703205 IFU Indexed Titanium Bases for C-Revision 01

ITEMS

CODE	DESCRIPTION	CE MARK
ZD35.008	INDEXED TITANIUM BASE FOR C 0.8	CE 1984
ZD35.009	INDEXED TITANIUM BASE FOR C 1.5	CE 1984
ZD35.010	INDEXED TITANIUM BASE FOR C 2.5	CE 1984
ZD35.011	INDEXED TITANIUM BASE FOR C 3.5	CE 1984
ZD35.012	INDEXED TITANIUM BASE FOR C 4.5	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

INDEXED TITANIUM BASES FOR C

This device is intended for a specialized procedure, which must be performed only by professionals qualified in Dental Implants with specific training in CAD/CAM technology, on the Sirona Dental CAD/CAM System for digitalization and confection of custom prostheses.
For optimum results, use the product knowing the appropriate techniques and always apply them under appropriate conditions.

DESCRIPTION

The Indexed Titanium Base for C is an intermediate prosthetic abutment manufactured in titanium alloy. It presents a cylindrical format with indexing guide for coping fitting. It has a cementable portion area of 4.7 mm with gingival height variations from 0.8 to 4.5 mm. The geometry of the cementable portion area of the Indexed Titanium Base for C is compatible with L blocks in zirconia or lithium disilicate available for CEREC®. Indexed Titanium Bases for C are supplied along with a coupled screw.

INDICATIONS FOR USE

This product is indicated to be installed over the implant, providing support for customized prosthetic restorations such as copings or crowns.

APPLICATIONS

This product is indicated according to the available interocclusal space, existing transmucosal height and three-dimensional implant position.
Custom-made prosthetic structures must be used in single-unit restorations cemented over the Indexed Titanium Base for C which is screwed on the implant.
It is recommended to use the CAD/CAM technique through the Sirona Dental CAD/CAM System.

WARNING

Indexed Titanium Bases for C are supplied straight/without angulation and cannot be modified.
Implants in combination with Indexed Titanium Bases for C with angled prosthetic structures are recommended according to the following table:

Ø Implant (mm)	Mouth region for installation	Max. angulation of prosthetic structure	Zirconia	IPS e.max CAD
3.5	1-2	20°	✓	✓
≥ 4.3	1-8	20°	✓	✓

Implants of diameter of 3.5 mm associated with crowns / copings / structures angled up to 20° are only recommended for the incisor region (1-2).
Implants of diameter greater than or equal to 4.3 mm associated with crowns / copings / structures angled up to 20° are recommended for all the regions of the mouth (1-8).

CONTRAINDICATIONS

The Indexed Titanium Base for C does not allow any customization, being contraindicated for cases of multi-unit restorations and not compatible with Software Sirona Galileos®.
This product is contraindicated for patients exhibiting signs of allergy or hypersensitivity to the chemical elements of the material: titanium alloy Ti6Al4V-ELI.

HANDLING

FOR INTRAORAL SCANNING: Select and install the Indexed Titanium Base for C on the implant according to preplanning. Insert the Scanbody compatible with the equipment of CAD/CAD system used over the abutment, and perform scanning as indicated by the manufacturer. Ensure the correct fit of the Scanbody on the Indexed Titanium Base for C.

FOR PLASTIC MODEL SCANNING: Perform molding of the implant according to preplanning, considering the clinical situation of the patient and the implant interface. Use artificial gingiva on the plaster model to simulate the patient's soft tissue. Confection the plaster model according to appropriate techniques. Select and install the Indexed Titanium Base for C on the Analog. Insert the Scanbody compatible with the equipment of CAD/CAD system used over the abutment, and perform scanning as indicated by the manufacturer. Ensure the correct fit of the Scanbody on the Indexed Titanium Base for C.

DESIGN OF THE STRUCTURE OF THE PROSTHESIS: Design the prosthesis structure according to the previous prosthetic planning and the raw material to be used. Indexed Titanium Bases for C for Zinedent implants can be used with the Sirona products, with any of the libraries of the Sirona inLab Software (Version 3.65) or Sirona CEREC® Software (Version 4.2) along with Sirona products, as shown in the table below:

Products to be used along with the Indexed Titanium Base for C				
Library	Scanbody* (Sirona)	REF Scanbody* Omnicam (Sirona)	REF Scanbody* Bluecam / Ineos (Sirona)	Griding Block***
NBB 3.4 L	L	6431329	6431303	inCoris ZI meso (L) IPS e.max CAD (L)
NB A 4.5 L				
SSO 3.5 L				
S BL 3.3 L				
S BL 4.1 L				
BO 3.4 L				

*The Scanbody to be used with the Indexed Titanium Base for C is not supplied by Zinedent; it is an accessory of the Sirona Dental CAD/CAM System.

**The material to be used with the Indexed Titanium Base for C is not supplied by Zinedent; inCoris ZI meso (L) is sold by Sirona and IPS e.max CAD is sold by Ivoclar Vivadent.

Design the external form of the meso-structure according to the preparation guidelines for the superstructure required.

Note: The minimum wall thickness around the wall of the screw channel of the structure is variable according to the material, as shown in the following table. The maximum angulation of the structure cannot exceed 20°. The degree of structure tapering cannot exceed 6° (coping). Regarding an angled structure, the cementable portion height from the emergence profile (prosthetic height) cannot exceed 10 mm.

Material	**Minimum Thickness (mm)**
Zirconia	0.5
IPS e.max CAD	0.9

Make sure not to exceed an angle of 20° between the implant axis and the restoration axis. If the meso-structure is designed to receive aesthetic ceramic, make sure that this will not narrow the channel for the screw. The cavity for fitting the meso-structure on the Indexed Titanium Base for C cannot be coated. Make sure there are no sharp edges in the design of the meso-structure. Before confectioning the

prosthesis structure, ensure that the size of the machining block is compatible with the design. Confection the piece as indicated, using Sirona CEREC® MC X, inLab MC XL, or inLab MC X5 machining equipment.

CLINICAL PROOF OF THE PROSTHESIS STRUCTURE: Perform a clinical proof of the created structure on the Indexed Titanium Base for C. Ensure its proper fit between the pieces, clinically and with an X-ray. Make sure there is occlusal and interproximal space and that the structure of the prosthesis still meets the aesthetic and functional requirements. Finalize the restoration according to prosthetic planning and appropriate techniques.

CEMENTATION OF THE INDEXED TITANIUM BASE FOR C: It is recommended to screw the Indexed Titanium Base for C onto the implant analog throughout the process of prosthesis finishing. For that, place the abutment over the analog and slightly tighten in with the 0.9 Screwdriver. The surface of the Indexed Titanium Base for C for prosthesis structure cementation must be blasted (aluminum oxide, 50 µm, maximum pressure of 2 bar). Protect the access of the screw (with Teflon and resin compound) during the cementation process. Note: it is recommended to use chemically activated resin cements for bonding on metals (e.g. Panavia – Kuraray). On Lithium Disilicate (IPS e.max CAD), the use of IVOCLAR Multilink cement is required. Handling of the cement must follow its manufacturer's instructions. Apply the cement on the external portion of the Indexed Titanium Base for C and press the restoration, fitting it according to the indexing guide. Remove excessive cement which overflows through its hole. After setting of the cement, unscrew the structure from the analog and removed the excessive cement remaining on the edges of the Indexed Titanium Base for C. When Lithium Disilicate is applied, the use of high-opacity cement is mandatory.

INSTALLATION OF THE CUSTOMIZABLE PROSTHESIS: Clean and sterilize the assembly (abutment and custom prosthesis) before placing it in the mouth. After these procedures, position the assembly in the patient's mouth using the 0.9 Screwdriver with the indicated torque of 20 N.cm. Perform any necessary occlusal and interproximal adjustments.

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.

SANITATION

This product must be cleaned and sterilized before its installation in the mouth.

1st step: Fully immerse the part in enzymatic detergent (diluted according to the manufacturer). 2nd step: Wash in ultrasonic cleaner for approximately 10 to 15 minutes. 3rd step: Rinse with distilled water in abundance, until wastes from the solution are completely removed. The use of nylon brushes is recommended. 4th step: Dry with a clean and dry cloth or with compressed air. 5th step: Perform a visual inspection, observing if there are any failures in the cleaning process. If there are still wastes, the part must be once again immersed in detergent – 1st step – and, if necessary, the cleaning must be performed with the aid of a nylon brush. Repeat the rinsing and drying sequence.

PRESENTATION AND STERILIZATION

This product is supplied along with a coupled screw.

This product is for single use only and supplied sterile by the method of ethylene oxide, being unitarily packaged. The final prosthesis must be sterilized before its installation in mouth.

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 prosthetic interface of the Indexed Titanium Base for C does not allow any customization.
• Make sure that the manufacturer's recommendations are shared between the dentist and the laboratory during the confection process of the prosthesis.
• Inform the laboratory that any modification or damage to the prosthetic interface requires the piece to be discarded and remade.
• 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.
• Use appropriate material and technique for the implant impression procedure.
• The Indexed Titanium Base for C is not indicated for multi-unit restorations.
• The Indexed Titanium Base for C is not indicated for cementation in the mouth.
• Regarding the systemic appearance, consider the general state of the patient's health according to applicable literature. Regarding the local appearance, observe the conditions of the intraoral tissues.
• Special care must be taken during the design of the prosthesis so that the interocclusal space will not be insufficient or excessive.
• The sterilization is guaranteed only if the sterile barrier (full blister) 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.
• The material selection of the prosthesis structure must consider general aspects of the patient.
• During installation, make sure to align the abutment to the implant insertion axis. Ensure it is perfectly seated on the implant. To do so, it is recommended to take periapical X-rays according to the parallel technique.
• 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.
• Be aware in cases of patients that present signs of allergy or hypersensitivity to chemical elements of the material: titanium alloy Ti6Al4V-ELI.
• This product must be used sterile.
• Do not use the product if its packaging is damaged.
• Do not use the product with its validity expired.
• For immediate load application, check the torque indication of the implant installed.
• Consult the torque to be applied to the prosthetic abutment used. Excess or insufficient torque may cause undesirable results.
• Check passivity and perform the occlusal and interproximal adjustment after the installation of the prosthesis, taking care to avoid compromising the implant/prosthesis assembly.
• 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.