

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

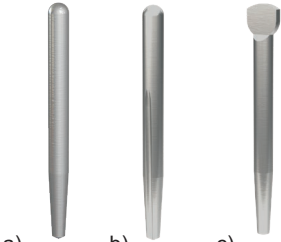
Restoration of chewing function and improved aesthetics.

The summary of safety and clinical performance (SSCP) for the implantable devices covered by these instructions for use, is available on our homepage, accessible at this address: <https://www.cmsa.ch/docs>.


5 Product description

Product	Description
 <p>a) b)</p>	<p>Mooser root canal post</p> <ul style="list-style-type: none"> – Conical profile of the endodontic part. – Two post heads: <ul style="list-style-type: none"> – Ceramicor® precious metal post with adhesive 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 adhesive head

 <p>a) b) c)</p>	<p>CM root canal post</p> <ul style="list-style-type: none"> – Cylindro-conical profile of the endodontic part. – Two post heads: <ul style="list-style-type: none"> – Ceramicor® precious metal post with adhesive 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.
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- a) CM root canal post with adhesive head (without groove)
b) CM root canal post with adhesive head (with groove)
c) CM root canal post with flat head (with groove)

 <p>a)</p>	<p>MP post</p> <ul style="list-style-type: none"> – Cylindro-conical profile of the endodontic part. – Two post versions: <ul style="list-style-type: none"> • 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
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- 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.

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

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.

8 Compatible products

Not applicable.

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

10 Prescription

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

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.

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.

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

14 Preventive measures

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- 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).

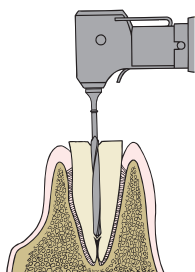
17 Scope of application

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.

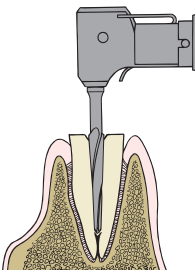
- Post crowns
- Cast abutments
- Temporary abutments

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

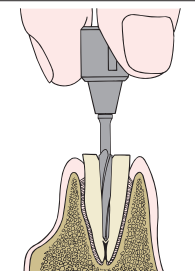
After successful completion of root canal treatment, mechanically enlarge the root canal with the reamer of the corresponding size.

**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.

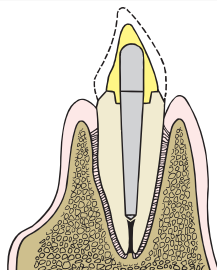


The final calibration of the root canal is prepared manually with the reamer of the corresponding size by means of the Thomas socket wrench. The sinking depth and the parietal fit of the root post are checked with the post gauge.

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.

Procedure examples:

MP post yellow (smallest root canal post)

Prepare the root canal mechanically with the MP root canal reamer yellow (Cat. No. 20000441).

MP post green (largest root canal post)

Prepare the root canal mechanically with the MP root canal reamer yellow (Cat. No. 20000441).

Then continue with the MP root canal reamer red (Cat. No. 20000447)

Then continue with the MP root canal reamer blue (Cat. No. 200004451)

Complete the preparation with the MP root canal reamer green (Cat. No. 200004455)

Please note that the ascending order must be strictly adhered to. Otherwise, the root canal reamer will exert too much pressure on the root canal, resulting in possible fracture.

Root canal posts in burn-out plastic

The mechanical properties of the cast alloy must include proof stress R_p 0.2% of at least 500 MPa. The sprues must be arranged such that elimination of the wax and plastic, as well as flow of the liquid alloy into the form of the casting object is optimised (avoid acute angles and sharp corners). Use of aggressive surfactants, which could damage the shape of the root canal post, should be avoided. It is advantageous to use high-strength and shock-resistant investment material (e.g. CM 20) and to avoid the rapid casting technique (speed method).

Preheating the casting cylinder: pay attention to slow temperature rise. With the opening down, place the cast cylinder in the furnace (facilitates the flow and elimination of the wax and plastic). Maintain at 250 – 300°C until the model is completely eliminated. Maintain this temperature as long as possible (30 – 45 min.). Perform the cast according to the specifications of the alloy manufacturer. Slowly cool to room temperature. Should casting defects such as bubbles or a lack of precision on one edge occur, the cast can be reworked provided this does not affect the precision and original dimensions.


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.

19 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 implants with water and a soft toothbrush as well as an interdental brush. Do not use toothpaste to avoid damage.

Pay attention to regular cleaning of the anchorage 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.

The user is also obliged to regularly study the latest developments of the Cendres+Métaux SA products listed in Table 1 and their applications.

Please note: the descriptions contained in this document are not sufficient for the immediate application 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



Cat. No.	Product name	Material	Single use	Labelling	Basic UDI-DI
Root canal posts Mooser					
05003505	Adhesive head C (Size 1)	Ceramicor®	YES	CE 0483	764016651000048EB
05003506	Adhesive head C (Size 2)	Ceramicor®	YES	CE 0483	764016651000048EB
05003507	Adhesive head C (Size 3)	Ceramicor®	YES	CE 0483	764016651000048EB
05003509	Adhesive head C (Size 4)	Ceramicor®	YES	CE 0483	764016651000048EB
05003589	Flat head T (Size 1).	Titanium	YES	CE 0483	764016651000048EB
05003590	Flat head T (Size 2)	Titanium	YES	CE 0483	764016651000048EB
05003591	Flat head T (Size 3)	Titanium	YES	CE 0483	764016651000048EB
05003592	Flat head T (Size 4)	Titanium	YES	CE 0483	764016651000048EB
072310	Root canal drill (White) Post size 1	Steel	NO	CE 0483	764016651000060DZ
072311	Root canal drill (Yellow) Post size 2	Steel	NO	CE 0483	764016651000060DZ
072312	Root canal drill (Red) Post size 3	Steel	NO	CE 0483	764016651000060DZ
072313	Root canal drill (Blue) Post size 4	Steel	NO	CE 0483	764016651000060DZ
072314	Pilot reamer (White) Post size 1	Steel	NO	CE 0483	764016651000060DZ
072315	Pilot reamer (Yellow) Post size 2	Steel	NO	CE 0483	764016651000060DZ
072316	Pilot reamer (Red) Post size 3	Steel	NO	CE 0483	764016651000060DZ
072317	Pilot reamer (Blue) Post size 4	Steel	NO	CE 0483	764016651000060DZ
070287	Reamer (White) Post size 1	Steel	NO	CE 0483	764016651000019E4
072318	Reamer (Yellow) Post size 2	Steel	NO	CE 0483	764016651000019E4
070288	Reamer (Red) Post size 3	Steel	NO	CE 0483	764016651000019E4
072319	Reamer (Blue) Post size 4	Steel	NO	CE 0483	764016651000019E4
070221	Thomas spanner key	Steel	NO	CE	764016651000013DQ
070483	Post gauge size 1-4	Steel	NO	CE 0483	764016651000061E3
072414	Coupling piece	Steel	NO	CE	764016651000014DS
08000003	Root canal posts Mooser Endobox	Steel	NO	n/a	n/a
CM root canal post					
05003194	Adhesive head C (Size 1)	Ceramicor®	YES	CE 0483	764016651000048EB
05003195	Adhesive head C (Size 2)	Ceramicor®	YES	CE 0483	764016651000048EB
05003202	Adhesive head C (Size 3)	Ceramicor®	YES	CE 0483	764016651000048EB
05003210	Adhesive head C (Size 4)	Ceramicor®	YES	CE 0483	764016651000048EB
05003211	Adhesive head C (Size 5)	Ceramicor®	YES	CE 0483	764016651000048EB
05003219	Adhesive head C (with cement flow-off groove) (Size 1)	Ceramicor®	YES	CE 0483	764016651000048EB
05003226	Adhesive head C (with cement flow-off groove) (Size 2)	Ceramicor®	YES	CE 0483	764016651000048EB
05003234	Adhesive head C (with cement flow-off groove) (Size 3)	Ceramicor®	YES	CE 0483	764016651000048EB
05003242	Adhesive head C (with cement flow-off groove) (Size 4)	Ceramicor®	YES	CE 0483	764016651000048EB
05003250	Adhesive head C (with cement flow-off groove) (Size 5)	Ceramicor®	YES	CE 0483	764016651000048EB
05003584	Flat head T (with cement flow-off groove) (Size 1)	Titanium	YES	CE 0483	764016651000048EB
05003585	Flat head T (with cement flow-off groove) (Size 2)	Titanium	YES	CE 0483	764016651000048EB

Cat. No.	Product name	Material	Single use	Labelling	Basic UDI-DI
05003586	Flat head T (with cement flow-off groove) (Size 3)	Titanium	YES	CE 0483	764016651000048EB
05003587	Flat head T (with cement flow-off groove) (Size 4)	Titanium	YES	CE 0483	764016651000048EB
05003588	Flat head T (with cement flow-off groove) (Size 5)	Titanium	YES	CE 0483	764016651000048EB
072326	Root canal drill (White) Post size 1	Steel	NO	CE 0483	764016651000060DZ
072321	Root canal drill (Yellow) Post size 1	Steel	NO	CE 0483	764016651000060DZ
072327	Root canal drill (Red) Post size 3	Steel	NO	CE 0483	764016651000060DZ
072328	Root canal drill (Blue) Post size 4	Steel	NO	CE 0483	764016651000060DZ
072329	Root canal drill (Green) Post size 5	Steel	NO	CE 0483	764016651000060DZ
070243	Reamer (White) Post size 1	Steel	NO	CE 0483	764016651000019E4
070244	Reamer (Yellow) Post size 2	Steel	NO	CE 0483	764016651000019E4
070245	Reamer (Red) Post size 3	Steel	NO	CE 0483	764016651000019E4
070246	Reamer (Blue) Post size 4	Steel	NO	CE 0483	764016651000019E4
070247	Reamer (Green) Post size 5	Steel	NO	CE 0483	764016651000019E4
070221	Thomas spanner key	Steel	NO	CE	764016651000013DQ
070483	Post gauge size 1-5	Steel	NO	CE 0483	764016651000061E3
072414	Coupling piece	Steel	NO	CE	764016651000014DS
08000003	Endobox Root canal posts	Steel	NO	n/a	n/a




















MP-Post

200004301	MP-Post X yellow size 1	Steel	YES	CE 0483	764016651000048EB
200004310	MP-Post X red size 2	Steel	YES	CE 0483	764016651000048EB
200004319	MP-Post X blue size 3	Steel	YES	CE 0483	764016651000048EB
200004328	MP-Post X green size 4	Steel	YES	CE 0483	764016651000048EB
200004302	MP-Post Standard K yellow size 1	Korak	YES	n/a	764016651000062E5
200004311	MP-Post Standard K red size 2	Korak	YES	n/a	764016651000062E5
200004320	MP-Post Standard K blue size 3	Korak	YES	n/a	764016651000062E5
200004329	MP-Post Standard K green size 4	Korak	YES	n/a	764016651000062E5
200004441	Root canal drill yellow (Size 1)	Steel	NO	CE 0483	764016651000060DZ
200004447	Root canal drill red (Size 2)	Steel	NO	CE 0483	764016651000060DZ
200004451	Root canal drill blue (Size 3)	Steel	NO	CE 0483	764016651000060DZ
200004455	Root canal drill green (Size 4)	Steel	NO	CE 0483	764016651000060DZ
200004436	MP root canal drill	Steel	NO	CE 0483	764016651000060DZ
200004442	MP auxiliary drill	Steel	NO	CE 0483	764016651000060DZ
070221	Thomas spanner key	Steel	NO	CE	764016651000013DQ

30 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.
www.cmsa.ch/docs
-  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