Instructions for Use

System of Bilateral Fixation for Bucomaxilo

Legends of the symbols used on packaging

REF	Product Code	LOT	Batch Number
DD/MM/YYYY	Manufacturing Date		Read Use Instructions
2	Single Use Product		Do not use if the packaging is violated
NON STERILE	Non Sterile		Avoid exposure to direct sunlight
	Caution - Fragile	CE XXXX	Mark CE according to Directive 93/42/CEE – MDD – When Applicable.
	Keep Protect of Humidity		

Specifications and technical characteristics of the product

Technical Name: System of Non-Rigid Fixation, Non-Absorbable for Osteosynthesis

Commercial Name: System of Bilateral Fixation for Bucomaxillo

Components of the System:

- Mini Plates (Low Profile/Standard);
- Cortical Screw Ti Cross Drive;

Raw Material:

- Mini Plates (Low Profile/Standard) – Pure Titanium;
- Screws –Titanium Alloy (Ti-6Al-4V);

Non Sterile Product

Sterilization Method: Sterilization by humid heat (autoclave)

Validity: Indeterminate

Description

The System of Bilateral Fixation for Bucomaxilo consists of a set of implants, surgically invasive long-term use, consisting of mini plates (standard and low profile) and screws, used in procedures of osteosynthesis bucomaxillofacial.

The product was designed for non rigid internal fixation of the segments cranial and third middle of face, in orthognathic surgical procedures (correction of dental facial deformities) and trauma (synthesis of cranium-maxillofacial fractures).

Below description of components that compose the System of Bilateral Fixation for Bucomaxillo:

The **Mini Plates (Low Profile/Standard)** are manufactured from pure titanium, in two versions: low profile (thickness 0.8 mm) and standard (thickness 1.0 mm). They have several lengths and various shapes, with or without bridge, to enable to the surgeon a wide range of possibilities and applications.

The Mini Plates – Low Profile (thickness 0.8 mm) permit a higher flexibility because they have a smaller thickness, while the Mini Plates – Standard (thickness 1.0 mm) are more resistant and are an option for the surgeon who will evaluate each case and will choose the most appropriate plate.

They present innovative design and double face, which allows its use both by the right and left side. His angled characteristic and anatomical shape allows better adaptation to the bone, avoiding unnecessary bends and minimizing the material fatigue and consequent fracture. Since they do not have right and left side is possible obtaining a more compact box with a higher range of designs in smaller space, enabling a variation of plates that adapt to various types of situations for osteosynthesis.

					
Mini Plate T 100º Bridge Double Face (Low Profile/ Std)	**Mini Plate T Bridge (Low Profile/ Std)**	**Mini Plate L 110º Bridge 15º Right Double Face (Low Profile/ Std)**	**Mini Plate L 110º Bridge 15º Left Double Face (Low Profile/ Std)**	**Mini Plate L Bridge Double Face (Low Profile/ Std)**	**Mini Plate Y Bridge Double Face (Low Profile/ Std)**

				
Mini Straight Plate Bridge (Low Profile/ Std)	**Mini Straight Plate (Low Profile/ Std)**	**Mini Orbital Plate (Low Profile/ Std)**	**Mini Plate for Genioplasty**	**Mini Straight Plate Double Face (Low Profile/ Std)**

The **Screws** are made from titanium alloy (Ti-6Al-4V) in two versions: self tapping and self drilling (conical). They have asymmetrical thread profile and shallow (type HA). The screw head has crack of insertion type cross (cross drive) with fitting type conical (bottom part). The component is marketed in diameters 2.0 and 2.3 mm, the latter for emergency cases, with lengths ranging from 04 to 20 mm.

	
Cortical Screw Ti Cross Drive – "MD" Type (Self Tapping)	**Screw Cortical Ti Cross Drive Conical (Self Drilling)**

Composition

The selected materials for product composition present the required properties to achieve the desired performance for the System of Bilateral Fixation for Bucomaxillo (see description of the desired performance in section 1.6 of this technical report). This selection considered factors as the biocompatibility and other properties required for the product.

The pure titanium– used for mini plates manufacturing (Low Profile and Standard) – and the titanium alloy (Ti-6Al-4V) – used for screws manufacturing – have properties that make them ideal materials to producing of implantable medical devices. Its main properties are the biocompatibility, mechanical resistance and wear resistance.

The pure titanium used for manufacturing of Mini Plates (Low Profile/Standard) meets specified requirements by standard ASTM F-67 - Standard Specification for Unalloyed Titanium, for Surgical Implant Applications (UNS R50250, UNS R50400, UNS R50550, UNS R50700).

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

The choice of these materials is due to their mechanical and metallurgic characterization well defined as the results in service – widely described in the worldwide literature – confirming that they are biocompatible and have appropriate mechanical strength for the proposed aims.

Indication and Purpose

The System of Bilateral Fixation for Bucomaxillo is indicated for non rigid internal fixation of the cranial and middle third segments of face, in orthognathic surgical procedures (correction of dental facial deformities) and trauma (synthesis of cranium-maxillofacial fractures), based on indications already established in the literature.

The procedure of fractures fixation and corrections with control of anatomical alignment, that need of immediate internal fixation, according to strategies of treatment adopted by the surgeon in the several anatomical regions is indicated for the following typical clinical applications:

- Fractures of face bone and cranium caused by accidents, for example, accidental falls, automobile accidents, projectiles, aggression or sports practice, etc;
- Orthognathic and craniofacial osteotomies;
- Fixation of grafts in the face bone and cranium;
- Corrective surgeries;
- Support for orthodontic treatment;

The application of the product must consider the defect, the pathology, bone characteristics, loads and muscle forces (tension and traction) on the segment to be treated. The use of the product presents restrictions in osteotomies that result in free spaces with highest incidence of load.

The product described here was developed for use in the circumstances described above, so that any other uses are considered contraindicated or without scientific support.

Contraindication

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 active general infection or specifics that can lead the complications with the fixation;
- Patients with general state impaired and/or immune compromised unable to be submitted to a surgical procedure;
- Patients with sensitivity to a foreign bodies, in this case, tests should be performed;
- Patients with osteoporosis and others bone disorders (for example: osteoradiation) that may compromise the osteosynthesis.
- Patients that use narcotic substances, alcohol or smoke;
- Patients with oral infection;
- Patients with unsatisfactory quality of oral hygiene.

Forms of presentation

The implants that compose the System of Bilateral Fixation for Bucomaxillo are supplied in the non sterile product condition.

The Mini Plates (Low Profile/Standard) are available for marketing unitarily packed in double plastic packaging of polypropylene.

The component Cortical Screw Ti Cross Drive is available for marketing packed in plastic support of polycarbonate inside of polypropylene plastic packaging.

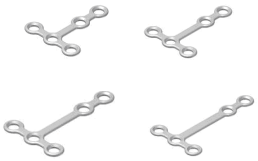
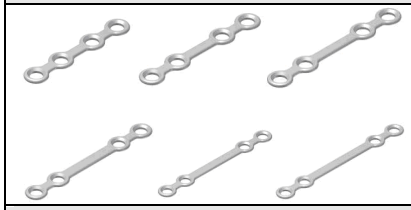
Inside of second packaging follow a leaflet with the use instructions, in which presents the sterilization procedures, as well as the instructions for handling and product use.

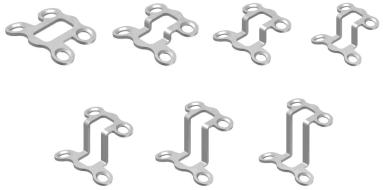
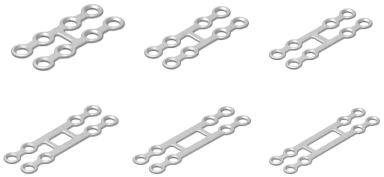
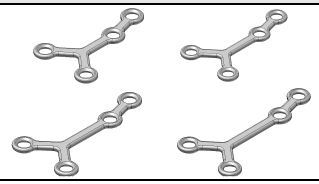
On the packaging is glued a label containing the necessary information for the product identification.

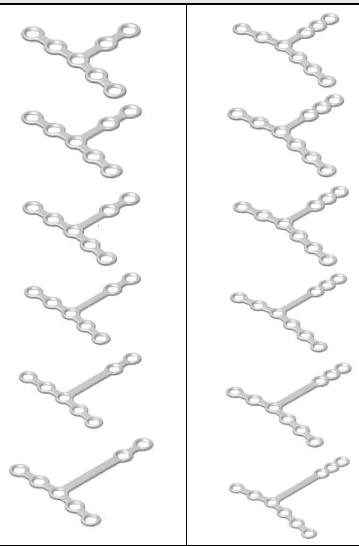
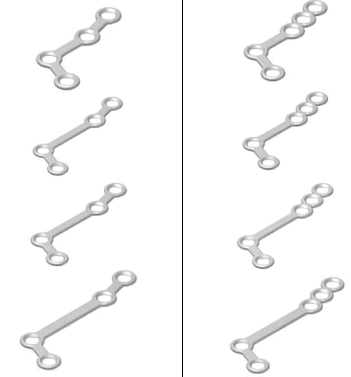
The System of Bilateral Fixation for Bucomaxillo is comprised by the following components, being that each one of these components is available for marketing in the following dimensions:

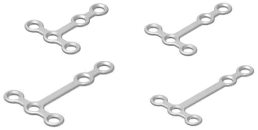
List of Components that compose the System of Bilateral Fixation for Bucomaxillo

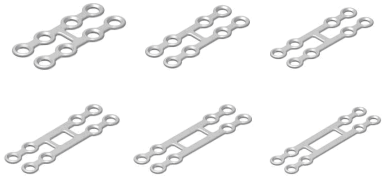
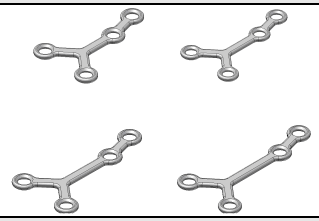
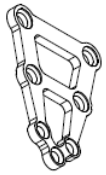
Mini Plates – Low Profile						
Illustrative Images		**Code**	**Description**	**Dimensions**	**Raw Material**	**Packaged Quantity**
		04.19.51.XXXXX	Mini Plate T 100° Bridge – Double Face Low Profile	**Thickness:** 0.8 mm; **Length:** 18.9, 20.4, 21.9, 22.4, 23.9, 24.9, 25.4, 27.9, 28.4, 30.8, 31.4 and 34.4 mm; **Width:** 23.6, 24.3, 24.9, 25.8, 26.4, 26.8, 29.5, 30.1, 30.5, 31.3, 31.8 and 32.2 mm; **Length Bridge:** 07.5, 09.0, 10.5, 13.5, 16.5 and 19.5 mm; **Quantity Holes:** 07 and 09 holes;	Pure Titanium	01
		04.19.52.XXXXX	Mini Plate L 110° Bridge 15° R – Double Face Low Profile	**Thickness:** 0.8 mm; **Length:** 23.2, 24, 26.1, 27, 29, 29.9, 32 and 32.9 mm; **Width:** 10.2, 10.3, 10.4 and 10.5 mm; **Length Bridge:** 09, 12, 15 and 18 mm; **Quantity Holes:** 04 and 05 holes;	Pure Titanium	01

		04.19.53.XXXXX	Mini Plate L 110° Bridge 15° L – Double Face Low Profile	**Thickness:** 0.8 mm; **Length:** 18.6, 19.4, 21.4, 22.2, 24.2, 25.1, 27 and 27.9 mm**;** **Width:** 10.6, 10.7 and 10.8 mm; **Length Bridge:** 09, 12, 15 and 18 mm; **Quantity Holes:** 04 and 05 holes;	Pure Titanium	01
		04.19.54.XXXXX	Mini Plate L Bridge – Double Face Low Profile	**Thickness:** 0.8 mm; **Length:** 17.9, 19.9, 20.9, 22.9, 23.9, 25.9, 26.9, 28.9, 29.9 and 31.9 mm; **Width:** 10.4 and 16.4 mm; **Length Bridge:** 07.5, 10.5, 13.5, 16.5 and 19.5 mm; **Quantity Holes:** 04 and 06 holes;	Pure Titanium	01
		04.19.55.XXX50	Mini Plate T Bridge – Low Profile	**Thickness:** 0.8 mm; **Length:** 19.4, 22.4, 25.4 and 28.4 mm **Width:** 16.4 mm; **Length Bridge:** 09, 12, 15 and 18 mm; **Quantity Holes:** 05 holes;	Pure Titanium	01
		04.19.56.XXX40	Mini Straight Plate Bridge – Low Profile	**Thickness:** 0.8 mm; **Length:** 23.9, 26.9, 29.9, 32.9, 35.9 and 38.9 mm; **Width:** 4.4 mm; **Length Bridge:** 07.5, 10.5, 13.5, 16.5 and 19.5, 22.5 mm; **Quantity Holes:** 04 holes;	Pure Titanium	01

	04.19.57.000XX	Mini Orbital Plate – Low Profile	**Thickness:** 0.8 mm; **Length:** 34, 45.2 and 82.8 mm; **Width:** 6.5, 8.7 and 23.3 mm; **Quantity Holes:** 06, 08 and 16 holes;	Pure Titanium	01
	04.19.58.000XX	Mini Straight Plate – Low Profile	**Thickness:** 0.8 mm **Length:** 22.4, 28.4, 46.4, 70.4 and 94.4 mm **Width:** 4.4 mm; **Quantity Holes:** 04, 05, 08, 12 and 16 holes;	Pure Titanium	01
	04.19.59.000XX	Mini Plate for Genioplasty	**Thickness:** 0.6 mm; **Length:** 11.4, 13.4, 15.4, 17.4, 19.4, 21.4 and 23.4 mm; **Width:** 16.4 mm; **Advance length:** 00, 02, 04, 06, 08, 10 and 12 mm; **Quantity Holes:** 04 holes;	Pure Titanium	01
	04.19.60.XXX80	Mini Straight Plate Double Bridge – Low Profile	**Thickness:** 0.8 mm; **Length:**23.9, 26.9, 29.9, 32.9, 35.9 and 38.9 mm; **Width:** 10.4 mm; **Length Bridge:** 07.5, 10.5, 13.5, 16.5, 19.5 and 22.5 mm; **Quantity Holes:** 08 holes;	Pure Titanium	01
	04.19.62.XXX40	Mini Plate Y Bridge – Double Face Low Profile	**Thickness:** 0.8 mm **Length:** 23.7, 25.7, 27.7 and 29.7 mm **Width:** 15.1 mm; **Length Bridge:** 08, 10, 12 and 14 mm **Quantity Holes:** 04 holes;	Pure Titanium	01

Mini Plates – Standard						
Illustrative Images		**Code**	**Description**	**Dimensions**	**Raw Material**	**Packaged Quantity**
		04.19.63.XXXXX	Mini Plate T 100° Bridge – Double Face Standard	**Thickness:** 1.0 mm; **Length:** 18.9, 20.4, 21.9, 22.4, 23.9, 24.9, 25.4, 27.9, 28.4, 30.8, 31.4 and 34.4 mm; **Width:** 23.6, 24.3, 24.9, 25.8, 26.4, 26.8, 29.5, 30.1, 30.5, 31.3, 31.8 and 32.2 mm; **Length Bridge:** 07.5, 09.0, 10.5, 13.5, 16.5 and 19.5 mm; **Quantity Holes:** 07 and 09 holes;	Pure Titanium	01
		04.19.64.XXXXX	Mini Plate L 110° Bridge 15° R – Double Face Standard	**Thickness:** 1.0 mm; **Length:** 23.2, 24, 26.1, 27, 29, 29.9, 32 and 32.9 mm; **Width:** 10.2, 10.3, 10.4 and 10.5 mm; **Length Bridge:** 09, 12, 15 and 18 mm; **Quantity Holes:** 04 and 05 holes;	Pure Titanium	01

		04.19.65.XXXXX	Mini Plate L 110° Bridge 15° L – Double Face Standard	**Thickness:** 1.0 mm; **Length:**18.6, 19.4, 21.4, 22.2, 24.2, 25.1, 27 and 27.9 mm**;** **Width:**10.6, 10.7 and 10.8 mm; **Length Bridge:** 09, 12, 15 and 18 mm; **Quantity Holes:** 04 and 05 holes;	Pure Titanium	01
		04.19.66.XXXXX	Mini Plate L Bridge – Double Face Standard	**Thickness:** 1.0 mm; **Length:**17.9, 19.9, 20.9, 22.9, 23.9, 25.9, 26.9, 28.9, 29.9 and 31.9 mm; **Width:**10.4 and 16.4 mm; **Length Bridge:** 07.5, 10.5, 13.5, 16.5 and 19.5 mm; **Quantity Holes:** 04 and 06 holes;	Pure Titanium	01
		04.19.67.XXX50	Mini Plate T Bridge – Standard	**Thickness:** 1.0 mm; **Length:**19.4, 22.4, 25.4 and 28.4 mm **Width:** 16.4 mm; **Length Bridge:** 09, 12, 15 and 18 mm; **Quantity Holes:** 05 holes;	Pure Titanium	01
		04.19.68.XXX40	Mini Straight Plate Bridge – Standard	**Thickness:** 1.0 mm; **Length:** 23.9, 26.9, 29.9, 32.9, 35.9 and 38.9 mm; **Width:** 4.4 mm; **Length Bridge:** 07.5, 10.5, 13.5, 16.5 and 19.5, 22.5 mm; **Quantity Holes:** 04 holes;	Pure Titanium	01

	04.19.69.000XX	Mini Orbital Plate – Standard	**Thickness:** 1.0 mm; **Length:** 34, 45.2 and 82.8 mm; **Width:** 6.5, 8.7 and 23.3 mm; **Quantity Holes:** 06, 08 and 16 holes;	Pure Titanium	01
	04.19.70.000XX	Mini Straight Plate – Standard	**Thickness:** 1.0 mm **Length:** 22.4, 28.4, 46.4, 70.4 and 94.4 mm **Width:** 4.4 mm; **Quantity Holes:** 04, 05, 08, 12 and 16 holes;	Pure Titanium	01
	04.19.71.XXX80	Mini Straight Plate Double Bridge – Standard	**Thickness:** 1.0 mm; **Length:** 23.9, 26.9, 29.9, 32.9, 35.9 and 38.9 mm; **Width:** 10.4 mm; **Length Bridge:** 07.5, 10.5, 13.5, 16.5, 19.5 and 22.5 mm; **Quantity Holes:** 08 holes;	Pure Titanium	01
	04.19.72.XXX40	Mini Plate Y Bridge – Double Face Standard	**Thickness:** 1.0 mm **Length:** 23.7, 25.7, 27.7 and 29.7 mm **Width:**15.1 mm; **Length Bridge:** 08, 10, 12 and 14 mm **Quantity Holes:** 04 holes;	Pure Titanium	01
	04.19.73.00000	Mini Triangular Plate	**Thickness:** 1.5 mm **Length:** 24.85 mm **Width:**17.9 mm **Quantity Holes:** 07 holes;	Pure Titanium	01

Cortical Screw Ti Cross Drive					
Illustrative Images	**Code**	**Description**	**Dimensions**	**Raw Material**	**Packaged Quantity**
	04.24.58.200XX	Cortical Screw Ti Ø 2.0 mm Cross Drive – “MD” Type	**Diameter:** 2.0 mm; **Length:** 04, 05, 06, 07, 08, 10, 12, 14, 16, 18 and 20 mm	Titanium Alloy (Ti-6Al-4V)	04
	04.24.58.230XX	Cortical Screw Ti Ø 2.3 mm Cross Drive – “MD” Type	**Diameter:** 2.3 mm; **Length:** 04, 05, 06, 07, 09 and 11 mm	Titanium Alloy (Ti-6Al-4V)	04
	40.24.01.200XX	Cortical Screw Ti Ø 2.0 mm Cross Drive Conical	**Diameter:** 2.0 mm; **Length:** 05 and 06 mm	Titanium Alloy (Ti-6Al-4V)	04

The correct selection of components and measures of the System of Bilateral Fixation for Bucomaxillo that will be implanted is responsibility of the surgeon in charge 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 implantation of the System of Bilateral Fixation for Bucomaxillo aforementioned.

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

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

See below list of instrumentals available by manufacturer or by them indicated to implantation of the System of Bilateral Fixation for Bucomaxillo:

- 0B.25 – Maxillofacial Instrumental Set - Dual Side 2.0 mm;

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 System of Bilateral Fixation for Bucomaxillo, the team in charge should consider the following warnings 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 teams, with specific knowledge and training on techniques for osteosynthesis in the facial bones, being the responsibility of the surgeon the choice and mastery of the technique to be applied;
- The selection and inadequate choice of the implants to be utilized, as the mistakes at the indication, handling and surgical technique can cause stress and excessive 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 plates should be modeled in order to avoid repetition of movements at the same point, because this repetition can lead to fatigue and consequent fracture of the material;
- The plates should NEVER be remodeled;
- The used in patients with predisposing to disobey the medical guidelines and restrictions after surgery, such as children, elderly, individuals with neurological disorders or addicts on drug, represent a greater risk for failure of the implant;
- The risk for failure of the implant are greater in patients engaged in efforts activities or practice sports activities;
- The product should not be utilized if it cannot have a bone support adequate to ensure the stability of the implant;
- The application of the product in patients with bone stock improper can damage the fixation of screw, compromising the technical result consequently;
- The patient must have periodic medical monitoring to check the conditions of the implant, the bone and adjacent tissues;
- The medical criteria, can be used an antibioticterapy prophylactic pre and perioperative, and the antibioticterapy in cases where there is a local predisposition and/or systemic or where there is occurrence of infections;
- The implant should not be used with components from other manufacturers or purpose. The combination of implant of manufacturers or different purpose can result in incongruence between the components;

- The care of this material are the responsibility of 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;
- 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;
- Handle with care;
- Single use product - Do not reuse;
- The implants should NEVER be reused, although they may look undamaged, prior to the tensions that they have undergone can cause imperfections that would reduce the lifetime of the product in a reimplantation;
- Non Sterile Product - should be sterilized before use and handled properly to avoid contamination;
- Inadequate sterilization of the implants can cause infection;
- PROHIBITED REPROCESSING;
- Date of manufacture and batch number: See label.

Adverse Effects

Every surgical procedure presents risks and potential complication, and some common risks are infection, bleeding, allergic reactions drug and anesthetic risks, among others, may still be associated with the deployment of the product, the following complications and adverse effects:

- Damage to nerves with sensory or motor loss;
- Absence or delay of the bone healing resulting in implant disruption;
- Loosening, displacement, deformation, twisting or breakage of the implant;
- Deformation or fracture of the implant;
- Pain, discomfort or abnormal sensations due to the product;
- Reaction to foreign body;
- Necrosis of bone or adjacent soft tissues.;
- The decision to remove the implant due to the adverse effects aforementioned is the surgeon responsible.

Use Instructions

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

- The care of this material is the responsibility of the personnel, which should follow the standards and/or other local regulations applicable;
- The product should be handled with due care in appropriate locations (center of materials and operating rooms);
- The product should only be used by specialized surgical teams, with specific knowledge and training on techniques of osteosynthesis in facial bones, and is responsibility of the surgeon the choice and mastery of the technique to be performed;
- Plates should be modeled only once, considering its better adaptation to the bone surface. The better adapted to the bone plate is, the better the results of fixation;
- The modeling of the plates must avoid repeating the same movement point, since such repetition can lead to fatigue and consequent fracture of the material;
- Plates should NEVER be remodeled;

- 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 applies for screw fixation;
- The shelf-life of the implant is characterized by the time required to execute the bone healing, limiting to a maximum of 01 (one) year. After this period, in the absence or problems with bone healing, these conditions can represent a risk of implant failure by excessive mechanical stress;
- May be necessary the review' surgery, in the above cited case or if is observed the loosening of components;
- For application of the product is necessary the use of specific instrumental , indicated in the topic "Support Material", and due to possibility of functional and/or dimensional incompatibility should not be used with instruments other 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:

- Appropriate care and restrictions during the postoperative period. The ability and willingness of patients to follow these guidelines are one of the most important aspects in an orthopedic surgical procedure in the bone synthesis;
- 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 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 (pseudoarthrosis) 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 System of Bilateral Fixation for Bucomaxillo is supplied in the non sterile condition and should be removed from its original packaging and packed in proper recipient for sterilization (provided by the manufacturer) before use.

The indicated sterilization method for the product 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

The sterilization of the components of System of Bilateral Fixation for Bucomaxillo should be done as parameters described in the table below:

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

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

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

Cleaning

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

When components use, 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' equipments with the help of descaling substances, the manufacturer guidelines should be adopted.

Contamination Risk

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

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 applied.

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 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 implanted product traceability. 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 information required for product traceability, following, are recorded in the piece or can be obtained from the label inside the packaging of the same:

- Company logo;
- Batch of manufacturing;
- Code of the piece;

The traceability information are necessary to notify the department of health and/or the patient himself to the Sanitary Surveillance Agency - ANVISA and the manufacturer, when the occurrence of serious adverse events, to conduct reasonable 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 Ltda

Avenida Brasil, nº. 2983 – Distrito Industrial – Rio Claro/ SP – Brasil

CEP: 13505-600

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

Technical Responsible: Miguel Lopes Monte Júnior – CREA 0601150192

CE 0297 (according to Directive 93/42/CEE - MDD)

When Applicable

Review: 00

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Registration ANVISA #: 10417940081

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.