

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.microdentssystem.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 maxillary and mandible.

DESCRIPTION

Implant Microdent System S.L. 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 catalogues or on the website

Microdent EKV implant

Microdent EKV 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 lateral taper implant core, unlike Ektos implant, allows a compacting effect of the foam mass of bone that influences bone increased primary retention.

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 EKV implant is made of pure titanium grade 4 according to ISO 5832-2:1999 standard and present surface treatment for greater roughness over the whole area of osseointegration

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 EKV implant presents a range of two platforms, 3.50 and 4.50 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)

The implants are available in different lengths:

- Implant core Ø 3,70 mm with available length of 8, 10, 12, 14 and 16 mm.

- Implant core Ø 4,20 mm with available length of 6, 8, 10, 12, 14 and 16 mm.

- Implant core Ø4,80 mm with available length of 6, 8, 10, 12, 14 and 16 mm.

MICRODENT EKV IMPLANTS PRESENTATION.

Packaging and sterility

Microdent EKV 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-EKV.

Angles of more than 30° 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 addiction, 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, localised 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 personalised by the professional according to the type of bone where the implant is to be fitted. The recommendations given below are exclusively based on the use of Microdent special atraumatic expanders for use in expansion, use of material different from this could result in an inadequate alveolus for the implant that you wish to insert in the osteotomy.

Implant platform	Ø 3,50												Ø 4,50					
	Ø 3,70						Ø 4,20						Ø 4,80					
Core diameter	Ø 3,70						Ø 4,20						Ø 4,80					
Implant length	8	10	12	14	16	6	8	10	12	14	16	6	8	10	12	14	16	
With classic drill Cortical FC20 Pilot F1812 / 1817	3																	
	4																	
With new drill, Cortical F200	4																	
Expander nº 1	8	8	8	8	8	6	8	8	8	8	8	6	8	8	8	8	8	
Expander nº 2	8	10	12	14	16	6	8	10	12	14	16	6	8	10	12	14	16	
Expander nº 3	8	10	12	12	12	6	8	10	12	12	12	6	8	10	12	14	16	
Expander nº 4												6	8	8	10	10	10	
Expander nº 5																		

The information given in the table above refers to the depth that should be reached with each instrument required to obtain the desired alveolus. Control of depth will be done with the aid of the marks on the instruments.

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.

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 metal implant holder, and the transport cap for the manual insertion of the implant, which contains the cover screw for 1st surgery.

Microdent EKV implant characteristics allow insertion of the implant manually assisting a torque wrench or by using the micromotor.

If you insert the implant into the osteotomy (in the first turns) noticing more effort than usual is advised to remove the implant socket and increase it with a larger drill. The forced entry of an implant may damage it.

We recommend not to exceed a couple of 40 Ncm insertion. To control this effort can help the reference torque ratchet wrench LDR1070.

If we proceed to the insertion of the implant with the help of micromotor, regulate its speed for maximum control over the insertion process.

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.

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.



Do not use if the package is damaged.



Reference number.



Use before expiration date.



Please follow the instructions for use.



Sterilized by irradiation.



Batch number.



Manufacturer.



Precaution, consult the warnings.

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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