703190 IFU Hybrid Technique Copings-Revision 03

ITEMS

CODE	DESCRIPTION	CE MARK
ZD18.001	MULTI SCREW HYBRID COPING BRASS	without CE
ZD18.002	MULTI SCREW HYBRID COPING TI	CE 1984
ZD18.003	MULTI SCREW HYBRID COPING CAST	without CE
ZD18.004	MULTI SCREW HYBRID COPING BRASS	without CE
ZD18.005	MULTI SCREW HYBRID COPING TI	CE 1984
ZD18.006	MULTI SCREW HYBRID COPING CAST	without CE
ZD18.008	SINGLE SCREW HYBRID COPING TI	CE 1984
ZD18.009	SINGLE SCREW HYBRID COPING BRASS	without CE
ZD18.010	SINGLE SCREW HYBRID COPING CAST	without CE

REGULATORY TABLE

Non-sterile / 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

Symbology	Description
NON-STERILE	Non-sterile
	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

HYBRID TECHNIQUE COPINGS

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.

DESCRIPTION

In order to perform the One Step Hybrid Technique, four exclusive prosthetic abutments are necessary:
Brass Coping: prosthetic abutment of laboratory use that presents a conical geometry in the external portion to fit on the cast coping. Its inner portion presents a compatible fitting to the planned prosthetic abutment.
Cast Coping: cylindrical prosthetic abutment that presents external retentions for waxing. Its inner portion presents a compatible fitting to the planned prosthetic abutment.
Titanium Coping: prosthetic abutment with external retentions and treated surface (porous or rough) for cement retention. It is the prosthetic intermediary of the one step hybrid technique which is cemented to the metallic structure and screwed between the intermediary and the prosthesis.
Working Screw (in laboratory): 1.2 mm fitting in one end and, in the other end, a compatible thread with the diameter of the prosthetic intermediary.

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

The one step hybrid technique is used for multi-unit screw-retained prostheses when there is the need to obtain passivity of the metallic structure without welding and regardless of the metal dimensional change after the casting process.

CONTRAINDICATIONS

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

HANDLING

In order to use the prosthetic abutments for the one step hybrid technique in two-stage procedures, previous preparation of the soft tissues can be performed by using a healing abutment.
After installing the intermediaries in the mouth, transfer their position through molding with the corresponding impression coping according to appropriate techniques.
CAST METALLIC STRUCTURE: Place the Brass Copings over analogs that correspond to the intermediary prosthetic abutment. On top of the Brass Copings, place the Cast Copings, fastening them with Working Screws (long). After that, connect with acrylic resin the Cast Copings that are parallelly connected. Perform the structure waxing and, once it is concluded, remove the Working Screws, submitting the infrastructure to the casting process with specific metallic alloy. Place the casting structure over the Brass Copings in order to check the fitting passivity. If necessary, provide internal wear in the regions

corresponding to the Cast Copings, which are now casted in metal, aiming to achieve structure passivity on Brass Copings. Once the structure passivity is achieved, perform internal retentions in Cast Copings in order to create mechanical retentions for the cement. Apply a thin layer of primer specific for metal (alloy primer) on this area. Substitute the Brass Copings, which present a slightly greater dimension (0.10 mm), for Titanium Copings, fastening them over their corresponding Analogs with their corresponding Screws (short).
Apply the primer specific for metal (alloy primer) on the external portion of Titanium Copings, obliterating the input hole with wax to avoid the entry of resinous cement. Also on the outer surface of the Titanium Copings and on the internal portion that corresponds to the Coping in the structure, apply a dual resinous cement. Still with fresh cement, press the structure over the Titanium Copings, immediately removing any overflown excess from the orifice. After cementing it, unscrew the infrastructure from the model and remove all the excess of remaining cement from the Titanium Copings edge. NOTE: For the cementation, it is recommended to use dual resinous cement Panavia F (Kuraray Co Ltd Tokyo-Japan) and the primer specific for metal Alloy Primer (Kuraray Co Ltd Tokyo-Japan). Follow the cement manufacturer's instructions. Proof and tests of passivity and adaptation of the prosthesis structure must be performed.
The Copings used in the one step hybrid technique must be used with the 1.2 Screwdriver, applying the recommended torque of 10 N.cm.

PRESENTATION AND STERILIZATION

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

PRECAUTIONS

• It is recommended to clean the final prosthesis before its installation in the mouth.
• 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 design of the prosthesis 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.
• Be aware in cases of patients that present signs of allergy or hypersensitivity to chemical elements of the material: titanium alloy Ti6Al4V-ELI.
• 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.
• 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.

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.