

PRECAUTIONS AND INSTRUCTIONS FOR USE OF DENTAL

INSTRUMENTS (Class I & Ila)

Microdent Orthodontics microimplants System

For proper use of our products is recommended that practitioner is trained. Implant System Microdent S.L. organizes periodic training courses, which reports on the particularities of each of the components of surgical instruments and their proper use. 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 System Microdent S.L. placed on the market surgical instruments required to allow the application and use of orthodontic systems.

DENTAL INSTRUMENTS DESCRIPTION FOR MICRODENT ORTHODONTICS MICROIMPLANTS SYSTEM

For proper selection of our products are advised to consult the published catalogs of products.

Specific dental instruments for Microdent Orthodontics Microimplants Standard

The specific instruments required by the Standard microimplants system consists of:

- Insertion key of the microimplant with mechanical drive:
 - This key is connected to the head orthodontic microimplant allows transporting it to its point of insertion and the screw and the detachment of orthodontic microimplant. This key is provided with a fastening system that allows connection to the contrangle for actuation and use. Surgical instruments equipped contrangle attachment, as ISO 1797, should not be employed at a torque greater than 70 Ncm.
- This key is made of stainless steel. - Insertion key of the microimplant with manual drive:

This key is connected to the head orthodontic microimplant allows transporting it to its point of insertion and the screw and the detachment of orthodontic microimplant. This key is provided with a fastening system that allows connection to the manual screwdriver orthodontic (reference MIADTM) for its actuation and use. This key is made of stainless steel.

Specific dental instruments for Microdent Orthodontics Microimplants Versatile

The specific instruments required by Versatile microimplants system consists of: - Insertion key of the microimplant with mechanical drive:

This key is connected to the head orthodontic microimplant allows transporting it to its point of insertion and the screw and the detachment of orthodortic microimplant. This key is provided with a fastening system that allows connection to the contrangle for actuation and use. Surgical instruments equipped contrangle attachment, as ISO 1797, should not be employed at a torque greater than 70 Ncm. This key is made of stainless steel.

- Insertion key of the microimplant with manual drive:

This key is connected to the head orthodontic microimplant allows transporting it to its point of insertion and the screw and the detachment of orthodontic microimplant. This key is provided with a fastening system that allows connection to the manual screwdriver orthodontic (reference MIADTM) for its actuation and use. This key is made of stainless steel.

<u>Common dental instruments for Microdent Orthodontics Microimplants</u> Instruments commonly used for any systems of Orthodontics Microdent microimplants comprises the following products:

Cruciform screwdriver with mechanical drive:

It is indicated for screw and detachment of orthodontic micro-implant. This screwdriver tip having cross shaped to adapt to the grooves that are observed in orthodontic microimplant head, is provided with a fastening system that allows connection to the contrangle for actuation and use. Surgical instruments equipped contrangle attachment, as ISO 1797, should not be employed at a torque greater than 70 Ncm. This screwdriver is made of stainless steel.

Cruciform screwdriver with manual drive:

It is indicated for screw and detachment of orthodontic micro-implant. This screwdriver tip having cross shaped to adapt to the grooves that are observed in orthodontic microimplant head, is provided with a fastening system that allows connection to the manual screwdriver orthodontic (reference MIADTM) for actuation and use.

- This screwdriver is made of stainless steel
- Manual screwdriver of orthodontic (MIADTM) This screwdriver allows connection and use of instruments that require manual operation. Use of this screwdriver facilitates the use of tools from a position that favors extraoral amplitude of the visual field of the user. This instrument is made of aluminum.

PRESENTATION OF DENTAL INSTRUMENTS MICRODENT ORTHODONTICS

Packaging

Implant Microdent System S.L. ensures that all Microdent Orthodontics instruments follow a manufacturing process, control and extreme cleaning before being packaged.

Dental instruments are packed in blister or bag. Both the external packaging and the internal container have a label containing the batch number, size and model of instrument.

Instrument supply state

Dental instruments are not sterile. Before using, product 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

Surgical Kits

Microdent supplies different models of kits that allow a rational organization, and proper storage of surgical instruments. Kits surgery or boxes are manufactured from high performance thermoplastic materials which allow undergo the process of steam sterilization in an autoclave. For proper sterilization is advised to follow the parameters listed in the previous section.

LABELLING SYMBOLS

Product label shows the following indications:



Reference Number.



Please follow the instructions for use.



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Precaution, consult the warnings.

Manufacturer.

Lot number.

WARNINGS AND PRECAUTIONS

Dental instruments are part of an overall design concept, having adequate use with products manufactured by Implant Microdent System SL, therefore, the combination of Microdent Orthodontic products 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 DENTAL INSTRUMENTS " 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. When the instruments has come into contact with pollutants, especially blood and saliva, must be cleaned and sterilized before use on another patient. For proper cleaning of surgical instruments should follow the following instructions:

- Do not use cleaning or disinfection with chlorine or acids.
- Avoid all products containing an aldehyde, given the ability to attach these proteins.
- Remove carefully all post-operative waste left on the surface or inside the surgical instruments.
- For this work use a nylon bristle brush.
- In the case of instruments with cutting edges, to avoid as much as possible the contact bumps and other instruments that may damage the surface and / or the cutting edges thereof.
- Immediately after proceeding to the cleaning process, rinse with distilled water and dry thoroughly.
 Improper drying can cause occurrence of oxidation points in the products.

Surgical instruments, is subject to wear and use, remain the responsibility of the user the periodic renewal of these products. Implant System Microdent S.L. advised that the availability of substitutes. In general, during the oral use of our products the user must take precautions to prevent aspiration by the patient.

LIABILITY, SAFETY AND WARRANTY

If the protective packaging of product is damaged during delivery, Implant Microdent System S.L. will replace it free of charge. This will not be the case if there is evidence of product manipulation. 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.



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(Instruments with manual drive)

(Instruments with mechanical drive)