SINUS ELEVATOR KIT
(Non sterile)

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/instructions-for-use
To open pdf files you need the free Adobe Acrobat Reader.

INTENDED USE
Implant Microdent System S.L. placed on the market the Sinus Elevator Kit composed of surgical instruments that allows the application of the sinus lift technique.

DIRECTIONS FOR USE
The Sinus Elevator is dimensioned to allow insertion of implant core nucleus 4.20 and 5.00 mm and which have a length up to 10 mm.
The Sinus Elevator Kit is complemented with the following instruments:
- Thread former.
- Key actuator, short or long version.
- Key to the assembly and disassembly of the instrument.
- Cylindrical drills, equipped with adjustable stop, for the preparation of the osteotomy to receive Sinus Elevator.
- Manually operated drills to form the apical area of the osteotomy.

All surgical instruments composing the system Sinus Elevator is 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 are packed in blister or bag. The product contained two identical labels, one in the back of the blister and the other in the box that houses the blister.

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.
- Place the product in FDA- cleared sterilization accessories, such as bag or containers, are to be used for the recommended sterilization parameters. We recommend steam sterilize (autoclave) using a pre-vacuum cycle. Please observe the characteristics of equipment you have. The parameters recommended by ANSI / AAMI ST79 are:
- Temperature: 270°F/132°C
- Exposure time: 4 minutes.
- Drying time: 20 minutes.

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.

RECOMMENDED SURGICAL PROTOCOL
Sinus Elevator instrument does not have the same dimensions as the implant therefore requires a different surgical protocol regarding preparation of the implant osteotomy. The surgical protocol that follows should be particularized conditions according to the patient's bone.
The technique described below may be supplemented, if required, with the use of either autologous bone graft, animal biomaterials or synthetic materials.
Prior to use Sinus Elevator surgical protocol should have as much information about the morphology and size of the area subantral.

- Open the flap for access to bone support.
- Perform a measurement of bone.
- Dot with drill FC20 and not exceed a depth of 3mm.
- Milling 2-3 millimeters of the second cortex with drill 1.80mm.
- Make a peroapical Rx to confirm the total height of the sinus.
- With drill 1.8mm, milling up to 1 mm before the second cortex.
- Final drill. Maximum diameter 2.80 for insertion of implants core 4.20 and maximum diameter 3.20 for implants core 5.00 (drills have depth marks to 6 and 8 mm).
- Milling the apical area of the socket, to remove the concavity created by the action of the final drill. This step is optional character being due evaluated in a subantral area characteristics
- Pass thread former. Not be exceeded drill depth previously made, given the risk of destruction of the thread created.
  Use shaper CF42R for subsequent insertion of the implant core 4.20 mm.
  Use shaper CF50R for subsequent insertion of the implant core 5.00 mm.
- Insert Sinus Elevator in the osteotomy created.
  To be taken into account that the instrument has a feed capacity of 4mm.
- Activating the plunger Sinus Elevator. The advancement of the plunger must be done slowly and gently.
- Once achieved the displacement of the sinus wall to withdraw the instrument and start the implant insertion.
- After inserting the implant, proceed to suture the soft tissues.

CONTRAINDICATIONS
Contraindications to the use of the Sinus Elevator are the same contraindications having dental implant:
Serious internal medicine problems, bone metabolism disorders, uncontrolled coagulation disorders, uncooperative or unmotivated patients, alcoholism or drug addition, psychosis, functional disorders resistant to treatment present for some time, xerostomy, weakened immunological system, illnesses requiring regular use of steroids, allergy to titanium, uncontrolled endocrine disorders.
Relative contraindications:
Previously irradiated bone, diabetes, anticoagulant medication / hemorrhagic diabetes, bruxism, parafunctional habits, unfavorable bone anatomy, addiction to tobacco, uncontrolled periodontitis, maxillary illnesses and alterations of the oral mucous membrane susceptible to treatment, pregnancy, poor oral hygiene.
Local contraindications:
Insufficient bone available or inadequate bone quality, local remains of roots.

WARNINGS AND PRECAUTIONS
The surgical instrument is part of an overall design concept, having adequate use with implants manufactured by Implant Microdent System S.L., therefore, the use of instruments outside the mark can cause no optimal operation of these products.

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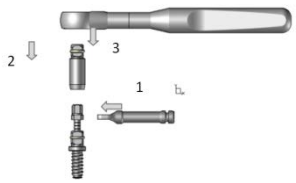
When the surgical instruments has come into contact with pollutants, especially blood and saliva, should be cleaned and sterilized before use on another patient.
Products should be used only for the purpose for which they were specified.
We warn you about the risk of toxicity and allergenicity for patients sensitive to the materials described under “DIRECTIONS FOR USE ".
Before surgery is the responsibility of the professional user to check:

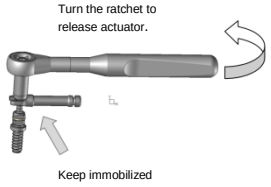
- The state of the abutment packaging and if it matches the required product for the patient.
- The state of the instrument it-self to verify that it is optimal.

Implant Microdent System S.L. recommends you should have substitute products.

Instructions for disassembly Sinus Elevator.
To make a correct and effective cleaning Sinus Elevator, its components must be disassembled. This should follow the following guidelines:

- Insert disassembly key into the instrument lock.
- Insert drive key on the drive nut.
- Insert ratchet.
- Maintain strong union between the disassembly key and the instrument.
- Turn the ratchet counterclockwise, as shown in the following image, to get the unlocking nut.
- Proceed with the disassembly of each of the components.





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

LABELLING SYMBOLS
Product label shows the following indications:

Non-sterile


Consult Instructions for use

CONTRAINDICATIONS
None Known.

LIABILITY, SAFETY AND WARRANTY
If due to transportation, packaging and product content was damaged, Implant Microdent System S.L.shall return it at no charge.
Evidence of product handling disclaims liability indicated above.
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.

Manufactured by: Implant Microdent System S.L.
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Made in Spain.