

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

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. Likewise, this information is available on the website of the company www.microdentsystem.com and various publications issued.

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 different types of steel: stainless and tempered.

The ratio of instruments of class 1R is as follows: **extraoral wrench, ratchet and torque wrench, thread shapers, thread cleaners, screwdrivers, expanders, dilators, manual wrench for expanders and dilators, cortical fix, implant extractor, extractors of pins, impactor, surgical hammer, orthodontic instruments, adapter, prolonger, positioning of mini-capitel, key for implant holder and key for unlocking pillars.**

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, except kit boxes type.
- 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.



Lot number.



Precaution, consult the warnings.



Manufacturer.

USE

Due to its special characteristics of use, the following instruments have specific instructions: **expanders, dilators, cortical fix, implant extractor, extractor of fractured pins and orthodontic instruments** (see instruction as appropriate).

For the rest of the instruments they should refer to the indications of this instruction.

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.

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.

When the instruments have 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.

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



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