703181 IFU TEC-2 IMPLANT-Revision 03

ITEMS

CODE	DESCRIPTION	CE MARK
ZD09.001	TEC-2 IMPLANT 3.5X13	CE 1984
ZD09.002	TEC-2 IMPLANT 4.3X13	CE 1984
ZD09.003	TEC-2 IMPLANT 4.3X8	CE 1984
ZD09.004	TEC-2 IMPLANT 4.3X10	CE 1984
ZD09.005	TEC-2 IMPLANT 4.3X11.5	CE 1984
ZD09.006	TEC-2 IMPLANT 4.3X16	CE 1984
ZD09.007	TEC-2 IMPLANT 5.0X8	CE 1984
ZD09.008	TEC-2 IMPLANT 5.0X10	CE 1984
ZD09.009	TEC-2 IMPLANT 5.0X11.5	CE 1984
ZD09.010	TEC-2 IMPLANT 5.0X13	CE 1984
ZD09.011	TEC-2 IMPLANT 5.0X16	CE 1984
ZD09.012	TEC-2 IMPLANT 3.5X8	CE 1984
ZD09.013	TEC-2 IMPLANT 3.5X10	CE 1984
ZD09.014	TEC-2 IMPLANT 3.5X11.5	CE 1984
ZD09.015	TEC-2 IMPLANT 3.5X16	CE 1984

REGULATORY TABLE

Sterile R / Single use / CE 1984

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

Symbology	Description
MAT	Material used
STERILE R	Product sterilized through gamma rays
	Do not reuse
	Refer to instructions for use
40° C	Upper limit of temperature
	Keep dry

Symbology	Description
	Keep protected from sunlight
	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

TEC-2 IMPLANTS

This device is intended for a specialized procedure, which must be performed by professionals qualified in 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

TEC-2 Implants are manufactured in commercially pure titanium (grade 4).

MACROGROMETRY: • Morse taper prosthetic interface with internal hexagonal indexer; • Unique prosthetic interface, regardless of implant diameter; • Tapered format with trapezoidal profile threads.

SURFACE: rough surface obtained by double treatment: abrasive blasting and acid substraction.

Implant diameters (mm)	Lengths (mm)
3.5, 4.3, and 5.0	8, 10, 11.5, 13, and 16

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 TEC-2 Implant is indicated for surgical intraoral installation, in bone types III/IV or in bone types I/II after using the Bone Tap, according to Lekholm & Zarb (1985) bone quality classification. It is used to support single- or multiple-unit prostheses in immediate or conventional loading protocols. It may be installed immediately after dental root extraction. Note: For the purposes of immediate loading, primary stability must reach, at least, 32 N.cm and the patient must present physiological occlusion.

CONTRAINDICATIONS

Implants of diameter of 3.5 mm associated with 30° angled abutments are contraindicated for final single-unit rehabilitation in the molar region.

This product is contraindicated for patients exhibiting signs of allergy or hypersensitivity to the chemical elements of the material: titanium.

This product is contraindicated in the presence of acute inflammatory or infectious processes in live tissue, unsuitable bone volume and/or quality, systemic complications or diseases such as; bone metabolism disorders, blood clotting disorders, unsuitable healing capacity, incomplete jawbone growth, uncooperative and not motivated patient, abuse of drugs or alcohol, psychosis, prolonged functional disorders which resist any treatment with medications, xerostomia, weakened immunological system, diseases which require the use of steroids, endocrine diseases, insufficient oral hygiene, and pregnancy.

HANDLING

Perform drilling of the bone bed using drills in good cutting conditions with rotation between 500 and 800 rpm for bone types III/IV and between 800 and 1200 rpm for bone types I/II, under abundant irrigation. Select the sequence of drills according to the selected implant. The insertion depth of the drills must comply with the planning of the implant final position. In order to install TEC-2 implants in bone types I/II, use the Bone Tap as the last instrument before implant placement, with rotation of 30 rpm, under abundant irrigation. For infraosseous positioning of the coronal portion of the implant, it is recommended to add 1 to 2 mm in length to the implant during surgical instrumentation. Countersink Drills present three markings which correspond to the planned position of the implant in relation to the bone crest: leveled, 1 or 2mm below the alveolar crest. The drills and Bone Taps must be used in accordance with their own instructions for use.

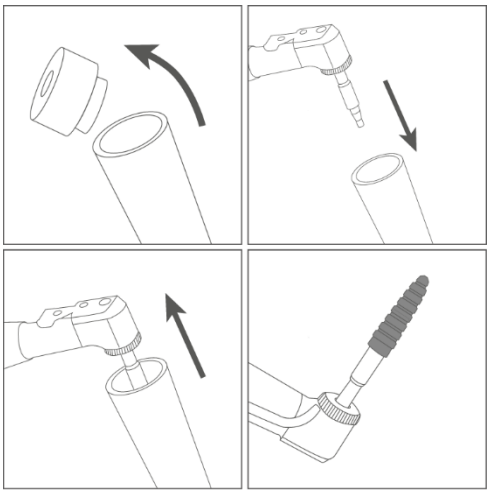
	Starter Drill	Twist Drill 2.0	Twist Drill 3.5	Countersink Drill 2.8 / 3.5	Twist Drill 4.3	Countersink Drill 3.6 / 4.3	Twist Drill 5.0	Countersink Drill 4.3 / 5.0	Bone Tap 3.5	Bone Tap 4.3	Bone Tap 5.0
3.5 mm	✓	✓	✓	*					**		
4.3 mm	✓	✓	✓		✓	*				**	
5.0 mm	✓	✓	✓		✓		✓	*			**

✓ Recommended sequence

* Optional

** Recommended for bone types I and II

INSTALLATION OF THE DENTAL IMPLANT



WARNING: The images are merely illustrative and do not represent the actual dimensions and features of the product.

• The cardboard and blister packaging must be opened, manually, without the use of sterile gloves. • Break the seal of the cardboard packaging and remove the blister. • Remove the protection from the blister pack. • Deposit the sterile vial over the surgical field. NOTE: The clear tube and implant must be handled with a sterile surgical glove, in a surgical environment. • Hold the vial using the non-dominant hand and take the lid off. • For installation using a surgical motor, hold the implant with the Screwdriver for Contra-Angle, keeping the connection stable and slightly rotating the vial, searching for the perfect fit between connection and implant. • Take the implant to the surgical cavity. • In the surgical motor, use maximum torque of 32 N.cm and rotation of 30 rpm. • Complete the installation of the implant with the Ratchet, with the Screwdriver for Ratchet. • Laser marking in the end of the connection indicates the final position of the implant (1, 2 or 3 mm infraosseous). • The maximum installation torque suggested is of 60 N.cm. • At the end of the installation, ensure that one of the six spherical indications on the screwdriver body, which correspond to the surfaces of the internal indexer of the implant, is facing towards the vestibular surface.

• Load application, according to torque, is described in the following table:

Load Application	Min. Torque (N.cm)	Max. Torque (N.cm)
Delayed Loading*	10	60
Immediate Loading	32	60

* Associated with the use of Healing Abutment. When the installation torque is less than 10 N.cm, the use of the Cover Screw is recommended.

PROSTHETIC SEQUENCE

In the immediate postoperative period, according to the chosen loading protocol, install the cover screw, healing abutment or prosthetic abutment, respecting the recommendations and limitations.

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 and supplied sterile by the gamma radiation method, being unitarily packed in a packaging that offers triple protection: carton box, blister and clear tube.

PRE-OPERATORY AND PROSTHETIC PLANNING

The model, diameter, length, position and quantity of implants must be selected for each clinical case, considering the anatomy, quality and quantity of bone and space available. When necessary, execute the wax-up diagnostic of the patient. In situations in which there are relatively high loads, special care must be taken to ensure the suitable alignment of the implant(s), abutment(s) prosthetics(s) and prosthesis.
The maximum angulation allowed for TEC-2 implants is 30° degrees, since the maximum angulation of prosthetic abutments is also 30 degrees.

PRECAUTIONS

• Due to the limited mouth opening in the posterior region, an assessment is required prior to the installation of long implants in the region of premolars and molars. The installation of long implants in these regions may require them to be installed at an angle.
• 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.
• Treatment with bisphosphonates results in potential risk of peri-implant osteonecrosis.

• 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, loosening or fracturing of the prosthetic screws.
• The material to be used during the procedure must be sterile.
• This product is for single use and cannot be reused.
• 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 and efficacy and disclaims any warranty of products.
• Do not use the product if its packaging is damaged.
• 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 with its validity expired.
• The maximum installation torque suggested is of 60 N.cm. Insertion torque greater than the one recommended can make the system inoperative.
• Check passivity and perform occlusal and interproximal adjustment after installation of the prosthesis, avoiding impairment of the implant/prosthesis assembly.
• Ensure that the parts are not swallowed or aspirated by the patient.
• Before each procedure, make sure the pieces are properly seated.

• 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

The installation of dental implants, as well as any other surgical procedure, may cause a slight discomfort and localized edema. More persistent symptoms can occur such as: chronic pain related to the dental implant, permanent paresthesia, dysesthesia, loss of maxillary/mandibular bone edge, systemic of localized infection, oroantral or oronasal fistula, adjacent teeth affected unfavorably, irreversible damage to adjacent teeth, fracturing of the implant, jaw, bone or prosthesis, esthetic problems, injury of the nerves, exfoliation, hyperplasia.
Any failure in osseointegration and loss of the prosthesis during treatment may be caused by: inadequate osteotomy, infections, diseases or systemic problems, low quality or volume of the remaining bone, absence or failure of irrigation, use of nonspecific instruments and/or instruments without cutting power, poor oral hygiene, occlusal trauma, lack of prosthetic passivity and lack of specific training.

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.