MATERIALS TO FACILITATE THE PROVISION OF BONE
Precautions and instructions for use

These usage instructions should be read before using the materials supplied by IMPLANT MICRODENT SYSTEM S.L.U as they contain essential information to avoid misuse.
The descriptions below have been written for dental professionals. Therefore, we recommend they receive instructions from an expert professional in the fields, who has received adequate information. Implant Microdent System S.L.U offers regular training courses on the use of their products.
The user must ensure that the selected product is suitable for the planned purposes and procedures.
These instructions for use are available in pdf format at the following web address: www.microdentsystem.com/instrucciones-uso
To open pdf files you need the free Adobe Acrobat Reader.

INTENDED USE
Implant Microdent System S.L.U put on the market the necessary equipment to facilitate the provision of bone in areas with periodontal defects. These instrumental allow to hold the titanium tissular sheet and titanium mesh in the maxilla or mandible.

DESCRIPTION
The material mentioned is composed of the following components:

Titanium tack
Clinical indication: It is an instrument designed for fixation of the titanium mesh or membrane. Tacks are available in two sizes: 3 mm for hard bone and 5 mm for soft bone.
Material: Tacks are made in titanium grade 5 according to ISO 5832-3. Tasks of 5 mm are presented blue anodized for easy identification.
Method of application: After the required sterilization of the product, inserting the tack into the impactor and transported to the desired position. Knock in the titanium tack in bone through the mesh or membrane, positioned at right angle and striking with a hammer on the impactor. After the therapeutic period unscrew the pin with a screwdriver (Hex 0.90) and remove it with tweezers carefully to prevent aspiration by the patient.
Precautions: The contact surface of the membrane must be free of biological tissue that may prevent proper seating of the tack on the membrane.
To release the impactor is unnecessary excessive force, only the impactor should be tilted to one side and automatically separated from the tack.

Osteosynthesis screws
Clinical Indication: Osteosynthesis screws are indicated for fixation of titanium mesh, membranes and bone grafts block , in case of atrophic maxilla resorbed or bone defects.
Osteosynthesis screws are available in three diameters, 1.20, 1.50 and 2.00 mm, and in different lengths to solve the needs of the treatment.
Osteosynthesis screws are presented anodized for easy identification, blue screws diameter 1.20, violet screws diameter 1.50 and green screws diameter 2.00 mm.
Material: Osteosynthesis screws are made of titanium grade 5 according to ISO 5832-3.
Method of application: Surgical techniques and technologies required for the preparation of materials for regeneration are outside the scope of these instructions
- Sterilization of the product.
- Preparation of the graft and / or membrane following manufacturer's instructions.
- Perform the bore for passage of the screw and the countersink for accommodating the head of the screw in the implant and / or membrane.
- Perform the hole in the receiving area prior to insertion of the scre . Depending on the bone quality by patient can be avoided this step or reduce the drilling depth to ensure the primary retainer screw.
- Insert the screw in the appropriate key and transported to the insertion point, proceed to screw turning clockwise until a stable fixation of the graft and / or material to retain. It is recommended to not exceed a maximum of 5 Ncm torque on the screws diameter 1.20 (blue) and 15 Ncm screw having a diameter of 1.50 to 2.00 mm (purple and green) .
- To loosen the screw screwdriver or wrench slightly tilt the key and the key separation will occur over the screw.
- After the treatment required period for regeneration to proceed to the removal of the screws.

Precautions : The contact surface of the fixture must be clean tissue , biological or additional material that may impede the proper settlement of this on bone patient support .

PRESENTATION OF MATERIALS
Packaging
Implant Microdent System S.L.U ensures that all material follow a manufacturing process, control and extreme cleaning before being packaged.
Materials are packed in blister. The product contained will be identified in two identical labels, one in the back of the blister and the other in the box housing the blister.

Materials supply state.
Tack and self-tapping pin are **not sterile**. Before placing then, materials must be sterilized, at customer sites.
For the correct sterilization of the product you should follow the following steps:
- Removing the product from the packaging supplied. This package does not allow the proper sterilization of the product contained.
- Enter the product in a container or bag suitable for sterilization and to ensure no contamination until its use.
  We recommend the process of steam sterilization by autoclaving. Please observe the peculiarities of computer you have. The parameters recommended by UNE-EN ISO 17665-1 and EN ISO 17665-2 are:
- Temperature: 134 ° C
- Cycle of sterile: 3 '

LABELLING SYMBOLS
Product label shows the following indications:


Single use only.

Reference Number.


Please follow the instructions for use.

Lot number.


Precaution, consult the warnings.


Manufacturer.

CONTRAINDICATIONS
None known.

TEMPORALY SIDE EFFECTS,
These materials can cause pain, swelling and difficulty in speaking.
It is the responsibility of the user, communication with patients of possible complications that may arise. Before any symptoms or discomfort the patient must go to consulting your practitioner.

WARNINGS AND PRECAUTIONS
These materials are part of an overall design concept, having appropriate design to products manufactured by Implant Microdent System S.L.U
When the materials have come into contact with pollutants, especially blood and saliva, it should not be reused for not having the full assurance of its removal, even cleaned and sterilized, since the transmission of these contaminants can cause illnesses such as AIDS, hepatitis , STDs.
Another reason for the material would not reuse any damages that may be suffered by the geometry of the improper use.
Electrosurgery is not indicated because of the conductivity of the products.

Before proceeding with surgery, it is the user's responsibility to check the product, the container and to make sure it is the right product for the patient.
In general, during the oral use of our products the user must take precautions to prevent aspiration by the patient.

LIABILITY, SAFETY AND WARRANTY
The above instructions have been approved by Microdent Implant System S.L.U as a means of proper use for the use of these products, but can not provide a detailed description of the process, it is not possible to make a detailed description of the different surgical techniques and / or prosthetic used throughout the world.
The use of these products must be performed only by specialists familiar with the techniques and procedures surrounding its use.
Any abnormalities should be carefully analyzed for effectiveness and possible adverse consequences and documented.
The guarantee will apply to Implant Microdent System S.L instruments provided they have been used following the instructions indicated.
For a refund of the products that mention these instructions should follow the guidelines established in our conditions of sale and delivery.

Implant Microdent System S.L.U
Pol. Ind. Can Magre C/. Carles Buïgas, 1
08187 Sta. Eulalia de Ronçana, Barcelona (Spain)

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