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Root canal posts

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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 Section 29. 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 Section 29.

3 Intended use

The products are intended for prosthetic restorations 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 website and accessible at this address: www.cmsa.ch/docs.

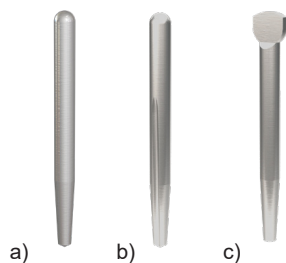
5 Product description



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.
- 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.

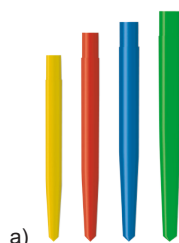
- a) Mooser root canal post with flat head
b) Mooser root canal post with adhesion head



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.
- 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.
 - 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.

 The recommended speed for the root canal instruments is 450 to a maximum of 1200 rpm.

6 Indications

These products are inserted into the tooth root if the dental crown is largely destroyed. They are intended for providing retention for posts for composite resin build-ups, or cast post build-ups, in the context of endodontic treatment.

- Post crowns
- Casted post copings with retentive elements to retain removable dental prostheses.
- Direct retentive elements to retain removable dental prostheses.

7 Contraindications

- 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.
- Patients who are unable to keep the regularly required check-up appointments for health reasons.
- Patients with bruxism or other para-functional habits.
- Patients with allergies to materials used in the product, see Section 19.
- Existing clinical picture in the patient's mouth does not permit the correct application of the products.

8 Compatible products

- Anchors
- Post crowns
- Abutments
- Cements and adhesives for the fixation to natural teeth
- Mainly composite filling and build-up materials, rarely amalgams, for individual build-ups
- Dental precious metal alloys like ceramic -, casting - or universal alloys, solders, and laser welding wire.

To fabricate the finished denture, a number of general laboratory supplies are required in addition to the products listed under Section 29. The following gives a selection of materials that Cendres+Métaux SA offers in its portfolio.

08052138	Polyurock Kit	080181	CM soldering investment (4 kg)
08052137	Polyurock Mixer	080229	CM soldering paste
08052149	ABF Wax Universal	08052307	Legabril Diamond (50 g)
08052150	ABF Wax Creativ light		
08052151	ABF Wax Creativ dark		
08052154	ABF Wax Special		
08052148	ABF Wax Margin		
08052153	ABF Wax Position		
08052152	ABF Wax Tecno		
08055014	Livento® invest Powder (50 x 100 g)		
083739	Livento® invest Liquid (1000 ml)		

9 Qualification of the specialist

Expertise in professional dentistry and dental technology is assumed. The current Instructions for Use must be available at all times and be completely read and understood before the first application. The fabrication of dentures and their maintenance may only be performed by qualified specialists.

 Important information for the specialist

 Warning symbol for increased caution

10 Prescription

Federal laws in the USA prohibit the use by or sale to unlicensed dentists.

11 Side effects

 This product must not be used in patients with allergies or suspected allergies to materials used in the product (see Section 19), or only after prior allergological clarification.

Auxiliary instruments may contain nickel.

If applied as intended, side effects can be excluded.

12 Warnings** Magnetic resonance (MR) 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

N/A

14 Preventive measures

- The product components are supplied non-sterile. For more information see Section 16 «Reprocessing».
- Only original tools and parts may be used for this work. For information and additional details, please contact your Cendres+Métaux SA representative.
- Before any procedure, ensure that all required product components are available in sufficient quantity.
- For your own safety, always wear suitable protective clothing. In particular when grinding, we recommend wearing protective goggles and a dust mask as well as the use of a suction unit.
- Secure parts against aspiration.
- The mechanical cleaning by patients with a toothbrush and toothpaste may lead to premature wear.
- 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

Products that are intended for single use and are labelled «single-use» accordingly are subject to a certain amount of stress, increased wear, and even loss of functionality during their use.



Multiple application of products labelled «single use» was not tested. This can impair the safety, function and performance of the products as well as increase the risk of transmitting infections.

16 Reprocessing

The prosthetic work, including all system components, must be cleaned, disinfected and, if appropriate, sterilised prior to each work step. Materials made of metal alloys, high-performance polymers (Pekkton®) and ceramics are suitable for steam sterilisation. With the exception of Pekkton®, components made of plastics are not suitable for steam sterilisation. Consider published national guidelines when selecting a disinfection and sterilisation process and the Instructions for Use «Reprocessing 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.

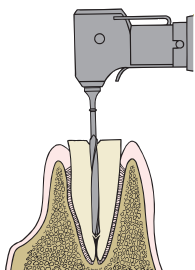
- Post crowns
- Cast abutments
- Temporary abutments

18 Procedure

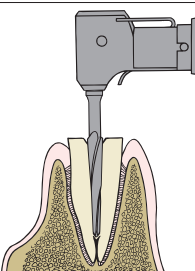
The tooth root must first be treated endodontically. The tooth or root is then prepared based on the specific indication. The choice of prosthetic products to be used depends on the X-ray, anatomy and root canal situation (length and diameter).



When using the post gauge intraorally, remove the posts from the ring holder.

18.1 Mooser / CM root canal post

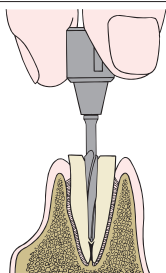
After successful completion of root canal treatment, mechanically enlarge the root canal with the reamer of the corresponding size.

**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.

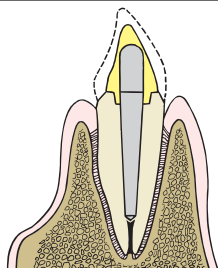


The final calibration of the root canal is prepared manually with the reamer of the corresponding size by means of the Thomas socket wrench. The sinking depth and the parietal fit of the root post are checked with the post gauge.

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

More detailed information on the materials as well as their compositions can be found in the product-specific material data sheets, the product information as well as the product list compiled in Section 29. All relevant documents can be found on the website www.cmsa.ch/docs by entering the relevant product name.

20 Notes on storage



Insofar as no specific information on storage is given on the packaging of the product, we recommend storing the product in its original packaging, in a dry place, at room temperature and without direct sunlight. 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 the patients are motivated and instructed with regard to caring for their teeth as well as dentures.

Permanent and removable dentures are subject to considerable stress. Signs of wear are normal 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 teeth and dentures after every meal. Cleaning of dentures includes cleaning of the connecting element. Gentlest cleaning can be achieved by cleaning the restoration under running water with a soft toothbrush and the connecting element in the mouth with an interdental brush. The most intensive cleaning of the restoration is achieved with the aid of an ultrasonic device and a cleaning additive suitable for dentures.

Never clean the high precision connecting elements with toothpaste as this could lead to damage. Caution should also be exercised in the case of aggressive cleaning agents or tablets as this could damage the high-quality connecting element or impair its function.

Regular cleaning of the anchorage can prevent inflammation of the soft tissue.

22 Ordering information

The information relevant to your order can be found in the product list in Section 29 of this document. The product information is also helpful. This and other relevant documents can be found on the website www.cmsa.ch/docs by entering the relevant product name.

23 Availability

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

24 Traceability of the lot number

The lot numbers of all parts used must be documented to ensure traceability.

25 Complaint

Cendres+Métaux SA must be notified immediately of any incident that has occurred with regard to the product. To do this, please contact your customer advisor or send us your message by e-mail to the address complaints-cmbrand@cmsa.ch. In serious cases, also send a report to the competent authority where you are domiciled.

26 Safe disposal

The products 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. Cendres+Métaux SA products are parts of an overall concept and may only be used or combined with the appropriate original components and instruments. Otherwise, the manufacturer rejects any responsibility and liability. In case of complaints, please always include the lot number.

The use of third party products not distributed by Cendres+Métaux SA in connection with the products mentioned in the product list in Section 29 will void any warranty or other express or implied obligation of Cendres+Métaux SA.

Responsibility regarding the suitability of a product for the specific patient case is at the discretion of the specialist.

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 of Cendres+Métaux SA products.

The specialist is obliged to regularly study the latest developments of the products mentioned in the product list in Section 29 and their applications.

It should be noted that the descriptions contained in this document are not sufficient for the immediate application of Cendres+Métaux SA products. Expertise in dentistry, dental technology and instructions by an experienced specialist in the use of the products mentioned in the product list under Section 29 is always necessary.

In case of inconsistencies in translations, the English language version shall prevail.

29 Product list

Cat. No.	Product name	Material	Single use	Labelling	UDI-DI
Root canal posts Mooser					
05003505	Adhesive head C (Size 1)	Ceramicor®	YES	CE 0483	07640173099062
05003506	Adhesive head C (Size 2)	Ceramicor®	YES	CE 0483	07640173099079
05003507	Adhesive head C (Size 3)	Ceramicor®	YES	CE 0483	07640173099086
05003509	Adhesive head C (Size 4)	Ceramicor®	YES	CE 0483	07640173099093
05003589	Flat head T (Size 1).	Titanium	YES	CE 0483	07640173099109
05003590	Flat head T (Size 2)	Titanium	YES	CE 0483	07640173099130
05003591	Flat head T (Size 3)	Titanium	YES	CE 0483	07640173099147
05003592	Flat head T (Size 4)	Titanium	YES	CE 0483	07640173099161
072310	Root canal drill (White) Post size 1	Steel	NO	CE 0483	07640166512561
072311	Root canal drill (Yellow) Post size 2	Steel	NO	CE 0483	07640166512578
072312	Root canal drill (Red) Post size 3	Steel	NO	CE 0483	07640166512585
072313	Root canal drill (Blue) Post size 4	Steel	NO	CE 0483	07640166512592
072314	Pilot reamer (White) Post size 1	Steel	NO	CE 0483	07640166512608
072315	Pilot reamer (Yellow) Post size 2	Steel	NO	CE 0483	07640166512615
072316	Pilot reamer (Red) Post size 3	Steel	NO	CE 0483	07640166512622
072317	Pilot reamer (Blue) Post size 4	Steel	NO	CE 0483	07640166512639
070287	Reamer (White) Post size1	Steel	NO	CE 0483	07640173092797
072318	Reamer (Yellow) Post size 2	Steel	NO	CE 0483	07640173091554
070288	Reamer (Red) Post size 3	Steel	NO	CE 0483	07640173092803
072319	Reamer (Blue) Post size 4	Steel	NO	CE 0483	07640173091561
070221	Thomas spanner key	Steel	NO	CE	07640166511861
070483	Post gauge size 1-4	Steel	NO	CE 0483	07640166519348
072414	Coupling piece	Steel	NO	CE	07640166514855
08000003	Root canal posts Mooser Endobox	Steel	NO	N/A	07640173091325
CM root canal post					
05003194	Adhesive head C (Size 1)	Ceramicor®	YES	CE 0483	07640173099185
05003195	Adhesive head C (Size 2)	Ceramicor®	YES	CE 0483	07640173099192
05003202	Adhesive head C (Size 3)	Ceramicor®	YES	CE 0483	07640173099208
05003210	Adhesive head C (Size 4)	Ceramicor®	YES	CE 0483	07640173099215
05003211	Adhesive head C (Size 5)	Ceramicor®	YES	CE 0483	07640173099222
05003219	Adhesive head C (with cement flow-off groove) (Size 1)	Ceramicor®	YES	CE 0483	07640173099239
05003226	Adhesive head C (with cement flow-off groove) (Size 2)	Ceramicor®	YES	CE 0483	07640173099246
05003234	Adhesive head C (with cement flow-off groove) (Size 3)	Ceramicor®	YES	CE 0483	07640173099253
05003242	Adhesive head C (with cement flow-off groove) (Size 4)	Ceramicor®	YES	CE 0483	07640173099260
05003250	Adhesive head C (with cement flow-off groove) (Size 5)	Ceramicor®	YES	CE 0483	07640173099277
05003584	Flat head T (with cement flow-off groove) (Size 1)	Titanium	YES	CE 0483	07640173099338
05003585	Flat head T (with cement flow-off groove) (Size 2)	Titanium	YES	CE 0483	07640173099345
05003586	Flat head T (with cement flow-off groove) (Size 3)	Titanium	YES	CE 0483	07640173099352
05003587	Flat head T (with cement flow-off groove) (Size 4)	Titanium	YES	CE 0483	07640173099369
05003588	Flat head T (with cement flow-off groove) (Size 5)	Titanium	YES	CE 0483	07640173099376
072326	Root canal drill (White) Post size1	Steel	NO	CE 0483	07640173091585
072321	Root canal drill (Yellow) Post size1	Steel	NO	CE 0483	07640173091578
072327	Root canal drill (Red) Post size 3	Steel	NO	CE 0483	07640173091592
072328	Root canal drill (Blue) Post size 4	Steel	NO	CE 0483	07640173091608
072329	Root canal drill (Green) Post size 5	Steel	NO	CE 0483	07640173091615
070243	Reamer (White) Post size 1	Steel	NO	CE 0483	07640173092742
070244	Reamer (Yellow) Post size 2	Steel	NO	CE 0483	07640173092759
070245	Reamer (Red) Post size 3	Steel	NO	CE 0483	07640173092766
070246	Reamer (Blue) Post size 4	Steel	NO	CE 0483	07640173092773
070247	Reamer (Green) Post size 5	Steel	NO	CE 0483	07640173092780
070221	Thomas spanner key	Steel	NO	CE	07640166511861
070481	Post gauge size 1-5	Steel	NO	CE 0483	07640166519331
072414	Coupling piece	Steel	NO	CE	07640166514855
08000003	Endobox Root canal posts	Steel	NO	N/A	07640173091325

Cat. No.	Product name	Material	Single use	Labelling	UDI-DI
MP-Post					
200004301	MP-Post X yellow size 1	Steel	YES	CE 0483	07640166515265
200004310	MP-Post X red size 2	Steel	YES	CE 0483	07640166515272
200004319	MP-Post X blue size 3	Steel	YES	CE 0483	07640166515289
200004328	MP-Post X green size 4	Steel	YES	CE 0483	07640166515296
200004302	MP-Post Standard K yellow size 1	Korak	YES	N/A	07640166517955
200004311	MP-Post Standard K red size 2	Korak	YES	N/A	07640166517986
200004320	MP-Post Standard K blue size 3	Korak	YES	N/A	07640166518013
200004329	MP-Post Standard K green size 4	Korak	YES	N/A	07640166518044
200004441	Root canal drill yellow (Size 1)	Steel	NO	CE 0483	07640166515319
200004447	Root canal drill red (Size 2)	Steel	NO	CE 0483	07640166515333
200004451	Root canal drill blue (Size 3)	Steel	NO	CE 0483	07640166515340
200004455	Root canal drill green (Size 4)	Steel	NO	CE 0483	07640166515357
200004436	MP root canal drill	Steel	NO	CE 0483	07640166515302
200004442	MP auxiliary drill	Steel	NO	CE 0483	07640166515326
070221	Thomas spanner key	Steel	NO	CE	07640166511861

The products in the "Root canal posts" family are assigned the following basic UDI-DI:

Product	Basic UDI-DI
Handles	764016651000013DQ
	764016651000014DS
Reamers	764016651000019E4
Root canal gauges	764016651000061E3
Root canal mechanic instruments	764016651000060DZ
Root canal posts	764016651000048EB
	764016651000066ED

30 Labelling on packaging/symbols

	Date of manufacture
	Manufacturer
	Catalogue number
	Lot number
	Quantity
 www.cmsa.ch/docs	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
	Protect from sunlight
	Attention, observe accompanying documents
	Clear product identification
	European Authorised Representative
	Importer
	Medical device

