MICRODENT GNV IMPLANTS
Precautions and instructions for use.

These instructions for use must be read before using the implants and materials supplied by IMPLANT MICRODENT SYSTEM S.L.U. as they contain information to avoid errors of use.
The following descriptions are written for professionals in the dental implant field. For this reason, we recommend instructions for handling be given by an expert user, who has received adequate training. Implant Microdent System S.L.U. offers regular training courses on the use of their products.
Users must make sure that the product chosen is appropriate for the planned purpose 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 GNV dental implants are internal 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 lateral conical shape of the implant core, that differentiates the implant Genius, enables a compacting effect of the spongy bone mass, which results in a greater retaining effect of the implant.
The design of the connection features a conical housing that ends in a cylindrical section. This connection enables the sealing of the implant-prosthesis joint and the behavior of this union as a single unit. The anti-rotation system of the prosthetic connection is formed by six grooves extending axially to the implant, inherent to rehabilitation treatment with dental implants.
Microdent GNV implant has an upper beveled surface for biological growth. Bone growth on this surface enables a reduction of gingival retraction inherent to rehabilitation treatment with dental implants.
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 GNV 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 the implant is defined from the platform to the apical area of the implant.
Microdent GNV implants are available in a range of four platforms: 3.50, 4.00, 4.50 and 5.00 mm.
The implants are available in different lengths: 8, 10, 12, 14 y 16 mm according to the platform.

PRESENTATION OF MICRODENT GNV IMPLANTS.

Packaging and sterility
Microdent GNV 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 closure 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 the 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-GNV.
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 illnesses.
- 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 PRODUCED 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 has come into contact with contaminants, especially blood and/or saliva, it must not be reused, as there is no assurance they will be eliminated, even if cleaned and sterilized, due to the fact that transmission of these contaminants can cause diseases such as AIDS, hepatitis or STDs.
Another reason for not reusing the implant is the possible damage it may have suffered in 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 form this could result in an inadequate alveolus for the implant that you wish to insert in the osteotomy.

Implant platform	**Ø3,50**					**Ø4,00**					**Ø4,50**					**Ø5,00**				
Core diameter	Ø3,50					Ø4,00					Ø4,50					Ø5,00				
Implant length	8	10	12	14	16	8	10	12	14	16	8	10	12	14	16	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	8	8	8	8	8	8	8	8	8	8	8	8	8	8	8
Expander nº 2	8	10	12	14	16	8	10	12	14	16	8	10	12	14	16	8	10	12	14	16
Expander nº 3	8	10	12	12	12	8	10	12	12	12	8	10	12	14	16	8	10	12	14	16
Expander nº 4											8	8	10	10	10	8	10	12	14	14
Expander nº 5																8	8	10	12	12

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.

Manual insertion of the implant

Implant Microdent System S.L.U. recommends this type of implant to be inserted manually, due to its characteristics.
Remove the transport cap from the plastic support and place it on 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. 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. Forcing the implant could cause damage.
Once the implant has been 2/3 inserted in length, finish the insertion using a ratchet or torque spanner. Inserting the implant, remove the metal implant holder, using 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 this option is chosen, it is highly important to maintain the desired alignment of the implant for its correct insertion.
Take the micromotor, fit spanner LC44 and then insert on the metal implant holder of the implant.
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, from 15 to 25 rpm, 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.

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 clockwise, using screwdriver Hex. 1,20.
We recommend a torque of 5 Ncm.
Proceed to stitch 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.

REF Reference number.


Use before expiration date.


Please follow the instructions for use.

STERILE R Sterilized by irradiation.

LOT Batch number.

Precaution consult the warnings.

Manufacturer.

GTIN Global trade ítem number.

LIABILITY, 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 following the given instructions.

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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