MICRODENT EKTOS IMPLANTS
(Sterile)

Caution: Federal law restricts this device to sale by or on the order of a licensed practitioner

These usage instructions should be read before using the implants and materials supplied by IMPLANT MICRODENT SYSTEM S.L. 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. 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/instructions-for-use
To open pdf files you need the free Adobe Acrobat Reader.

INTENDED USE
Microdent Ektos Implant System is indicated for surgical placement in the upper or lower jaw arches, for single-stage or two-stage surgical procedures and cemented, screw retained restorations or overdentures. Microdent Ektos Implant System is intended for immediate placement and 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.

DIRECTIONS FOR USE
Microdent Ektos dental implants are internal connection endosseous implants. During pre-operative planning, it must be determined that there is adequate height and width of bone to allow implant placement.
The implant has an internal hexagonal connection.
The implant has a self-tapping external thread and in the apical part has three notches.
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 and Ø 7.00 mm)

The implants are available in different lengths: 8, 10, 12, 14, 16 and 18 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 implant has an abutment, which is secured to a plastic support and fitted with a cap. The 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.
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. 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.
Storage
Store sterilized products in a dry, clean, and dust-free environment at modest temperatures of 5°C to 40°C / 41°F–104°F

PLANNING AND LOAD
Before proceeding with the surgical part of implant rehabilitation, it is the responsibility of the user to carefully plan the process.
Appropiate radiographic pre-operative analysis is necessary to determinate the position of important anatomical structures.
To maximise 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. 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, 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, and hyperplasia.

WARNINGS
When the implant comes into contact with contaminants, especially blood and/or saliva, it must not be reused. There is no guarantee that these contaminants can be eliminated, even if the implant is cleaned and sterilized, and they 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.
Small diameter implant and angled abutment are not recommended for the posterior region of the mouth.

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. 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.

MRI SAFETY INFORMATION
The implant and the abutments have not been evaluated for safety and compatibility in the MR environment. The implant and the abutments have not been tested for heating, migration, or image artifact in the MR environment. The safety of the implant and the abutments in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

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

	Plat 3.50		**Plat 4.50**	**Plat 5.70**	
Implant core	3.70	4.20	4.80	5.80	7.00
Cortical drill	FC20	FC20	FC20	FC20	FC20
Pilot drill 1.8 mm. Short/long	FP1812/FP1817	FP1812/FP1817	FP1812/FP1817	FP1812/FP1817	FP1812/FP1817
Intermediate drill	F250	F250 / F280	F250 / F280	F250 / F280	F250 / F280
Intermediate drill			F320	F350 / F380	F350 / F380
Intermediate drill					F450 / F480
Final drill (* depending on the type or bone quality)	F280	F320	F350	F450	F580
	F300	F350	F380	F510	

Microdent disposal guide drills to avoid alveolar parallel deviations.

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 / 18 mm) displayed by the drills distributed by Implant Microdent System S.L. The F580 is the only drill that has a previous mark to 4 mm. Osteotomy procedure: use drills in optimum cutting 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.

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 multifunction abutment, and the cap which contains the cover screw for 1st surgery. Finally for the manual insertion of the implant use the manual key for multi-function (PMFLLIM).
Microdent Ektos implant characteristics allow insertion of the implant manually assisting a torque wrench or by micromotor using the contra-angle key for multifunction (PMFLLIC).
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 PMFLLID.
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.
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 MH120C, 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 ABUTMENTS
Preprosthetic abutments, healing abutments, are supplied in non-sterile condition. They must be processed in the dentist's installations.
For correct sterilization of the product, follow these steps:
- Remove the product from its packaging. 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

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.
	Precaution, consult the warnings.		Use before expiration date.
	Prescription only		Sterilized by irradiation.

LIABILITIES, SAFETY AND GUARANTEE

If the sterility packaging of the implant is damaged during delivery, Implant Microdent System S.L. 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. 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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