Instructions for Use

Buccomaxillofacial System of Plates and Screws

Keys used on packaging and labeling

REF	Reference Number (filled with product code)		Avoid Direct Exposure to sunlight
LOT	Lot Number		Keep Dry
	Read Instructions for Use		Fragile, Handle with care
Material	Titanium		Do not Use if package is violated
	Manufacturing Date		Expiry date
	Non-Sterile		Single-use Product

Technical Name: Non-rigid, non-absorbable fixation system for osteosynthesis

Commercial Name: Buccomaxillofacial system of plates and screws

Raw Material: Plates – commercially pure titanium (ASTM F67)
Screws – Ti-6Al-4V titanium alloy (ASTM F136)

Non-Sterile Product

Expiry date: Undetermined

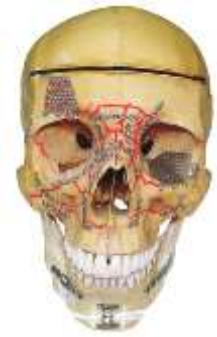
Description

This product is a system for buccomaxillofacial osteosynthesis, applicable to cranial and superior face regions (plates and screws with diameter of 1,5 mm) segment of the medium third of the face (plates and screws with diameter of 2,0 mm) and mandibular segments (plates and screws with diameter of 2,4). It consists of a surgically invasive, long-term use set of implants, constituted by plates and screws used in orthognathic and trauma procedures.

The plates composing the system are presented in micro, mini and macro versions, whose thicknesses are respectively 0,6 mm, 1,0 mm and 2,0 mm for several lengths and various formats, with or without bridge. This configuration provides a varied range of possibilities and applications to the surgeon, concerning cases of syntheses of cranium-maxillo-facial fractures, corrections of bony malformations and mandibular reconstructions.

With a cortical thread profile and cross drive connection, the screws that compose the system are equally presented in micro, mini and macro versions, with diameters of 1,5 mm, 2,0 mm and 2,4 mm respectively. Screw pitch can be 0,50 mm or 0,75 mm, according to the length of the screws, that vary between 3 mm and 20 mm.

Below is an illustrative image of some of the possible applications of the Buccomaxillofacial System of Plates and Screws:

Composition

The Buccomaxillofacial System of Plates and Screws is manufactured in titanium, due to its properties that make it the ideal material for implant production. Titanium is a material whose main properties are biocompatibility and high mechanical resistance, therefore, titanium presents itself as being the best option, both from a tissues' tolerance and initiation of immunological complications of low degree points of view, for the manufacturing of these implants.

The screws are manufactured from alloyed titanium, with 4% Aluminum and 6% Vanadium (F136) and extra-low interstitial atoms (ELI), due to its strength characteristics, while the plates are produced from F67 commercially pure titanium, that presents the necessary malleability characteristics for the surgeon to mold the plates, during surgical procedure.

The titanium alloy and the commercially pure titanium used for the manufacturing of the Buccomaxillofacial System of Plates and Screws complies, respectively, with the requirements specified by ASTM F136 and ASTM F67 standards

The choice of those materials is due to their well defined mechanical and metallurgical characterization, as well as to the results in service – widely described in worldwide literature – that confirm that those metals are biocompatible and possess mechanical strength that is adequate to the intended purposes.

Indication and purpose

The Buccomaxillofacial System of Plates and Screws is indicated for surgical orthopedic, dental and aesthetic or repairing plastic procedures on the cranium-maxillo-facial region. It aims for reconstruction, fixation, stabilization and correction of pre-existing deformities or the ones caused by trauma, fractures of the skull bones, cranioplasty, craniofacial osteotomy and craniotomy.

The application technique of these implants demands bony reserve necessary for the real fixation of the screws, however when that is impossible, the technical result may be jeopardized.

The application of these implants shall take into consideration the muscular forces (tension and traction) on the area of application, the defect, failure and the bone pathology to be corrected. The decision and the responsibility of its indication and use pertain exclusively to the surgical team responsible for the treatment that must have technical knowledge and training on the material to be used.

The plates shall be carefully adapted to the anatomic area of application, however, the multiple molds and folds may lead to their weakening and loss of qualities, promoting fractures after their application and, because of that, they should be avoided, not being recommended, under any circumstance, their reutilization.

The load restrictions are more related to the mandible, which demands more effort from the implant. In that case, the recommendation is to use, preferably, the screws indicated for that region (screws for osteosynthesis or for mandibular reconstruction – Macro Plates and Macro Screws), unless the surgical technique demands the opposite. In that case the implant selection is made according to the criteria and under the responsibility of the surgeon.

Following is the indication and specific purposes of the Buccomaxillofacial System of Plates and Screws:

1,5 mm Implants (Micro plates and Micro screws) – The indications and purposes of the 1,5 mm implants are face comminuted fractures, more specifically areas like medium and superior third of the face, therefore areas of little mechanical effort, as well as in the naso-orbit-ethmoidals (NOE) fractures.

2,0 mm Implants (Mini Plates and Mini Screws) – The indications and purposes of the 2,0 mm implants are the symphysis and molar curved areas. The plates, by presenting malleability, provide anatomical reduction and restoration of dental occlusion. The mini plates (1,0 mm thickness) have general indication in buccomaxillofacial traumatology and for the mandible, due to their bigger stiffness. The mini screws, by their turn, permit application through monocortical fixation (intra-oral access) or bicortical fixation (extra-oral access).

2,4 mm Implants (Macro Plates and Macro Screws) – Indications and purposes of the 2,4 mm implants are the reconstruction and stabilization of deformities, be they pre-existent or caused by trauma, in the mandible region.

Contraindications

The following are relative contraindications to the use of the device. The indication of the procedures is left to the surgeon in charge, after a thorough study of the case.

Certain allergies to titanium: in that case the doctor shall make the pertinent exams and evaluate the pertinence of carrying out the surgery.

Particular conditions of the patient: senility, alcoholism and infections. These conditions shall be carefully investigated by the doctor, who should alert the patient regarding the risks brought by such these characteristics.

Reutilization of the devices: the reutilization of the devices is totally contraindicated, once the correct performance of the plates and screws is not guaranteed in case of their reuse.

Forms of Presentation

The implants that compose the Buccomaxillofacial System of Plates and Screws are supplied in non-sterile conditions.

Plastic Package - Plates

Plastic packing and support - Screws

The plates are provided unitarily packaged in a double plastic bag of polypropylene, in which there is a leaflet with the respective instructions for use.

The screws can be packaged in a double plastic bag, such as the plates, when provided unitarily in the package, in which there is also a leaflet with instructions for use. Another option is packaging the product in polycarbonate plastic holder (primary packaging) with four screws each, packed in a polypropylene plastic bag (secondary packaging), in which there is a leaflet with instructions for use

In the second case, the color of the support indicates the diameter of the screw. Additionally, the support is engraved with lot number and product code of the material, for traceability purposes. An orange support is used for 1,5 mm diameter screws, a blue support is for 2,0 mm diameter screws, a green support is used for 2,4 mm diameter screws and, finally, a red support is used for emergency screws with 1,7 mm, 2,3 mm and 2,7 mm diameters.

The Buccomaxillofacial System of Plates and Screws is composed of the implants described below, available in the following dimensions:

Micro screws - Ø 1.5 mm and Ø 1.7 mm (emergency) – Produced from F136 titanium alloy

Code	Description	Characteristics and Technical Specifications of the Product
04.24.58.15XXX	Cortical Screw Ti 1,5 - Cross Drive - Type “MD”	Available with 03, 04, 05, 06, 07, 09, 11, 13, 15 and 17 mm of length.
40.24.01.15XXX	Cortical Screw Ti 1,5 - Cross Drive - Conic	Available with 04, 05, 06, 07, 09 and 11 mm of length.
04.24.58.17XXX	Cortical Screw Ti 1,7 - Cross Drive - Type "MD"	Available with 03, 04, 05, 06,07 and 09 mm of length.

Micro plates – Produced from F67 commercially pure titanium

Code	Description	Characteristics and Technical Specifications of the Product
04.18.12.XXXXX	Rigth “L” Bridge Micro Plate 100° - Type “MD”	Available with 02x03 holes with 8,5 mm of bridge
04.18.13.XXXXX	Left “L” Bridge Micro Plate 100° - Type “MD”	Available with 02x03 holes with 8,5 mm of bridge
04.18.14.XX000	Straight Micro Plate - Type “MD”	Available with 04, 06, 08 and 16 holes.
04.18.15.XXXXX	Straight Bridge Micro Plate - Type “MD”	Available with 04 and 06 holes by 06, 08 and 10 mm of bridge.
04.18.16.XX000	Orbital Micro Plate - Type “MD”	Available with 04, 06, 08 and 10 holes.
04.18.17.06055	Double "Y" Micro Plate - Type “MD”	Available with 06 holes by 5,5 mm of bridge
04.18.18.05XXX	Bridge Micro Plate "Y" - Type “MD”	Available with 05 holes by 07 and 10 mm of bridge
04.18.19.05XXX	Bridge Micro Plate "T" - Type “MD”	Available with 05 holes by 08 and 10 mm of bridge
04.18.19.06000	Micro Plate "T" 6 Holes - Type “MD”	Available with 06 holes
04.18.20.04000	Micro Plate "L" - Right - Type “MD”	Available with 02x02 holes
04.18.20.04XXX	Bridge Micro Plate "L" - Right - Type “MD”	Available with 04 holes by 07, 08, 05 and 10 mm of bridge.
04.18.21.04000	Micro Plate "L" - Left - Type “MD”	Available with 02x02 holes
04.18.21.04XXX	Bridge Micro Plate "L" - Left - Type “MD”	Available with 04 holes by 07, 08, 05 and 10 mm of bridge.
04.18.22.10000	Right Molded Micro Plate for Vertical Osteotomy without Advance - Type “MD”	Available in version without advance - Right
04.18.22.10XXX	Right Molded Micro Plate for Vertical Osteotomy - Type “MD”	Available with 03, 05, 07, 09 m of advance.
04.18.23.10000	Left Molded Micro Plate for Vertical Osteotomy without Advance - Type “MD”	Available in version without advance - Left
04.18.23.10XXX	Left Molded Micro Plate for Vertical Osteotomy - Type “MD”	Available with 03, 05, 07, 09 m of advance.
04.18.24.04XXX	Chin Micro Plate with Horizontal Adjust - Type “MD”	Available with 04 holes by 01, 03, 05, 07, 09 and 11 m of advance.
04.18.25.XXXXX	Micro Mesh Plate 0,65 - Type “MD”	Available with 0,65 mm thickness by 31x29,5, 47x31, 61x60, 85x55, 91x90, 133,5x129, 151x133,5 mm
04.18.26.00040	Clover Micro Plate 4 Holes	Available with 0,65 mm thickness x 4 holes
04.18.26.02010	Bridge Micro Plate 2 Holes x 10 mm - CMF	Available with 0,65 mm thickness x 4 holes x 10 mm
04.18.28.XXXXX	Support Micro Plate	Available with 0,65 mm thickness x 2x2 holes, 2x3 holes, 2x4 holes, 2x5 holes, 3x5 holes, 4x5 holes,

04.18.29.000XX	Micro Plate Drilling Closure	Available with 0,65 mm thickness x Ø 12 mm, Ø 15 mm, Ø 17 mm, Ø 22 mm,

Mini screws – Ø 2.0 mm and 2,3 mm (emergency) – Produced from F136 titanium alloy

Code	Description	Characteristics and Technical Specifications of the Product
04.24.58.20XXX	Cortical Screw Ti 2,0 - Cross Drive - Type “MD”	Available with 04, 05, 06, 07, 08, 10, 12, 14, 16, 18 and 20 mm length.
40.24.01.20XXX	Cortical Screw Ti 2,0 - Cross Drive - Conic	Available with 04, 05, 06, 07, 09, 11 mm length.
04.24.58.23XXX	Cortical Screw Ti 2,3 - Cross Drive - Type “MD”	Available with 04, 05, 06, 07, 08, 09, 10, 11, 12, 14, 16, 18, 20 and 22 mm length.

Mini plates – Produced from F67 commercially pure titanium

Code	Description	Characteristics and Technical Specifications of the Product
04.19.22.05090	Right “L” Mini Plate “L” 100º - MD Type	Available with 02x03 holes by 09 mm of bridge
04.19.23.05090	Left “L” Mini Plate “L” 100º - MD Type	Available with 02x03 holes by 09 mm of bridge
04.19.25.XX115	Bridge Mini Plate Calibrated - Type “MD”	Available with 04 and 06 holes by 11,5 mm of bridge
04.19.26.XX000	Orbital Mini Plate Orbital - Type “MD”	Available with 06, 08 and 10 holes.
04.19.27.04120	Right “L” Mini Plate - Type “MD”	Available with 04 holes by 12 mm of bridge
04.19.28.04120	Left “L” Mini Plate - Type “MD”	Available with 04 holes by 12 mm of bridge
04.19.29.XX000	Straight Mini Plate - Type “MD”	Available with 04, 05, 08, 12 and 16 holes.
04.19.30.XX120	Left “L” Mini Plate 100° - Type “MD”	Available with 02x02 and 03x04 holes by 12 mm of bridge.
04.19.31.XX120	Right “L” Mini Plate 100° - Type “MD”	Available with 02x02 and 03x04 holes by 12 mm of bridge.
04.19.32.06000	Mini Plate "T" - Type “MD”	Available with 03x03 holes.
04.19.33.04060	Right “L” Mini Plate - Type “MD”	Available with 02x02 holes by 06 mm.
04.19.34.04060	Left “L” Mini Plate - Type “MD”	Available with 02x02 holes by 06 mm.
04.19.35.06000	Mini Plate "I" - Type “MD”	Available with 06 holes.
04.19.36.04000	Mini Plate "T" - Type “MD”	Available with 02x02 holes.
04.19.37.04110	Mini Plate "T" - Type “MD”	Available with 02x02 by 11 mm of bridge.
04.19.38.XX000	Mini Plate "Y" 5 Holes - Type “MD”	Available with 02X03 and 02x04 holes.
04.19.39.06120	Double "Y" Mini Plate 6 Holes x 12,0 mm - Type “MD”	Available with 06 holes by 12 mm of bridge
04.19.40.05120	Right “TMini Plate 100° - Type “MD”	Available with 03x02 holes by 12 mm of bridge
04.19.41.05120	Left “T” Mini Plate 100° - Type “MD”	Available with 03x02 holes by 12 mm of bridge
04.19.42.07125	Mini Plate "T" - Type “MD”	Available with 05x02 holes by 12,5 mm of bridge
04.19.43.04095	Sagittal Mini Plate with Horizontal Adjust - Type “MD”	Available with 04 holes by 09,5 mm of bridge
04.19.44.03XXX	Chin Pre Molded Mini Plate with Horizontal Adjust - Type “MD”	Available with 04, 06, 08, 10 and 12 mm advance.
04.19.45.04XXX	Fix Pre Molded Mini Plate for Chin - Type “MD”	Available with 03, 05, 07 and 09 mm advance.

04.19.46.XXXXX	Mini Mesh Plate 0,65mm x 103,3mm x 103,3mm	Available with 0,65 mm thickness by 085x055 and 103,3x103,3 mm

Macro screws – Ø 2.4 mm and Ø 2,7 mm (emergency) – Produced from F136 titanium alloy

Code	Description	Characteristics and Technical Specifications of the Product
04.24.58.24XXX	Cortical Screw Ti 2,4 - Cross Drive - Type “MD”	Available with 07, 09, 11, 13, 15, 17 and 19 mm length.
04.24.58.27XXX	Cortical Screw Ti 2,7 - Cross Drive - Type “MD”	Available with 07, 09, 11, 13, 15, 17, 19 and 21 mm length.

Macro Plates – Produced from F67 commercially pure titanium

Code	Description	Characteristics and Technical Specifications of the Product
04.21.01.000XX	Short Angled Macro Plate A/C	Available with 04 and 06 holes.
04.21.04.04035	Macro Plate with Angled Drilling A/C 4 Holes x 3.5	Available with 04 holes
04.21.04.04040	Macro Plate with Angled Drilling A/C 4 Holes x 4.0	Available with 04 holes
04.21.05.00004	Orbital Macro Plate	Available with 04 holes
04.21.08.000XX	Bridge Short Macro Plate A/C	Available with 04 and 06 holes.
04.21.09.000XX	Bridge Short Macro Plate C/S	Available with 04 and 06 holes.
04.21.10.000XX	Bridge Long Macro Plate A/C	Available with 04 and 06 holes.
04.21.11.000XX	Bridge Medium Macro Plate A/C	Available with 04 and 06 holes.
04.21.03.00027	Angled Long Macro Plate C/S Right	Available with 27holes.
04.21.13.00027	Angled Long Macro Plate C/S Left	Available with 27 holes.
04.21.07.000XX	Straight Macro Plate C/S	Available with 24 and 36 holes.
04.21.06.00024	Straight Macro Plate A/C	Available with 24 and 36 holes.
04.21.02.00027	Angled Long Macro Plate A/C Right	Available with 27 holes.
04.21.12.00027	Angled Long Macro Plate A/C Left	Available with 27 holes.

List of Support Materials:

Support materials are the instruments solely designated for implantation of components that compose the Buccomaxillofacial System of Plates and Screws.

These instruments are manufactured from stainless steel that meets the requirements specified by ASTM F899 - *'Standard Specification for Stainless Steel for Surgical Instruments',* which provide high strength and durability.

The instruments below are not subject to this registration process and must, therefore, be purchased separately and always from the same manufacturer of the plates or from a manufacturer indicated by the same.

The instruments provided by MDT, or by a manufacturer of its designation, to perform surgeries for implantation of Buccomaxillofacial System of Plates and Screws are:

Buccomaxillofacial instrumental GII – 1,5

Item	Code	Description
01	02.01.20.01518	Cross Drive Wrench 1.5/1.8mm MD type with fast coupling
02	02.10.02.11065	Helicoidal Drill w/ coupling Ø 1.16 x 65 mm
03	02.10.11.11036	Drill w/ Stop and coupling Ø 1.16 x 3 x 65mm
04	02.10.11.11056	Drill w/ Stop and coupling Ø 1.16 x 5 x 65mm
05	02.10.11.11076	Drill w/ Stop and coupling Ø 1.16 x 7 x 65mm
06	02.11.01.15200	Handle for fast coupling wrench 1.5 mm MD type
07	02.02.03.30011	Double guide Ø 3.0 / 1.1 mm

08	02.28.02.00002	Rhomb point pliers
09	02.05.00.10030	Depth measurer 30 mm
10	02.08.02.00002	Straight nippers for plate
11	02.08.02.00004	Angulate nippers for plate and screw 1,5/2,0mm
12	02.16.02.00004	Nippers for bony fixation Backhaus type
13	02.08.02.00003	Nippers for Plate fixation
14	02.08.00.00158	Nippers for plate
15	02.28.04.15002	Modeling pliers for bucco-maxillo plates GII 1.5mm
16	02.28.06.00000	Cut pliers for 1,5/2,0 mm
17	02.63.18.07201	Molded box in aluminum f/ bucco-maxillo GII 1.5mm
18	02.63.19.07201	Molded tray in aluminum nº1 f/ bucco-maxillo GII 1.5mm
19	02.63.19.07202	Molded tray in aluminum nº2 f/ bucco-maxillo GII 1.5mm
20	02.63.02.20072	Case with lid for bucco-maxillo Plates GII 1.5mm Type “MD”
21	02.63.02.30072	Case with lid f/ bucco-maxillo Screws GII 1.5mm Type “MD”

Buccomaxillofacial instrumental GII – 2,0

Item	Code	Description
01	02.28.02.00002	Rhomb point pliers
02	02.08.00.00158	Nippers for plate
03	02.06.04.00000	Cheek remover
04	02.11.01.20200	Cable for fast coupling wrench 2.0 mm MD Type
05	02.02.03.30015	Double guide Ø 3.0 / Ø 1.5 mm
06	02.05.00.10030	Depth measurer 30 mm
07	02.09.01.24042	Reducing cannula 2.4 mm
08	02.30.00.30050	Trocar Ø 3.0 mm
09	02.01.20.02023	Cross drive wrench 2.0/2.3 mm MD type with fast coupling
10	02.04.02.30082	Countersink bit with fast coupling
11	02.03.05.20195	Calibred male 2.0mm MD type
12	02.01.01.24100	Hexagonal wrench for limiter
13	02.10.02.15090	Helicoidal Drill w/ coupling Ø 1.58 x 90 mm
14	02.10.11.15036	Drill w/ Stop and coupling Ø 1.58 x 3 x 65mm
15	02.10.11.15056	Drill w / Stop and coupling Ø 1.58 x 5 x 65mm
16	02.10.11.15076	Drill w/ Stop and coupling Ø 1.58 x 7 x 65mm
17	02.29.00.47000	Limiter for transbuccal guide 2.0mm
18	02.08.02.00002	Straight Nippers for plate
19	02.08.02.00004	Angulate nippers f/ plate and screw 1,5/2,0mm
20	02.16.02.00004	Nippers for bony fixation Backhaus type
21	02.08.02.00003	Nippers for Plate fixation
22	02.02.06.20000	Transbuccal guide 2.0mm
23	02.28.04.20002	Modeling pliers for bucco-maxillo plates GII 2.0mm
24	02.28.06.00000	Cut Pliers 1.5/2.0mm
25	02.63.02.20073	Case with lid for bucco-maxillo plates GII 2.0 Type “MD”
26	02.63.02.30073	Case with lid for bucco-maxillo screws GII 2.0 Type “MD”
27	02.63.18.07301	Molded box in Aluminum f/ bucco-maxillo GII 2.0
28	02.63.19.07301	Molded tray nº1 in aluminum f/ bucco-maxillo GII 2.0
29	02.63.19.07302	Molded tray nº2 in aluminum f/ bucco-maxillo GII 2.0

Important

The instruments are provided decontaminated, but not sterilized. Inadequate sterilization of surgical instruments may cause infection.

The surgical instruments are subject to wear with normal use, and therefore, may break.

The instruments shall be used uniquely for their intended purposes; they shall be regularly inspected so that possible wear and damage is detected.

For more information about the instruments, consult the representative.

Adverse Effects

Every surgical procedure presents risks and the possibility of complications, the infections, bleedings, drug allergic reactions and anesthetic risks being some common ones, among others. The following complications and adverse effects can also be associated with the implantation of the product:

- Absent or delayed union resulting in rupture of the implant;
- Deformation or fracture of the implant;
- Loosening or displacement of the implant;
- Sensitivity or reaction to foreign body;
- Pain or discomfort due to the product;
- Nerve damage caused by surgery;
- Necrosis in bones or soft tissue;
- Inadequate healing;
- Bone fracture and postoperative pain.

The decision for implant removal, in case of adverse effects, is made by the surgeon in charge.

Restrictions for use

The product shall only be used by surgeons with specialization in osteosynthesis techniques, therefore, it is necessary that the surgeon assumes responsibility for the correct execution of the surgical technique, possessing due mastery over it, as generally recognized, both on theory and practice.

Any complications due to wrong indications, incorrect selection of the operative technique, as well as complications due to limitation of the applied treatment method, or due to lack of asepsis, are not responsibilities of the manufacturer.

Warnings and precautions

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

- The Buccomaxillofacial System of Plates and Screws must only be used after a detailed analysis of the surgical procedure to be adopted and after reading these instructions for use;
- The product must be used by specialized surgical teams, with specific knowledge and capability about osteosynthesis techniques, being the responsibility of the surgeon the choice and mastery over the technique to be applied;
- Under medical criteria, the use of bone graft associated with the product may be required;
- The use in patients with predisposition to disobey medical guidelines and postoperative restrictions, such as children, elderly, mentally ill and/or chemically addicted people may pose a greater risk of device failure;
- The risks of failure of the implant are greater in patients engaged in strenuous activities or in sports activities during postoperative period, going against medical restrictions;
- The product shall not be used if an adequate bone support does not exist to ensure implant stability;

- Under medical criteria, pre and perioperative prophylactic antibiotic therapy may be used, as well as antibiotic therapy in cases where there is a local and/or systemic predisposition or where there is occurrence of infections;
- Caring for this material is responsibility of the qualified personnel, which should follow the applicable standards and/or other local regulations;
- Falls or crushing of the product on hard surfaces may damage it. Right after opening the packaging, inspect the integrity of the product. Do not use it if any abnormality is observed;
- The opening of the package for surgical use must be done by nurses qualified for this procedure;
- Devices inside violated and/or damaged packaging shall not be directly discarded in order to prevent its inadvertent use;
- Using the product along devices from other manufacturers may lead to incongruence between implanted devices;
- There is need of periodic medical follow-up to detect possible changes in the implant status and the adjacent bone. Only the follow-up can detect possible loosening of components;
- Improper selection and choice of implants to be used, as well as mistakes in indication, handling and application technique can cause excessive tensions and tractions on the implant, possibly leading to failure by fatigue, fracture or implant looseness;
- Dislocation of the material after its implantation may be detected in rare occasions, generally as an intrinsic complication of the procedure, usually not related to bad use or to a structural defect of the material;
- Every surgical procedure presents risks and the possibility of complications, the infections, bleedings, drug allergic reactions and anesthetic risks being some common ones, among others;
- The instruments used for implantation of the Buccomaxillofacial System of Plates and Screws shall be carefully inspected before their use. Instruments that present signs of wear or property losses shall not be used.
- The manufacturer is exempt of responsibility for damages caused by incorrect or inadequate use of the material;
- Inadequate sterilization of surgical instruments may cause prosthetic infection;
- Never reuse an implant, because even without external apparent damage, previous mechanical stresses may shorten its life cycle;
- The clinical results and the durability of the implants are extremely dependent on the application of a precise surgical technique;
- Handle with care;
- Single use product – DO NOT REUSE;
- Non-Sterile Product – It must be sterilized before use and handled correctly to avoid contamination;
- REPROCESSING PROHIBITED;
- Date of manufacturing, expiry date and lot number: see product label;
- The product described herein was developed for use in the circumstances above, so that all other uses are considered contraindicated or without scientific support.

Non Sterile product

The product shall be removed from its original package, washed and conditioned in appropriate container supplied by the manufacturer, for sterilization of the implants before their use. The product shall be correctly manipulated to avoid contamination.

Single Use Product – Do not reuse

After being used, the Buccomaxillofacial System of Plates and Screws shall not be used again.

The storage area for the product shall be under protection from direct light incidence – for packaging and label preservation – free from humidity and contaminating substances.

The patient shall be informed about:

The responsible surgical team shall guide the patient or his legal representative about:

- The patient should be properly instructed on the postoperative care. The patient's ability and will to follow the instructions constitute one of the most important aspects in an orthopedic surgical procedure;
- The fact that the risks are higher when the product is used in patients with predisposition to disobey medical guidelines, care and postoperative restrictions, such as children, elderly, mentally ill and/or chemically addicted people;
- 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 physical effort, early load and other situations;
- The need to restrict strenuous activities or sports practice during the postoperative period, whose extension is defined by the surgeon in charge;
- The increase of postoperative complications risk in patients' with morbid obesity;
- The necessity for periodic medical follow-up to check the conditions of the implant, the bone and adjacent tissues;
- The fact that not performing a revision surgery for periods above one (1) year, in cases where bone fusion did not occur (pseudoarthrosis), may lead the implant to mechanical failure;
- The necessity of a revision surgery in cases of loosening of components;
- The fact that implants can interfere with results from imaging examinations. Thus, implant users should report this fact when undergoing such examinations;
- Listed information in this topic: "Guidance to the patient and/or the Legal Representative" and also in the topic "Adverse Effects".

Instructions for use

Buccomaxillofacial osteosynthesis is a technique of established utility in the treatment of pathologies originating from various etiologies and reparative surgeries in cranium maxillo facial area for reconstruction, fixation, stabilization and correction of deformities, be they pre-existent or caused by traumas and its accomplishments, usually is part of buccomaxillofacial surgeon's training.

The selection criteria for the size of the screws and respective plates depend on the conditions of the affected bone portion, type of fracture and surgical technique, which is of the surgeon's responsibility.

The following instructions concern only to particularities of the procedure performed with use of the system. To use the product, the following instructions shall be followed:

- The implants that compose the system shall be handled exclusively in suitable environments (outpatient facility or operating rooms) with due care (shall only be handled with sterile gloves);
- Proceed with sterilization of the implants that compose the system according to the instructions recommended below;
- The Buccomaxillofacial System of Plates and Screws shall be applied and adapted according to the appropriate surgical techniques and demands;
- The Buccomaxillofacial System of Plates and Screws shall only be used with its respective surgical instruments;
- The application of the implants of the Buccomaxillofacial System of Plates and Screws shall be carried out along tooth lock;

- The implants can be applied through intra (monocortical) or extra (bicortical) oral techniques;
- The method of use shall follow a sequence that optimizes the characteristics of the system.

Sterilization

The production of the implants of the Buccomaxillofacial System of Plates and Screws is performed with great care to assure to the surgeon the safety and quality of the operative result. The medical personnel should also contribute to obtain the expected operative result, giving due attention to the manipulation and use of the devices, mainly in reference to sterilization, to minimize as much as possible the risks of prosthetic infection.

That way, the indicated sterilization method for the implants that compose the Buccomaxillofacial System of Plates and Screws is autoclaving (steam sterilization), to be performed at the hospital.

In order to perform this procedure, the manufacturer provides suitable containers (cases) for autoclaving, which have grooves and cover for circulation of super saturated steam, in accordance with ABNT NBR 14332 - "Stainless steel Surgical and dental Instrument - Guidelines on handling, cleaning and sterilization'.

The plates shall be removed from the plastic package and conditioned in the case; their handling and manipulation shall be carried out in a way to avoid contamination.

The screws, conditioned in their respective supports, shall be removed from the plastic packages and those supports shall be coupled to the cases according to their sizes.

Now follows a description of the recommended parameters for sterilization of the implants that compose the Buccomaxillofacial System of Plates and Screws:

Sterilization Parameters

The implants that compose the Buccomaxillofacial System of Plates and Screws do not present special demands in relation to the sterilization method, however, the following parameters are recommended for sterilization of the implants:

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

The chosen sterilization process, in any case, must meet the EN556 standard, which states that the theoretical probability of the presence of vital microorganisms is, at most, 1 by 10^{-6} (SAL [*Sterility Assurance Level]* level of sterility assurance = 10^{-6}).

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

Risk of Contamination

Considering that the implants that compose the Buccomaxillofacial System of Plates and Screws, being implantable materials, make contact with tissue and corporal fluids, there is a risk of biological contamination and transmission of viral diseases such as hepatitis and HIV, etc. in case of their removal.

Therefore, the removed implants of the system shall be treated as potentially contaminant materials.

Product Disposal

After removal, the implants that compose the Buccomaxillofacial System of Plates and Screws shall be discarded and they should not be reused under any circumstance.

The devices that were explanted or regarded as inappropriate for use must be discarded. It is highly recommended that before discarded, the parts are cut, bent or sanded.

To dispose explanted plates, follow the local legal procedures for disposal of potentially contaminating products.

Single use product – Do not reuse

Traceability

To ensure traceability of the implanted product and comply with the health surveillance requirements, the surgeon or his team must register the information about the implanted product in the patient's medical record. Furthermore, such information must be forwarded to the distributor of the product and to the patient, in order to complete the traceability cycle of the implanted product. The necessary information for traceability is relative to the product used, surgery and patient, such as below:

- Name of patient who received the implant;
- Surgeon's name;
- Hospital's name;
- Manufacturer's name;
- Supplier's name;
- Surgery date;
- Product Code;
- Product Lot Number;
- Quantity used;
- Product registration at ANVISA;

Necessary information for the traceability of the product, as follows, are engraved on the product or can be obtained from the label on its package:

- Company's logo;
- Manufacturing lot number;
- Product code.

The traceability information is necessary for notification by the health service and/or the patients themselves to Sanitary Surveillance Agency - ANVISA and the manufacturer when there is occurrence of serious adverse events, for conducting appropriate investigations.

Storage

A cool, dry place is recommended, away from direct sunlight.

The implants cannot be stored directly on the floor (minimum height = 20 cm), cannot be placed on high shelves near light bulbs (to avoid drying of the package or erasing the label) and cannot be stored in areas where contaminants like insecticides, pesticides or cleaning materials are used.

Transportation

The implants shall be carefully transported, avoiding falls and friction in order to avoid defects on the product's surface finish.

Keep the implants always in their original packaging until the moment of use, under the responsibility of the medical/hospital staff designated for this purpose, remembering to always pay attention to the integrity of the packaging.

Manufacturing date, expiry date 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 (19) 2111-6500
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ALERT
INSTRUCTIONS FOR USE

These INSTRUCTIONS FOR USE are available in a non-printed format, through the manufacturer's website at www.mdt.com.br.

The INSTRUCTIONS FOR USE at the website are indexed by REGISTRATION/CADASTRE ANVISA´s NUMBER and respective TRADE NAME of the product, informed at the label of the product purchased.

All the INSTRUCTIONS FOR USE provided at 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 of interest to the user, the INSTRUCTIONS FOR USE may be provided in printed form, with no extra cost. This request shall be taken to the Customer Service Department (in Portuguese, SAC) (Customer Service Department) of the manufacturer, as follows:

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.

MDT Implantes

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