703157 IFU Analog-Revision 03

ITEMS

CODE	DESCRIPTION	CE MARK
ZD01.001	IMPLANT ANALOG	without CE
ZD01.002	MULTI SCREW ABUTMENT ANALOG	without CE
ZD01.003	SINGLE SCREW ABUTMENT ANALOG	without CE
ZD01.004	INDEXED ABUTMENT ANALOG	without CE
ZD01.005	INDEXED ABUTMENT ANALOG	without CE
ZD01.006	INDEXED ABUTMENT ANALOG	without CE
ZD01.007	INDEXED ABUTMENT ANALOG	without CE

REGULATORY TABLE

Non-sterile / Single Use / without CE

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
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

ANALOG

This device is intended for a specialized procedure, which must be performed by professionals trained in Prosthesis over implants. For optimum results, use the product knowing the appropriate techniques and always apply them under appropriate conditions.

DESCRIPTION

Analogs are prosthetic abutments for laboratory use, manufactured in titanium alloy. They present a geometry with channels that favor their retention on the plaster model.
They are available in the models listed in the table below:

Analog	Dimensions (mm)	Visual
for Implant	Single size	Metallic
for Multi Screw Abutment	Ø4.1 and Ø5.0	
for Indexed Abutment	3.3x4, 3.3x6, 4.5x4 and 4.5x6	
for Single Screw Abutment	Single size	Blue

INDICATIONS FOR USE

Indicated for use in laboratory phase during the obtention of the plaster model for preparing the prosthesis over implant, reproducing the dimensions and the positioning of the prosthetic intermediate or implant.

APPLICATIONS

Analogs are used in the laboratory phase while obtaining the plaster model for producing the prosthesis over implant, reproducing the dimensions and the positioning of the implant or prosthetic intermediate.

CONTRAINDICATIONS

Wear of any type on this product is contraindicated.

HANDLING

Perform the impression of the implant or prosthetic abutment by using the corresponding Impression Coping and following the appropriate techniques. After obtaining the mold, screw/plug the Analog into the Impression Coping. When applicable, for screw tightening, use torque and wrench/connection as indicated by the screw/prosthetic abutment. Pour rubbery material to simulate the soft tissue of the patient. Pour the plaster in the mold, covering the whole Analog. After the plaster setting phase, separate the mold from the plaster. Unscrew/unplug the Impression Coping from the Analog.

PRESENTATION AND STERILIZATION

This product is for single use and supplied non-sterile, being unitarily packaged.

PRECAUTIONS

• After making the prosthesis, evaluate its fit by placing it over the Analog.
• Inadequate 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.
• 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.
• Do not use the product with its validity expired.
• When making the prosthesis, consult the torque indicated for the prosthetic abutment used. Excessive torque may cause undesirable results, rendering the system inoperable.
• 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

Adverse effects are not expected as long as the product is used in accordance with its instructions for use.

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.