MICRODENT EKTOS IMPLANTS
Precautions and instructions for use.

These usage instructions should be read before using the implants and materials supplied by IMPLANT MICRODENT SYSTEM S.L.U. as they contain essential information to avoid misuse.
The descriptions below have been written for implant professionals. Therefore, we recommend they receive instructions from an expert professional in the fields, who has received adequate information. Implant Microdent System S.L.U. offers regular training courses on the use of their products.
The user must ensure that the selected product is suitable for the planned purposes and procedures.
These instructions for use are available in pdf format at the following web address: www.microdentsystem.com/instrucciones-uso
To open pdf files you need the free Adobe Acrobat Reader.

INTENDED USE
Microdent Dental implants are intended for surgical placement in the upper or lower jaw to provide a means for prosthetic attachment in single tooth restorations and in partially or fully edentulous spans with multiple single teeth utilizing delayed or immediate loading, or as a terminal or intermediary abutment for fixed or removable bridgework, and to retain overdentures.
Microdent Dental implants are intended for immediate function on single tooth and/or multiple tooth applications when good primary stability is achieved, with appropriate occlusal loading, in order to restore chewing function.
Small diameter implants are indicated only for replacement of central and lateral incisors in the maxillar and mandible.

DESCRIPTION
Implant Microdent System S.L.U. has developed a series of implantology solutions to meet the individual needs of patients. This is followed by a description of these solutions, but for a proper selection of our products are advised to consult the published catalogs or on the website

Microdent Ektos implant
Microdent Ektos implants are internal connection endosseous subgingival that can be used with deferred load or immediate load techniques. Insertion of this implant in a subgingival or submerged position will ensure a correct appearance of the subsequent rehabilitation.
The external thread of self-tapping type implant and multiple inputs, together with the geometry of the grooves presents the apical area of the implant allow ease in insertion and a high primary retention.
Microdent Ektos implant is made of pure titanium grade 4 according to ISO 5832-2:1999 standard and presents the treated surface for greater roughness over the whole area of osseointegration. This surface treatment is presented in two formats: full sandblasting (AT), when engraving from the cylindrical surface which arises from the platform to the apical region thereof, and neck polished (CP) when etching is avoided in the transmucosal area (1 mm).
Cover screw accompanying the implant is made of titanium grade 5 according to ISO 5832-3:1999.
The multifunction pillar and retention screw of the prosthesis are made of titanium grade 5 according to ISO 5832-3:1999.
The nominal length of the implant is defined from the platform to the apical area of the implant.
Ektos Microdent implant presents a range of three platforms, 3.50, 4.50 and 5.70 mm and a diverse array of cores for each.
- Platform Ø 3.50 mm (cores available Ø 3.70 and Ø 4.20 mm)
- Platform Ø 4.50 mm (equipped with Ø 4.80 mm core)
- Platform Ø 5.70 mm (provided core Ø 5.80 mm)

The implants are available in different lengths: 6, 8, 10, 12, 14 y 16 mm depending on platform.

Microdent Ektos implant for structures
Microdent Ektos implant for structures is a subperiosteal implant or juxtaposed bone of internal connection, which supports use with after loading techniques.
The apical area of the implant, endosseous integration area, has an outer self-tapping screw type. In the neck part, the implant has a thread which enables connection regarding the titanium mesh.
The dental Microdent Ektos implant for structures made of pure titanium, grade 4 according to ISO 5832-2:1999 standards and presents the treated surface for greater roughness over the whole area of osseointegration. The surface treatment is complete sandblasting having (AT), and the etched area extends the entire length of the implant.
Cover screw accompanying the implant is made of titanium grade 5 according to ISO 5832-3:1999.
The multifunction pillar and retention screw of the prosthesis are made of titanium grade 5 according to ISO 5832-3:1999.
The nominal length of the implant is defined from the platform to the apical area of the implant.
Microdent Ektos implant presents a range of three platforms, 3.50, 4.50 and 5.70 mm and a diverse array of cores for each.
- Platform Ø 3.50 mm (core available Ø 3.85 mm)

The implants are available in different lengths: 6 and 8mm according to platform

MICRODENT EKTOS IMPLANTS PRESENTATION.
Packaging and sterility
Microdent Ektos dental implants undergo an exhaustive manufacturing, control and cleaning process before packaging, in a sterile area, being subsequently sterilized by irradiation.
The implant has an abutment, which is secured to a plastic support and fitted with a transport cap. The transport cap holds the closure screw on the opposite side of the implant.
The multi-function abutment accompanying the implant provides the following advantages for use:
- Transport allowing transmission required torque to proceed with the insertion of the implant into the osteotomy.
- To provide closed tray impressions. For this application an impression cap supplied separately required.
- Be used as prosthetic abutment with temporary or permanent.

The multi-function abutment is attached to the implant with screw retention definitive prosthesis.
The plastic support is inside a container that maintains sterility through a metal heat-sealed operculum. The immunity and protection of this sterile barrier system is by means of a threaded cap that seals the outside packaging and guarantees that the contents have not been handled.
Both the external packaging and the internal container have a label giving the batch number, size and model of implant and the use by date.
For correct follow-up of required product traceability, this label should be adhered to or its information recorded in the patient's medical record.
Implant Microdent System S.L.U. will accept no responsibility for the re-sterilization of implants, irrespective of the method used or the person who undertook the procedure. An implant that has already been used or is not sterile must not be fitted, under any circumstances.

PLANNING AND LOAD
Before proceeding with the surgical part of implant rehabilitation, it is the responsibility of the user to carefully plan the process.
To maximize load capacity, it is recommended, whenever possible, to use implants of greater diameter and/or the greatest number possible.
To help with selecting the implants required for rehabilitation, Implant Microdent System S.L.U. has issued x-ray templates reference PPQ-EK.
Angles of more than 30º over the vertical of the implant should be avoided.

CONTRAINDICATIONS
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.

SIDE EFFECTS, INTERACTIONS AND COMPLICATIONS CAUSED BY DENTAL IMPLANTS.
Activities requiring great physical effort should be avoided during the period immediately after the insertion of dental implants.
The following are some of the possible complications after fitting dental implants:
- Transitory problems:

Pain, inflammation, difficulty in speaking, gingivitis.
- Longer lasting problems:

Chronic pain associated to the dental implant, permanent paresthesia, dysesthesia, bone loss in the maxillary crest, localized or systemic infections, oroantral or oronasal fistulas, harmful influence on neighboring teeth, irreversible damage to neighboring teeth, aesthetical problems, damage to the nerve, exfoliation, hyperplasia.
It is the responsibility of the user, communication with patients of possible complications that may arise. Before any symptoms or discomfort the patient must go to consulting your practitioner.

WARNING
In case that implants do not exhibit good stability is not recommend immediate load.
If the implant comes into contact with contaminants, especially blood and/or saliva, it must not be reused, as there is no guarantee they can be eliminated, even if cleaned and sterilized, as these contaminants can transmit diseases such as AIDS, hepatitis or STDs.
Another reason for not reusing the implant is the possible damage it may have suffered to its geometry due to inadequate handling.
Electro surgery is not recommended due to the conductivity of the dental implants.
Before proceeding with the surgery, it is the user's responsibility to check the implant container to ensure it is the right product for the patient. Implant Microdent System S.L.U. recommends having replacement products available.
During the intraoral use of our products the user must take the necessary precautions to avoid the patient aspirating any part of them.

SURGICAL PROTOCOL
Preparing the alveolus
These recommendations are to be taken as a general guide and should be personalized by the professional according to the type of bone where the implant is to be fitted.

MICRODENT EKTOS

Protocol with classic Drills

Platform	**3,50**		**4,50**	**5,70**
Implant core	3,70	4,20	4,80	5,80
Cortical drills	FC20			
Pilot drill Short / Long	FP1812 / FP1817			
Intermediate Drill	F250	F250 / F280*	F250 / F280*	F250 / F280*
Intermediate Drill			F320	F350 / F380*
Intermediate Drill				
Final drill (* Depending on the bone type or it quality)	F280*	F320*	F350*	F450*
	F300*	F350*	F380*	F510*

Protocol with new Drills

Platform	**3,50**		**4,50**	**5,70**
Implant core	3,70	4,20	4,80	5,80
Cortical drills	F200			
Intermediate Drill	F250	F250 / F290*	F250 / F290*	F250 / F290*
Intermediate Drill			F320	F350 / F380*
Intermediate Drill				
Final drill (* Depending on the bone type or it quality)	F290*	F320*	F350*	F450*
	F320*	F380*	F420*	F510*

Microdent have some guided drills to minimize the deviation of alveolar parallelization

The depth of the alveolus should be in accordance with the length of the implant, the use of depth marks (6 / 8 / 10 / 12 / 14 / 16 and 18 mm) displayed by the drills distributed by Implant Microdent System S.L.U. is recommended osteotomy procedure: use drills in optimum cutting/cleaning condition, carry out intermittent perforation and ensure good irrigation of the drill to avoid overheating the bone.
We recommend regular rotation of surgical drills to avoid using drills in bad condition or cutting incorrectly.
It is advisable to previously work the alveolus with a milling protocol adapted to each type of bone and area, even if it is the same patient.

Since the external irrigation only deepens between 2 and 3 mm, once the drill is inside the surgical socket, it is recommended that every 3 or 4 seconds the drill be removed from the alveolus, always moving and without stopping irrigation, for avoid excessive heating of the bone
In excessively hard bones, perform the normal milling protocol, inserting and completely removing the drill from the socket, to facilitate the replacement of the serum and lower the temperature of the same.

Alveolar osteotomy can also be prepared with atraumatic Microdent expanders, especially in cases of narrow bony ridge or when you want a greater use of patient's bone support (see information on www.microdentsystem.com).

Fitting the implant
Open the implant container by unscrewing the plastic cap and breaking the safety seal of the packaging. Remove the metal operculum - the sterile barrier of the packaging system.
Deposit the contents of the container on a clean surface; you will see a plastic support on which the implant is fitted with its multi-function abutment. Plastic cap contains the cover screw for 1st surgery.
Manual insertion of the implant
If the insertion is to be manual, place the key PMFLLIM on the Multi-function abutment.
To extract the implant from the plastic support, press the support lightly in the direction of the opening where it is housed. The implant is joined to the key; this helps to place it in the patient's mouth without having to touch it. Insert the implant into the osteotomy and begin securing the implant by turning it clockwise.
If on inserting the implant in the osteotomy (on the first threads) you notice having to use more force than usual, we recommend removing the implant from the alveolus and increasing its size with a larger burr. Forcing the implant could cause damage.
Once the implant is 2/3 inserted in length, finish the insertion by using the PMFLLIC or PMFLLID keys. After implant insert remove the Multi-function abutment with the aid of screwdriver Hex. 1,20.
We recommend using an insertion torque not greater than 40 Ncm and in no case exceed an insertion torque of 50 Ncm. to avoid the appearance of aseptic necrosis and implant loss. To control torque, the torque-measuring ratchet, reference LDR1070, is recommended.

Inserting the implant mechanically
If the implant is to be inserted using a micromotor, insert the adaptor reference PMFLLIC that was previously fitted to the hand piece, over the metal implant holder.
To extract the implant from the plastic support, press the support lightly in the direction of the opening where it is housed.
Move the implant to the osteotomy and proceed inserting it, regulating the speed of the micromotor to obtain maximum control over the process. Inserting the implant, remove the metal implant holder, using screwdriver Hex. 1,20.
Handpiece is intended for insertion of implants, should not be used for applying the final torque, being recommended for this purpose the dynamometric wrenches. Skip this recommendation may result in a mismatch or disable the handpiece.
We recommend using an insertion torque not greater than 40 Ncm. and in no case exceed an insertion torque of 50 Ncm. to avoid the appearance of aseptic necrosis and implant loss. To control torque, the torque-measuring ratchet, reference LDR1070, is recommended.

In both forms of implant insertion, soft tissues must be prevented from invading the alveolus, since they harbor a wide variety of bacteria.
It is advisable to observe during the insertion that said alveolus is completely filled with blood clot, in this way the implant will be impregnated by surface tension and blood cells.

Fitting the cover screw for 1st surgery:
The cover screw is housed in the transport cap on the opposite side to the implant.
Like the implant, it is sterile.
Once the implant has been inserted into the osteotomy, remove the cover screw from the transport cap using screwdriver hex 1.20, turning it gently anticlockwise.
Carefully take it to the implant, insert it and screw in the accessory by turning it clockwise.
We recommend a tightening torque of 5 Ncm.
Proceed to stitching the soft tissue.

PREPROSTHETIC AND PROSTHETIC ABUTMENTS
Preprosthetic abutments, straight and divergent healing pillars, are supplied in sterile condition.
To learn more about the different prosthetic solutions for this implant system, see the catalogue or our website.

LABELLING SYMBOLS
The product label will give the following information:


Single use only.

REF Reference number.


Please follow the instructions for use.

LOT Batch number.


Precaution. consult the warnings.


Do not use if the package is damaged.


Use before expiration date.

STERILE R Sterilized by irradiation.


Manufacturer.

GTIN Global trade item number.

LIABILITIES, SAFETY AND GUARANTEE
If the sterility packaging of the implant is damaged during delivery, Implant Microdent System S.L.U. will replace it free of charge. This will not be the case if there is evidence of product manipulation.
The guarantee applies to Implant Microdent System S.L.U. implants as long as they have been used in accordance with the indicated instructions of use.
To proceed with returns of products mentioned in these instructions for use, please follow the regulations of our sales and supply conditions.


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