

These usage instructions should be read before using the orthodontic microimplants and 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 and orthodontic 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.

INTENDED USE

Implant Microdent System S.L.U developed for its Versatile & Short Versatile Microdent Orthodontics microimplants, various orthodontic solutions to meet the particular needs of patients.

DESCRIPTION OF VERSATILE MICRODENT ORTHODONTICS MICROIMPLANT ABUTMENTS

This is followed by a description of orthodontic microimplant abutments that complement the Versatile Microdent Orthodontics microimplants System, but for an adequate selection of our products it is recommended to consult the published product catalogs or our website.

Cover screw

Clinical indication: Indicate for the filling of the internal thread of the micro-implant.

Material: Cover screws are made in titanium grade 5 according to ISO 5832-3.

Method of application: After the required sterilization of the cover screw, insert the screw into the hex wrench (Hex. 1.20) and transported to the position of the microimplant. Hand tight screw by turning clockwise until the screw-microimplant contact. It is recommended not to exceed a maximum torque of 15 Ncm.

Precautions: The microimplant contact surface must be clean tissue or biological remains that may prevent proper seating of the screw.

Chain set

Clinical indication: Is placed on the microimplant located in the retromolar area and allow the application of tensile stresses.

Material: The chain screw, support and the chain are made in stainless steel.

Method of application: After microimplant insetion, insert the screw into the hex wrench (Hex. 1.20) and transported to the position of the microimplant setting in turn support chain. Hand tight screw by turning clockwise until the screw-microimplant contact. It is recommended not to exceed a maximum torque of 15 Ncm.

Precautions: The microimplant contact surface must be clean tissue or biological remains that may prevent proper seating of the screw.

Lateral bracket

Clinical indication: Used as a support and anchoring of arches on microimplants. Allows the use of arches 0.018"x0.025". For fixation on microimplant requires the use of the retention screw.

Material: Lateral bracket is made in stainless steel.

Method of application: Place the bracket on the microimplant, ensuring the proper settlement and proceed to their union through the corresponding retention screw, this requires the use of a 1.20 mm hex wrench. We recommend a 15 Ncm torque for fixing screws.

Precautions: The microimplant contact surface must be clean tissue or biological remains that may prevent proper seating of the screw.

Palatal bar support

Clinical indication: It is indicated for maxillary appliances. Allows the use of 0.9 mm diameter bar. For fixation on microimplant requires the use of the retention screw.

Material: Palatal bar support is made in stainless steel.

Method of application: After making the appliances required by the patient, place the palatal bar support on the microimplant, ensuring the proper settlement and proceed to their union through the corresponding retention screw, this requires the use of a 1.20 mm hex wrench. We recommend a 15 Ncm torque for fixing screws.

Precautions: The microimplant contact surface must be clean tissue or biological remains that may prevent proper seating of the screw.

Retention screw

Clinical indication: Indicate for union between the orthodontic abutments and the microimplant.

Material: Retention screws are made in stainless steel.

Method of application: For screwing it, it is required the use of 1.20 mm hex wrench, recommending a maximum torque of 15Ncm

Precautions: Before inserting the pillar you should clean the threads of the implant.

PRESENTATION OF MICRODENT ORTHODONTICS MICROIMPLANT ABUTMENTS

Packaging

Implant Microdent System S.L.U ensures that all Versatile & Blind Platform Microdent Orthodontics microimplant abutments follow a manufacturing process, control and extreme cleaning before being packaged.

Orthodontic microimplant abutments 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.

To make the proper monitoring of the required traceability of these products, the label must be adhered or these data must be transcribed to patient records.

Abutments supply state.

Orthodontic microimplant abutments are **not sterile**. Before placing then, abutments 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.

PRECAUTIONS AND INSTRUCTIONS FOR USE OF ORTHODONTIC MICROIMPLANT ABUTMENTS

Versatile Microdent Orthodontics microimplants System

CONTRAINDICATIONS

None known.

TEMPORALY SIDE EFFECTS,

Orthodontic microimplant abutments can cause pain, swelling, difficulty in speaking and increased risk of caries.

WARNINGS AND PRECAUTIONS

Orthodontic microimplant abutments are part of an overall design concept, having adequate use with microimplants manufactured by Implant Microdent System SL, therefore, the combination of Microdent orthodontic microimplant abutments with others outside the mark can cause no optimal operation of these products. Products should be used only for the purpose for which they were specified.

We warn you about the risk of toxicity and allergenicity for patients sensitive to the materials described under "DESCRIPTION OF MICRODENT ORTHODONTICS MICROIMPLANT ABUTMENTS".

Orthodontic microimplants abutments to be tapped as cover screw, chain screw and retention screw are designed to be applied with 15Ncm torque. We recommend using tools calibrated to this torque to avoid exceeding this value and to avoid the possibility of damaging the manipulate device.

In prosthetic laboratory tests it is recommended not to exceed a torque of 15Ncm for retaining screws.

It is imperative to clean the threads of the microimplant, before attaching the abutments.

When the abutment has 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 not reusing abutments would be any damage that its geometry may have suffered by improper use.

Electrosurgery is not indicated because of the conductivity of orthodontic microimplants.

Before proceeding with surgery, it is the user's responsibility to check the microimplant, the container and to make sure it is the right product for the patient.

Implant Microdent System S.L.U advised the availability of substitute products.

In general, during the oral use of our products the user must take precautions to prevent aspiration by the patient.

During orthodontic treatment, there is more risk of tooth caries and gum disease. This is due to increased food impaction by the retentive action of the apparatus, with orthodontics treatment more food gets everywhere and is retained. The doctor should inform the patient, to avoid this is as simple as having good oral hygiene after each meal and do a thorough cleaning of teeth, gums and the apparatus.

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.U abutments 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.

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