

Instructions for use

Root canal posts

The use and periodic maintenance of root canal posts must be carried out exclusively by skilled persons.
Only original tools and parts may be used for this work.

Upon publication, these instructions for use supersede all previous editions.

The manufacturer is not liable for any damages due to the user disregarding the instructions for use below.

Intended use

Root canal posts manufactured by Cendres+Métaux SA are inserted into tooth roots with large-scale deterioration of the dental crown. They are intended for stabilizing tooth roots and for providing retention for root caps, abutments or post crowns in the context of endodontic treatment. The root canal posts are posts and provide retention of abutments fabricated in the mouth.

General information

Traceability of the batch numbers

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

Sterilization

The root canal posts, cutting drills and auxiliary instruments are supplied non-sterile.
All metal components must be sterilized and cleaned prior to use. Sterilization is performed as steam sterilization at 134°C, duration: 18 min. (see Care and maintenance surgical and prosthetic instruments www.cmsa.ch/dental)

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 proven efficacy in disinfection.

All parts made of plastic must be disinfected with a high EPA-registered disinfectant prior to use.

Recommended: Cidex® OPA Solution. Strictly follow the manufacturer's instructions.

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 further information, please contact your Cendres+Métaux representative.

The drilling depth must be determined from the X-ray image. Auxiliary instruments may contain nickel (see Labeling on packaging).

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

These instructions for use are not sufficient for immediate use of the root canal posts. Dental or laboratory knowledge is required, as well as an introduction to handling the Cendres+Métaux root canal posts by an experienced person. Courses and training are regularly offered by Cendres+Métaux. Only original tools and parts may be used for this work.

If the root canal post breaks, an endo safety system can be used to carefully remove the fragment.

Preventive measures

- The components are supplied non-sterile. Proper preparation of the components prior to use in the patient is described in the «Sterilization» and «Disinfection» chapters.
- For intraoral use, all products must be generally secured against aspiration.
- No cutting work may be carried out in the patient's mouth.

Specification

Conical profile

Indication

- Root canal post caps for partial and hybrid dentures,
- post crowns,
- cast abutments,
- temporary work (30 day).

Contraindication

If a snug fit root canal preparation is not possible in the case of a very large root canal.

Periodontitis, severe gum disease, poor oral hygiene, caries and marginal inter-occlusal space.

Otherwise, based on today's scientific knowledge, there are no restrictions on indication for precious metal posts after successful endodontic treatment.

The titanium root posts are only suitable for temporary work due to the geometry of the post head.

In patients with allergies to one or more elements of the attachment materials. Lacking cooperation of the patient with respect to follow-up/recall instructions.

Patients with bruxism or other parafunctional habits.

Rx only

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

Materials

The root canal posts are manufactured from cold worked material. For this reason they possess a high mechanical strength.

1. Precious metal root canal posts

Ceramicor®

Non-oxidising gold-platinum alloy. Ceramicor® is suited for casting-on with all precious metal alloys. **Ceramicor® is not suited for casting-on with non-precious metal alloys.**

2. Titanium root canal posts

Root posts for temporaries in pure titanium (grade 4, standard ASTM F 67). **Titanium is not suited for casting on.**

All materials listed are corrosion-resistant and exhibit excellent mechanical strength.

Description

The root posts are available in 4 sizes and with 3 different post heads. The precious metal root posts and the root canal instruments are colour coded. The colour code for the root canal posts is given by the colour of the boxes. However, the titanium root posts are number coded.

For the root canal preparation there is a root canal drill, a pilot reamer and a reamer supplied for each size.

Post heads

The **adhesive head (A)** is the ideal solution for all elastic impression compounds. Thanks to its special shape, the impression remains undamaged even with non-parallel abutments. A possible repositioning is carried out with slight finger pressure on the root canal post.

The **retention head (B)** is especially conceived for cores, which are directly modelled in the mouth and subsequently cast.

The **flat head (C)** is reserved for titanium root canal posts for temporary work (30 days).

Important information

The root canal posts are part of a system and must only be used with corresponding original parts and instruments according to the recommendations of the manufacturer. Otherwise, any responsibility by the manufacturer will be refused.

The root posts must not be exchanged, neither in the impression, nor on the master model (even with identical sizes and shapes). Changes of position would result. The colour coded plastic rings on the posts must be removed before impression taking. The root post alloys are not suited for firing ceramic on to them (CTE). Therefore, care has to be taken that the posts are covered with wax resp. with the casting alloy.

Do not clean any cutting instruments in the ultrasonic cleaner as this could blunt the instruments. Avoid high forces, tilting or leverage in order to prevent danger of instrument fracture.

Observe that cutting instruments should be used max. 10 times only.



Safety measures

To prevent swallowing or aspiration, several precautions must be taken e.g. rubber dam, instruments secured by dental floss. Protect your eyes by wearing protection glasses.

Interaction

Interactive effects (e.g. electrochemical processes) after appropriate application have not become known.

Instructions for use

Fig. 1

Mechanically enlarge the root canal with the root canal drill of the corresponding size, after successful treatment of the root canal.

Fig. 2

Mechanically prepare the root canal with the pilot reamer, which shows already a conical shape.

Fig. 3

The final calibration of the root canal is carried out manually with the reamer of the corresponding size, using the Thomas spanner key.

Following this, the sinking depth and the parietal fit of the root post are checked with the root canal calibre.

As a torsion and overload protection a central inlay must be prepared.

Fig. 4

Cementing

Fill the root canal with cement by means of a lentulo (strictly observe the instructions for use issued by the cement manufacturer). Ensure that the post is situated in its final position.

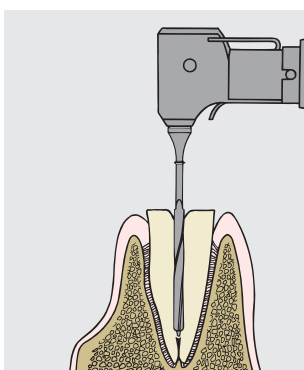


Fig. 1

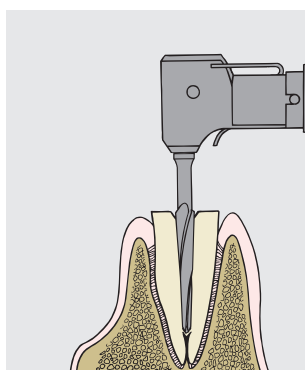


Fig. 2

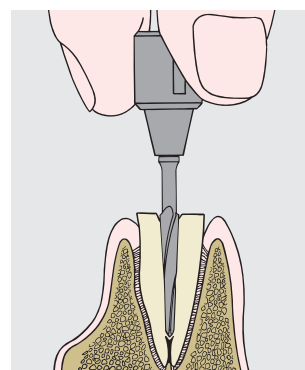


Fig. 3

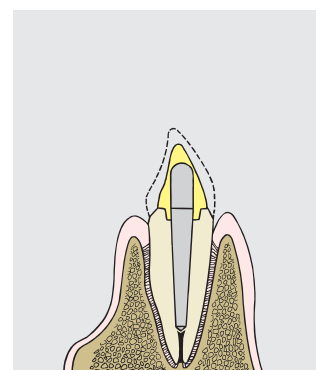


Fig. 4

Symbol / Name	Composition in weight %					Melting range °C	Hardness in delivered condition HV5	Hardness after casting-on HV5
	Au	Pt	Pd	Ir	Ti			
C = Ceramicor	60.0	19.0	20.0	1.0		1400–1490	260	205
T = Titanium					> 98.9375	–	280	–

Cleaning and care

It is best to clean your teeth and your dentures after every meal. For further information, please contact your Cendres+Métaux representative.

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.

Only original tools and parts may be used for this work.

In case of complaints, please always include the batch number.

Labeling on packaging / symbols



Date of manufacture



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.



Cendres+Métaux SA products with CE labeling meet the requirements of the Medical Device Directive 93/42/EEC.



Do not re-use



Non-sterile



Keep away from sunlight



Attention (observe accompanying documents)