



703178 IFU Lab Scanbody-Revision 03

ITEMS

CODE	DESCRIPTION	CE MARK
ZD08.011	INDEXED IMPLANT SCANBODY	without CE
ZD08.023	MULTI SCREW ABUTMENT SCANBODY	without CE
ZD08.025	ABUTMENT SCANBODY	without CE

REGULATORY TABLE

Non-sterile / Single Use / without CE

Symbology	Description	Symbology	Description	Symbology	Description
	Product size		Material used		Keep protected from sunlight
	Product code		Non-sterile		Do not use if package is damaged
	Batch Number		Do not reuse		Notification required by FDA for United States market
	Date of manufacture		Refer to instructions for use		Representative in the European Community
	Shelf life		Upper limit of temperature		Manufacturer
	Quantity		Keep dry		

ADDRESSES

Manufactured by: ZINEDENT İMPLANT ÜRETİM A.Ş.
Kızılırmak Mah. Ufuk Ünv. Cd. 1445. Sok. 2/B 8 Çukurambar-Çankaya-Ankara/TÜRKİYE

European Representative: Intradent AG, Peter Merian-Weg 12 CH-4052, Basel, Switzerland

Batch and date of manufacture: see label

LAB SCANBODY

This device is intended for a specialized in-laboratory 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 Dental Wings, exocad or 3Shape scanning softwares.

DESCRIPTION

The Scanbody for laboratory use is manufactured in Polyetheretherketone (PEEK - high-performance polymer, specific for medical use) and presents a cylindrical shape. 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.

APPLICATIONS

This product is exclusively used in laboratory for transferring to the software the exact position and orientation of the implant/prosthetic abutment. For this transference, the plaster model is scanned using the CAD/CAM technology, according to each case planned, respecting the diameters and indications of tolerances of the implants/abutments.

CONTRAINDICATIONS

This product is not indicated for intraoral scanning.

This product cannot be customized.

HANDLING

Place the Scanbody over the corresponding Analog on the plaster model. Its adaptation on the Analog 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 Analog axis, avoiding its locking or causing damages to the system.

For the scanning procedures, the scanning device manufacturer's instruction must be followed. If using a spray for the scanning, follow the manufacturer's instructions and avoid spraying over the Scanbody.

PRESENTATION AND STERILIZATION

This product is for single use and supplied non-sterile, being unitarily packaged. It is supplied along with a screw in titanium alloy.

PRECAUTIONS

- If its platform is damaged, using this piece can lead to unsatisfactory scanning results.
- Before using the product, ensure that it is clean and it has the same prosthetic platform for use.
- 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.
- 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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exocad is a trademark or registered trademark of exocad GmbH.
3Shape is a trademark or registered trademark of 3Shape A/S.

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