Instructions for Use

Oral Plates and Screws System – Lock Type

Legends of the symbols used on packaging

	Product Code		Batch Number
	Date of Manufacturing		See instructions for use
	Caution - Fragile		Avoid direct exposition to sunlight
	Protect from Humidity		Single use product
	Do not use if package is damaged		Non Sterile

Characteristics and Technical Specifications of the Product:

Technical Name: Oral Maxillofacial Osteosynthesis System

Trade Name: Oral Plates and Screws System – Lock Type

Components of the system:

- Plates;
- Screws;
- Accessories: Angle Reinforcement, Screw for Angle Reinforcement and Modeling Screw

Raw Material: Plates – Pure Titanium – ASTM F-67;
Screws – Titanium Alloy (Ti-6Al-4V) – ASTM F-136

Non Sterile Product

Sterilization Method: Sterilization by humid steam (Autoclave);

Validity: Indeterminate

Description

This product is a rigid fixation system[1] for oral maxillofacial osteosynthesis applicable to the mandibular segment, which consists of a set of implants, surgically invasive long-term use, consisting of plates and screws used for oral maxillofacial facial in osteosynthesis procedures.

The product presents a locking system differs from its similar that provides the mechanical locking between the plates and screws, so as not to allow micro-movements between these parts. The plates are equipped with threads in their holes and the screws of a metric thread on the inferior part of the head that screws together. These innovations provide to the system better stability and better load distribution on the plate.

The plates are the most commonly used in trauma because of its purpose are less thick as it is intended to fixation and stabilization of mandibular fractures less complex or to fixing the grafts in reconstruction of small mandibular bone segments.

The reconstruction plates because of its purpose - total or partial reconstruction - are much thicker than the first, since it is intended to mandibular reconstruction with use of grafts for treatment of large and complex comminuted fractures or in cases of reconstruction of large bone segments (osteotomy for treatment of tumors) with application of grafts.

[1] Rigidity refers to the presence of devices that prevent movement between the plate and screw component (threaded holes)

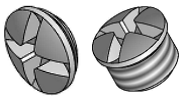
	
Trauma Plates	**Reconstruction Plates**

With a cortical type screw into the body and cross type insertion slot (cross drive), the screws that comprise the system presents the macro version with 2.4 mm. The thread pitch is 1 mm and the length of the screws varies between 7 and 21 mm.

	
Non Locking screw	**Locking screw (Lock type)**

Accessories

The system also has accessories as angled reinforcement and modeling screws. The first is intended, as appropriate (at the criteria of the surgeon) to be used on reconstruction plates in its angled portion, the region where it receives greater mechanical stress during their functionality. The second is used to cover the holes in the plate during its modeling, and the surgeon may choose to remove or not these screws after assembly of the system.

		
Angle Reinforcement	**Screw for Angle Reinforcement**	**Modeling Screw**

Composition

The Oral Plates and Screws System - Lock Type is made of titanium due to its properties which makes it an ideal material for the production of implants. Titanium is a material, whose main properties are: high mechanical strength and biocompatibility, titanium thus presents itself as the best option, both in terms of tissue tolerance, as the triggering of immunological complications of low-grade to the manufacture of these implants.

The screws are manufactured from titanium alloy Ti-6Al-4V (ASTM F-136), due to their resistance characteristics, while the plates are made from pure titanium (ASTM F-67) which presents the characteristics of flexibility required for modeling of plates by the surgeon during surgery.

The titanium used in the manufacture of Oral Plates and Screws System - Lock Type meets the requirements specified by ASTM F-67 and ASTM F-136 respectively.

The choice of these alloys is due to its mechanical and metallurgical characterization of well defined, as the results in service - widely reported in the world literature - which confirms that these alloys are biocompatible and possess adequate mechanical strength for the proposed.

Indication and Purpose

The Oral Plates and Screws System – Lock Type is indicated to fixing and stabilization of fractures of the mandible segments, for osteosynthesis of corrective osteotomy in the treatment of congenital deformation, acquired or from the development and for fixation of grafts in reconstructive surgeries.

The macro plates for trauma with 1.5 mm of thickness are specifically indicated for:

- Fixing and stabilization of multiples facial fractures, but less complex;
- Fixing and stabilization of the graft in reconstructive surgeries of small mandible segments, considering the extension and complexity of the operated segment;

The plates of partial or total reconstruction with 3.0 mm of thickness are specifically indicated for:

- Fixing and stabilization of facial reconstruction with application of graft for treatment of large and complex comminuted fractures;
- Reconstruction of osteotomy for treatment of tumors of large mandibles segments with graft application;

The application of the product must consider the defect, pathology, bone characteristic and the muscular loads and strength (stress and traction) on the segment to be treated.

For safety use of the product the fixing must be performed only in bone segments with adequate support to ensure the stability of the implant.

The characterization of adequate bone support for the deployment of the product are very specific and vary according to the severity of clinical cases being treated, so the decision for the deployment of the product should consider all general and special factors related to surgery procedure and the clinical case being treated.

The decision and responsibility for the indication and use are exclusive of the surgical team responsible for treatment, which should have the technical knowledge, training and ambiance with the product.

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

Below are listed the contraindication on use the product, where the surgeon is responsible, after a rigorous study, the indication of the procedures:

- 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 realized;
- 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.

Presentation forms

The implants that comprise the Oral Plates and Screws System – Lock Type are supplied as non sterile products, and the sterilization method indicated is the autoclave procedure to be performed in the hospital.

The plates are supplied, unitarily set with double plastic bag packaged (polypropylene). The screws can be supplied in two forms:

- Screws packed into double plastic bag package (polypropylene), single package or 10 screws per package.
- Screws packed into plastic supports (polycarbonate), (first package) with four screws each, into a plastic bag package (second package). The color of the support indicates the diameter

of the screw and in the support follows recorded the batch number and material code, for traceability purposes. The green support is used for screws with diameter of 2.4 and the red support is used for emergency screws with diameter of 2.7.

Into the second plastic package follows the leaflet with the instructions for correct use of the product. On the second plastic package is pasted a label with the information necessary to identify the product.

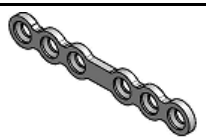
To sterilize the implants, the manufacturer provides its users a plastic container suitable for autoclaving sterilization. These containers are supplied in two models – one for storing the plates and screws unitarily supplied, and other to set the screws supplied in plastic support – which has slots in its wall and cover for circulation of the stem super saturated.

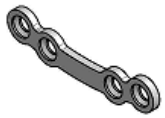
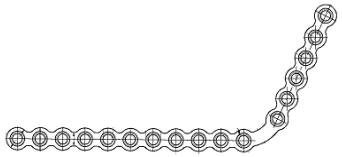
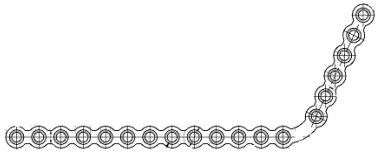
The Oral Plates and Screws System – Lock Type is comprised by the following components being each one of these components are available for marketing as the following dimensions:

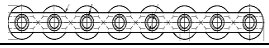
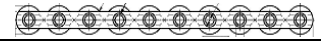
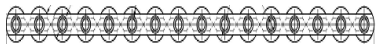
Screws

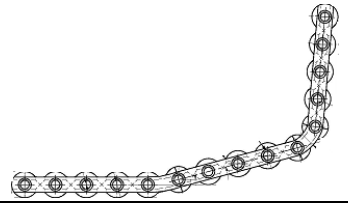
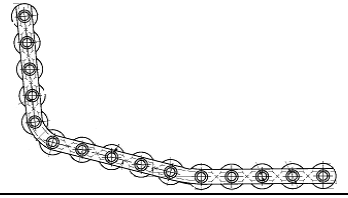
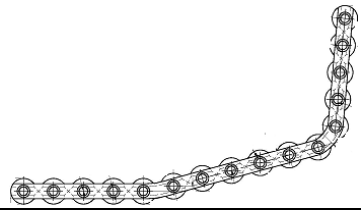
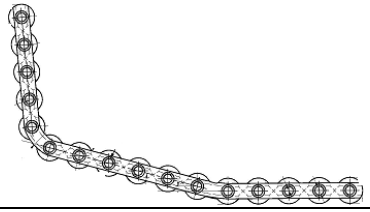
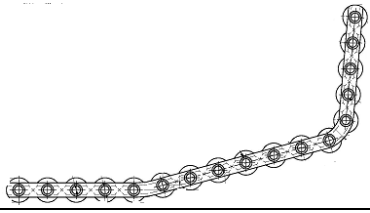
Code	Description	Dimensions (DxL)	Qty packed	Manufacturing Material	Image
04.24.58.24XXX	Cortical Screw Ti Ø 2,4 Cross Drive "MD" Type	**Ø 2.4 mm –** 07, 09, 11, 13, 15, 17 e 19 mm de length.	Unit (Plastic Package) 04 (Plastic Support) 10 (Plastic Package).	Titanium Alloy(Ti-6Al-4V)	
Code	**Description**	**Dimensions (DxL)**	**Qty packed**	**Manufacturing Material**	**Image**
04.24.72.24XXX	Cortical Screw Ti 2,4 Cross Drive Lock	**Ø 2.4 mm –** 07, 09, 11, 13, 15, 17 e 19 mm de length.	Unit (Plastic Package) 04 (Plastic Support) 10 (Plastic Package).	Titanium Alloy(Ti-6Al-4V)	
Code	**Description**	**Dimensions (DxL)**	**Qty packed**	**Manufacturing Material**	**Image**
04.24.58.27XXX	Cortical Screw Ti 2,7 Cross Drive "MD" Type	**Ø 2.7 mm –** 07, 09, 11, 13, 15, 17, 19 e 21 mm de length.	Unit (Plastic Package) 04 (Plastic Support) 10 (Plastic Package).	Titanium Alloy(Ti-6Al-4V)	
Code	**Description**	**Dimensions (DxL)**	**Qty packed**	**Manufacturing Material**	**Image**
04.24.72.27XXX	Cortical Screw Ti 2,7 Cross Drive Lock	**Ø 2.7 mm –** 07, 09, 11, 13, 15, 17 , 19 e 21 mm de length.	Unit (Plastic Package) 04 (Plastic Support) 10 (Plastic Package).	Titanium Alloy(Ti-6Al-4V)	

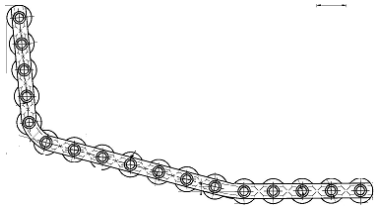
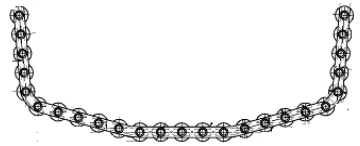
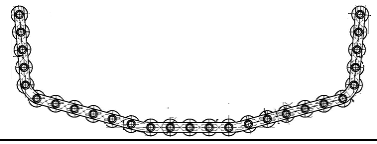
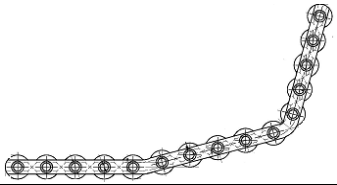
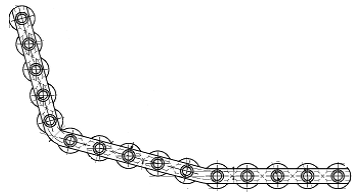
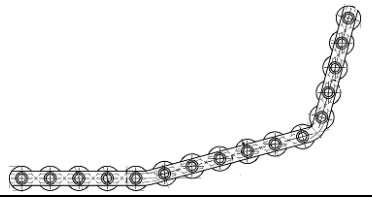
Plates*

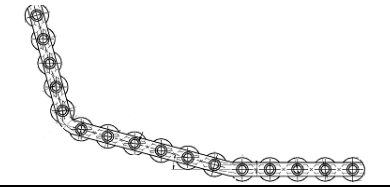
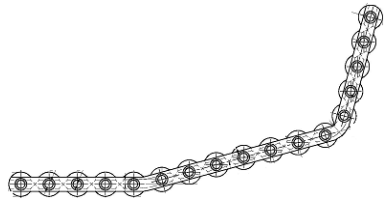
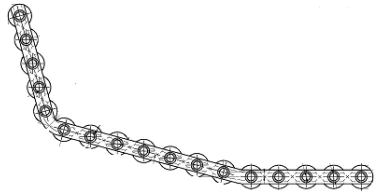
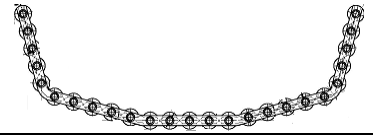
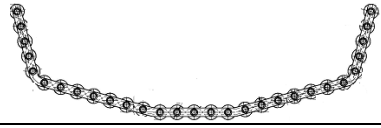
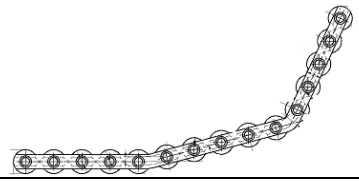
Code	Description	Dimensions (TxWxL)	Qty packed	Manufacturing Material	Image
04.21.15.00006	Straight Macro Plate 06 holes Lock	1.5x6.3x38.8 mm	01	Pure Titanium	
04.21.15.00008	Straight Macro Plate 08 holes Lock	1.5x6.3x51.8 mm	01	Pure Titanium	
04.21.15.00016	Straight Macro Plate 16 holes Lock	1.5x6.3x103.8 mm	01	Pure Titanium	
04.21.16.00006	Angled Macro Plate 06 holes Lock	1.5x6.3x32.9 mm	01	Pure Titanium	
04.21.16.00008	Angled Macro Plate 08 holes Lock	1.5x6.3x43 mm	01	Pure Titanium	
04.21.17.04090	Straight Macro Plate Bridge 04 holes x 09 mm Lock	1.5x6.3x28.3 mm	01	Pure Titanium	
04.21.17.04140	Straight Macro Plate Bridge 04 holes x 14 mm Lock	1.5x6.3x33.3 mm	01	Pure Titanium	
04.21.17.06110	Straight Macro Plate Bridge 06 holes x 11 mm Lock	1.5x6.3x43.3 mm	01	Pure Titanium	
04.21.18.04105	Curve Bridge Macro Plate 04 holes x 10,5 mm Lock	1.5x6.3x29.6 mm	01	Pure Titanium	

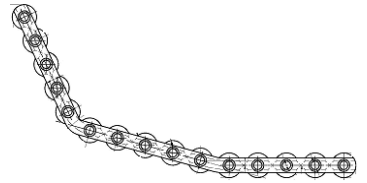
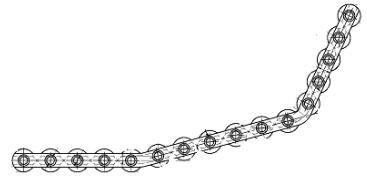
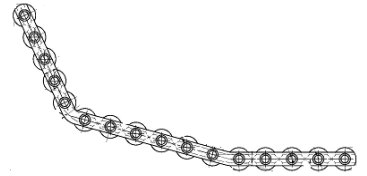
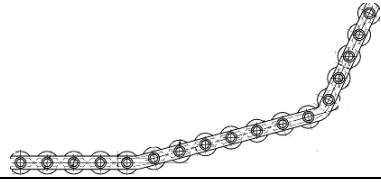
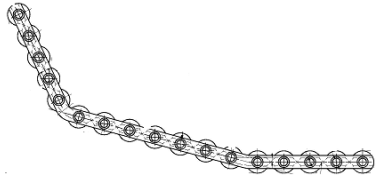
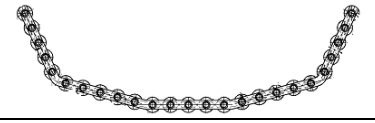
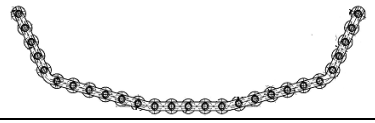
04.21.18.04155	Curve Bridge Macro Plate 04 holes x 15,5 mm Lock	1.5x6.3x34.4 mm	01	Pure Titanium	
04.21.19.00017	Angled Macro Plate right 17 holes Lock	1.5x6.3x94.8 mm	01	Pure Titanium	
04.21.20.00017	Angled Macro Plate left 17 holes Lock	1.5x6.3x94.7 mm	01	Pure Titanium	
04.21.19.00019	Angled Macro Plate right 19 holes Lock	1.5x6.3x107.7 mm	01	Pure Titanium	
04.21.20.00019	Angled Macro Plate left 19 holes Lock	1.5x6.3x107.6 mm	01	Pure Titanium	

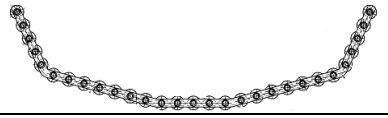
Code	Description	Dimensions (TxWxL)	Qty packed	Manufacturing Material	Image
04.21.21.00008	Straight Reconstruction Plate 08 holes Lock	3.0x8.5x78.5 mm	01	Pure Titanium	
04.21.21.00010	Straight Reconstruction Plate 10 holes Lock	3.0x8.5x98.5 mm	01	Pure Titanium	
04.21.21.00012	Straight Reconstruction Plate 12 holes Lock	3.0x8.5x118.5 mm	01	Pure Titanium	
04.21.21.00014	Straight Reconstruction Plate 14 holes Lock	3.0x8.5x138.5 mm	01	Pure Titanium	
04.21.21.00016	Straight Reconstruction Plate 16 holes Lock	3.0x8.5x158.5 mm	01	Pure Titanium	

04.21.22.15110	Angled Reconstruction Plate 110º x 15 holes right Lock	3.0x8.5x106.1 mm	01	Pure Titanium	
04.21.23.15110	Angled Reconstruction Plate 110º x 15 holes left Lock	3.0x8.5x106.5 mm	01	Pure Titanium	
04.21.22.16110	Angled Reconstruction Plate 110º x 16 holes right Lock	3.0x8.5x115.8 mm	01	Pure Titanium	
04.21.23.16110	Angled Reconstruction Plate 110º x 16 holes left Lock	3.0x8.5x116.2 mm	01	Pure Titanium	
04.21.22.17110	Angled Reconstruction Plate 110º x 17 holes right Lock	3.0x8.5x125.4 mm	01	Pure Titanium	

04.21.23.17110	Angled Reconstruction Plate 110º x 17 holes left Lock	3.0x8.5x125.8 mm	01	Pure Titanium	
04.21.24.25110	Angled Reconstruction Plate 110º x 25 holes Lock	3.0x8.5x163.7 mm	01	Pure Titanium	
04.21.24.27110	Angled Reconstruction Plate 110º x 27 holes Lock	3.0x8.5x183 mm	01	Pure Titanium	
04.21.24.29110	Angled Reconstruction Plate 110º x 29 holes Lock	3.0x8.5x202.3 mm	01	Pure Titanium	
04.21.22.15120	Angled Reconstruction Plate 120º x 15 holes right Lock	3.0x8.5x113.2 mm	01	Pure Titanium	
04.21.23.15120	Angled Reconstruction Plate 120º x 15 holes left Lock	3.0x8.5x112.9mm	01	Pure Titanium	
04.21.22.16120	Angled Reconstruction Plate 120º x 16 holes right Lock	3.0x8.5x122.6 mm	01	Pure Titanium	

04.21.23.16120	Angled Reconstruction Plate 120º x 16 holes left Lock	3.0x8.5x122.6 mm	01	Pure Titanium	
04.21.22.17120	Angled Reconstruction Plate 120º x 17 holes right Lock	3.0x8.5x132.2 mm	01	Pure Titanium	
04.21.23.17120	Angled Reconstruction Plate 120º x 17 holes left Lock	3.0x8.5x132.2 mm	01	Pure Titanium	
04.21.24.25120	Angled Reconstruction Plate 120º x 25 holes Lock	3.0x8.5x177.4 mm	01	Pure Titanium	
04.21.24.27120	Angled Reconstruction Plate 120º x 27 holes Lock	3.0x8.5x196.7 mm	01	Pure Titanium	
04.21.24.29120	Angled Reconstruction Plate 120º x 29 holes Lock	3.0x8.5x216 mm	01	Pure Titanium	
04.21.22.15130	Angled Reconstruction Plate 130º x 15 holes right Lock	3.0x8.5x119.7 mm	01	Pure Titanium	

04.21.23.15130	Angled Reconstruction Plate 130º x 15 holes left Lock	3.0x8.5x119.7 mm	01	Pure Titanium	
04.21.22.16130	Angled Reconstruction Plate 130º x 16 holes right Lock	3.0x8.5x129.4 mm	01	Pure Titanium	
04.21.23.16130	Angled Reconstruction Plate 130º x 16 holes left Lock	3.0x8.5x129.4 mm	01	Pure Titanium	
04.21.22.17130	Angled Reconstruction Plate 130º x 17 holes right Lock	3.0x8.5x139 mm	01	Pure Titanium	
04.21.23.17130	Angled Reconstruction Plate 130º x 17 holes left Lock	3.0x8.5x138.9 mm	01	Pure Titanium	
04.21.24.25130	Angled Reconstruction Plate 130º x 25 holes Lock	3.0x8.5x191 mm	01	Pure Titanium	
04.21.24.27130	Angled Reconstruction Plate 130º x 27 holes Lock	3.0x8.5x210.4 mm	01	Pure Titanium	

04.21.24.29130	Angled Reconstruction Plate 130º x 29 holes Lock	3.0x8.5x229.7 mm	01	Pure Titanium	

[1] All plates that comprise the Oral Plates and Screws System – Lock Type are moldable. Guidelines and care with the modeling and shaping of the plates are described in the topics "Instructions for Use" and "Warnings and Precautions"

Accessories

Code	Description	Dimensions	Qty packed	Manufacturing Material	Image
04.31.07.00110	Angled Reinforcement 110º	4.5x10.5x29 mm	01	Pure Titanium	
04.31.07.00120	Angled Reinforcement 120º	4.5x10.5x28.5 mm	01	Pure Titanium	
04.31.07.00130	Angled Reinforcement 130º	4.5x10.5x27.7 mm	01	Pure Titanium	
04.43.02.00000	Screw for Angled Reinforcement	Ø 4.0x5.1 mm	01	Titanium Alloy(Ti-6Al-4V)	
04.43.02.00015	Cover Screw for Modeling Plate 1.5 mm	Ø 4.0x1.7 mm	01	Titanium Alloy(Ti-6Al-4V)	
04.43.02.00030	Cover Screw for Modeling Plate 3.0 mm	Ø 4.0x4.0 mm	01	Titanium Alloy(Ti-6Al-4V)	

Support Material List:

The support materials are the instruments designed only for deployment of the Oral Plates and Screws System – Lock Type.

These instruments are made of stainless steel which meets the requirements specified by ASTM F899 – Standard Specification for Stainless Steel for Surgical Instruments and have high strength and durability.

The instruments below are not purpose of this register and should therefore be purchased separately and always from the same manufacturer of the implant or indicated by the manufacturer.

See below for the instruments available from MDT or indicated by the manufacturer to perform surgery of deployment of Oral Plates and Screws System – Lock Type:

Instrumental – Oral Plates and Screws System – Lock Type

Cheek retractor
Guide Tran oral 2.4 mm
Trocar Ø 4,0mm
Limiter for 2.4 mm Guide Tran oral
Hexagonal screwdriver for Limiter
Double Guide Ø 4.0 / 1.8
Cross Drive screwdriver 2.4 / 2.7 w / Quick Coupler
Drill Helical Coupling Ø 1.8 x
Drill Helical Coupling Ø 1.8 x
Drill Helical Coupling Ø 1.8 x 160 mm
Guide cannula 50 mm
Guide cannula 15 mm
Depth gauge 30 mm
Forceps for plate
Graduated tap 2,4mm GII System
Modeling Cover Screw
Cutting Pliers Double Action
Modeler Pliers Plates
Manual Modeler Plates 2,4/2,7
Handle for quick coupler 2,4mm w/ lock
Modeling Cover Screw 3mm
Modeling Cover Screw 1,5mm
Template for Macro Straight Reconstruction Plate 8 holes
Template for Macro Straight Reconstruction Plate 10 holes
Template for Macro Straight Reconstruction Plate 12 holes
Template for Macro Straight Reconstruction Plate 14 holes
Template for Macro Straight Reconstruction Plate 16 holes
Template for Macro Angled Reconstruction Plate L/R 50º 15 holes
Template for Macro Angled Reconstruction Plate L/R 50º 16 holes
Template for Macro Angled Reconstruction Plate L/R 50º 17 holes
Template for Macro Angled Reconstruction Plate 50º 25 holes
Template for Macro Angled Reconstruction Plate 50º 27 holes
Template for Macro Angled Reconstruction Plate 50º 29 holes
Template for Macro Angled Reconstruction Plate L/R 60º 15 holes
Template for Macro Angled Reconstruction Plate L/R 60º 16 holes
Template for Macro Angled Reconstruction Plate L/R 60º 17 holes
Template for Macro Angled Reconstruction Plate 60º 25 holes
Template for Macro Angled Reconstruction Plate 60º 27 holes
Template for Macro Angled Reconstruction Plate 60º 29 holes
Template for Macro Angled Reconstruction Plate L/R 70º 15 holes

Template for Macro Angled Reconstruction Plate L/R 70º 16 holes
Template for Macro Angled Reconstruction Plate L/R 70º 17 holes
Template for Macro Angled Reconstruction Plate 70º 25 holes
Template for Macro Angled Reconstruction Plate 70º 27 holes
Template for Macro Angled Reconstruction Plate 70º 29 holes

The instruments are provided decontaminated, but not sterilized. The surgical instruments are subject to wear and tear during the normal use, and it can therefore break.

Inadequate sterilization of surgical instruments can cause infection.

The instruments should be use only for its purpose and should be inspect regularly to check for possible wear and tears and damage.

For more information about the instrumental, consult the representative.

Warning and Precautions

To use the product the team should consider the following warnings and precautions:

- The Oral Plates and Screws System – Lock Type must be utilized after a detailed analysis of the surgical procedure to be adopted and the reading of this instruction for use
- The product should only be used by specialized surgical teams, with specific knowledge and training on techniques for osteosynthesis in the facial bones, and it is 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 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 Oral Plates and Screws System – Lock Type should not be utilized if it cannot have a bone support adequate to ensure the stability of the implant;
- The patient must have periodic medical monitoring to check the conditions of the implant, the bone and adjacent tissues;
- Be advice that the use of antibioticterapy in cases where there is a local predisposition 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;
- 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;
- 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;
- The plates should NEVER be remodeled;
- The application of the product in patients with inadequate bone stock may weaken the hold of the screws, thus compromising the technical result.
- 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:

- Absence or delay of the bone healing resulting in implant disruption;
- Loosening, displacement, deformation, twisting or breakage of the implant;
- Deformation and fracture of the implant;
- Damage to nerves with sensory or motor loss;
- 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 mentioned above is the surgeon responsible.

Instructions for Use

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 the facial bones, and is responsibility of the surgeon the choice and mastery of the technique to be applied;
- To stabilize or mandibular reconstruction, the product can be applied using techniques intra (monocortical - the screws reach and secure only to the external cortex of the mandible) or extra (bicortical - the screws reach and secure the outer and inner cortex of the mandible) oral ;
- 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 will be.
- 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;
- The plates should NEVER be remodeled;
- The length of the fixation screw for the plates will depend on the choice of technique to be adopted, intra (monocortical) or extra (bicortical) oral;
- The insertion of screws with locking (lock type) for plate fixation with locking (lock type) should be conducted in line perpendicular to the plate;
- For the procedures that involve the pattern of occlusion, it is recommended to perform osteosynthesis with the use of lock jaw;
- In cases of component loosening, revision surgery should be performed;

- 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.

Guidance to the patient

The surgical team responsible should guide the patient on:

- 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;
- The fact that the risks are higher when using in patients with predisposition to disobey the medical guidelines, care and post-operative restrictions, such as children, elderly, individuals with neurological disorders or addicts;
- The fact that the product does not replace and does not have the same performance of normal bone and therefore can break or release due to excessive stress or activities of early load and other situations;
- The necessity of restricting the realization of exertion activities or sports during the postoperative period;
- The need for periodic medical monitoring to check the conditions of the implant, the bone and adjacent tissues;
- The fact that not having revision surgery in a period exceeding 01 (one) year, where there was no bone healing may lead to implant mechanics failure;
- The need for revision surgery in cases of loosening of the components;
- The susceptibility of interference with test results for images. Thus, patients with implants should report this fact of being a carrier of metallic implant when the need for it;
- The information listed in this topic "Guidelines for Patient " and in the "Adverse Effects".

Sterilization

The Oral Plates and Screws System – Lock Type is supplied in a non sterile condition, and shall be taken from the original package (plastic) and set into a properly container for sterilization (supplied by the manufacturer) before its use.

The indicated sterilization method to sterilize the product is the humid heat (Autoclave).

The implants are supplied decontaminated by the manufacturer, however they shall be properly handle and sterilized according to the following instructions, in order to avoid contamination of the implant and cause infection to the patient.

<u>Sterilization parameters</u>

The sterilization of the product must be performed according the following parameters:

Method	Cycle	Temperature	Exposition Time
Humid heat (autoclave)	Pre-Vacuum Sterilization (Vacuum) Dry	134ºC to 137ºC	10 minutes

The sterilization process must meet the theoretical probability of presence of microorganisms vital to a maximum of $1x10^6$ (SAL [Sterility Assurance Level] sterility assurance level = 10^{-6}).

The conditions of the equipment (autoclave) used during the sterilization process (a program for calibration, maintenance, so forth) as well as ensuring the use of an appropriate sterilization process and proof of product sterility is the responsibility of trained staff (central material) health service.

Cleaning

The following procedures describe are applied to the implants and their surgical instruments.

When the use of the product, they shall be taken from its package and washed with alcohol for medical use at 70% + distillate water 30%.

After the cleaning, the products must be rinse with distillate water and dried with cleaning cloth that does not release fibers.

If the cleaning process is performed with termo-desinfector equipments with the help to remove the encrusting substances, the guidelines of the manufacturer must be adopted.

Risk of Contamination

It is an implantable product, where there is a need for explantation, there are risks of biological contamination and transmission of viral diseases.

In order to minimize these risks, the product explanted should be treated as potentially contaminating material, and should adopt the standards and/or other local regulations applicable.

Product Disposal

The components explanted or considered unsuitable for use should be discarded. It is recommended that prior to disposal, the product is adulterated, and to such the parts may be cut, twist or filing.

The product must be discarded in appropriate locations, to avoid contamination of the environment and other individuals. It is recommended the adoption of legal local regulations for disposal of the products potentially contaminants.

Product for single use – do not reuse.

Traceability

To ensure the traceability of the implanted product, and comply with the requirements for health surveillance, the surgeon or his team must register with the patient's medical record the information about the product. Furthermore, such information must also be passed to the distributor of the product and the patient in order to complete the cycle of the product traceability established. The information necessary for traceability are on 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

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 storage, it is dry and airy place, with no incidence of exposure to light, moisture or contaminants.

The implants cannot be stored directly on the floor. Therefore the use of shelves with at least 20 cm of height is recommended.

The product should be kept in their original packaging until the moment of its use, while opening the package for surgical use and handling of the product should be performed by qualified personnel for this procedure;

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

For information about the date of manufacture and lot number: see label.

Other information

Manufactured and distributed by:
MDT – Indústria Comércio Importação e Exportação de Implantes SA
Av. Brasil, nº. 2983 – Distrito Industrial
Rio Claro/SP – CEP 13505-600
Phone/ Fax: (55-19) 2111-6500
Technical Responsible: Miguel Lopes Monte Júnior – CREA 0601150192

Registration ANVISA #: 10417940070
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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

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