

# Cendres+Métaux abutment (Zi) on titanium base / Custom-made device

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10.2013

Instructions for use

Use of the product must be carried out exclusively by skilled persons.

The issuing of these instructions for use renders all previous versions invalid.

The manufacturer rejects any liability for damages resulting from non-compliance with these instructions for use.

## Intended use

The product is a custom-made abutment, which is bonded directly to the Medentika titanium base. Information on available implant libraries and recommendations can be viewed on the Internet at [www.cmsa.ch/dental](http://www.cmsa.ch/dental).

## General information

Close cooperation between the surgeon, dentist and dental technician is essential for successful treatment. It is essential to ensure safety against aspiration and that no changes are made to the implant platform.

## Traceability of the batch numbers

The corresponding batch numbers must be recorded to ensure traceability.

## Disinfection

After any fabrication or modification, the prosthetic work must be cleaned and disinfected according to national guidelines.

When choosing the disinfectant, ensure that:

- It is suitable for cleaning and disinfection of dental prosthetic components.
- It is compatible with the materials of the products to be cleaned and disinfected.
- It has tested efficacy in disinfection.

**Recommended:** Cidex® OPA Solution. Strictly follow the manufacturer's instructions.

## Sterility:

The component is supplied non-sterile and should be cleaned and sterilized according to the standard procedures in dental laboratories.

If required, the abutment can be steam-sterilized for five minutes at 135°C.

## MRT environment:

The product has not been evaluated / tested in an MRT environment with regard to overheating and movement.

## Indications

- Connecting element between titanium base and cap/crown.

## Contraindications

- Patients with bruxism or other para-functional habits.
- Lacking cooperation of the patient with respect to follow-up / recall instructions.
- In patients with allergies to one or more elements of the materials.
- The torque of the respective screws must correspond to the values specified by the respective implant manufacturers.
- Abutments with an angle correction of more than 20° in relation to the implant axis.
- Minimum wall thickness of the abutment should not be less than 1 mm.
- Do not use titanium bases with unsuitable diameters.
- Titanium bases and screws are intended for single use only.

The products carry the CE sign.  
See packaging for details.

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## Warnings

This product may not be used in patients with allergies to one or more elements of the materials. In patients with suspected allergy to one or more elements of the materials, this product may only be used following allergological clarification and proof of non-existence of an allergy. For further information, please contact your Cendres+Métaux representative.

These instructions for use are not sufficient for immediate use of the Cendres+Métaux Abutment. Knowledge of dental medicine or technology provided by an experienced person is required. Courses and training are regularly offered by Cendres+Métaux. It is obligatory to observe the procedural instructions of the implant manufacturers or the manufacturers of the attachment elements.

## Preventive measures

- The components are supplied non-sterile. Proper preparation of the components prior to use in the patient is described in the chapter on «Disinfection» and «Sterilization».
- Pay attention to regular cleaning of the denture to prevent any inflammation of the soft tissue.
- For intraoral use, all products must be generally secured against aspiration.

Please ensure that you are using the suitable impression posts, materials and laboratory components. When using already used laboratory implants, it is recommended to examine these beforehand with a magnifying glass or under a microscope for scratches, damage or foreign matter on the platform surface.

Only use the original screws from the implant manufacturer. Please ensure that the connecting elements have been used according to the manufacturer's recommendations.

Use a screwdriver suitable for the system and observe the torque for the respective abutment.

The component is supplied non-sterile and should be cleaned and sterilized according to the standard procedures in dental laboratories.

## Clinical procedure

Cendres+Métaux refers to literature references and instructions for use of the implant companies.

## Laboratory procedure

### Fabrication of a plaster model:

- Check the position of the impression post at implant level and screw the laboratory implant to the impression post.
- Cast the impression with dental plaster with low setting expansion and fabricate a master model with a gingival mask.
- Allow the model to harden sufficiently to avoid changes in size.
- Check that all laboratory implants sit tight in the model.

### Fabrication of restoration after receipt of the abutment:

- The models should be articulated to avoid prior contact.
  - If required, small modifications can be made using a diamond drill or disc with fine graining at low pressure and sufficient water cooling.
  - As preparation for bonding, the connection geometry of the titanium base is placed in a laboratory analog and secured with the abutment screw.
  - Seal screw head/screw channel with a soft wax or pliable silicone.
  - The bonding surfaces of the titanium base and the zirconium abutment are sandblasted using aluminum oxide 110  $\mu\text{m}$  at a max. pressure of 2 bar, after which the bonding surfaces are to be cleaned of dust and grease.
  - Wet the dust- and grease-free bonding surfaces with primer, then apply suitable adhesive to the bonding surface of the titanium base. (We recommend: Panavia F 2.0, Kuraray or Rely X Unicem, 3M Espe)
- Please follow the instructions of the respective manufacturer.
- Place zirconium abutment on titanium base with a right/left movement and check for correct positioning. Excess adhesive should be removed immediately.
  - The result must be a gap-free transition between the zirconium abutment and the platform of the titanium base.
  - After the adhesive has cured, excess including any in the screw channel must be carefully removed with appropriate rotating grinding tools (rubber polishing).
  - A cap/crown is fabricated using conventional casting techniques or CAD/CAM and cemented to the abutment.

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## Material

ZrO<sub>2</sub> (Y-TZP) according to ISO 13356 and DIN EN ISO 6872.  
CE 0297.

| Reference analysis<br>% | ZrO <sub>2</sub> + HfO <sub>2</sub> + Y <sub>2</sub> O <sub>3</sub> | Y <sub>2</sub> O <sub>3</sub> | HfO <sub>2</sub> | Al <sub>2</sub> O <sub>3</sub> | Other oxides |
|-------------------------|---|-------------------------------|------------------|--------------------------------|--------------|
|                         | > 99  | 4.5–6.0                       | < 5.0            | < 0.5                          | < 0.5        |

For further information, please contact your Cendres+Métaux representative.

## Disclaimer / validity

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The processing and surgical insertion of the prosthesis and control are the responsibility of a specialist physician who assumes complete responsibility.

## Availability

Not all products are available in every country.

## Labeling on packaging / symbols



Manufacturer



Catalogue number



Batch code



Quantity



Consult instructions for use

Rx only

Attention: According to US federal law, this product may only be sold by or on behalf of a physician.



Do not re-use



Non-sterile

Custom-made device