PRECAUTIONS AND INSTRUCTIONS FOR USE OF SURGICAL INSTRUMENTS
(IR Class)
Condensation and expansion system

Its total or partial reproduction and distribution it not allowed without prior consent of Implant Microdent System.

For a correct use of our products it is recommended that the professional is trained in the particularities of its use. Implant Microdent for proper use of our products is recommended that practitioner is trained. Implant System Microdent S.L.U organizes periodic training courses, which reports on the particularities of each of the components of surgical instruments and their proper use.

DISTRIBUTION OF THE RULES OF USE

Implant Microdent System S.L.U makes available to the user the rules of use in electronic format ("pdf"), in accordance with regulation (EU) nº 2021/2226.

The user can consult these rules in electronic format, free of charge and within the period desired, at the following web address: www.microdentsystem.com/instrucciones-de-uso
(To consult or download these rules it is necessary to have the free adobe acrobat reader)

The user has the right to request implant Microdent System S.L.U, if necessary, the rules of use in paper format, such request can be made through the commercial of the assigned area, via telephone: +34 938 447 650 or by downloading these rules, on the website of Implant Microdent System S.L.U www.microdenttsystem.com

INTENDED USE

Implant Microdent System S.L.U. puts on the market the system of compaction and bone expansion composed of that surgical instrument that allows the application of the technique of condensation and horizontal and atraumatic bone expansion of the maxilla: expanders and dilators

DESCRIPTION AND USE

These instructions describe the system for performing the surgical protocol of bone compaction and expansion, as well as it supporting components necessary during the surgical procedure to prepare the implant bed:

Instrumental for the technique of bone expansion and condensation:

- Expanders: to prepare the alveolus implantio.
- Dilators: to work together with expanders in the preparation of the implant alveolus.

- Circular drill. : for longitudinal drilling.
- Pilot drill. : for initial drilling.
- Ridge opening cutter. : to open crest.
- Extender. :p will allow better access to torque
- Manual key and pin. : to apply force.
- Optionally you can use the wrench or torque wrenches and the extraoral wrench. : to adjust the force

Raw material

All the surgical instruments and their support components that make up the expansion system have been selected based on the properties indicated for their use, in accordance with Regulation (EU) 2017/745, the instruments described in this standard of use are made of stainless steel. 1.4305 (AISI303) ASTM A 582. (Carbon 0.10% / Manganse (Mn) 2.0% / Phosphorus (P) 0.045% / Sulfur (S) 0.15 – 0.35 % / Silicon (Si) 1.0% / Chrome (Cr) 17.0 – 19.0 % / Nickel (Ni) 8.0-10.0 5)
We remember to check with patients for possible allergies to raw materials.

PRESENTATION OF MICRODENT SURGICAL INSTRUMENTS

Packaging

Implant Microdent System S.L.U. 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.
Before the first use and any reuse, they must be cleaned and sterilized following the procedures described in the cleaning and sterilization instructions.

Sterilization:

For the correct sterilization of the product, you should follow the following steps:

Removal of the product from the container in which it is supplied. This packaging does not allow the proper sterilization of the contained product.
Place the product in a container or bag suitable for sterilization (e.g., CrosstexSCL2) and that guarantees non-contamination until its final use.
The process of steam sterilization by autoclave is recommended (e.g., SATELEC-VELA170). The particularities of the equipment that is owned must be taken into account.
Note: All autoclaves or sterilizers must comply with the requirements of SN EN 13060, EN 13060, EN285, EN ISO 17665-1 or AAMIST79, or the relevant national regulations and must be validated, maintained, and checked in accordance with these standards. The instructions for use of the manufacturer of the autoclave/sterilizer must be respected.

The recommended parameters according to UNE-EN ISO 17665-1 and UNE-EN ISO 17665-2 are:
- Temperature: 134º C (273°F)
- Sterilization cycle: 3'
For proper preservation: Once the sterilization is finished, the product has to be left inside the sterilization bags. The bags must be opened only at the time of reuse of the product. Sterilization bags can normally maintain sterility inside, except when the packaging is damaged. Therefore, pay attention and do not use the components if the bags in which they were kept were altered; sterilize in new bags before using the product again. The shelf life of sterilized products from non-bags debe superar el advised by the manufacturer of these. The product must be kept in a cool, dry place, keeping it away from direct sunlight, water, and heat sources.

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Expanders and expanders are reusable instruments that must be inspected before each reuse to ensure that their integrity and maintenance are maintained. If there is any visible evidence of surface deformation or corrosion, or if the readability of the marks is compromised, the instruments should not be reprocessed and should be discarded.
The surgical instruments are subject to wear and tear due to their use, not being able to determine a specific number of renewal uses, being the responsibility of the user the periodic renewal of these products, based on the state of this.

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.
Raw material: Rande R:500 (Polyphenylsulfore9 TDS (Silicone)
For proper sterilization is advised to follow the parameters listed in the previous section.

RECOMMENDED SURGICAL PROTOCOL
The technique described below can be complemented, if required, with the use of bone grafting, whether autologous, biomaterials of animal origin or synthetic
materials.
Prior to addressing the protocol for the use of the bone condensation and / or expansion system, we must have maximum information about the morphology
and dimensions of the subantral area.
Generic Procedure:
- Opening of the flap for access to the bone support.
- Perform a bone measurement.
- Osteotomy with tungsten, disc or piezoelectric burrs.
- Pilot drill.
- Expansion insert 1.
- Expansion insert 2.
- Expansion insert 3, 4 and 5, depending on the diameter to be condensed, expanded or the implant to be inserted:
    - expander 3 for implants with a diameter up to 3.8.
    - expander 4 for implants with a diameter up to 4.5.
    - expander 5 for implants with a diameter up to 5.0.

- Optionally you can finish configuring the socket with a cutter according to the implant to be inserted.
- Once the appropriate socket is achieved, start the insertion of the selected implant.
- After insertion of the implant, proceed to the soft tissue suture.
- The dilators are used:
    - In the case of condensation, due to its shorter length than the expander, when the opening of the oral cavity does not allow the insertion of the expanders.
    - In expansion, as support, for the maintenance of expanded space.

There is a manual where the different processes are illustrated: "Microdent Bone Expansion and Condensation", it can be consulted at the following web address: www.microdentsystem.com/product.

CONTRAINDICATIONS

Contraindications to the use of the Sinus Lift-Fix Cortical 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.U, therefore,
the use of instruments outside the mark can cause no optimal operation of these products.
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 “DESCRIPTION… ".
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.U. recommends you should have substitute products.
In general, during the intraoral use of our products the user must take due precautions to avoid their aspiration by the patient.

MAINTENANCE, CLEANING AND REUSE INSTRUCTIONS

As stated in EN ISO 17664, it is the responsibility of the user/processor to ensure that the processing/procedure for reuse is carried out using appropriate equipment/materials and personnel to ensure the efficiency of the processes. The user/processor must evaluate any deviation from the following instructions in order to ensure the efficiency of the process.

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Before the procedure for re-use (at the point of use):
- Dispose of worn single-use instruments and reusable instruments immediately after use.
- Remove excessive debris from reusable devices to be handled for reuse, rinse devices with cold water.

Transport from the point of use to the refurbishment area:
- Once the removal of dirt and excess waste is carried out, place the reusable instrument in a container suitable for transport to the reconditioning area, which guarantees any contamination of the personnel or the environment.
- If the device to be reconditioned must remain a reasonable time (care must be taken not to exceed a time greater than 1h from its use to the reconditioning) until its transport to the reconditioningarea, keep the devices in a closed container and covered with a damp cloth, to prevent the residues from drying out.
- If the washing and reconditioning procedure is external, they must be packed in a container conditioned for transport, ensuring that the personnel or the environment are not contaminated.

The following cleaning process has been validated in accordance with applicable international standards and guidelines. (AAMI TIR30)
Cleaning process:
Meticulously remove all postoperative residues that have remained on the surface or inside of the surgical instruments.
For this work use a nylon bristle brush(p. e.g., MEDSAFE MED-100.33), at least 20 seconds.
Once the instruments have been disassembled, immerse themselves in ultrasonic equipment(p. e.g., CEIA CP831 31LT.) the pieces in 1000 ml of water, with 150 ml of alkaline disinfectant (p. e.g., DeterUltrason).
Avoid any product containing an aldehyde, given their ability to fix proteins.
Start the ultrasound cleaning cycle(p. e.g., CEIA CP831 31LT.) for 20 minutes.
Immediately after proceeding to the cleaning process, rinse with distilled water.
Then proceed to dry the pieces with compressed air or single-use wipes, clean and lint-free.
Note.
It is recommended:
- In the case of instruments that have cutting edges, avoid as far as possible blows and contact with other instruments, which may damage the surface and / or the cutting edges of these.
- Incorrect drying can cause the appearance of surface oxidation points in the products.

Once the whole process has been carried out, the instruments do not need a calibration to guarantee their operation.
The surgical instruments are subject to wear and tear due to their use, not being able to determine a specific number of renewal uses, being the responsibility of the user the periodic renewal of these products, based on the state of this.

There is a maintenance manual for the different surgical and prosthetic instruments "MAINTENANCE OF SURGICAL AND PROTESIC INSTRUMENTS", can be consulted at the following web address: www.microdentsystem.com/instrucciones-de-uso

STORAGE, HANDLING AND TRANSPORT

The device should be stored and transported dry in its original container at room temperature and should not be exposed to direct sunlight. Improper storage or transport can affect the characteristics of the device and cause it to fail.

ELIMINATION

It is the responsibility of the surgical instrument user to safely dispose of product that may be contaminated or can no longer be used, such as medical waste, in accordance with local health guidelines, legislation or national and government policy.
The separation, recycling or disposal of packaging material should be carried out in accordance with national and governmental packaging legislation, as appropriate.

INTENDED USER AND PATIENT GROUPS:

Surgical instruments should be used by dental health professionals.
Surgical instruments should be used in patients undergoing treatment with dental implants.
The user of Implant Microdent System S.L.U products is responsible for determining whether or not a product is indicated for each patient and each circumstance.
The age range indicated between 19 to 99 years, without exclusion of sex.

RESPONSIBILITIES, SAFETY AND GUARANTEE

This product is part of a global concept and should only be used together with the associated original products according to the instructions for use and recommendations of Implant Microdent System S.L.U.
The non-recommended use of products manufactured by third parties together with the products of Implant Microdent System S.L.U will void any warranty or other obligation, express or implied by Implant Microdent System S.L.U
Implant Microdent System S.L.U declines any responsibility, whether implicit or explicit, and will not be responsible for any direct, indirect, punitive or other damages that occur by or are related to any error in the judgment or practice of the professional in the use of Implant Microdent System products.

Serious Incident Notice:

For patients/users/third parties in the European Union and in countries with an identical regulatory regime (Regulation 2017/745/EU on medical devices); Yes. During the use of these devices or as a result of their use, a serious incident occurs, please notify the manufacturer and your national authority. The contact information for the manufacturer of this device for reporting a serious incident is as follows:
https://microdentsystem.com/sites/default/files/ claim-form

User Training

The user is also obliged to regularly study the latest developments relating to this product and its applications. In case of doubt, the user must contact Implant Microdent System S.L.U. since the use of this product is under the control of the user, this will be his responsibility. Implant Microdent System S.L.U does not assume any responsibility for the damages produced as a result.

If due to transport, the packaging and the product contained therein is damaged, Implant Microdent System S.L.U will return it free of charge.
Evidence of product handling exempts from the above liability.
The warranty will be applied to the products of Implant Microdent System S.L. U provided that they have been used following the instructions for use indicated.

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To proceed with the return of the products mentioned in these instructions for use, the rules established in our conditions of sale and supply must be followed.

LABELLING SYMBOLS
Product label shows the following indications:

REF	Reference Number..	MD	Medical Device.
	Please follow the instructions for use.	UDI	Unique identifier code.
LOT	Lot number.		Instructions for use available at https://microdentsystem.com/instrucciones-de-uso-english-version
	Precaution, consult the warnings.		
	Manufacturer.		Manufacturing date

Basic UDI-DI information: The basic UDI-DI of the devices that are described in these rules of use is:

Producto	Núm. Basic UDI-DI
Expander	843426301InstExpansorBH
Dilator	843426301InstDilatador2H
Drills	843426301InstFresasSE
Spanner	843426301InstLlavesSR
Extender	843426301InstProlongadoYK

Manufacturer by: Implant Microdent System S.L.U
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