MICRODENT SYSTEM 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
Microdent System dental implants are external connection endosseous subgingival implants 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 the implant, of the self-cutting type, together with the geometry of the grooves it has on the apical area of the implant, enables it to be inserted easily, as well as offering high primary retention.
Microdent System dental implants are made of grade 4 pure titanium, in accordance with ISO 5832-2:1999 standard, with a surface treatment to achieve greater roughness in the entire osseointegration area.
The cover screw accompanying the implant is manufactured in grade 5 titanium, in compliance with ISO 5832-3:1999 standard.
The nominal length of implant is defined from 1 mm below the platform to the apical area of the implants.
Microdent System implant is presented in a range of four platforms, 3.50, 4.20, 5.10 and 5.60 mm.
The implants are available in different lengths: 6, 8, 10, 12, 14, 16 mm, according to the platform. For easy identification of the platforms, the metal implant holders are colour-coded as indicated below:
Platform Ø 3.50 mm (cores available Ø 2.80 and Ø 3.25) dark blue
Platform Ø 4.20 mm (cores available Ø 3,30, 3,50, 3.80, Ø 4.20) violet
Platform Ø 5.10 mm (cores available Ø 4.20 and Ø 5.00) green
Platform Ø 5.60 mm (cores available Ø 5.00 and Ø 5.50) yellow

MICRODENT SYSTEM IMPLANTS PRESENTATION.
Packaging and sterility
Microdent System dental implants undergo an exhaustive manufacturing, control and cleaning process before packaging, in a sterile area, being subsequently sterilized by irradiation.
The implant has a metal holder, which is secured to a plastic support and fitted with a transport cap. The transport cap holds the cover screw on the opposite side of the implant.
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 PPQM.
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.

Protocol with classic drills

Platform	3,50		4,20				5,10		5,60
Implant core	2,80	3,25	3,30	3,50	3,80	4,20	4,20	5,00	5,50
Cortical drill	FC20								
Pilot drill Short / Long	FP1812 / FP1817								
1st drill 2.5mm				F250/ F280	F250/ F280	F250/ F280	F250/ F280	F250/ F280	F250/ F280
2nd drill 3.2mm						F320	F320	F320	F320
3rd drill 3.5mm							F350	F350	F350
4th drill 3.8mm								F380	F380
5th drill 4.2mm									F420
6th Drill 4.5mm									F450
Final drill Bone type II/IV	F180	F250	F250	F280	F300	F350	F350	F380	F450
Final drill Bone type I,II	F250	F280	F280	F300	F320	F380	F380	F420	F510
Form drill*	FC350	FC350	FC420	FC420	FC420	FC420	FC510	FC510	FC550

Protocol with new drills

Platform	3,50		4,20				5,1		5,60
Implant core	2,80	3,25	3,30	3,50	3,80	4,20	4,20	5,00	5,50
Cortical drill	F200								
Intermediate drill		F250	F250	F250	F250	F250	F250	F250	F250
Intermediate drill					F290	F290	F290	F290	F290
Intermediate drill								F320	F320
Intermediate drill									F350
Intermediate drill									F380
Intermediate drill									F420
Final drill (* depending on the type or quality of the bone).		F290*			F320*	F320*	F320*	F380*	F450*
	F250	F290	F290	F290	F320	F350	F350	F420	F480
Conform platform*	FC350	FC350	FC420	FC420	FC420	FC420	FC510	FC510	FC550

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/cleanning 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.
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 metal implant holder, and the transport cap for the manual insertion of the implant, which contains the cover screw for 1st surgery.
Manual insertion of the implant
If the insertion is to be manual, remove the transport cap from the plastic support and place it on the metal implant holder with the implant.
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 transport cap; 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 extension adaptable to the metal implant holder reference ACC44 or ACL44 and if this is not possible, due to particular space conditions, remove the metal implant holder with the aid of screwdriver Hex. 1,75 and finish the process with the adaptor for the corresponding securing of the model of implant being inserted.
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 LC44 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.
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.

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. 0,90, and Hex. 1,20 in the case of platform 5.60 implants, 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 15 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.


Do not use if the package is damaged.


Use before expiration date.

STERILE R Sterilized by irradiation.


Manufacturer.

GTIN Global trade ítem number.

Precaution consult the warnings.

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.

Implant Microdent System S.L.U.
Pol. Ind. Can Magre C/. Carles Buïgas, 1
08187 Sta. Eulalia de Ronçana (Barcelona)
Spain

CE
0051