MICRODENT EKTOS IMPLANTOLOGICAL SYSTEM (EK, EKC AND E3KC)

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.
The multifunction abutments are used as a support element for the dental rehabilitation required by the patient. The multifunction abutments are suitable for cement-retained or cement-screwed restorations.

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 four platforms,2.90, 3.50, 4.50 and 5.70 mm and a diverse array of cores for each.
- Platform Ø 2.90 mm (equipped with core Ø 3.20 mm).
- 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 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 Ektos implant system implants, depending on the country of commercialization, can be presented in 3 different formats:

1. With metallic implant holder, which will perform the function of a protractor.
2. With multi-function abutment, which can perform the functions of: protractor, closed tray transfer and / or provisional prosthetic abutment.
3. Without any type of conveyor.

1.In the case of an implant holder:
The implant that includes a metallic implant holder is presented mounted on a plastic support, as well as the transport plug. In the opposite part to the implant, the transport plug houses the closing screw.
Said plastic support is presented inside a container that maintains sterility by means of a heat-sealed metallic seal. The immunity and protection of this sterile barrier system is carried out by means of a screw cap that seals the outer container and guarantees non-manipulation of the content.
2.In the case of a multi-function abutment:
The implant that is accompanied by an abutment is presented mounted on a plastic support, as well as the transport plug. In the opposite part to the implant, the transport plug houses the closing screw.
The multifunction abutment that accompanies the implant provides the following advantages of use:
- Serve as an implant holder allowing the transmission of the torque required to proceed to insert the implant into the osteotomy.
- Allow the taking of impressions with closed tray. A separately supplied impression cap is required for this application.
- Be used as a prosthetic abutment on a provisional or definitive basis.

The multifunction abutment is presented attached to the implant with the retention screw of the final prosthesis.
3.In the case of not having any type of conveyor:
To remove the implant from the plastic support, an adapter will be needed. Once you have it, press the support slightly in the direction of the opening where it is housed.

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. Implant Microdent System S.L.U has a manual of surgical protocols for consultation.

EKTOS Implant Drill Protocol

Platform	2,90	3,50		4,50	5,70
Implant core	3,20	3,70	4,20	4,80	5,80
Cortical drill	F200				
Intermediate drill	F250	F250	F250/F290*	F250/F290*	F250/F290
Intermediate drill				F320	F320/F350
Intermediate drill				F350	F380/F420
Final drill (* depending on the type or quality of the bone).	F200	F290*	F320*	F380*	F450*
		F320*	F350*	F420*	F510*

E3KC Implant Drill Protocol

Platform	2,90	3,50		4,50	5,70
Implant core	3,20	3,70	4,20	4,80	5,80
Cortical drill	F200				
Intermediate drill	F250	F250/F290	F250/F290	F250/F290*	F250/F290
Intermediate drill				F320	F320/F350
Intermediate drill				F350	F380/F420
Final drill (* depending on the type or quality of the bone).	F290	F320*	F320*	F380*	F450*
		F350*	F350*/F380*	F420*	F510*

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, a plastic support / container will emerge in which:

1. The implant will be mounted with its metallic implant holder, and the transport plug for manual insertion of the implant, which in turn contains the 1st surgery closure screw.
2. The implant will be attached to the multifunction abutment, and the transport plug for manual insertion of the implant, which in turn contains the 1st surgery closure screw.
3. It will contain the implant without a transporter and a cap that contains the 1st surgery closure screw.

Manual insertion of the implant
If it is mounted with an implant holder:
If the implant is to be inserted manually, remove the transport plug from the plastic holder and place it on the metal implant holder of the implant.
To dislodge the implant from the plastic support, apply slight upward pressure in the direction of the opening where it is housed. The implant will come out attached to the transport plug that will help it to be transported to the mouth without the need for contact with the implant. Insert the implant into the osteotomy and start the implant entry by turning clockwise.
If when inserting the implant in the osteotomy (in the first turns) you notice a greater effort than usual, it is advisable to remove the implant from the socket and increase its capacity. Forced entry of an implant could damage it.
Once you have the implant inserted in 2/3 of its length, finish the insertion with the help of a ratchet or torque wrench. Once the implant has been inserted, remove the metallic implant holder using the Hex screwdriver. 1.20
If it is mounted with a multifunction abutment:
If the implant is to be inserted manually, place the PMFLLIM key on the Multifunction Abutment of the implant.

To dislodge the implant from the plastic support, apply a slight vertical force to the vial. The implant will come out attached to the key that will help it to be transported to the mouth without the need for contact with the implant Insert the implant into the osteotomy and start the implant entry by turning clockwise.
If, when inserting the implant in the osteotomy (in the first turns), you notice a greater effort than usual, it is advisable to remove the implant from the socket and increase its capacity. Forced entry of an implant could damage it.
Once you have the implant inserted in 2/3 of its length, finish the insertion with the help of a PMFLLIC or PMFLLID key. Once the implant is inserted, remove the Multifunctional Abutment using the Hex screwdriver. 1.20.

Without conveyor:

Insert the reference of the CEKAF29C - CEKAF3545C - CEKAF57C (short adapters) or CEKAF29L - CEKAF3545L - CEKAF57L (long adapters) directly into the dental implant.
To remove the implant from the plastic holder, slightly press the holder in the direction of the opening where it is housed.
Move the implant to the osteotomy and proceed to insert it.

Inserting the implant mechanically

In the case of choosing this option, it is very important to always maintain the alignment of the implant with the desired direction to obtain a correct insertion of the implant.

If it is mounted with an implant holder:

Take the micromotor, mount the LC44 key and then insert it over the metal implant holder of the implant.
To dislodge the implant from the plastic support, apply light pressure to it in the direction of the opening where it is housed.
Transport the implant to the osteotomy and proceed to insert it by regulating the speed of the micromotor, from 15 to 25 rpm, to obtain maximum control over the process.
Once the implant has been inserted, remove the metallic implant holder using the Hex screwdriver. 1.20.

If it is mounted with a multifunction abutment:

Take the micromotor, mount the PMFLLIC key and then insert on the implant multi-function abutment.
To dislodge the implant from the plastic support, apply a slight force to the outside of the container.
Transport the implant to the osteotomy and proceed to insert it by regulating the speed of the micromotor, from 15 to 25 rpm, to obtain maximum control over the process.
Once the implant has been inserted, remove the Multifunctional Abutment using the Hex.1,20 screwdriver.

Without conveyor:

Insert the reference of the adapter E3KLLIC29C - E3KLLIC3545C - E3KLLIC57C (short) or E3KLLIC29C - E3KLLIC3545C - E3KLLIC57C (long) that was previously installed in the handpiece, directly on the dental implant.
To remove the implant from the plastic holder, slightly press the holder in the direction of the opening where it is housed.
Move the implant to the osteotomy and proceed to insert it, regulating the speed of the micromotor to obtain maximum control over the process.

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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