



















## 703186 IFU Multi Screw Abutments-Revision 03

### ITEMS

CODE	DESCRIPTION	CE MARK
ZD15.001	MULTI SCREW STRAIGHT ABUTMENT 1.5	CE 1984
ZD15.002	MULTI SCREW STRAIGHT ABUTMENT 2.5	CE 1984
ZD15.003	MULTI SCREW STRAIGHT ABUTMENT 3.5	CE 1984
ZD15.004	MULTI SCREW 17 ABUTMENT 1.5	CE 1984
ZD15.005	MULTI SCREW 17 ABUTMENT 2.5	CE 1984
ZD15.006	MULTI SCREW 17 ABUTMENT 3.5	CE 1984
ZD15.007	MULTI SCREW 30 ABUTMENT 1.5	CE 1984
ZD15.008	MULTI SCREW 30 ABUTMENT 2.5	CE 1984
ZD15.009	MULTI SCREW 30 ABUTMENT 3.5	CE 1984
ZD15.013	MULTI SCREW 17 ABUTMENT INDEXED 1.5	CE 1984
ZD15.014	MULTI SCREW 17 ABUTMENT INDEXED 2.5	CE 1984
ZD15.015	MULTI SCREW 17 ABUTMENT INDEXED 3.5	CE 1984
ZD15.016	MULTI SCREW 30 ABUTMENT INDEXED 1.5	CE 1984
ZD15.017	MULTI SCREW 30 ABUTMENT INDEXED 2.5	CE 1984
ZD15.018	MULTI SCREW 30 ABUTMENT INDEXED 3.5	CE 1984
ZD15.019	MULTI SCREW STRAIGHT ABUTMENT 4.5	CE 1984
ZD15.020	MULTI SCREW STRAIGHT ABUTMENT 5.5	CE 1984

### REGULATORY TABLE

		<b><i>Sterile EO / Single Use / CE 1984</i></b>			
Symbology	Description				Description
	Product size		Sterile - ethylene-oxide		Do not use if package is damaged
	Product code		Do not reuse		CE Mark for European Community market
	Batch Number		Refer to instructions for use		Notification required by FDA for United States market
	Date of manufacture		Upper limit of temperature		Representative in the European Community
	Shelf life		Keep dry		Manufacturer
	Quantity		Keep protected from sunlight		
	Material used				

### 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

# MULTI SCREW ABUTMENTS

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.

Zinedent prosthetic abutments in titanium are used as intermediaries between implants placed intraorally and prostheses, planned according to each case and aiming at esthetics and function.

## DESCRIPTION

The Multi Screw Abutment is an intermediate prosthetic abutment manufactured in titanium alloy.

On one of their ends, Multi Screw Abutments present a geometry that enables the fitting of the impression coping, provisional coping for provisory prosthesis confection, final prosthesis and protection cylinder, and prosthetic screw fixation, with appropriate connection.

Multi Screw Abutments are supplied along with a coupled screw, in a rotational format in relation to the prosthesis, being available according to the table below:

Abutment	Format	Gingival Heights (mm)
Straight	Regular	1.5, 2.5, 3.5, 4.5, 5.5
Angled 17°	Regular / Indexed	1.5, 2.5, 3.5
Angled 30°		

## 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 indicated according to the available interocclusal space, existing transmucosal height and three-dimensional implant position.

It is used for screw-retained multi-unit restorations over implant in maxilla or mandible, in immediate or conventional rehabilitation procedures.

## CONTRAINDICATIONS

This product cannot be customized.

This product is contraindicated for patients exhibiting signs of allergy or hypersensitivity to the chemical elements of the material: titanium alloy Ti6Al4V-ELI.

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

## HANDLING

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

Select the Multi Screw Abutment according to prosthetic planning and install it on the implant using the recommended torque and connection (see table below). Ensure the proper fit between abutment and implant and install the protection cylinder.

For the impression procedures, fit the corresponding Impression Coping on the selected Multi Screw Abutment. Ensure its proper fit and perform the impression with appropriate materials. Prepare the plaster model and use the coping to confection the prosthesis structure according to appropriate laboratory techniques. Passivity and adaptation tests concerning the prosthesis structure must be performed.

For the installation of the final prosthesis, remove the protection cylinder from the abutment and install it with the recommended torque and connection. Protect the access to the screw with teflon and resin.

Multi Screw Abutment	Torque Connection	Recommended Torque (N.cm)
Straight	Multi Screw Abutment Driver	32
Indexed/Regular Angled 17° / 30°	0.9	15

## 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.

## PRESENTATION AND STERILIZATION

This product is for single only and supplied sterile by the method of ethylene oxide, 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.
- It is clinically recommended to maintain the minimum interocclusal space of 4.4 mm and still consider the necessary space for the restoration material.
- 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.
- Make sure to use a prosthetic screw that is compatible with the prosthetic interface and prosthetic abutment.
- 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 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.
- 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.
- 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.

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