

Cendres+Métaux Bar (CoCr and Ti) / Custom-made device

1 / 3
07.2013

Instructions for use

The use, activation, deactivation, repair and periodic maintenance of attachment elements must be carried out exclusively by skilled persons. Only original tools and parts may be used for this work.

The mechanical cleaning of attachment elements using a toothbrush and toothpaste may lead to premature wear of the functional parts.

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 an individual implant-supported bar design for edentulous patients.

The original Cendres+Métaux matrices are to be used.

The matrices must be used according to the manufacturer's instructions.

Information and recommendations can be viewed on the Internet at 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

If attachment elements are composed of parts with different batch numbers, then all corresponding batch numbers need to be recorded to ensure traceability.

Disinfection

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.

Sterilization:

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

If required, the bar can be steam-sterilized for five minutes at 135°C. The use of non-sterile products may lead to tissue infections or contagious diseases.

MRT environment:

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

Indication

- Implant-supported restorations at implant and/or multi-unit abutment level.
- Anchorage for a removable prosthesis (e.g. plastic cover prosthesis).
- Alternative solution: Cover bar with plastic (wrap around design).

Contraindications

- All cases with lengths and parameters exceeding maximum limits. (see parameters for bar design)
- Patients with bruxism or other para-functional habits.
- Lacking cooperation of the patient with respect to follow-up / recall instructions.
- Unilateral prostheses without transversal support.
- In patients with allergies to one or more elements of the attachment materials.
- Do not solder or laser.

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

Cendres+Métaux Bar (CoCr and Ti) / Custom-made device

Warnings

This product may not be used in patients with allergies to one or more elements of the attachment 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 Bar. 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 bar to prevent any inflammation of the soft tissue.
- For intraoral use, all products must be generally secured against aspiration.
- The male parts must be placed parallel to the axis of insertion.
- Undercuts must be blocked out.
- The original matrices are to be used.

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.
- The soft tissue must be at least 2 mm thick for the laboratory implants to protrude at least 2 mm from the plaster model.
- Check that all laboratory implants sit tight in the model.

Transfer key for the model:

- Fabricate a plastic framework with temporary abutments not secured against rotation.
- Send to dentist to check fit in the patient's mouth and thus the accuracy of the model.
- Use a synthetic base and fabricate a wax occlusal rim to determine relations to align the models properly in an articulator.

Fabrication of tooth set-up:

- Articulate the models using the wax occlusal rim (and the facial arch).
- Prepare a diagnostic tooth set-up on the master model and send to dentist for fitting and checking.

Fabrication of prosthesis after receipt of the milled bar:

- The models should be articulated to avoid premature contact.
- Check of accurate, passive fit of the bar on the model and in the patient's mouth. If the bar does not fit passively, it needs to be fabricated anew.
- Fabricate the prosthesis according to standard protocol.
- The stability of the restoration can be strengthened by a framework made of non-precious metal which is integrated into the prosthesis.
- Incorporate the secondary components of the selected mounting elements into the prosthesis.
- Following polymerization, remove the restoration from the model and finish the areas in contact with soft tissue to ensure the best possible support of the surrounding tissue and optimal hygiene around the implants.

Cendres+Métaux Bar (CoCr and Ti) / Custom-made device

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.

Parameters for bar design

The following table gives the most important design parameters for each bar type.

Type of bar	Shape of bar	Max. extension	Max. span
Dolder® Macro joint	Defined	20 mm	40 mm
Dolder® Micro joint	Defined	13.5 mm	35 mm
Dolder® Macro attachment	Defined	20 mm	40 mm
Dolder® Micro attachment	Defined	13.5 mm	35 mm
Round bar	Defined	10 mm	25 mm
Ackermann	Defined	20 mm	40 mm
Wrap around	Free form	25 mm	50 mm

Next to the basic design parameters given in the table, the following conditions should be taken into consideration:

- In case of an extension, the distal wall of the cylinder (connection zone for the extension) must have a thickness of 1 mm.
- In case of extensions greater than 10 mm, the thickness of the cylinder (connection zone for the extension) must be 1.5 mm.
- In case of beveled distal cylinders, the minimum thickness of the cylinder wall at the head of the screw may not be less than 0.25 mm.
- When using screw-retained retention elements, a circular wall thickness of at least 1 mm must be present around the thread.

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

Custom-made device