

Instruction manual



English

Date of issue: 17 April 2018

Indications for use:

The ZZ BASE RAW ABUTMENT is a customizable abutment that is intended for use with an endosseous implant to support a prosthetic device in a partially or completely edentulous patient. The abutment's intended use is to support single and multiple unit prosthesis in the mandible or maxilla. The prosthesis is to be cemented onto the abutment. The abutment screw is intended to secure the abutment to the endosseous implant.

Product description:

The ZZ BASE RAW ABUTMENT is a prosthodontic piece for the creation of complex dental prostheses and serve as interface between the implant and the superstructure. The ZZ BASE RAW ABUTMENT has one pre-fabricated connection to the implant and one to the Raw Abutment Holder. It is intended to be processed in dental laboratories by experienced dental professionals. The final devices are one-piece customized dental titanium abutments. Each platform is compatible with a certain implant system in a certain size. Further information about the compatibilities can be found in our product catalogue or on our website: www.zirkonzahn.com.

Material:

The products are made out of a titanium alloy (Ti6Al4V, medical grade 5) in accordance with ISO 5832-3 resp. ASTM F136.

Product-options and application:

- ZZ BASE ABC: Customizable abutment without hex. For multi-unit restorations only. DO NOT USE WITH SINGLE CROWNS
- ZZ BASE ABCH: Customizable abutment with hex. For single crowns and multi-unit restorations.

To examine the stability of multi-unit bridges, tighten the screw (see torque on packaging label) and check that there is no space between the implant shoulder and the abutment (Sheffield-Test).

Necessary conditions for the application of ZZ BASE RAW ABUTMENT products:


- The implant has to be placed in accordance with the manufacturer's information.
- The implant has to be screwed with the manufacturer's recommended screwdriver.
- The implant needs to be prepared for the use of the abutment.

△ A stable connection between the implant and the abutment is essential for the stability of the final restoration.

Application:

- Design the shape of your ZZ BASE RAW ABUTMENT in your CAD software. Consider the following parameters:

Minimal wall thickness:	0.5 mm
Maximal angulation:	20°
Minimum height of customizable area:	3.5 mm

- Place the ZZ BASE RAW ABUTMENT blank in the Raw Abutment Holder (see instructions "Raw Abutment Holder Application").
- Mill the designed abutment. Use appropriate milling equipment.
- Finalize the milled abutment (e.g. polishing, anodizing)
- Create a suprastructure for your milled ZZ BASE RAW ABUTMENT.
- Clean the restoration prior to sending it to the dentist.
- Sterilize the ZZ BASE RAW ABUTMENT according to the sterilization method described hereunder.
- Position the abutments with the fitting surface towards the implant. Insert the suitable screw through the screw channel. Make sure that the screw channel and the connection surface are free of impurities, in order to ensure an interlocking connection.
- Screw the ZZ BASE RAW ABUTMENT with the corresponding clinical screw onto the implant (see the back of the packaging, symbol  or torque table at <http://www.zirkonzahn.com/assets/files/brochueren/INT-Drehmomentabelle-fuer-Zirkonzahn-schrauben.pdf>.)
- Make sure that the restoration is fixed and shows no signs of movement. In case of multiunit bridges, tighten the screw (see torque on packaging label) and check that there is no gap between the implant and the abutment.
- Cement the coping according to the regular dental procedures (see instructions „Conventional cementation of a zirconia crown on Raw-Abutment“). The dental cement needs to match the framework material (consult the manufacturer's specifications).

Torque:

The torques (=tightening torques) envisaged for the corresponding ZZ BASE RAW ABUTMENT describe the force needed to tighten the screws. The recommended torque values are indicated on the packaging or on <http://www.zirkonzahn.com/assets/files/brochueren/INT-Drehmomentabelle-fuer-Zirkonzahn-schrauben.pdf>.

Caution: Before tightening or loosening the screw, ensure that the screwdriver is well seated on the screw head.


Contraindications:

- Allergy to one of the following substances and their compounds: titanium (Ti), vanadium (V), aluminium (Al), nitrogen (N), hydrogen (H), iron (Fe) and carbon (C)
- Bruxism
- Restorations with aspect ratio, length: implant length > 1:1.20
- Disproportionally high mechanical impact on the pieces caused by the patient
- Poor oral hygiene
- Insufficient space available.

Side effects:

- no side effect expected with correct usage;
- in case of damage, there is no need to take any further action. The broken part has to be replaced.

Precautions:

- This device is delivered as set, which consists of one ZZ BASE RAW ABUTMENT and one clinical screw. Screws may only be used once. Laboratory screws may not be used intraorally.
- The correct fit of the prosthetic restoration and the retaining element needs to be checked at every follow up examination. If the screw is loosened during the follow up examination, it has to be replaced by a new one.
- The ZZ BASE RAW ABUTMENT devices are intended to be used by experienced dental professionals to produce custom-made abutments.
- The ZZ BASE RAW ABUTMENT devices are delivered non-sterile. Sterilize all parts before inserting them into the patient's mouth. Sterilize the ZZ BASE RAW ABUTMENT parts before inserting as follows:
Steam sterilization: At 134 °C for 4 minutes in a prevacuum sterilizer or at 121 °C for 15 minutes in a gravity displacement sterilizer. The product sterility is the user's responsibility. The user should consult the manufacturer's instructions for sterilization of the coping/restoration material.
- Only product combinations specified by Zirkonzahn (see catalogue) may be assembled. Otherwise, ZZ BASE parts and the implant could be damaged during the insertion or the combination could not provide adequate functionality (poor fitting accuracy, less resistance, etc.). The compatible implant system is indicated on the device label of the ZZ BASE RAW ABUTMENT devices.
- The ZZ BASE RAW ABUTMENT devices are single-use devices. All products, labelled with this symbol , are to be used only once. If this product is still used more times, cross-contamination, malfunction, inaccuracy and other risks may occur.

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- Materials that are used in combination with the ZZ BASE RAW ABUTMENT, e.g. dental cements, are to be processed as specified by the manufacturer.
- The ZZ BASE RAW ABUTMENT may be adapted individually. However, under no circumstances, the pre-fabricated implant connection may be modified. It is not allowed to sandblast or differently process the fitting surface of the implant. Any modification of the pre-fabricated connection to the implant results in loss of approval as medical device.
- The ZZ BASE ABC model must not be used for single crowns

This instruction for use complies with the technical status quo and our own experience. The user will be held fully responsible for the correct use of the product. The manufacturer is not liable for poor results, because he has no influence on the processing. The user (dental technician) has to inform the dentist about all necessary steps (e.g. sterilization), before application in the patient's mouth. The dental technician has to take care that all information of this instruction manual will be given to the dentist. Any claims for damages shall concern exclusively the commercial value of our products. For further information, please visit our website: www.zirkonzahn.com.

Magnetic resonance: ZZ BASE products have not been evaluated for safety and compatibility in the magnetic resonance (MR) environment. They have not been tested for heating, migration, or image artifact in the MR environment. The safety of the ZZ BASE products in a MR environment is unknown. Scanning a patient who has this medical device (ZZ BASE) may result in patient injury.

Storage and stability:

The product is delivered non-sterile and has to be stored in the original packaging in dry and dust-free conditions.

Note: Not all models are available in all countries.

CAUTION: US Federal law restricts these devices to sale by or on the order of a licensed practitioner in the dental sector.

Information:

Producer: Zirkonzahn srl – Via An der Ahr 7 – 39030 Gais – Italy – www.zirkonzahn.com
Emergency Phone: +39 0474 066 660 (Mon. - Fri. 8 am - 6 pm)

N.B.: Medical products are non-returnable.

Zirkonzahn S.r.l.

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Legend

Explanation of symbols used



Manufacturer



Date of manufacture

REF

Article number



LOT number



Do not re-use



Read Instructions

Rx only

To be sold by or on the order of a licensed dentist



Non-sterile