703206 IFU Titanium Coping-Revision 02

ITEMS

CODE	DESCRIPTION	CE MARK
ZD18.013	MULTI SCREW TITANIUM COPING	CE 1984
ZD18.014	SINGLE SCREW TITANIUM COPING	CE 1984

REGULATORY TABLE

Sterile EO / Single Use / CE 1984

Symbology	Description
SIZE	Product size
REF	Product code
LOT	Batch Number
	Date of manufacture
	Shelf life
Qty	Quantity
MAT	Material used

STERILE EO	Sterile - ethylene-oxide
	Do not reuse
	Refer to instructions for use
	Upper limit of temperature
	Keep dry
	Keep protected from sunlight

Symbology	Description
	Do not use if package is damaged
CE 1984	CE Mark for European Community market
Rx only	Notification required by FDA for United States market
EC REP	Representative in the European Community
	Manufacturer

ADDRESSES

Manufactured by: ZİNEDENT 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

Titanium Coping

This device is intended for a specialized procedure, which must be performed only by professionals qualified in Dental Implants. For optimum results, use the product knowing the appropriate techniques and always apply them under appropriate conditions, including in an operating room.
Prosthetic abutments used as intermediaries between the installed implant and the prosthesis, planned according to each case, aiming at esthetics and function.

DESCRIPTION

The Titanium Coping is manufactured in titanium alloy and presents a cylindrical shape with external retentions for acrylic resin fixation. One of its ends presents a fitting for the installation over the corresponding implant/abutment.

INDICATIONS FOR USE

The Zinedent Implant System is intended to be surgically placed in the bone of maxilla or mandible to provide support for prosthetic devices, such as artificial teeth, to restore chewing function. It may be used with single-stage or two-stage procedures, for single or multiple restorations and may be loaded immediately when there is good primary stability and appropriate occlusal loading.

APPLICATIONS

This product is used in the confection of single- or multi-unit screw-retained prostheses over the prosthetic abutment or implant. It can be used directly in the mouth or in laboratory, using plaster models and analogs.
While selecting the abutment, make sure of the indication for use of the selected piece. Antirotational abutments are indicated for single-unit prostheses and rotational abutments for multi-unit prostheses.

CONTRAINDICATIONS

This product is contraindicated for patients exhibiting signs of allergy or hypersensitivity to the chemical elements of the material: titanium alloy.
This product is contraindicated for insufficient interocclusal space and unsatisfactory three-dimensional position of the implant.

HANDLING

In order to use the Titanium Coping in two-stage procedures, previous preparation of the soft tissues can be performed by using a healing abutment.
This product can be used in two different ways:
1. After installing the intermediary in the mouth, transfer its position through molding with the corresponding impression coping, according to appropriate techniques. Screw the coping over the analog and customize it according to the available interocclusal space. Produce the provisional prosthesis. Prosthesis structure adaptation and passivity tests must be performed. The autopolymerizable pacifying agent must be used in order to mask the grey aspect of the metal, preventing the provisional prosthesis to become translucent, which is very common when using acrylic resins.
2. The coping can be directly screwed in the mouth over the implant or intermediary, as indicated. Customize it, with abundant irrigation, according to the available interocclusal space. Produce the provisional prosthesis directly over it. Prosthesis structure adaptation and passivity tests must be performed.

For the installation, use the 1.2 Screwdriver with torque of 10 N.cm. For intraoral fixation, use a sterile screw.

TRACEABILITY LABEL

This product is supplied along with three labels that allow its traceability and must be attached to the following documents: • Medical record; • Collection tax document; • Document to be delivered to the patient (ask your advisor). The identification and traceability are performed through numeric codes REF and LOT.

PRESENTATION AND STERILIZATION

This product is for single use only and supplied sterile by the ethylene oxide method, being unitarily packaged. This product is supplied along with a sterile screw.

PRECAUTIONS

• It is recommended to clean the final prosthesis before its installation in the mouth.
• Ensure that the implant stability is sufficient to withstand the installation torque of the prosthetic abutment and its functional load, according to the implant instructions for use.
• This product is for single use only 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.
• Use appropriate material and technique for the impression procedure.
• Regarding the systemic appearance, consider the general state of the patient's health according to applicable literature. Regarding the local appearance, observe the conditions of the intraoral tissues.
• Special care must be taken during the provisional prosthesis confection so that the interocclusal space will not be insufficient or excessive.
• The sterilization is guaranteed only if the sterile barrier (full blister) is not damaged.
• This product must be used immediately after the opening of its packaging, in the moment of the procedure. If it is not used, discard it.
• The material selection of the prosthesis structure must consider general aspects of the patient.
• During installation, make sure to align the abutment to the implant insertion axis. Ensure it is perfectly seated on the implant. To do so, it is recommended to take periapical X-rays according to the parallel technique.
• Inadequate surgical and/or prosthetic 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.
• Do not use the product if its packaging is damaged.
• Do not use the product with its validity expired.
• For immediate load application, check the torque indication of the implant installed.
• Consult the torque to be applied to the prosthetic abutment used. Excess or insufficient torque may cause undesirable results.
• Check passivity and perform the occlusal and interproximal adjustment after the installation of the prosthesis, taking care to avoid compromising the implant/prosthesis assembly.
• Before each procedure, ensure the pieces fit perfectly.
• Ensure that the parts are not swallowed or aspirated by the patient.

• 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.

MAGNETIC RESONANCE IMAGING (MRI) - SAFETY INFORMATION

The Zinedent Implant System has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of the Zinedent Implant System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

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.

Not all products are available in all countries. Please, contact the authorized distributor.