



MICRODENT GENIUS IMPLANT ABUTMENTS

(Non 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 that they receive instructions from an expert professional in the field, 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 Genius 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 Genius 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

Implant Microdent System SL developed for each of their implant systems, various preprosthetic and prosthetic solutions to meet the particular needs the patients. This is followed by a description and direction for use of Microdent Genius implant abutments. For a complete directions for use, please read entire the Prosthesis Manual and Laboratory Manual prior to using the device.

Healing Abutments

Clinical indication: These abutments are used for the maintenance of tissue overture. Healing abutments are available in different heights. The chosen abutment must exceed gingiva height.

Material: Healing abutments are made of titanium grade 5 according to ISO 5832-3.

Method of application: After the required sterilization of the healing abutment, insert the surgery key (hex 1.20) and transport it to the position of the implant. Hand tight screw by turning clockwise until the abutment-implant contact. It is recommended not to exceed 25Ncm as maximum torque.

Precautions: The platform of the implant should be clean from tissue or bones rests which may prevent the proper seating of the abutment on the implant. Before inserting the abutment you should clean the threads of the implant by a corresponding Microdent internal thread cleaner.

Abutments for cement-screw prosthesis (Conical and Angled abutments)

Clinical indication: These abutments are available with flap, without flap and angled.

Material: The abutments for cemented prosthesis are made on titanium grade 5 according to ISO 5832-3.

Method of application: After the shaping and preparation of the abutment by the dental laboratory, place the abutment over the implant, ensuring the proper settlement in respect to the implant platform. Then proceed to join them with a retention screw using the 1.20 mm hex wrench. We recommend a 30Ncm torque for fixing screws. Once abutment is fixed to implant, prosthetic rehabilitation cementation can take place.

Precautions: Implant platform should be clean from tissue or bones rests which may prevent the proper seating of the abutment on the implant. Before inserting the abutment you should clean the threads of the implant by a corresponding Microdent internal thread cleaner.

Abutments for cement-screw prosthesis (Conical abutments for immediate loading)

Clinical indication: These abutments are used for immediate provisional and final cemented prosthesis, either, single or multiple.

Material: The abutments for immediate loading are made on titanium grade 5 according to ISO 5832-3.

Method of application: Once the implant has been placed in the osteotomy, insert the abutment over the implant and join them with the corresponding retention screw. Proceed to the impression taking using the impression coping and preparing the provisional immediate prosthesis. Attach the abutment to the implant with the retention screw using the 1.20 mm hex wrench (a maximum torque of 20 Ncm is recommended). Once abutment is fixed to implant, prosthetic rehabilitation cementation can take place.

Precautions: Implant platform should be clean from tissue or bones rests which may prevent the proper seating of the abutment on the implant. Before inserting the abutment you should clean the threads of the implant by a corresponding Microdent internal thread cleaner.

Abutments for overdenture retention (Ossclia retention abutment)

Clinical indication: These abutments are used for overdenture retention. Systems for retention of overdenture are Ossclia retention abutment. To know the particularities of each overdenture retention system, please consult the catalog of products.

Material: The abutments for overdenture retention are made of titanium grade 5 according to ISO 5832-3, with the exception of plastic retainers which are made on thermoplastic material.

Method of application: Attach the chosen overdenture retention system over the implants using a 1.20hex wrench. Then insert the plastic retainers over the abutments and proceed to cement these in overdenture. Recommended torque of 30Ncm for fixing the abutments.

Precautions: Implant platform should be clean from tissue or bones rests which may prevent the proper seating of the abutment on the implant. Before inserting the abutment you should clean the threads of the implant by a corresponding Microdent internal thread cleaner.

Abutments for screwed prosthesis

Mini Capitel abutment

Clinical indication: These abutments are used for multiple screw prosthesis. Mini Capital abutment is complemented by Mini Capitel prosthetic solutions required for a screwed prosthesis. For more details, consult the manual of products.

Material: Abutments for cemented prosthesis are made of titanium grade 5 according to ISO 5832-3.

Method of application:

For this implant system is available only Mini Capitel rotation that consists of a single body. Select the appropriate abutment depending on the patient's gingival height, transport the abutment to the mouth using the key reference UTSNTICP and apply torque using the key reference UTSNLEC. Recommended torque is 30Ncm.

The prosthetic rehabilitation abutments will join the Mini Capitel with the screw holding the prosthesis UTSNTR and use the key reference MH120CAP. Torque of 10 to 15Ncm is recommended.

Precautions: Implant platform should be clean from tissue or bones rests which may prevent the proper seating of the abutment on the implant. Before inserting the abutment you should clean the threads of the implant by a corresponding Microdent internal thread cleaner.

Angled Mini Capitel abutment

Clinical indication: The angled Mini Capitel abutment is used in situations where the Mini Capitel abutment does not absorb implants disparallelism. The angled Mini Capitel abutment is complemented by Mini Capitel prosthetic solutions, which is needed for the creation of screwed prosthesis. For more details, consult the manual of products.

Material: The abutments of cemented prostheses are made of titanium grade 5 according to ISO 5832-3.

Method of application: Select the appropriate abutment depending on the disparallelism of the implant using the corresponding retention screw. To fix the retention screw of the prosthesis uses the MH120CAP key. We recommend a 30 Ncm torque for fixing the screw. The prosthetic rehabilitation will join Mini Capitel abutment with the screw holding the prosthesis UTSNTRA and use the key reference MH120CAP. Torque of 10 to 15Ncm is recommended.

Precautions: Implant platform should be clean from tissue or bones rests which may prevent the proper seating of the abutment on the implant. Before inserting the abutment you should clean the threads of the implant by a corresponding Microdent internal thread cleaner.

Prosthesis retention screw

Clinical indication: These abutments are used for union between the prosthetic abutments and the implant.

Material: Prosthesis retention screws are made on titanium grade 5 according to ISO 5832-3.

Method of application: To screw it, use the 1.20 mm hex wrench (a maximum torque of 30Ncm is recommended).

Precautions: Before inserting the abutment you should clean the threads of the implant by a corresponding Microdent internal thread cleaner.

PRESENTATION OF MICRODENT GENIUS SYSTEM IMPLANT ABUTMENTS

Packaging

Implant Microdent System S.L ensures that all prosthetic abutments follow a manufacturing process, control and extreme cleaning before being packaged.

Preprosthetic and prosthetic Microdent Genius abutments are packed in blister. The product contained will be identified in two labels, one in the back of the blister and the other in the box housing the blister.

To make the proper monitoring of the required traceability of these products, the label must be adhered or this data must be transcribed to patient records.

Abutments supply state.

Microdent Genius abutments **are not sterile**. Before placing them, abutments must be sterilized, especially in the case of preprosthetic abutments as healing abutment, at customer sites.

For the correct sterilization of the product you should follow the following steps:

- Removing the product from the packaging supplied. 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

LABELLING SYMBOLS

Product label shows the following indications:

	A single use, do not reuse		Consult Instructions for use
	Non-sterile		Prescription only

CONTRAINDICATIONS

None known.

TEMPORARY SIDE EFFECTS

Preprosthetic and prosthetic abutments can cause pain, swelling, and difficulty speaking.

WARNINGS

Microdent Genius preprosthetic and prosthetic abutments are part of an overall design concept. Their design has been adapted to be used with implants manufactured by Implant Microdent System S.L, therefore, the use of abutments from other trademarks might cause a non-optimal performance of our products.

Products should be used only for the purpose for which they were specified.

We warn you about the risk of toxicity and allergenicity for patients sensitive to the materials described under "DESCRIPTION OF MICRODENT GENIUS IMPLANT ABUTMENTS".

We recommend using tools calibrated to this torque to avoid exceeding this value and to avoid the possibility of damaging the manipulate device. In prosthetic laboratory tests it is recommended not to exceed a torque of 15Ncm for retention screws.

It is imperative to clean the threads of the implant, before attaching the prosthesis, by means of relative thread cleaners manufactured by Implant Microdent System S.L

When the abutment 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 abutments would be any damage that its geometry may have suffered by improper use.

Electrosurgery is not indicated because of the conductivity of dental implants.

Before surgery is the responsibility of the professional user to check:

- The state of the abutment packaging and if it matches the required product for the patient.
- The state of the abutment it-self to verify that it is optimal.

Implant Microdent System S.L recommends you should have substitute products.



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In general, during the oral use of our products the user must take precautions to prevent aspiration by the patient. Small diameter implant and angled abutment are not recommended for the posterior region of the mouth.

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.

LIABILITY, SAFETY AND WARRANTY

The above instructions have been approved by Implant Microdent System S.L as a means of proper use for the use of these products, but cannot provide a detailed description of the process, it is not possible to make a detailed description of the different surgical techniques and / or prosthetic used throughout the world.

The use of these products must be performed only by specialists familiar with the techniques and procedures surrounding its use.

Any abnormalities should be carefully analyzed for effectiveness and possible adverse consequences and documented.

The guarantee will apply to Implant Microdent System S.L abutments 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.

Manufactured by: Implant Microdent System S.L.
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Made in Spain