Instructions for Use

Intermaxillary Fixation System

Subtitles of the symbols used on the packaging label

	Catalogue Number		Keep Protected from Moisture
	Date of Manufacture		Batch Number
	Single-Use Product		Read the Instructions for Use
	Non-Sterile		Do not use if the package is violated
	Caution - Fragile		Avoid direct exposure to sunlight

Features and technical specifications of the product

Technical Name: Maxillary Fixation Device

Trade Name: Intermaxillary Fixation System

System Components:

- Intermaxillary Fixation Screw
- Malleable Wire for Cerclage

Raw Materials:

- **Screw:** Titanium Alloy (Ti-6Al-4V) – ASTM F-136;
- **Wire:** Stainless Steel Alloy (18Cr-14Ni-2.5Mo) – ASTM F-138;

Non Sterile product

Sterilization Method: Sterilization by moist heat (Autoclave)

Shelf Life: Undetermined

Description

The Intermaxillary Fixation System is classified as surgically invasive device for short-term use, destined for fixation and Intermaxillary block (maxilla and mandible) during and after surgical procedure of maxillofacial osteosynthesis or for dental occlusion in procedures of closed reduction of fracture.

The product is composed by Titanium Screws in diameter of 2.0 mm for 08, 10, 12 and length of 14 mm; by the Cerclage Wire in a diameter of 0.5 mm for the mandible bone fixation, helping the osteosynthesis in the suitable position.

Composition

The material selected for the composition of the product has the required properties to achieve the desired performance. This selection took into account factors such as biocompatibility and physical, chemical and mechanical properties required for the product.

The components that make up the Intermaxillary Fixation System are made of titanium alloy (Ti-6Al-4V) and of stainless steel alloy (18Cr-14Ni-2.5Mo). These materials are considered ideal for manufacturing of implantable medical devices, whose main properties are biocompatibility, mechanical and corrosion resistance.

The titanium alloy (Ti-6Al-4V) used for manufacture of Intermaxillary Fixation Screw component meets the requirements specified by the standard ASTM F-136 - Standard Specification for Wrought

Titanium-6Aluminum 4Vanadium ELI-(Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401).

The stainless steel (18Cr-14Ni-2.5Mo) used for manufacture of Malleable Wire for Cerclage component meets the requirements specified by the standard ASTM F-139 – Standard Specification for Wrought 18Chromium-14Nickel-.25Molybdenum Stainless Steel Sheet and Strip for Surgical Implants (UNS S31673).

The choice of these materials for the manufacture of the Intermaxillary Fixation System was based on similarity criteria (results widely described in literature) and their biocompatibility features and physic-chemical and mechanical properties proven by the specification standards of these materials.

Indication and Purpose

The Intermaxillary Fixation System is indicated for fixation and Intermaxillary block (maxilla and mandible) during and after surgical procedure of maxillofacial osteosynthesis or for dental occlusion in procedures of closed reduction of fracture. Its purpose is the mandible bone fixation, in order to provide a suitable environment for fracture healing.

This is an invasive product for short-time use and can be implantable for MAXIMUM 30 DAYS, and must be removed after this period.

The product described herein was developed for use as described above. So, any other different use is considered contraindicated or with no scientific support.

Contraindications

Following, are listed the related contra indications for the device use, leaving to the surgeon in charge the 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, 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 components that compose the Intermaxillary Fixation System are available for marketing in the non-sterile product condition, unitarily packed (malleable wire for Cerclage) or in 04 unities (screw for intermaxillary fixation) in polypropylene plastic double packaging, together with a note with the respective use instructions.

There is a label pasted on the packaging which contains the necessary information for the product identification.

The Intermaxillary Fixation System consists of the following components, and each one of these components is available for marketing in the following dimensions:

List of Components that compose the Intermaxillary Fixation System

Components					
Illustrative Images	**Code**	**Description**	**Dimensions**	**Manufacturing Material**	**Packaged Quantity**
	04.43.09.20008	Intermaxillary Fixation Screw Ø 02x08 mm	**Ø 2,0 mm –** 08, 10, 12, 14 mm	Titanium Alloy (Ti-6Al-4V) ASTM F136	04
	04.43.09.20010	Intermaxillary Fixation Screw Ø 02x10 mm			
	04.43.09.20012	Intermaxillary Fixation Screw Ø 02x12 mm			
	04.43.09.20014	Intermaxillary Fixation Screw Ø 02x14 mm			
	04.08.04.00005	Malleable Wire for Cerclage 0,5 mm	**Ø 0,5 mm –** 1000 mm	Stainless Steel Alloy (18Cr-14Ni-2.5Mo) ASTM F138	01

The correct selection and combination of components, dimensions and surgical technique for use of the product is responsibility of the surgeon that should be familiar with the material, method of application and surgical procedure to be adopted.

The success of the procedure is linked to the correct selection, positioning and fixation of the devices, which are the responsibility of the surgeon that evaluates 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.

Supporting Material

The supporting materials are instrumentals designed solely for implantation/explantation of components that compose the Intermaxillary Fixation System.

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 Intermaxillary Fixation System:

Item	Description
1	Cross Drive Wrench 2,0/2,3mm Type MD for Contra-Angle
2	Cross Drive Wrench 2,0/2,3mm Type MD w/ Quick Coupling
3	Grip with Quick Coupler Ø30mm
4	Slide Cutter 1,5
5	Hexagonal Wrench with Quick Coupling 3 mm
6	Hexagonal Wrench for Counter Angle 3 mm
7	Drill w/ Stop for Counter Angle Ø 1,58 x 8 mm
8	Drill w/ Stop and Coupling Ø 1,58 x 8 x 50 mm
9	Tweezers to model Wire
10	Case for Intermaxillary Fixation Screw

The instruments 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.

The component Intermaxillary fixation screw is self-perforating, so, for the implanting procedure, the surgeon may or may not make a pre hole using one of the two drills which are part of the supporting material (not object of this registration) up to the instrument pre-defined stop. Then the screws are inserted using one of the four drivers in the support material (not the object of this registration).

Next, the Malleable Wire for Cerclage component is cut using the slide cutter in a size the surgeon considers sufficient for the patient blocking. The surgeon shapes the Malleable Wire for Cerclage using the tweezers. Then the surgeon passes it thru the holes in the Intermaxillary Fixation Screw component, locking the wire, thus performing the maxillo-mandibular locking.

For explantation, the component Wire for Cerclage is cut using the slide cutter and removed from the Intermaxillary Fixation Screw holes. Next, the screws are removed using one of the four drivers.

For more information about the instruments, consult the representative.

Warning and Precautions

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

- The Intermaxillary Fixation System 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, being the responsibility of the surgeon the choice and dominion of the technique to be applied;
- 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 product;
- Invasive product for short-term use, for MAXIMUM 30 DAYS, and must be removed after this period.
- The care of this material is responsibility of the qualified personnel, which should follow the standards and/or other local regulations applicable;
- 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 violated;
- Handle with care;
- Single use product – Do not reuse;
- Non Sterile Product – must be sterilized before use and handled properly to avoid contamination;
- Improper sterilization of implants can cause infection;
- REPROCESS PROHIBITED;
- 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.

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 applicable.
- 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 stabilization techniques in osteosynthesis, being the surgeon in charge by the choice and dominion of the surgical technique to be performed;
- For the application of the Intermaxillary Fixation System is necessary the use of specific instrumental, indicated in topic: “Support Material”. They should not be used with other instruments than those indicated by the manufacturer.

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 an orthopedic 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 dependents;
- The fact that the product can interfere with results of imaging examinations;
- The listed information in this topic “Guidance to the patient and/or the Legal Representative”.

Sterilization

The product is supplied in non-sterile condition and should be removed from its original packaging and packed in proper recipient for sterilization (provided by the manufacturer) before use.

The indicated sterilization method for sterilization of components that integrate the Intermaxillary Fixation System is the sterilization by moist heat (autoclave);

The components are provided decontaminated by manufacturer, but should be properly handled and sterilized, as instructions below, to avoid implant contamination and consequent infection to the patient.

Sterilization Parameter

The sterilization of the components should be done as parameters described in the table below:

Method	Cycle	Temperature	Exposure Times
Moist Heat (autoclave)	Pre-Vacuum Sterilization (vacuum)	134º to 137º	10 minutes

	Drying		

The sterilization process must meet the theoretical probability of the presence of vitals microorganisms to a maximum of $1x10^6$ (S.A.L. [Sterility Assurance Level] = 10^6).

The equipment conditions (autoclave) used during the sterilization process (maintenance, calibration program, etc.) as well as the guarantee of use of a proper sterilization process and the product sterility proof is responsibility of qualified personal (material center) of the health service.

Cleaning

The cleaning procedures described as follow are applied to the components that integrate the Intermaxillary Fixation System and their respective surgical instrumentals.

When using the components, these should be removed of its packaging and cleaned with alcohol for medical aims at 70% + distillate water 30%.

After cleaning the product must be rinsed with sterile distillate water and dried with cleaning cloth that does not release fibers.

If the cleaning process is made by thermo disinfectors' equipment with the help of descaling substances, the manufacturer guidelines should be adopted.

Contamination Risk

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

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

Product Discard

The explanted components 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 components 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.

REPROCESS 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 following Information needed for the product traceability are engraved on the piece or may be acquired from the label of the product package:

- Company logotype;
- Manufacturing batch;
- Piece code.

Traceability information is required for notifying the Sanitary Surveillance Agency ANVISA, either by the health service or by the patient him/herself, when serious adverse events occur, so that it helps to drive appropriate investigations.

Storage and Transport

For the storage it is recommended dry and airy place, without exposure to light incidence, humidity or contaminants substances. The storage place humidity and temperature must be monitored and kept below 40ºC.

The implants cannot be stored directly on the floor. It is recommended the use of shelves with minimal height of 20 cm.

The product should be kept in its original packaging until the moment of its use, being that the surgical packaging opening and handling should be done by trained personal for this procedure.

The product should be transported properly, avoiding falls and friction that can damage the structure and surface of the part.

For information about manufacturing date and batch number: see label.

Further Information

Manufactured and distributed by:

MDT – Indústria Comércio Importação e Exportação de Implantes SA
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.: 10417940086
Review: 00
Issue: August, 26th 2013

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.