

Instructions for use for

Root canal anchor with retention-head

The use and periodic maintenance of root canal anchors 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 anchors 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 anchors are threaded posts and provide retention of cores 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.



Rx only

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

These instructions for use are not sufficient for immediate use of the root canal anchors. Dental or laboratory knowledge is required, as well as an introduction to handling the Cendres+Métaux root canal anchor 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 anchor breaks, a trephine drill 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.

Further hints

for processing are available in the Dental documentation of Cendres+Métaux and in the Internet by visiting www.cmsa.ch/dental.

Specification

Root canal posts with retention-head, endodontic part without screw thread.

Advice

The Pirec system is not compatible with the root canal anchor system Rotex®.

Indication

- Direct abutments
- Larger fillings with amalgam or composite

Contraindication

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 marginal inter-occlusal space.

Materials

Root canal anchor Titanium grade 5 (Ti6Al4V)

S = Syntax TiAl6V4 (grade 5)

Ti > 89.478 %, Al 6.00 %, V 4.00 %

Care and maintenance

All components are supplied **non-sterile** to the customer.

Therefore, all products need to be disinfected. Surgical instruments must be sterilized prior to use. Adhere strictly to the manufacturer's instructions for the use of disinfectants (duration of application and concentration).

Sterilization is performed as steam sterilization at 134 °C, duration: 18 min. (EN 13060).

Reusable surgical instruments must be disinfected immediately after use and then cleaned to remove any deposits (use a nylon brush if necessary). Thoroughly rinse the instruments with water, place in an autoclave bag or surgical cassette and sterilize according to the above parameters. Not recommended for stainless steel: Chloric disinfectants or cleaning agents or agents contaminated with chlorine (e.g. by physiological saline solution), disinfectants or cleaning agents containing oxalic acid.

Important information

The Pirec is part of a system and must only be used with the corresponding original parts and instruments according to the recommendations of the manufacturer. Otherwise, any responsibility by the manufacturer will be declined. Do not clean any cutting instruments in the ultrasonic cleaner as this could blunt the instruments. Avoid high pressures, tilting or leverage in order to prevent danger of instrument fracture.

Observe that cutting instruments should be used maximum 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 protective glasses.

Instructions for use

1. Starting situation

root canal therapy completed, Gutta Percha in root canal.

2. Selection of the fiberglass post

Size selection is based on the X-ray, the anatomy and the post hole canal situation (length and diameter).

3. Preparation of the root canal

Penetrate the root filling material to the desired depth with a hot instrument or a small Peso reamer running at moderate speed.

Enlarge the canal to the desired dimension using the MP root canal drill (Order No. 200004436).

The correct depth for every reamer size is marked by a notch on the reamer.

Always start with the smallest and go to the next. Do not jump sizes, the reamer may exert too much torque on the root, get stuck or break.

Example:

Pirec yellow

use Pirec / Endo-Snap root canal drill yellow (Order No. 200004446)

Pirec green

start with Pirec / Endo-Snap root canal drill yellow (Order No. 200004446)

go to the Pirec / Endo-Snap root canal drill red (Order No. 200004450)

go to the Pirec / Endo-Snap root canal drill blue (Order No. 200004454)

finish with Pirec / Endo-Snap root canal drill green (Order No. 200004458)

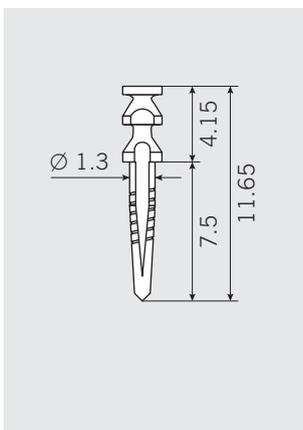
Finally cut a recess of a depth of about 0.5 mm into the top surface of the root using the special front-end-cutting-instrument.

4. Control

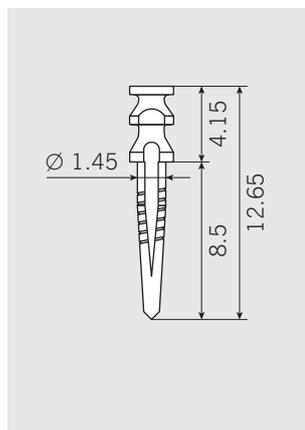
Try-in the Pirec and check for correct seating.

5. Fixation of the root canal post

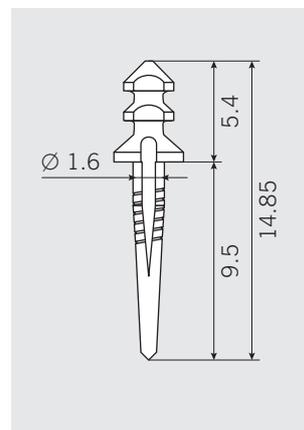
Insert the attachment into the special index provided, coat the post with cement and slide it slowly into the canal.



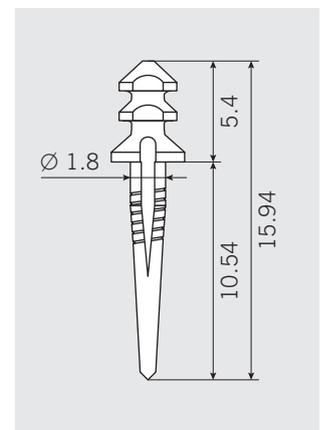
200004299



200004308



200004317



200004326

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)