Cendres+Métaux Crowns and Bridges (Zirconia) / Custom-made device

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.

Taking into account the indications, tooth preparation, selected materials and features of the laboratory scanner, the specified parameters at http://www.cmsa.ch/dental (select English language), under Products > Digital Solutions > Digital Solutions Product are to be used as guide values. Own experience and knowledge are required for accurately-fitting restorations.

For software updates or when using a different/new scanner, caution is advised and when necessary, contact Cendres+Métaux Customer Service.

Intended use
Custom-made, cemented single-unit framework or bridge for a crown on natural teeth or implant abutments.

Disinfection/sterilization
The single-unit frameworks or bridges are supplied non-sterile and should therefore be disinfected prior to fitting, again after fitting and prior to cementation with a suitable disinfectant (e.g. 70 % ethanol solution).

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

Indications
- Anterior or posterior frameworks, fully anatomical crowns or bridges as prostheses.
- Prosthesis on teeth or implants.
- For a bridge length of up to 6 elements.
- Minimum thickness 0.4 mm.
- All buccal positions.
- Interdental connection in accordance with scientific literature: 6.0 mm² (for anterior bridge) up to 9.0 mm² (posterior bridge).

Fabrication

Fabrication | Single crown bridges | Bridges, number of intermediate elements
---|---|---
CAM milling, sintering and ceramic veneering | X | X | 2 | 2

X indexed, numbers give the maximum number of intermediate elements.

Contraindications
- All cases with lengths exceeding maximum limits.
- 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 material.
- More than one freely suspended bridge element as extension.

The products carry the CE Mark. See packaging for details.
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. Knowledge of dental medicine or technology provided by an experienced person is required. Courses and training are regularly offered by Cendres+Métaux.

Preventive measures
– The components are supplied non-sterile. Proper preparation of the components prior to use in the mouth 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.

Clinical procedure
Cendres+Métaux refers to literature references and instructions for use for the clinical procedure.

Laboratory procedure
Fabrication of a plaster model:
– Cast the impression with dental plaster with low setting expansion and fabricate a master model.
– Allow the model to harden sufficiently to avoid changes in size.

Reworking the framework for ceramic veneers:
– The models should be articulated to avoid premature contact.
– Check the framework for faults, adequate wall thickness and fit.
– If required, small modifications can be made using a diamond drill or disc with fine grain at low pressure and sufficient water cooling.
– Rinse the framework under water and dry it. It is now ready for further processing.

Cleaning:
– Steam cleaning

Ceramic veneers:
– Ceramics should be used which are designed for use with ZrO2.
– Please follow the manufacturer's instructions.
– After firing, the object is cooled in accordance with the instructions of use of the ceramics manufacturer. The characteristics of the ceramic furnaces are to be observed.

<table>
<thead>
<tr>
<th>Firing table</th>
<th>Heating rate °C/h</th>
<th>T max °C</th>
<th>Dwell time h</th>
<th>Cooling</th>
</tr>
</thead>
<tbody>
<tr>
<td>Crowns</td>
<td>600</td>
<td>1450</td>
<td>2</td>
<td>in furnace</td>
</tr>
<tr>
<td>Bridges</td>
<td>300</td>
<td>1450</td>
<td>2</td>
<td></td>
</tr>
</tbody>
</table>

Polishing
– Pre-polishing with rubber polisher.
– Polishing with a soft brush, felt and buffing wheel using Legabril Diamond.
– High-gloss polishing with soft brush and buffing wheel.
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Material
ZrO2 (Y-TZP) according to ISO 13356 and DIN EN ISO 6872.
CE 0297.

<table>
<thead>
<tr>
<th>Reference analysis</th>
<th>ZrO2 + HfO2 + Y2O3</th>
<th>HfO2</th>
<th>Al2O3</th>
<th>other oxides</th>
</tr>
</thead>
<tbody>
<tr>
<td>%</td>
<td>&gt;99</td>
<td>4.5–6.0</td>
<td>&lt;5.0</td>
<td>&lt;0.5</td>
</tr>
</tbody>
</table>

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

Disclaimer / validity
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Availability
Not all products are available in every country.

Labeling on packaging / symbols
- Manufacturer
- Catalogue number
- Batch code
- Quantity
- Consult instructions for use
- 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