# 703174 IFU Healing Abutments-Revision 02

## ITEMS

| CODE | DESCRIPTION | CE MARK |
|---|---|---|
| ZD06.001 | HEALING ABUTMENT 3.3X1.5 | CE 1984 |
| ZD06.002 | HEALING ABUTMENT 3.3X2.5 | CE 1984 |
| ZD06.003 | HEALING ABUTMENT 3.3X3.5 | CE 1984 |
| ZD06.004 | HEALING ABUTMENT 4.5X1.5 | CE 1984 |
| ZD06.005 | HEALING ABUTMENT 4.5X2.5 | CE 1984 |
| ZD06.006 | HEALING ABUTMENT 4.5X3.5 | CE 1984 |
| ZD06.009 | HEALING ABUTMENT 3.3X4.5 | CE 1984 |
| ZD06.010 | HEALING ABUTMENT 3.3X5.5 | CE 1984 |
| ZD06.011 | HEALING ABUTMENT 4.5X4.5 | CE 1984 |
| ZD06.012 | HEALING ABUTMENT 4.5X5.5 | 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

# HEALING ABUTMENTS

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

The Healing Abutment is a prosthetic abutment of provisory use manufactured in titanium alloy. There are indications of gingival heights marked on its body. One of its ends presents a fitting for the 1.2 Screwdriver. The Healing Abutments are available in diameters of 3.3 and 4.5, in the gingival heights of 1.5, 2.5, 3.5, 4.5, and 5.5mm.

## 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 Healing Abutment is used for the maintenance of soft tissues during osseointegration of implants, considering the conventional loading protocol.
It may be used in the implant installation surgery or in the reopening surgery (second surgical stage). It is indicated according to the interocclusal space available, existing gingival height, and three-dimensional position of the implant.

## CONTRAINDICATIONS

This product is contraindicated for patients exhibiting signs of allergy or hypersensitivity to the chemical elements of the material: titanium alloy Ti6Al4V-ELI.
The use of the Healing Abutment, in the same surgical stage, over implants that have not achieved 10 N.cm of installation torque is contraindicated.
Wear of any type is contraindicated for this product.

## HANDLING

After opening the sterile packaging, deposit the Healing Abutment over a sterile surface, capture it with the 1.2 Screwdriver and install it on the implant with maximum torque of 10 N.cm. When installed in the same surgical procedure of implant installation, suturing must be performed after fixating the Healing Abutment.

## PRESENTATION AND STERILIZATION

This product is for single use and supplied sterile by the ethylene oxide method, being unitarily packaged.

## PRECAUTIONS

- It is recommended to remove the device up to 6 months after its installation.
- During installation, ensure it is aligned with the implant insertion axis, avoiding lockings and damage to the thread.
- This product cannot be used for supporting removable prostheses.

• The maximum installation torque suggested is of 10 N.cm. Insertion torque greater than the one recommended can make the system inoperative.
• 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.
• Be aware in cases of patients that present signs of allergy or hypersensitivity to chemical elements of the material: titanium alloy Ti6Al4V-ELI.
• 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.
• This product must be used sterile.
• 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.
• Some of the possible causes of unsuccessful bone integration and loss of the prosthesis during the treatment are the following: unsuitable osteotomy, infections, deficient oral hygiene, occlusal trauma, systemic problems or diseases, low remaining bone quantity or quality, lack or failure of irrigation, use of instruments which are not specific and/or without cutting power and lack of specific training.
• 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.