Cendres+Métaux Crowns and Bridges (CoCr and Ti) / 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.

General information
Close cooperation between the dentist and the dental technician is essential for successful treatment.
It is particularly important to ensure an optimal load distribution through adaptation and fitting of the crown. This is achieved by adjusting the occlusion in relation to the antagonist.
It is essential to protect the components against aspiration when working in the mouth.
If the restoration needs to be modified, observe the edge areas and the occlusal surfaces. A minimum thickness of 0.4 mm should be maintained. Wear adequate protective clothing during modification to avoid breathing in dust of the cobalt-chromium alloy.
If fitting is performed in the mouth, we recommend cleaning the restoration under running water or with alcohol.

Traceability of the batch numbers
The corresponding batch numbers must be recorded to ensure traceability.

Disinfection / sterilization
After any fabrication or modification, the prosthetic work, including the matrix components, 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.

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

Indications
– Anterior or posterior frameworks or bridges as prostheses.
– Prosthesis on teeth or implants.
– For a bridge length of up to 8 elements.
– Minimum thickness 0.4 mm.
– All oral positions.
– Interdental connection in accordance with scientific literature: 6.0 mm^2 (for anterior bridge) up to 9.0 mm^2 (posterior bridge).

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.

CENDRES+ MÉTAUX

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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. Knowledge of dental medicine or technology provided by an experienced person is required. Courses and training are regularly offered by Cendres+Métaux.

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

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.

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.
– Roughly rework the frameworks with a crosscut hard metal milling tool and then with ceramic-bonded abrasive tool. Adhere to the same grinding direction to avoid overlapping on the alloy surface.

Blasting:
– Blast the finished reworked frameworks with unrecycled aluminum oxide (Al2O3). Blasting should not be performed too long (longer than approx. 0.5 sec.) at the same point.

Grain size	110 μm
Sandblasting pressure	2–4 bar

Cleaning:
– Steam cleaning

Oxidizing:
– Oxide firing is not necessary. Oxide firing can be performed for visual control of the framework quality. The framework surface must then be blasted again with pure aluminum oxide at a blasting pressure of 2–4 bar (approx. 110 μm) and then cleaned with steam blasting or in an ultrasonic device with distilled water for approx. 5 minutes.

Ceramic veneers:
– Ceramics should be used which are designed for use with CoCr and titanium respectively, at a thermal expansion coefficient of 14.1.
– Please follow the manufacturer's instructions.
– After firing, the object is cooled in accordance with the thermal expansion coefficient and the instructions of use of the ceramic manufacturer. The characteristics of the ceramic compounds (thermal expansion coefficient) and the ceramic furnaces are to be observed.
– All paste opaque compounds must be pre-dried longer (approx. 10 min.).
Pre-drying temperature: 300 °C–400 °C.

Polishing
– Exposed external metal surfaces must be high gloss-polished after final firing to completely remove the adhering oxide layer.
– 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
Titanium ELI (grade 5) according to ASTM B 348 and ASTM F 136.

Reference analysis %	C	Fe	O	N	H	Al	V	Ti
	Max. 0.08	Max. 0.03	Max. 0.20	Max. 0.05	Max. 0.015	5.50 6.75	3.50 4.50	Residue

Material
Cobalt-chromium alloy according to ASTM F75, ASTM F799, ASTM F1537, ISO 5832-4, ISO 5832-12.

Reference analysis %	C	Si	Ni	Fe	Mg	Cr	Mo	N	Co
	Max. 0.10	Max. 1.00	Max. 1.00	Max. 0.75	Max. 1.00	26.00 30.00	5.00 7.00	Max. 0.25	Residue

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

Disclaimer / validity
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.
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

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