Instructions for Use Root canal posts
(Mooser root canal post / CM root canal post / MP post)

1 Scope of application of instructions for use
These instructions for use apply to the products listed under Point 29 in Table 1. 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.

2 Trade name
See Point 29, Table 1.

3 Intended use
The components are intended for use for prosthetic restoration on natural teeth and to support procedures in the dental clinic or laboratory.

4 Expected clinical benefit
Restoration of chewing function and improved aesthetics.
For implantable products, link to "Summary of safety and clinical performance".
The summaries of safety and clinical performance (SSCP) for the implantable devices covered by these instructions for use, are available in the European database on medical devices EUDAMED, accessible at this address: https://ec.europa.eu/tools/eudamed

5 Product description
<table>
<thead>
<tr>
<th>Product</th>
<th>Description</th>
</tr>
</thead>
</table>
| **Mooser root canal post** | – Conical profile of the endodontic part.  
– Two post heads:  
– Ceramicor® precious metal post with adhesion head: Due to the special head geometry, the impression remains undamaged even with non-parallel abutments. The post can be repositioned in the impression with slight finger pressure.  
– Titanium post with flat head: The flat head serves as retention for the abutment material. For temporary work.  
– Available in four different sizes.  
– For root canal preparation, a reamer, a pilot trimmer, and for manual final calibration a trimmer, are available for each size. |
| a) | Mooser root canal post with flat head  
b) Mooser root canal post with adhesion head |
| **CM root canal post** | – Cylindro-conical profile of the endodontic part.  
– Two post heads:  
– Ceramicor® precious metal post with adhesion head, available with and without cement drainage groove in the endodontic part. Due to the special head geometry, the impression remains undamaged even with non-parallel abutments (use post or drainage groove for this purpose). The post can be repositioned in the impression with slight finger pressure.  
– Titanium post with flat head: The flat head serves as retention for the abutment material. For temporary work.  
– Available in five different sizes.  
– For root canal preparation, a reamer, and for manual final calibration a trimmer, are available for each size. |
| a) | CM root canal post with adhesion head (without groove)  
b) CM root canal post with adhesion head (with groove)  
c) CM root canal post with flat head (with groove) |
| **MP post** | – Cylindro-conical profile of the endodontic part.  
– Two post versions:  
• Steel post with flat head: The flat head serves as retention for the abutment material. For temporary work.  
• Plastic post in burn-out plastic: Economical alternative to prefabricated precious metal posts.  
– Available in four different sizes.  
– For the root canal preparation, a root canal drill and a reamer is available for each size |
| a) | MP burn-out post  
b) MP post with flat head |

Root canal instruments
– The instruments are standardised.  
– All instruments are colour-coded. Mix-ups can thus be ruled out.  
– A coupling piece is available to extend the instruments.
**Nomenclature**

To avoid mix-up, the

- Root canal instruments are colour-coded analogous to the size of the root canal post.
- The Ceramicor® root canal posts are colour-coded.
- The titanium root canal posts are number-coded.
- Root canal posts made of burn-out plastic are colour-injected in different plastics.

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**6 Indication**

These products are inserted into the tooth root if the dental crown is largely destroyed. They are intended for stabilizing tooth roots and for providing retention for root caps, abutments or post crowns in the context of endodontic treatment.

- Post crowns
- Cast abutments
- Temporary abutments

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**7 Contraindications**

- The titanium and steel root canal posts are not suitable for final restoration due to the geometry of the post head (flat head).
- If a snug fit root canal preparation is not possible in the case of a very large root canal.
- In the case of very thin-walled and/or brittle roots.
- Periodontitis, severe gum disease, poor oral hygiene, caries and low inter-occlusal space.
- Lacking compliance of the patient with respect to follow-up / recall instructions.
- Patients with bruxism or other para-functional habits.
- In patients with a pre-existing allergy to one or more elements of the attachment element materials.
- Existing clinical picture in the patient's mouth does not permit the correct application of the products.

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**8 Compatible products**

Not applicable.

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**9 User qualification**

The expertise of a professional dentist or dental technician is required. The current instructions for use must be available at all times and be completely read and understood before the first application. The manufacturing work and its maintenance must be carried out by qualified specialists.

Only original tools and parts may be used for this work. For information and additional details, please contact your Cendres+Métaux SA representative.

**Important information for the specialist**

**Warning symbol for increased caution**

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**10 Prescription**

Federal laws (USA) prohibit the use or sale by unlicensed dentists.

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**11 Side effects**

This product may not be used in patients with allergies to one or more elements of the product 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.

Auxiliary instruments and products made of steel may contain nickel. No known side effects if applied as intended.

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**12 Warnings**

**Magnetic resonance environment**

The device has not been evaluated for safety and compatibility in the MR environment.

The product has not been tested for heating or migration in the MR environment.

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**13 General information**

These instructions for use are sufficient for immediate application for the products described in this application area of the instructions for use. Dental or laboratory knowledge is required. Information: www.cmsa.ch/docs

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**14 Preventive measures**

- Only original tools and parts may be used for this work.
- The product components are supplied non-sterile. For more information see Point 16 Preparation.
- Secure parts against aspiration.
- Before any procedure, ensure that all required product components are available in sufficient quantity.
- For your safety, always wear suitable protective clothing.
- Do not clean any cutting instruments in the ultrasonic cleaner as this could blunt the instruments.
- Avoid high pressures, tilting or leverage to prevent the risk of instrument fracture.
- The root canal instruments should be used a maximum of 10 times only.
- The Mooser, CM and MP root canal post systems are not compatible with each other, i.e. the instruments indicated for the respective system must be used.

The root canal posts must not be exchanged (even with identical shapes and sizes). Changes of position may be the result.

- The colour-coded plastic rings on the root canal posts must be removed before impression-taking.
- Ceramicor® is a non-oxidizing gold-platinum alloy and is suitable for casting with all precious metal alloys.
- Ceramicor® is not suitable for casting with non-precious alloys.
- The castable root canal post in Ceramicor® precious metal alloys are not suitable for firing ceramic (CTE). Therefore, care has to be taken during modelling and finishing that the root canal post is covered with wax or casting alloy.

Products made of titanium are not suitable for casting.

Products made of steel are not suitable for casting.
15 Single use
– Unless labelled otherwise, the product components are only intended for single use.
Products that are marked for single-use are subject to a certain load during use, which can lead to wear, loss of function and/or malfunctions.
⚠️ Reuse of products marked as single-use products may compromise safety, function and performance.
Products for single-use have not been tested for reuse/reprocessing, which increases the risk of infection transmission.

16 Preparation
After any fabrication or modification and prior to use, the prosthetic work, including all system components, must be cleaned, disinfected and, if appropriate, sterilized. Materials made of metal alloys, high-performance polymers (Pekkton®) and ceramics are suitable for steam sterilization, whereas components made of plastic other than Pekkton® are not suitable. Consider published national guidelines when selecting a disinfection and sterilization process and the Instructions for Use “Preparation of surgical and prosthetic products” (www.cmsa.ch/docs).

17 Scope of application
These products are inserted into the tooth root if the dental crown is largely destroyed. They are intended for stabilizing tooth roots and for providing retention for root caps, abutments or post crowns in the context of endodontic treatment.
– Post crowns
– Cast abutments
– Temporary abutments

18 Procedure
The tooth root must first be treated endodontically. The tooth or root is then prepared based on the specific indication. The choice of prosthetic products to be used depends on the X-ray, anatomy and root canal situation (length and diameter).

18.1 Mooser / CM root canal post
After successful completion of root canal treatment, mechanically enlarge the root canal with the reamer of the corresponding size.

Mooser root canal post
Mechanically prepare the root canal with the pilot trimmer, which already has a conical shape.

CM root canal post
This work step is no longer necessary.

The final calibration of the root canal is prepared manually with the reamer of the corresponding size by means of the Thomas socket wrench. The sinking depth and the parietal fit of the root post are checked with the post gauge.
As a torsion and overload protection, a central inlay must be prepared.

CM root canal post
First groove in the post gauge from occlusal: total length of root canal posts with adhesion head.

Cementing: Use lentulo spiral fillers to apply the cement in the root canal (carefully observe the instructions for use of the cement manufacturer). Make sure that the post is in its final position. Remove the surplus cement.

18.2 MP post
The tooth root must first be treated endodontically. The tooth or root is then prepared based on the specific indication. The choice of root canal post size is made depending on the X-ray image and according to the canal preparation and anatomy.

Preparing the root canal
Penetrate into the gutta-percha using a hot probe or “spreader” up to the desired length (creation of a post canal). Expand and, if necessary, deepen the root canal using an MP root canal drill (Cat. No. 200004436). Prepare the root canal using the colour-coded reamers in ascending order to the required diameter. The required depth of the canal corresponds to the cutting section of the root canal reamer.
**Materials**

- Patient information
- Handling / follow-up
- Cleaning and care
- Traceability Lot number
- Ordering information
- Availability

**2021 Instructions for Use Root canal posts**

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**Materials**

Detailed information on the materials and their classification is given in the specific material data sheets, the catalogue as well as the product list given in Table 1 in Point 29. See website www.cmsa.ch/docs or the Cendres+Métaux SA Dental Documentation (available free of charge from all Cendres+Métaux SA subsidiaries, branches and dealers).

**20 Notes on storage**

The product must be stored in a dry place in its original packaging, at room temperature and without direct sunlight, unless otherwise stated on the packaging. Improper storage can influence the product properties and lead to failure of the restoration.

**21 Patient information**

**21.1 Handling / follow-up**

On the day of insertion of the dentures at the latest, the patient must be informed that regular follow-up care is necessary to maintain the health of the entire masticatory system and the functionality of the denture. Ensure that patients are motivated and instructed according to their own abilities such as manual dexterity and vision with regard to the handling and care of their teeth and dentures.

Permanent and removable dentures are subject to considerable stress in the mouth in a constantly changing environment, and thus more or less subjected to signs of wear. Wear is omnipresent in daily routine and cannot be avoided, only reduced. The amount of wear depends on the overall system.

Our endeavours are aimed at using materials that are as optimally matched as possible in order to reduce wear to an absolute minimum. Proper seating of the dentures on the mucosa must be checked at least once each year, and relining must be performed if required to prevent rocking movement (overload). We recommend checking the dentures at intervals of approx. 3 months initially and to replace the auxiliary parts such as retention inserts if necessary.

**21.2 Cleaning and care**

We recommend cleaning your teeth and your dentures after every meal. Cleaning of dentures includes cleaning of the connecting element. The gentlest cleaning is achieved by cleaning the connecting element under running water with a soft toothbrush. The most intensive cleaning is achieved when cleaning the dentures in a small ultrasonic device and adding a suitable cleaning agent. Never clean the high precision connecting elements with toothpaste. This could lead to damage. Caution should also be exercised in the case of unsuitable cleaning agents or tablets. This could also damage the high quality connecting element or impair its function. Only clean the connecting parts on the other teeth or connecting elements with toothpaste. This could lead to damage. Caution should also be exercised in the case of unsuitable cleaning agents or tablets. This could also damage the high quality connecting element or impair its function. Only clean the connecting parts on the other teeth or connecting elements with toothpaste. This could lead to damage.

Pay attention to regular cleaning of the anchorazge to prevent any inflammation of the soft tissue. For information and additional tips on caring for the instruments. (www.cmsa.ch/docs)

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

**22 Ordering information**

More detailed information on the catalogue numbers, the number of products and their classification can be found in the product list under Point 29 in Table 1, the specific product catalogue, the packaging and, in the case of individual products, also directly on the product itself. You can find further information on the website www.cmsa.ch/docs or the Cendres+Métaux SA Dental Documentation (available free of charge from all Cendres+Métaux SA subsidiaries, branches and dealers).

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

**23 Availability**

Some of the products described in this document may possibly not be available in all countries.

**24 Traceability Lot number**

The batch numbers of all parts used must be documented to ensure traceability. If different batch numbers are used for the products described in this application area of the instructions for use for the fabrication of dentures, all the batch numbers concerned must be recorded to ensure traceability.

**25 Complaint**

Cendres+Métaux SA must be notified immediately of any incident that has occurred with regard to the product to all branches, offices and dealers of Cendres+Métaux SA and, in case of serious cases, to the competent authority where the user is registered.
26 Safe disposal
The product must be disposed of in accordance with local laws and environmental regulations, taking into account the level of contamination. Cendres+Métaux LUX SA would be very pleased to accept precious metal waste. For information and additional details, please contact your Cendres+Métaux SA representative.

27 Trademarks
Unless explained specifically, all products marked with "®" are not registered trademarks of Cendres+Métaux Holding SA, but registered trademarks of the respective manufacturer.

28 Disclaimer
The manufacturer rejects any liability for damages resulting from non-compliance with these instructions for use. This product is part of an overall concept and may only be used or combined with the corresponding original components and instruments. Otherwise, the manufacturer rejects any responsibility and liability. In case of complaints, please always include the batch number.

The use of third party products not distributed by Cendres+Métaux SA in connection with the products listed in Table 1 will void any warranty or other express or implied obligations of Cendres+Métaux SA.

The user of Cendres+Métaux SA products is responsible for determining whether or not a product is suitable for a specific patient and a specific situation.

Cendres+Métaux SA disclaims any express or implied liability and shall not be responsible for any direct, indirect, punitive or other damages arising from or in connection with errors in professional judgement or practice in the use or installation of Cendres+Métaux SA products.

Specialist knowledge of dentistry, dental technology and instructions in handling the products listed in Table 1 by an operator with appropriate experience is always required.

29 Product list

<table>
<thead>
<tr>
<th>Cat. No.</th>
<th>Product name</th>
<th>Material</th>
<th>Single use</th>
<th>Multiple use</th>
<th>Basic UDI-DI</th>
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</thead>
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<tr>
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CM root canal post

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<th>Multiple use</th>
<th>Basic UDI-DI</th>
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<td>CM root canal post trimmer yellow (size 2)</td>
<td>Steel</td>
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Symbols

- Important information for the specialist
- Warning symbol for increased caution

Labelling on packaging / symbols

- Date of manufacture
- Manufacturer
- Catalogue number
- Batch code
- Quantity

Observe the instructions for use, which are available in electronic form at the address specified.

Rx only

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

Cendres+Métaux products with CE labelling meet the requirements of the relevant European requirements.

- Do not re-use
- Non-sterile
- Keep away from sunlight
- Attention, observe accompanying documents
- Unique Device Identification – UDI
- European Authorised Representative
- Importer in EU
- Medical device