703188 IFU Prosthetic Screws-Revision 03

ITEMS

CODE	DESCRIPTION	CE MARK
ZD16.001	WORKING SCREW HYBRID	without CE
ZD16.002	MULTI SCREW COPING SCREW 4.1	CE 1984
ZD16.003	MULTI SCREW COPING SCREW 5.0	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

PROTHETIC SCREWS

This device is intended for a specialized procedure, which must be performed by professionals qualified in Prosthesis over Dental Implants. For optimum results, use the product with the knowledge of appropriate techniques and always apply them under appropriate conditions, including in an operating room.

DESCRIPTION

The Prosthetic Screw is manufactured in titanium alloy. Its head presents a geometry to fit the corresponding Driver/Screwdrivers, which will enable its use. Its body presents a thread with a geometry that will enable its fixation. Prosthetic Screws are available according to the table below:

Prosthetic Screw	Description
Coping Screw	Appropriate geometry to be internally threaded in the intermediary and for its head to be seated on the internal portion of corresponding Coping.
Working Screw	Appropriate geometry to be internally threaded in the analog and for its head to be seated on the portion on cast coping.

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 Coping Screw is used to fixate the Coping on the intermediary. It is indicated for clinic use.
The Working Screw is used to fixate the Coping on the intermediary analog. It is indicated only for laboratory use.

CONTRAINDICATIONS

The Coping Screw is contraindicated for patients exhibiting signs of allergy or hypersensitivity to the chemical elements of the material: titanium alloy Ti6Al4V-ELI.
The Working Screw presents no contraindications as long as it is used according to its instructions for use.

HANDLING

Capture the Prosthetic Screw using appropriate Drivers/Screwdrivers, according to the information in the table below. During the installation, make sure to align it to the abutment insertion axis.

Prosthetic Screw	Recommended Torque (N.cm)	Driver/Screwdriver
Coping Screw 4.1	10	Screwdriver 1.2 mm
Coping Screw 5.0		
Working Screw	10	

TRACEABILITY LABEL

The Coping Screws are supplied along with three labels that allow their 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, being unitarily packaged. The Coping Screws are supplied sterile by the ethylene oxide method and the Working Screw is supplied non-sterile.

PRECAUTIONS

• During installation, ensure it is aligned with the implant insertion axis, avoiding lockings and damage to the thread. To do so, it is recommended to use periapical X-rays with the parallel technique.
• Observe the conditions of the intraoral tissue, bone quality and quantity of the bed receiving the implant, through radiographic and/or tomography examinations. Not performing the pre-surgical assessment may compromise the success of the procedure.
• As for the systemic aspect, consider the general health of the patient. In particular, one must be careful in cases of patients who have allergies to drugs, local or systemic factors that may interfere with the healing process of the bone tissues or soft tissues, or the process of osseointegration. For example, the bone already exposed to radiation in the head and neck area, diabetes mellitus, anticoagulation drugs, hemorrhagic diathesis, bruxism, parafunctional habits, anatomically unfavorable bone situation, tobacco abuse, uncontrolled periodontitis, treatable jaws pathologies and oral mucosa abnormalities.
• Applying an insertion torque higher than the one recommended and using inadequate Drivers/Screwdrivers can damage the product and render the system unusable.
• 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.
• For the sterile items, the sterilization is guaranteed only if the sterile barrier (full blister) packaging 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.
• 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.
• 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.