



703193 IFU Indexed Abutment Castable Coping-Revision 02

ITEMS

CODE	DESCRIPTION	CE MARK
ZD18.016	INDEXED ABUTMENT COPING CASTABLE	without CE
ZD18.018	INDEXED ABUTMENT COPING CASTABLE	without CE
ZD18.020	INDEXED ABUTMENT COPING CASTABLE	without CE
ZD18.021	INDEXED ABUTMENT COPING CASTABLE	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	Non-sterile		Do not use if package is damaged
	Batch Number		Do not reuse	Rx only	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 Ün. 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

INDEXED ABUTMENT CASTABLE COPING

This device is intended for a specialized procedure, which must be performed only by professionals qualified in Dental Implants. For optimum results, use the product knowing the appropriate techniques and always apply them under appropriate conditions, including in an operating room.

Prosthetic abutments indicated for prosthesis confection, used in laboratory to cast the base of elements which will be used in the intraoral rehabilitation.

DESCRIPTION

The Indexed Abutment Castable Coping is manufactured in castable polymer, presenting a cylindrical shape. One of its end presents a fitting for installation over the Indexed Abutment. Its body presents retentions for waxing.

Indexed Abutment Castable Copings are available in cementation portion heights of 4 and 6 mm, in diameters of 3.3 and 4.5 mm.

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

This product is used in the confection of the metallic structure of cement-retained prostheses over the Indexed Abutment.

While selecting the abutment, make sure of the indication for use of the selected piece. Indexed Abutments are indicated only for the confection of single-unit cement-retained prostheses.

CONTRAINDICATIONS

This product is contraindicated for insufficient interocclusal space and unsatisfactory three-dimensional position of the implant.

HANDLING

In order to use the Indexed Abutment Castable Coping in two-stage procedures, previous preparation of the soft tissues can be performed by using a healing abutment.

After installing the intermediary, transfer its position through molding with the corresponding impression coping, according to appropriate techniques. Fit the coping over the analog and perform waxing. The model obtained must be inserted in a compatible coating to the alloy used in the casting process. Thus, it is obtained the structure that will function as the base for acrylization or porcelain application. Prosthesis structure adaptation and passivity tests must be performed. Cementation is performed in mouth according to the instructions of the cement manufacturer. It is important to know the technique in order to avoid cement and chemical burns on tissues adjacent to the implant. Protect the access to the screw throughout the cementation process.

PRESENTATION AND STERILIZATION

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

PRECAUTIONS

- Ensure that the implant stability is sufficient to withstand the installation torque of the prosthetic abutment and its functional load, according to the implant instructions for use.
- 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 impression procedure.
- 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 waxing so that the interocclusal space will not be insufficient or excessive.
- 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.
- Inadequate surgical and/or prosthetic 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.
- 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.
- 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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