

PRECAUTIONS AND INSTRUCTIONS FOR USE OF SURGICAL INSTRUMENTS (Class IIa)

External & internal connection Implant 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 their implant systems.

SURGICAL INSTRUMENTS DESCRIPTION

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

All surgical instruments placed on the market by Implant Microdent System SL are made of stainless steel.

PRESENTATION OF MICRODENT SURGICAL INSTRUMENTS

Packaging

Implant Microdent System S.L. ensures that all surgical instruments follow a manufacturing process, control and extreme cleaning before being packaged. Surgical instruments may be in various forms of packaging. It will identify the product contained, with its corresponding label.

Instrument supply state.

Surgical 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 equipment 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.



Lot number.



Precaution, consult the warnings.



Manufacturer.

WARNINGS AND PRECAUTIONS

Surgical instruments are part of an overall design concept, having adequate use with products manufactured by Implant Microdent System SL, therefore, the combination of Microdent products with others outside the mark can cause no optimal operation of these products.

Surgical instruments equipped contra-angle attachment, as ISO 1797, should not be employed at a torque greater than 70 Ncm.

When the instruments have come into contact with pollutants, especially blood and saliva must be cleaned and sterilized before use on another patient.

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 "SURGICAL INSTRUMENTS DESCRIPTION".

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.

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.

The surgical instruments provided of contra-angle connection, according to the ISO 1797 standard, should not work at a torque greater than 70 Ncm.

Handpiece is intended for insertion of implants, should not be used for applying the final torque, being recommended for this purpose the dynamometric wrenches. Skip this recommendation may result in a mismatch or disable the handpiece.

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

For the instruments that are intended to screw rehabilitations, consult the instructions for use of the corresponding attachment.

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

Any abnormalities should be carefully analyzed for effectiveness and potential adverse consequences and documented.



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