

PRECAUTIONS AND INSTRUCTIONS FOR NON-MEDICAL DEVICE

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 product 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 products required to allow the application and use of their implant systems.

PRODUCT DESCRIPTION

For proper selection of our products are advised to consult the published product catalogs. Products are made of stainless steel, titanium grade 5 according to ISO 5832-3 and POM.

Implant Microdent System S.L. ensures that all products follow a manufacturing process, control and extreme cleaning before being packaged. These products are packed in blister, bag or box. The product contains identifying label with the batch number, size and model of product.

Product supply state

These products 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:

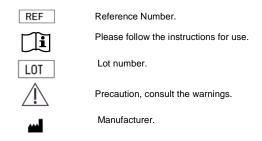
- Removing the product from the packaging supplied. This package does not allow the proper sterilization of the product contained.
- Enter the product in a container or bag suitable for sterilization and to ensure no contamination until its use.

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

LABELLING SYMBOLS

Product label shows the following indications:



WARNINGS AND PRECAUTIONS

These products 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.

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 "PRODUCT DESCRIPTION".

Before surgery is the responsibility of the professional user to check:

- The state of the product packaging and if it matches the required product for the patient.
 The state of the product it-self to verify that it is optimal.

For proper cleaning of these products 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 product.
- For this work use a nylon bristle brush.
- In the case of product with cutting edges, to avoid as much as possible the contact bumps and products 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.

These products are subject to wear and use, remain the responsibility of the user the periodic renewal of these products. Implant Microdent System S.L. recommends you should have substitute products.

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 the 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 products 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 possible adverse consequences and documented.

Implant Microdent System S.L. Manufacturer by:

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