703180 IFU Intraoral Scanbody-Revision 03

ITEMS

CODE	DESCRIPTION	CE MARK
ZD08.022	INDEXED IMPLANT INTRAORAL SCANBODY	CE Class I
ZD08.024	MULTI SCREW ABUTMENT INTRAORAL SCANBODY	CE Class I
ZD08.026	ABUTMENT INTRAORAL SCANBODY	CE Class I

REGULATORY TABLE

Non-sterile / Single use / CE Class I

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
CE	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

INTRAORAL SCANBODY

This device is intended for a specialized procedure, which must be performed by professionals qualified with specific training in CAD/CAM technology. For optimum results, use the product knowing the appropriate techniques and always apply them under appropriate conditions.
It is recommended to use the CAD/CAM Dental Wings software.

DESCRIPTION

The Intraoral Scanbody is manufactured in Polyetheretherketone (PEEK - high-performance polymer, specific for medical use). It is supplied along with a screw in titanium alloy–and is available according to the table below:

Scanbody	Identification on Scanbody	Format
Implant	8	Antirotational
Multi Screw Abutment	10	Rotational
Abutment	14	Antirotational

INDICATIONS FOR USE

Instrument to assist in transferring the position and orientation of the implant/prosthetic abutment installed in the mouth, respecting dimensions and tolerance indications, and aiming at esthetics and function.

APPLICATIONS

This product is used over implant/prosthetic abutment for transferring its position during intraoral scanning using the CAD/CAM technology.

CONTRAINDICATIONS

This product is not indicated for extraoral scanning.
This product cannot be customized.
This product is contraindicated for patients exhibiting signs of allergy or hypersensitivity to the chemical elements of the material: PEEK.

HANDLING

Screw the Scanbody over the corresponding implant/abutment. Its adaptation over it must be made through the use of the Screwdriver 1.2, with the application of a maximum torque of 10 N.cm.

Ensure the pieces fit perfectly, making sure there are no rotational or vertical gaps. If existing, these spaces indicate that the Scanbody is not properly fit and must be repositioned. Ensure the alignment of the Scanbody in the implant/abutment axis, avoiding its locking or causing damages to the system.

Follow the manufacturer’s instructions for the scanning procedure. If necessary and according to the manufacturer’s instructions, use scanning spray or liquid over the region, avoiding to spray on the Indexed Implant Intraoral Scanning.

After the scanning procedures, ensure the alignment between the Scanbody and the CAD/CAM library.

PRESENTATION AND STERILIZATION

This product is for single use and supplied non-sterile, being unitarily packaged. It is supplied along with a titanium screw. This product must be cleaned and sterilized before its use.
The following sterilization methods are recommended: moist heat (steam) autoclave, gravity-displacement or dynamic-air-removal (fractionated vacuum) cycle, unwrapped, 3-minute exposure at 132°C (270°F). The product must be unwrapped on an appropriate tray. Use the sterilized restoration immediately after sterilization, do not store.

PRECAUTIONS

• The use of the Indexed Implant Intraoral Scanbody is not indicated for scanning and confectioning multiple-unit prostheses.
• For multi-unit restorations, use an intermediate over the implant and the corresponding scanbody.
• Ensure not to use the scanning spray/liquid outside de oral cavity.
• Before using this product, ensure it is clean and that it has the same prosthetic interface as the implant/prosthetic abutment to be scanned.
• If its platform is damaged, using this piece can lead to unsatisfactory scanning results.
• Ensure that the implant stability is sufficient to withstand insertion and removal procedures of the Indexed Implant Intraoral Scanbody.
• 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 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.
• Consult the torque to be applied. The application of excessive or insufficient torque may lead to undesirable results.
• 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.
• 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.

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