

PRECAUTIONS AND INSTRUCTIONS FOR USE OF PROVISIONAL PROSTHESIS

External & internal connection Implant System

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.microdentssystem.com/instrucciones-uso

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

INTENDED USE

Provisional abutments are intended to be used to fabricate and support provisional restorations. Provisional abutments can be used for provisional restorations that the patient will use up the preparation of the final prosthesis.

DESCRIPTION

Implant Microdent System S.L.U developed for each of their implant systems, various prosthetic solutions to meet the particular needs of patients. This is followed by a description of prosthetic implant abutments that have been specially designed for the preparation of provisional prosthesis, but for an adequate selection of our products it is recommended to consult the published product catalogs or our website.

Provisional implant abutment (Peek abutment)

Clinical indication: These abutments are used for the temporary prostheses, either, single or multiple.

Material: Provisional abutments are made in polyetherketone (PEEK).

Delivery: Provisional implant abutments are supplied accompanied by the appropriate prosthetic retention screw.

Method of application: After the abutment carved and ready to proceed to the implant placement, ensuring the correct positioning relative to the platform of the implant. The implant abutment connection to be made through the retention screw, this requires the use of a hex wrench according to the implant system with which we work. We recommend a 20Ncm torque for fixing screws. Once pillar 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 pillar you should clean the threads of the implant by a corresponding Microdent internal thread cleaner.

Retention screw for provisional implant abutments

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

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

Method of application: For screwing it, it is required the use of a hex wrench according to the implant system with which we work. It is recommended not to exceed 20Ncm as maximum torque. We recommend using wrench with calibrated torque to avoid exceeding this value and the possibility of damaging the item you're manipulating.

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

Orientable corrector abutment (Angled peek abutment)

Clinical indication: These abutments are used for the temporary prostheses, either, single or multiple. These temporary abutments, presents different transmucosal heights to best fit the needs of the patient. We will use this type of pillars when required to correct the effects of implant placement is not parallel to each other, the pillar has a correction capability of $\pm 25^\circ$.

Material: Provisional abutments are made in polyetherketone (PEEK).

Delivery: Provisional angled ilmpant abutments are supplied accompanied by the appropriate prosthetic retention screw.

Method of application: After carving and abutment preparation by the dental laboratory, proceed to the pillar insertion over the implant, ensuring the correct positioning relative to the platform of the implant. The implant abutment connection to be made through the retention screw, this requires the use of a oscillating key, reference DTOC120. We recommend a 20Ncm torque for fixing screws. Once pillar is fixed to implant and has guided the pillar, 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 pillar you should clean the threads of the implant by a corresponding Microdent internal thread cleaner.

Retention screw for orientable correctos abutments

Clinical indication: Indicate for union between the prosthetic abutments and the implant.

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

Method of application: For screwing it, it is required the use of a oscillating key, reference DTOC120. It is recommended not to exceed 20Ncm as maximum torque. We recommend using wrench with calibrated torque to avoid exceeding this value and the possibility of damaging the item you're manipulating.

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

PRESENTATION OF IMPLANT ABUTMENTS

Packaging

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

Implant abutments are packed in blister. The product contained will be identified in two identical 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 these data must be transcribed to patient records.

Abutments supply state.

Implant abutments are not sterile. Before placing then, abutments must be sterilized, 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.
- Enter the product in a container or bag suitable for sterilization and to ensure no contamination until its use.

We recommend the process of steam sterilization by autoclaving. Please observe the peculiarities of computer you have. The parameters recommended by UNE-EN ISO 17665-1 and EN ISO 17665-2 are:

- Temperature: 134 ° C
- Cycle of sterile: 3'

LABELLING SYMBOLS

Product label shows the following indications:



Single use only.



Reference Number.



Please follow the instructions for use.



Lot number.

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Precaution, consult the warnings.



Manufacturer.

CONTRAINDICATIONS

None known.

TEMPORALY SIDE EFFECTS.

Prosthetic rehabilitation treatment can cause pain, swelling, and difficulty speaking.

WARNINGS AND PRECAUTIONS

The provisional implant abutments are part of an overall design concept, having adequate use with implants manufactured by Implant Microdent System S.L.U, therefore, the combination of Microdent abutments with others outside the mark can cause no optimal operation of these products.

It is recommended to remain in place longer than ninety (90) days.

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 PROVISIONAL PROSTHESIS".

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.U

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.U recommends you should have substitute products.

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

When the abutment 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 the abutment would not reuse any geometry damage by improper use.

Electrosurgery is not indicated due to dental implants conductivity.

LIABILITY, SAFETY AND WARRANTY

If due to transportation, packaging and product content was damaged, Implant Microdent System S.L. shall return it at no charge.

Evidence of product handling disclaims liability indicated above.

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

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