PRECAUTIONS AND INSTRUCTIONS FOR NON-MEDICAL DEVICE

Versatile 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 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. developed for Versatile Microdent Orthodontics microimplants, different products that enable the development of laboratory model that will enable the development and adaptation of orthodontic appliances that required by the patient.

PRODUCT DESCRIPTION

This is followed by a description of these products, but proper selection is advised to consult the published catalogs of products.

Transfer

Clinical indication: It is indicated for taking impressions of the microimplants.
Material: Transfer is made in stainless steel.
Indications for Use: Transfer screwed on the microimplant is performed manually, do not require the use of tools.
Precautions: Before inserting the transfer should proceed to clean the internal threads of microimplant. Before impression, verify that the flat face of the transferor is lined with a flat face of the microimplant.

Microimplant analog

Clinical indication: It is indicated for the development of working models in the laboratory.
Material: Analog is made in stainless steel.
Indications for Use: Screw the analog to the transfer considering the transfer / analog alignment and drain the laboratory model.
Precautions: There is an analog model for each family of microimplants, not being compatible.

PRODUCT PRESENTATION

Packaging

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 or bag. Both the external packaging and the internal container have a label containing 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:

REF	Reference Number.
	Please follow the instructions for use.
LOT	Lot number.
	Precaution, consult the warnings.
	Manufacturer.

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 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 "PRODUCT DESCRIPTION ".
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 SL advised the availability of substitute products.
When the product has come into contact with pollutants, especially blood and saliva, must be cleaned and sterilized before use on another patient.
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.
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.

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