPTIMA	11.5 x22x10 mm		
	04.36.30.10125	Fusimax ALP – Posterior Intersomatic Cage 12.5 mm – PEEK OPTIMA	12.5 x22x10 mm		
	04.36.30.10135	Fusimax ALP – Posterior Intersomatic Cage 13.5 mm – PEEK OPTIMA	13.5 x22x10 mm		

Illustrative Image	Code	Description	Dimensions (HxLxW)	Made of	Qty. Packed
	04.36.30.10008	Fusimax PLP – Posterior Intersomatic Cage 08.0 mm – PEEK OPTIMA	08x22x10 mm	Polyetheretherketone (PEEK) ASTM F-2026/ Pure Tantalum ASTM F-560	01
	04.36.30.10009	Fusimax PLP – Posterior Intersomatic Cage 09.0 mm – PEEK OPTIMA	09x22x10 mm		
	04.36.30.10010	Fusimax PLP – Posterior Intersomatic Cage 10.0 mm – PEEK OPTIMA	10x22x10 mm		
	04.36.30.10011	Fusimax PLP – Posterior Intersomatic Cage 11.0 mm – PEEK OPTIMA	11x22x10 mm		
	04.36.30.10012	Fusimax PLP – Posterior Intersomatic Cage 12.0 mm – PEEK OPTIMA	12x22x10 mm		
	04.36.30.10013	Fusimax PLP – Posterior Intersomatic Cage 13.0 mm – PEEK OPTIMA	13x22x10 mm		
	04.36.30.10014	Fusimax PLP – Posterior Intersomatic Cage 14.0 mm – PEEK OPTIMA	14x22x10 mm		
	04.36.30.20008	Fusimax PLP – Posterior Intersomatic Cage 08x20 mm – PEEK OPTIMA – Special;	08x20x10 mm		
	04.36.30.20010	Fusimax PLP – Posterior Intersomatic Cage 10x20 mm – PEEK OPTIMA – Special;	10x20x10 mm		
	04.36.30.20012	Fusimax PLP – Posterior Intersomatic Cage 12x20 mm – PEEK OPTIMA – Special;	12x20x10 mm		
	04.36.30.20014	Fusimax PLP – Posterior Intersomatic Cage 14x20 mm – PEEK OPTIMA – Special;	14x20x10 mm		
	04.36.27.00008	Fusimax TLP – Transforaminal Intersomatic Cage 08 mm – PEEK OPTIMA;	08 mm	Polyetheretherketone (PEEK) ASTM F-2026/ Pure Tantalum ASTM F-560	01
	04.36.27.00009	Fusimax TLP – Transforaminal Intersomatic Cage 09 mm – PEEK OPTIMA;	09 mm		
	04.36.27.00010	Fusimax TLP – Transforaminal Intersomatic Cage 10 mm – PEEK OPTIMA;	10 mm		
	04.36.27.00011	Fusimax TLP – Transforaminal Intersomatic Cage 11 mm – PEEK OPTIMA;	11 mm		
	04.36.27.00012	Fusimax TLP – Transforaminal Intersomatic Cage 12 mm – PEEK OPTIMA;	12 mm		
	04.36.27.00013	Fusimax TLP – Transforaminal Intersomatic Cage 13 mm – PEEK OPTIMA;	13 mm		
	04.36.27.00014	Fusimax TLP – Transforaminal Intersomatic Cage 14 mm – PEEK OPTIMA;	14 mm		

The correct selection of models and measures of the product that will be implanted is responsibility of the surgeon in charge who is also responsible for the technique adopted. The surgeon 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 are the responsibility of the surgeon that assesses the patient and decides which the 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 instrumentals designed solely for components that compose the Non Expansive Intersomatic Cage – PEEK OPTIMA implantation.

These instrumentals are made in stainless steel that meets the specified requirements by standard ASTM F-899 – Standard Specification for Stainless Steel for Surgical Instruments, which gives him high resistance and durability.

The instrumentals 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 list of instrumentals below available by manufacturer or by them indicated to implantation of the product:

- Instrument – Cervical Fusion Fusifix/ Fusimax
- Instrument – Lumbar Fusion Fusifix/ Fusimax
- Instrument –Transforaminal Intersomatic Cage Fusifix/ Fusimax

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 for possible wear and damage.

For more information about the instrumental, consult the representative.

Warning and Precautions

For use of the Non Expansive Intersomatic Cage – PEEK OPTIMA, 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 product must be only used by specialized surgical team, with specific knowledge and capacity on the vertebral column stabilization techniques, and the choice and dominion of the technique to be applied is under the responsibility of the surgeon;
- 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 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 should not be used if it do not have an adequate bone support to ensure the implant stability;
- The patient should undergo periodic medical monitoring to check the conditions of the implant, of the bone and adjacent tissues;
- A prophylactic pre and perioperative antibiotic-therapy, can be used under Medical Criteria and the antibiotic-therapy in cases where there is a local predisposition and/or systemic or where there is occurrence of infections;
- The product should not be used with implants made by other manufacturers or distinct aim;
- Qualified personnel should be in charge of looking after this material, which should follow the standards and/or further local regulations applicable;

- Fall and crushing on hard surfaces can cause damage to the product. Thus, it is necessary the operator 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 shelf-life is expired or the 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;
- REPROCESS PROHIBITED;
- STERILE Product – DO NOT re-sterilize;
- Manufacturing date, shelf-life and batch number: see label;

Adverse Effects

Every surgical procedure presents risks and possibility of complications, and some 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 bone 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 on the adjacent levels.

Use Instructions

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

- The care of this material is 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 implant useful life is characterized by the required time to effectuation of 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;
- A review surgery may be necessary, in the above cited case or if is observed the loosening of components;
- 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 in the vertebral column;
- 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 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 review surgery in a superior period of 01 (one) year, in cases in which bone fusion (pseudarthrosis) did 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. This way, 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 trade models which make up the Non Expansive Intersomatic Cage – PEEK OPTIMA are supplied in Sterile Condition product. The adopted sterilization method is Gamma Radiation (dosage of 25 kGy).

The production of the devices is realized with great care, in order to meet the intended performance for the product. This way, the surgical team and all other involved should handle the devices accurately so that infection risks are minimized.

STERILE Product – DO NOT RE-STERILIZE;

Do not use the product if the shelf-life is expired or the packaging is violated

Contamination Risk

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

In order to minimize such risks, the explanted components should be treated as contaminant potentially material and should be adopted the standardization and/or other local regulations applied.

Product Discard

The explanted devices or those regarded improper for use should be discarded. It is recommended, before discarding, that the product be mischaracterized, for this the 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 contaminants potentially 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 Commercial 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 batch 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

ANVISA Registration nº.: 10417940091
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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.

MDTImplantes