PRECAUTIONS AND INSTRUCTIONS FOR USE OF PROSTHETIC AND PREPROSTHETIC IMPLANT ABUTMENTS

Microdent Ektos 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.microdentsystem.com/instrucciones-uso
To open pdf files you need the free Adobe Acrobat Reader.

INTENDED USE

Cover screw and Healing abutments protect the inner configuration of the implant and contours the soft tissue during the healing phase.
The abutments (Conical, Angled and Capitel) are used for cemented and screw-retained restorations.
Castable restorative components (Overcast abutment) are intended for use as accessories to endosseous dental implants to aid in the fabrication of dental prosthetics.
Overdenture retention is appropriate for use with overdenture or partial dentures retained in whole or in part by endosseous implants in the mandible or maxilla.

DESCRIPTION (MICRODENT EKTOS)

Implant Microdent System S.L.U developed for each of their implant systems, various preprosthetic and prosthetic solutions to meet the particular needs of patients. This is followed by a description of preprosthetic and prosthetic Microdent Ektos system implant abutments, but for an adequate selection of our products it is recommended to consult the published product catalogs or our website.

Healing Abutments

Clinical indication: Healing pillars are available in different heights. Regarding election of the pillar, that exceed the gingival height once it has been fixed on the implant must be noted.
Material: Healing abutments are made of titanium grade 5 according to ISO 5832-3.
Method of application: Insert the key pillar in the appropriate surgery (hex 1.20) and transported to the position of the implant. Hand tight screw by turning clockwise until the abutment-implant contact. It is recommended not to exceed 15 Ncm 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 pillar you should clean the threads of the implant by a corresponding Microdent internal thread cleaner.

Pillars for cement-screw prosthesis (conical and angled Pillars)

Clinical indication: Suitable for prosthesis, either single or multiple. These abutments are available with flap, without flap and angled.
Material: The pillars for cemented prosthesis are made on titanium grade 5 according to ISO 5832-3.
Method of application: After carving and abutment preparation by the dental laboratory, proceed to the pillar insertion over the implant, ensuring the proper settlement respect to the implant platform and proceed to their union by means of relating retention screw for the prosthesis using a 1.20 mm hex wrench. 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.
Not recommended in multiple restorations on implants with divergent angles greater than 10º.

Pillars for cement- screw prosthesis (conical pillars for immediate loading)

Clinical indication: These abutments are used for immediate provisional and final cemented prosthesis, either, single or multiple.
Material: The pillars 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, the pillar can be inserted over the implant ensuring the proper settlement respect to the implant platform and proceed to their union through 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 through the relating retention screw using a 1.20 mm hex wrench. We recommend a 20 Ncm torque for fixing screws, for not to affecting the primary implant stability. 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.
Not recommended in multiple restorations on implants with divergent angles greater than 10º.

Pillars for overcast prosthesis

Clinical indication: These pillars are used for overcast prosthesis, either, single or multiple. The result will be a screwed prosthesis. Abutments for overcast prosthesis are overcast pillars, semicalcinable pillars and orientable semicalcinable abutments.
Material: Overcast pillars are made on Cr-Co according to ISO 5832-12. Calcinable chimney of semicalcinable pillars and orientable semicalcinable are made in POM thermoplastic material.
Method of application: After the completion of rehabilitation by the laboratory technician, proceed with the insertion of the implant itself, ensuring the proper settlement respect to the implant platform and proceed to their union through the corresponding prosthesis retention screw, this requires the use of a 1.20 mm hex wrench. We recommend a 20 Ncm torque for fixing screws of overcast rehabilitation and 15 Ncm for fixing screws of orientable semicalcinable abutment. For the development of overcast prosthesis you should follow MC_overcast directions, edited for this reason.
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.
Not recommended in multiple restorations on implants with divergent angles greater than 10º.

Abutments for overdenture retention

Clinical indication: These abutments are used for overdenture retention. Systems for retention of overdenture are ball set, spherical anchor set,Osscilia ball set and Micro Loc set. To know the particularities of each overdenture retention system, please consult the catalog of products.
Material: The abutments for overdenture retention are made in titanium grade 5 according to ISO 5832-3, with the exception of plastic retainers which are made in thermoplastic material.
Method of application: Attach the Osscilia overdenture retention system over the implants using a 1.20hex wrench and key SLTM for Micro Loc. Then insert the plastic retainers over the Osscilia abutments or Micro Loc and proceed to its cemented process over the overdenture.Recommended torque of 30Ncm for fixing the ball pillars and Micro Loc over the implant.
Precautions: Considering the characteristics of this type of abutment for overdenture retention is very important to follow these guidelines:

- Recommend that implants are placed parallel to each other and perpendicular to the occlusal plane, in any case the maximum disparalelism respect to the vertical must not be greater than 15 º.
- A minimum of two implants in the mandible and four in the maxilla are necessary for the retention of overdenture.
- If the implant has many angular divergences, it is convenient to use mesostructures.
- 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.
- The abutments for overdenture retention should not be reworked; this modification alters the proper functioning of the product and affects the mechanical stability.
- In these cases is relevant the passive fit of overdenture. To facilitate the achievement of the passive fit recommended coping cemented in the overdenture, directly in mouth.
- Non-removal of the prosthesis is recommended during the night or using occlusal splint, especially in the case of teeth grinding or bruxism patients, in order to avoid intraoral injury to the user or damage in the overdenture abutments.
- Regular visits to the revision of the prosthesis should be performed, with the purpose to control possible variations caused by changes in the gums or prosthesis.

Abutments for screwed prosthesis (Capitel system and capitel mini)

Straight Capitel abutment

Clinical indication: These abutments are used for multiple screw prosthesis. Capitel pillar system is complemented with prosthetic solutions required for a screwed prosthesis. For more details, see the product catalog.

PRECAUTIONS AND INSTRUCTIONS FOR USE OF PROSTHETIC AND PREPROSTHETIC IMPLANT ABUTMENTS

Microdent Ektos Implant System

Material: Pillars for cemented prosthesis are made of titanium grade 5 according to ISO 5832-3. Abutments are made of titanium grade 5, peek, Cr-Co and POM.
Method of application: Select the appropriate pillar depending on the implant and patient's gingival height.
Key reference UTSNTICP allows the transport of the pillar-to-mouth. To fix the pillar it is required the use of the keys reference UTSNLEC. Recommended torque for fixing the capitel system is 30Ncm.
The prosthetic rehabilitation pillars will join the 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 pillar you should clean the threads of the implant by a corresponding Microdent internal thread cleaner.
Capitel does not allow unit prosthesis (crowns).

Capitel abutment angled
Clinical indication: The abutment angled is used in situations where the capitel abutment does not absorb implants disparallelism. The pillar system is complemented by Capitel prosthetic solutions required for the fabrication of a prosthesis screwed. For more details, consult the catalog of products.
Material: The pillars of screw prosthesis are made of titanium grade 5 according to ISO 5832-3.
Method of application: Select the appropriate abutment depending on the disparallelism kept in the implants and fixing to the implant by the corresponding retention screw. For fixing the retention screw of the prosthesis requires the use of the key MH120CAP reference. We recommend a 30 Ncm torque for fixing the screw.
The prosthetic rehabilitation will join Capitel abutment with the screw UTSNTRA. For screwing it, it is required the key reference DTOC120. Torque of 10 to 15 Ncm 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 pillar you should clean the threads of the implant by a corresponding Microdent internal thread cleaner.

Prosthesis retention screw
Clinical indication: Indicate 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: For screwing it, it is required the use of 1.20 mm hex wrench, recommending a maximum torque of 30Ncm
Precautions: Before inserting the pillar you should clean the threads of the implant by a corresponding Microdent internal thread cleaner.

PRESENTATION OF MICRODENT EKTOS SYSTEM IMPLANT ABUTMENTS
Packaging
Implant Microdent System S.L.U ensures that all preprosthetic abutments follow a manufacturing process, control and extreme cleaning before packaged in sterile area and later sterilized by irradiation.
Implant Microdent System S.L.U ensures that all prosthetic abutments follow a manufacturing process, control and extreme cleaning before being packaged.
Preprosthesis and prosthetic Microdent Ektos 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.
Preprosthetic abutments supply state (Healing abutments)
Preprosthetic abutments are presented in sterile condition.
Prosthetic abutments supply state.
Prosthetic 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.
	Precaution, consult the warnings.
	Sterilized by irradiation (Applies only to preprosthetic abutments).
	Manufacturer.

CONTRAINDICATIONS
None known.

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

WARNINGS AND PRECAUTIONS
Microdent Ektos preprosthetic and prosthetic 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 Ektos System abutments with others outside the mark can cause no optimal operation of these 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 EKTOS IMPLANT ABUTMENTS".
Abutments which must be tapped as retaining screws and pillars for overdenture retention are designed to be applied with 30Ncm torque. 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 retaining 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.U

PRECAUTIONS AND INSTRUCTIONS FOR USE OF PROSTHETIC AND PREPROSTHETIC IMPLANT ABUTMENTS

Microdent Ektos Implant System

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 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.U recommends you should have substitute products.
In general, during the oral use of our products the user must take precautions to prevent aspiration by the patient.

LIABILITY, SAFETY AND WARRANTY

The above instructions have been approved by Implant Microdent System S.L.U 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.
The guarantee will apply to Implant Microdent System S.L.U abutments provided they have been used following the instructions indicated.
Rework products that are not intended or required to be customized to their suitability for the user, and especially in the case of overdentures abutments, excludes of responsibility to Microdent Implant System S.L.U and will result in the loss of warranty on the product.
For a refund of the products that mention these instructions should follow the guidelines established in our conditions of sale and delivery.

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

CE
0051