



MICRODENT ORTHODONTICS MICROIMPLANTS

Precautions and instructions for use.

These instructions for use must be read before using the microimplants and materials supplied by IMPLANT MICRODENT SYSTEM S.L.U. as they contain essential information to avoid errors of use.

The following descriptions are written for professionals in the dental 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.microdentssystem.com/instrucciones-uso

To open pdf files you need the free Adobe Acrobat Reader.

INTENDED USE

Microdent Orthodontics microimplants, which is a part of the Microdent Orthodontics solutions system, is a microimplant designed to be used as a fixed anchor in maxilla or mandible for connecting orthodontic appliances, thus facilitating the orthodontic movement of the teeth.

DESCRIPTION

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 Orthodontics microimplants allow to place arches of dimensions 0.018x0.025".

Microimplants are made of grade 5 titanium in compliance with ISO 5832-3:1996 Standards and the microimplants have a polished surface.

Microdent Orthodontics microimplants system is composed by:

Standard Microdent Orthodontics microimplants

Standard microimplant has an outer diameter of 1.60 mm.

Microimplants are available in lengths: 7, 9 and 11 mm.

Standard Fine Microdent Orthodontics microimplants

Standard Fine microimplant has an outer diameter of 1.30 mm.

Microimplants are available in lengths: 7, 9 and 11 mm.

Versatile Microdent Orthodontics microimplants

Versatile microimplant has an outer diameter 1.60 mm.

Microimplants are available in lengths: 7, 9 and 11 mm.

Versatile microimplant has an internal thread that allows abutments connection to resolve orthodontic treatment suggested by the doctor. For Microdent Orthodontics solutions consult the catalog or our website.

Short Versatile Microdent Orthodontics microimplants

Short Versatile microimplant presents two core dimensions. A core external of 1.60 mm of diameter and a 2.00 mm.

Microimplants with core diameter 1.60 mm are available in lengths of 9 and 11 mm.

Microimplants with core diameter 2.00 mm are available in lengths of 7 and 9 mm.

Short Versatile microimplant is a variation of Versatile design, whose main difference is to present a reduction in orthodontic head height and not has the transverse hole to apply tensile stresses. This microimplant does not allow attach metal arches.

Can be connected on the microimplant the Versatile Microdent Orthodontics microimplant abutments.

Indications for use of Microdent Orthodontics microimplants

Recommended uses of Microdent Orthodontics microimplants are many and varied, the most common being:

Anchoring for closing extraction spaces, retrusion and intrusion of incisors, rapid extrusion or intrusion of individual pieces, straightening of upper or lower molars, dental disimpacting, correction of medium lines, correction of asymmetrical occlusal planes, anchors with lack of teeth or periodontal and uses associated with lingual apparatus or techniques.

PRESENTATION OF MICRODENT ORTHODONTICS MICROIMPLANTS

Packaging and sterility

Microdent orthodontic microimplants go through an exhaustive manufacturing, control and cleaning process before being packaged in the sterile area and later sterilized by irradiation.

Both the external packaging and the internal container have a label containing the batch number, size and model of implant.

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 and the method used. An implant that has already been used or is not sterile must not be fitted, under any circumstance.

PLANNING AND LOAD

Before proceeding with the surgical part of the orthodontic treatment with microimplants, it is the user's exclusive responsibility to plan the process very carefully.

The microimplants can be fitted either perpendicular or at an oblique angle with regard to the cortical bone. Inserting into the cortical bone at an oblique angle increases the contact area, improving primary retention and permitting the use of longer microimplants.

The microimplant can be subject to load after being inserted. Dental overloading should be avoided; the force applied should not exceed 250 to 300 g and can be raised only up to 500 g in the case of 2.00 mm core microimplants.

CONTRAINDICATIONS

Serious internal medicine problems, inadequate control of inflammation prior to the orthodontics, 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 available bone or inadequate bone quality.

SIDE EFFECTS, INTERACTIONS AND COMPLICATIONS PRODUCED BY ORTHODONTICS MICROIMPLANTS.

The following are some of the possible complications after fitting Orthodontics microimplants:

Transitory disorders:

Pain, irritation of the soft tissues, inflammation, apthous ulcers, difficulty to speak, gingivitis, increased risk of caries.

Longer-lasting disorders:

Chronic pain associated to the dental implant, permanent paresthesia, dysesthesia, bone loss in the maxillary crest, effect on the tooth roots, localized or systemic infections, oroantral or oronasal fistulas, mobility of teeth, aesthetical problems, milolisis, damage in the nerve, exfoliation and hyperplasia.

WARNING

When the microimplant has come into contact with pollutants, especially blood and saliva, it should not be reused for not having the full assurance of its removal, even cleaned and sterilized, since the transmission of these contaminants can cause illnesses such as AIDS, hepatitis, STDs.

Another reason for not reusing abutments would be any damage that its geometry may have suffered by improper use.

Electro surgery is not recommended, due to the conductivity of the raw material used in the orthodontic microimplants.

Before proceeding with surgery, it is the user's responsibility to check the microimplant, the container and to make sure it is the right product for the patient.

Implant Microdent System S.L.U. recommends having replacement products available.

In general, during the oral use of our products the user must take precautions to prevent aspiration by the patient.

During orthodontic treatment, there is more risk of tooth caries and gum disease. This is due to increased food impaction by the retentive action of the apparatus, with orthodontics treatment more food gets everywhere and is retained. The doctor should inform the patient to avoid this is as simple as having good oral hygiene after each meal and do a thorough cleaning of teeth, gums and the apparatus.

SURGICAL PROTOCOL

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.

The Microdent orthodontic microimplant is self-perforating and self-threading. This gives the microimplant the capacity to be inserted without having to make a prior drilling before insertion. The aforementioned features of the microimplant do not avoid the need to carry out a prior perforation of the cortical when the characteristics of the bone, according to its type / density, require this. The drill suitable for this purpose reference is F1312 (Ø 1.30 mm.), with the exception of microimplants diameter 1.30 mm requiring the use of the drill F100 (Ø 1.00 mm.)

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When the direction of insertion of the implant is oblique to the bone, it is especially recommended to carry out a prior stippling with a spherical burr such as reference FP10.

Fitting the microimplant

- Apply local anaesthesia to the area that is to receive the microimplant.
- Open the sterilization protective container and deposit the contents on a clean surface.
- According to the characteristics of the patient's bone, the dentist will decide on whether to carry out an initial perforation of the cortical with the aim of minimising the torque required for inserting the microimplant.
- Place the microimplant in the corresponding adaptor, either to use it with the manual screwdriver or with the counter-angle. If the insertion is carried out by mechanical means, adjust the micro motor so it will not exceed 15 Ncm maximum torque. To carry out insertion manually, turn the screwdriver clockwise smoothly without pressing axially, allowing the advance of the microimplant on its thread.
- It is recommended to finish the microimplant insertion process by making an intraoral x-ray to ensure the process has been carried out correctly.

Disinserting the microimplant

Once the orthodontic treatment has finished, the disinsertion of the microimplant is carried out by using a screwdriver, without needing anaesthesia in most cases. To avoid osseointegration of the microimplant, it is recommended every 4-6 months, in the monitoring visits, for the dentist to rotate the microimplant so as to break the union between the bone and the microimplant.

LABELLING SYMBOLS

The product label will give the following information:

	Single use only.
	Reference number.
	Please follow the instructions for use.
	Batch number.
	Precaution consult the warnings.
	Sterilized by irradiation
	Manufacturer.
	Global trade item number.

LIABILITY, SAFETY AND GUARANTEE

If the protective packaging of the microimplant 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 will apply to Implant Microdent System S.L.U. microimplants provided they have been used following the instructions indicated.

For a refund of the products that mention these instructions should follow the guidelines established in our conditions of sale and delivery.



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0051