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## INSTRUCTIONS FOR USE

### MICRO PINS and MICRO SCREWS

#### Description – Micro Pins

The **Micro Pins** are available in two lengths: 3 mm and 5 mm. The first are recommended for the majority of applications, while the 5 mm Micro Pins provide greater stabilization in the case of a very soft bone. The special design of the Micro Pin with crestal coils guarantees greater fixation of the membrane and simplifies its removal, with the aid of a special screwdriver. Hexagonal engagement of 0.88 mm for easy removal.

The principal region of use is the upper jawbone.

#### Description – Micro Screws

The **Micro Screws** are self-tapping and made from low profile titanium alloy with a Ø1.5 and a Ø2.5 mm head, designed specifically to engage inner square tips (square engagement of 1.00 mm). This design guarantees excellent stability of the Micro Screws minimizing the risk of detachment during the application phase.

#### Application

The medical devices “Micro Screws and Micro Pins for maxillofacial and dental surgical use”, secure a membrane to the mandibular cortical bone, and/or to titanium meshes, and/or to small autologous / heterologous bone grafts.

#### Warnings / Precautions / Interactions

The medical devices “Micro Screws and Micro Pins for surgical use” are designed to be used solely by certified surgeons and /or dental specialists and dental graduates who are certified to practice.

Given the small size of Micro Screws and Micro Pins, a special tool (medical device inserter) is necessary allowing easy grip, during both the insertion and the extraction phase, thus eliminating technical errors during surgery, without compromising the health status of the patient.

Excessive mechanical pressure or excessive pressure in the infusion of saline solution, during the insertion / extraction, can cause damage to the bone.

#### Caution

A Micro Screw / Micro Pin is disposable and cannot be reused, as this could cause the onset of infections, or result in its inability to maintain its technical features.

Before use, check that the packaging is intact; otherwise, the sterility is not guaranteed and sterilization is necessary prior use. Sterilization process is described in a following paragraph.

#### Materials

The medical devices “Micro Screws and Micro Pins for surgical use” are manufactured of grade 5 Titanium (Ti-6Al4V ELI).

#### Sterilization

The medical devices “Micro Screws and Micro Pins for surgical use” are supplied in sterile conditions (sterilization by Ethylene Oxide); this condition is ensured when the box is undamaged. If the box is damaged or, if there is partial use of the Micro Screws or Micro Pins contained in the rigid case, the specialist can re-sterilize the same following the steps below:

Pack the rigid case with the Micro Screws or Micro Pins which are still unused (WARNING: the used Micro Screws or Micro Pins must be discarded, because they are contaminated and they are considered disposable; risk of onset of infections and/or loss of technical performance of the product) in an envelope (medical paper coupled with PET).

Sterilize with steam in an autoclave at 121°C for 15 minutes, or at 134°C for 10 minutes.

### Application – Micro Screws

Expose the part which will receive the Micro Screws and make the required holes with an irrigated drill at a low number of revs (500-700 revs min<sup>-1</sup>).



The pilot drill must have a diameter of 0.3-0.4 mm smaller, compared to the diameter of the Micro Screw.



The Micro Screw must only be positioned and removed using the special tip.

### Application –Micro Pins:


Expose the part which will receive the Micro Pin, engage the latter from the sterile blister using the special tool (inserter) and tap it gently into the preset site with the aid of a surgical hammer. To remove it, use the special spanner with hexagonal engagement, unscrew the nail and remove using surgical tweezers.

### Symbols used on labeling

-  :Date of production
-  :Do not reuse
- |         |     |
|---------|-----|
| STERILE | EIO |
|---------|-----|

 :Sterile unless the package is damaged or opened.  
Method of sterilization - E.O. Gas
-  :Read instructions of use
-  :Use until (month - year)
- LOT** :Batch Number
- |      |
|------|
| Ref. |
|------|

 :Product Code

 **0653** :This product is manufactured in compliance with the essential requirements of directive 93/42/EC. CE mark and identification number of the Notified Body

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