703160 IFU Equator O-Ring-Revision 04

ITEMS

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REGULATORY TABLE

Non-sterile / Single Use / CE 1984

Symbology | Description
-----------|-------------------
SIZE       | Product size
REF        | Product code
LOT        | Batch Number
date       | Date of manufacture
shelf life | Shelf life
qty        | Quantity
mat        | Material used

Non-STERILE | Description
--------------|-------------------
X              | Non-sterile
X              | Do not reuse
X              | Do not reuse

Symbology | Description
-----------|-------------------
Rx only     | Notification required by FDA for United States market
Rx only     | Representative in the European Community
Rx only     | Manufacturer

CE 1984 | CE Mark for European Community market

ADDRESS

Manufactured by: ZİNE DENT İMPLANT ÜRETİM A.Ş.
Kızılırmak Mah. Ufuk Ünv. Cd. 1445. Sok. 2/B 8 Çukurambar-Çankaya-Ankara/TÜRKİYE

European Representative: Instradent AG, Peter Merian-Weg 12 CH-4052, Basel, Switzerland

Batch and date of manufacture: see label
EQUATOR O-RING

This device is intended for a specialized procedure, which must be performed by professionals trained in Prosthesis over implants. For optimum results, use the product knowing the appropriate techniques and always apply them under appropriate conditions.

DESCRIPTION
The O-Ring is a prosthetic abutment manufactured in polymer. It has the function to retain the prosthesis (overdenture), being positioned between the Attachment and the Cylinder. The colors represent the different degrees of retention, according to the descriptions below:
- Pink: for soft retention;
- Purple: for rigid retention;
- Black: for laboratory use.

INDICATIONS FOR USE
Prosthetic abutment used in implant-supported prosthesis, planned according to each case and aiming at function and esthetics.

APPLICATIONS
Equator O-Rings are used as a set of retention of the prosthesis (overdenture) over the Attachment.

CONTRAINDICATIONS
The overdenture system over attachment is contraindicated in cases which the angulation between implants exceeds 30°. This product is contraindicated for patients exhibiting signs of allergy or hypersensitivity to the chemical elements of the material: polymer.

HANDLING
CHANGING THE O-RING: Remove the prosthesis from the mouth. With the aid of the O-Ring Extractor Tool, completely remove the O-Ring from the cylinder. Clean the prosthesis before installing the new O-Ring. Then, install the new O-Ring with the aid of the O-Ring Insertion Tool, placing some pressure on it until its proper fit.

PRESENTATION AND STERILIZATION
This product is for single use and supplied non-sterile, being unitarily packaged.

PRECAUTIONS
- It is recommended to clean the final prosthesis before placing it in the mouth.
- In situations of severe bone atrophy, it is suggested to carefully evaluate the indication for a removable prosthesis, as the rehabilitation stability is also related to mucosal support.
- It is recommended to use the O-Ring tools to correct the parallel alignment between dental implants and determine the correct distance between O-Ring and Attachment.
- An inadequate selection of the O-Ring or the absent use of an O-Ring tool may compromise the functioning of the prosthesis and can cause premature wear of the O-Ring.
- During the finishing procedure of the prosthesis, care must be taken not to damage the O-Ring.
• This device should be replaced regularly, every 8 months or when it stops functioning. The patient must be instructed to return to the clinic regularly to have the prosthesis retention checked.
• Observe the conditions of intraoral tissues through clinical exams, X-rays and/or tomography. Failure to perform the pre-surgical assessment may compromise the success of the procedure.
• Inappropriate planning can compromise the performance of the implant/prosthesis unit leading to failures of the system, such as loss or fracture of the implant, loss or fracture of abutments and/or prosthetic screws.
• This product is for single use and cannot be reprocessed.
• Reuse of this product may cause: adverse biological effects of residual products, microorganisms and/or substances resulting from previous uses and/or reprocessing; changes in physical, mechanical and chemical properties of products, macro and micro structural, that can put at risk the desired functionality. The reuse of this product does not guarantee its safety or efficacy and disclaims any warranty of products.
• Do not use the product if its packaging is damaged.
• Do not use the product with its validity expired.
• Before each procedure, ensure the pieces fit perfectly.
• Ensure that the parts are not swallowed or aspirated by the patient.
• Some of the possible causes of unsuccessful bone integration and loss of the prosthesis during the treatment are the following: unsuitable osteotomy, infections, poor oral hygiene, occlusal trauma, systemic problems or diseases, low remaining bone quantity or quality, lack or failure of irrigation, use of instruments which are not specific and/or without cutting power, and lack of specific training.
• Make sure you have all the necessary instruments for the procedure according to surgical planning.
• Before each procedure, check the conditions of the Zinedent surgical instruments, always respecting their useful life. Replace the instruments if there is damage, deleted markings, compromised sharpening, deformation or wear.
• Always use the Zinedent product sequence. The use of prosthetic abutments and/or instruments from other manufacturers does not ensure the perfect function of the Zinedent Implant System and exempts any product warranty.
• It is the professional’s responsibility to use the Zinedent products according to their instructions for use.

ADVERSE EFFECTS
Adverse effects are not expected as long as the product is used in accordance with its instructions for use.

POST-OPERATIVE PRECAUTIONS AND MAINTENANCE
Instruct the patient as to the need for a professional medical monitoring after the surgery and to obey the guidelines regarding precautions, hygiene and prescription of drugs. The professional in charge is responsible for providing these guidelines.

STORAGE CONDITIONS
This product must be stored, in its original packaging, in a clean and dry location, at a maximum temperature of 40˚C and protected from direct sunlight.
DISPOSAL OF MATERIAL
All products and consumables used in the surgery for the installation of dental implants may endanger the health of anyone who handles them. Before discarding them into the environment, it is recommended to observe the current legislation and adhere to it.

DATE OF EXPIRATION
Written on the label.

LIFE CYCLE
This product can be used for the maximum period of 8 months.

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