703191 IFU Cast Coping-Revision 03

ITEMS

CODE	DESCRIPTION	CE MARK
ZD18.007	MULTI SCREW HYBRID COPING CAST	without CE
ZD18.011	SINGLE SCREW IMPRESSION COPING CAST	without CE

REGULATORY TABLE

Non-sterile / Single Use / without CE

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

Symbology	Description
MAT	Material used
NON-STERILE	Non-sterile
	Do not reuse
	Refer to instructions for use
	Upper limit of temperature
	Keep dry

Symbology	Description
	Keep protected from sunlight
	Do not use if package is damaged
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

Cast 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 indicated for prosthesis confection, used in laboratory to cast the base of elements which will be used in the intraoral rehabilitation.

DESCRIPTION

The Cast Coping is manufactured in castable polymer and presents a cylindrical shape with external retentions for waxing. 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.
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 insufficient interocclusal space and unsatisfactory three-dimensional position of the implant.

HANDLING

In order to use the Cast Coping in two-stage procedures, previous preparation of the soft tissues can be performed by using a healing abutment.
After installing the implant or intermediary, 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. Perform waxing. The model obtained must be inserted in a compatible coating to the alloy used in the casting process. Thus, it is obtained the structure that will function as the base for acrylization or porcelain application. Prosthesis structure adaptation and passivity tests must be performed.
For the installation, use the 1.2 Screwdriver with torque of 10 N.cm. For laboratory use, use the screw that is supplied along with this product. For intraoral fixation, purchase 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 non-sterile, being unitarily packaged. This product is supplied along with a non-sterile screw for laboratory use.

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 waxing so that the interocclusal space will not be insufficient or excessive.
• 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.

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.