Cendres+Métaux custom-made products (CoCr, Ti, precious metal)

– Crowns and bridges
– Abutment
– Implant bridge

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.

1 Intended use
The products are individually fabricated prosthetic solutions on natural teeth, abutments or implants and serve to support prosthetic rehabilitation after veneering or further processing in the laboratory. Information on available implant libraries and recommendations can be viewed on the Internet at www.cmsa.ch/dental.
Original Cendres+Métaux female parts are to be used for restorations with attachment elements (e.g. M-SG® Star 1 attachment). The female parts must be used according to the manufacturer's instructions.

2 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 opposite jaw. It is essential to make sure that no changes are made to the implant platforms and that safety against aspiration is ensured.
If the restoration needs to be modified, observe the marginal areas and the occlusal surfaces. A minimum thickness of 0.4 mm should be maintained.
Wear adequate protective clothing during modification of the restoration to avoid breathing in dust of the cobalt-chromium, titanium and precious metal alloy.
If fitting is performed on the patient, we recommend cleaning the restoration under running water or with alcohol.

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

4 Sterilisation / disinfection
The components are supplied non-sterile.
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/has:
– suitable for cleaning and disinfection of dental prosthetic components.
– compatible with the materials of the products to be cleaned and disinfected.
– proven efficacy in disinfection.

Recommendation: Disinfection
All the parts must be disinfected before use with a «high EPA-registered hospital disinfectant».
Recommendation: Cidex® OPA Solution. It is essential to observe the manufacturer's instructions.
Plastic parts are not suitable for steam sterilisation.

Recommendation: Sterilisation
All metal components must be sterilised prior to use.

Sterilisation method
Steam sterilisation for sterilisation of the system components has been validated for the following procedure:
Gravity displacement steam sterilisation using the following sterilisation cycles:
– Packaging configuration: Unopened
– Exposure temperature at 132°C (275°F): 10 minutes
– Drying time: 1 minute
Allow system components to cool prior to use.
All plastic parts, except those made of Pekkton®, are not suitable for steam sterilisation.

The validated procedure requires use of FDA-approved sterilisers, sterilisation containers, sterilisation pouches, biological indicators, chemical indicators and other sterilisation accessories appropriately identified and recommended for sterilisation and the sterilisation cycle. The relevant authority should monitor the steriliser for use in accordance with an FDA-recognised sterility safety standard such as ANSI / AAMI ST79: 2010.

5 MRT environment:
The products have not been evaluated/tested in an MRT environment with regard to overheating and movement.

6 Indications
– Aesthetic prosthesis on natural teeth or implants.
– Anterior or posterior caps, fully anatomical crowns or bridges as prostheses.
– For a bridge length of up to 8 elements.
– Minimum thickness 0.4 mm.
– All oral positions.
– Cross-sections in accordance with scientific literature references and the general level of training of a dental technician:
6.0 mm^2 (for anterior bridge) up to 9.0 mm^2 (posterior bridge).

7 Contraindications
– All cases with lengths exceeding maximum limits.
– According to data provided by the implant manufacturers, various abutments and implants are not suitable for use in the posterior or incisor ranges respectively. This information can be found in the implant manufacturers' instruction for use and must be followed.
– Cases in which the mesial/distal extension is longer than a bridge element.
– The cap or bridge is not veneered and there is no occlusional contact to other metal attachments/restorations.
– Patients with bruxism or other para-functional habits.
– Work with a maximum of two intermediate elements.
– Lacking cooperation of the patient with respect to correct follow-up/recall instructions.
– In patients with allergies to one or more elements of the material.

8 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 information and additional details, please contact your Cendres+Métaux representative.

These instructions for use are not sufficient for immediate use. Dental or laboratory knowledge 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.

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

10 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 «Sterility».
– 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 sterilised according to the standard procedures in dental laboratories.

11 Laboratory procedure

Fabrication of a plaster model:
– The models should be articulated to avoid prior contact.
– 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:
– Check of accurate, passive fit of the framework on the model and in the patient's mouth. If the framework does not fit passively, it needs to be fabricated anew.
– If required, make minor modifications using a carbide drill. Rubber rollers are used for the shoulder area.
– A crown or bridge is manufactured employing conventional casting techniques or digital processes and cemented to the abutments.
– In case of screw-retained restorations, the work can be veneered directly with ceramics.

Reworking the framework for ceramic veneers:
– 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.
– Do not use diamonded abrasive tools!

Processing for CoCr and Ti before firing:
– Blast the finished reworked frameworks with unrecycled aluminium oxide (Al_2O_3).
Blasting should not be performed too long (longer than approx. 0.5 sec.) at the same point.

Grain size	110 μm
Blasting pressure	2.0–4.0 bar

Processing for precious metal before firing:
Please obtain further information on the valid instructions for use of the cast alloys www.cmsa.ch/dental

Esteticor® CC/ Esteticor® Lumina PF
– Blast the finished reworked frameworks with unrecycled aluminium oxide (Al_2O_3).
Blasting should not be performed too long (longer than approx. 0.5 sec.) at the same point.

Grain size	50 μm
Blasting pressure	2.0–4.0 bar

Cleaning:
– Steam cleaning

Oxidising CoCr/Ti:
– 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 aluminium oxide at a blasting pressure of 2–4 bar (approx. 110 μm) and then cleaned with a steam blasting device or in an ultrasonic device with distilled water for approx. 5 minutes.

Oxidising precious metal:
Esteticor® CC
– .5 min. with vacuum at 980° C.
Then allow to air-dry. The frameworks now display a uniform grey colour shade. Massive bridge constructions require a reduction in heating rate to 40–50° C/min. to allow reaching optimal heat uptake of the workpiece.

Esteticor® Lumina PF
– .10 min. with vacuum at 900° C.
Then allow to air-dry. The frameworks now display a uniform grey colour shade. Massive bridge constructions require a reduction in heating rate to 40–50° C/min. to allow reaching optimal heat uptake of the workpiece.

Oxide removal:
Esteticor® CC
– The oxide generated by oxide firing can be removed by blasting with aluminium oxide followed by thorough cleaning with steam blasting.

Grain size	50 μm
Blasting pressure	2.0–4.0 bar

Esteticor® Lumina PF
– The oxide generated by oxide firing for the Esteticor® Lumina PF alloy may not be removed by sandblasting, then to be cleaned thoroughly with steam blasting.
Acid wash in warm, pure 10 vol. % sulphuric acid (H_2SO_4).
Note: when using other mordants, the instructions for use of the respective manufacturers are to be observed.

Ceramic veneers:
– Ceramics should be used which are expressly designed for use with CoCr and titanium respectively at a thermal expansion coefficient of 14.1.
– Ceramics are to be used for precious metal alloys which are designed for a thermal expansion coefficient of 14.2/14.3.
– Please observe the manufacturer's instructions for firing temperature and other notes on processing.
– After firing, the object is cooled in accordance with the instructions of use of the ceramics 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.
– Do not use metal fixing pins.

Oxide removal after ceramic firing
CoCr / Ti
After ceramic firing, oxide can only be removed by very careful blasting with non-abrasive blasting agents (glass beads) at a maximum pressure of 2 bar.

Esteticor® CC
After ceramic firing, oxide can only be removed by very careful blasting with non-abrasive blasting agents (glass beads) at a maximum pressure of 2 bar.

Esteticor® Lumina PF
Acid wash in warm, pure 10 vol. % sulphuric acid (H_2SO_4) for 15 min.
Note: when using other mordants, the instructions for use of the respective manufacturers are to be observed.

Note:
Only clean the implant interfaces very carefully with non-abrasive blasting agents (glass beads) at a maximum pressure of 2 bar.

12 Solder and laser welded connections:
– Please see the corresponding instructions for use for detailed information on processing for precious metal alloys.
http://www.cmsa.ch/Dental/Download-Centre

13 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.

14 Material
Chemical composition

Esteticor Lumina PF®
Type 4

	Au + Pt metals	Au	Pt	Zn	Rh	Ir	Fe
Content in weight per cent	98.00	84.50	13.30	1.90	0.10	0.10	0.10

Esteticor® CC
Type 4

	Au + Pt metals	Pd	Ag	Au	In	Sn	Ga	Ru	B
Content in weight per cent	64.49	52.29	23.00	12.00	10.00	2.00	0.50	0.20	0.01

Dentalor® 60
Type 4

	Au + Pt metals	Au	Ag	Cu	Pd	Zn	Pt	Ir
Content in weight per cent	63.50	60.00	22.50	12.50	3.00	1.50	0.45	0.05

15. Physical properties

Esteticor Lumina PF®
Thermal coefficient of expansion (25–500°) $14.2 \times 10^{-6}\ K^{-1}$

Esteticor® CC
Thermal coefficient of expansion (25–500°) $14.3 \times 10^{-6}\ K^{-1}$

16. Mechanical properties

Esteticor Lumina PF®
Firing simulation: 900°C/10'/vac & IPS d'SIGN

Mould	Bar	Profile
Hardness HV5	205	210
Yield strength (Rm)	620MPa	620MPa
0.2 % Proof stress (Rp0.2)	530MPa	550MPa
Elongation	4%	3%

Dentalor® 60
Cast

	Bar
Hardness HV5	275
Yield strength (Rm)	815MPa
0.2 % Proof stress (Rp0.2)	800MPa
Elongation	12%

Esteticor® CC
Firing simulation: 980°C/5'/vac & Geller Creation CC

Mould	Bar	Profile
Hardness HV5	300	295
Yield strength (Rm)	900MPa	940MPa
0.2 % Proof stress (Rp0.2)	675MPa	660MPa
Elongation	10%	14%

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