

Instructions for use

Root canal anchor

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.

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.

Specification

Root canal anchor with retention head and self-cutting thread.

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.

Material

Rotex® and Rotex®-RD anchors are made of pure titanium (grade 4, standard ASTM F67). This material is corrosion-resistant and exhibits high mechanical strength.

It corresponds to the standard ASTM F 67-89.

Titanium is not suitable for casting.

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.

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.

Rx only

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

Important information

Rotex®- and Rotex®-RD root canal anchors 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. 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.

Description

The root canal anchors are available in 3 sizes and in 2 executions.

a. Rotex®-root canal anchor
with extended retention lamellae.

b. Rotex®-RD-root canal anchor
with reduced diameter of the retention head.

The endodontic part has a self-cutting thread, a rounded point, cement flow-off grooves and is slightly conical. These properties allow near tension-free setting of the root canal anchor.

The endodontical part is identical for both versions. The special head geometry of the Rotex®-RD root canal anchor ensures good anchoring of the build-up material even in limited spaces. With multi-rooted teeth, the Rotex®-RD can be combined with the Rotex® root canal anchor.

The **root canal instruments** are standardized, color-coded and have a depth mark or depth stop.

The root canal drills and the reamers are identical for Rotex® and Rotex®-RD system, only the face cutting drills are different.

A coupling piece is available to extend the instruments.



Rotex®



Rotex®-RD

Instruction for use

Fig. 1

After successful endodontical treatment of the root canal, the pattern is positioned on the x-ray for the choice of the anchor-size. The pattern shows the contour of the anchor at a scale of 1.2:1 and corresponds approx. to the scale of the x-ray. Afterwards, the root-canal is mechanically predrilled with the drill of the corresponding size. The mark on the shaft indicates the drilling depth.

Fig. 2

The preparation of the support area for the retention head is carried out with the face-cutting drill (sinking depth max. 0.5 mm). The entire base of the retention head should rest on the flat support area. Thus an optimal distribution of the forces is achieved.

Fig. 3

The calibration of the bore is prepared manually with the reamer of the corresponding size by means of the Thomas-spanner key.

Fig. 4

Thread-cutting

Insert the root canal anchor by means of the spanner key as far as possible into the root canal. The thread is now in contact with the root canal wall. Then make one turn in clockwise direction followed by 1/2 a turn in anti-clockwise direction in order to reduce the tensions acting on the root dentin. The end position is reached, when the retention head lies flat on the plane surface of the prepared root. After thread cutting remove the anchor and fill the root canal with cement using a lentulo.

Fig. 5

Reinsert the root canal anchor, initially turning in an anti-clockwise direction (A) until the thread of the anchor engages in the preformed grooves (this can be clearly felt). Then tighten clockwise (B) until the end position is reached. Remove the surplus cement and build up the crown core with a plastic build-up material.

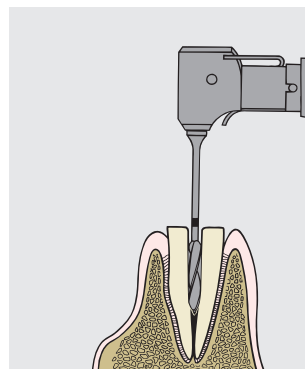


Fig. 1

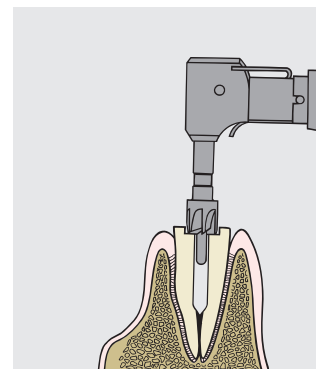


Fig. 2

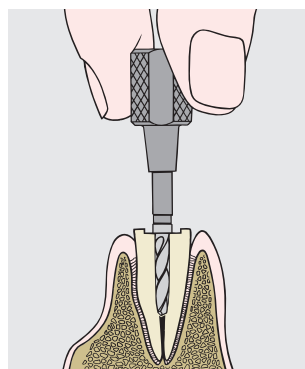


Fig. 3

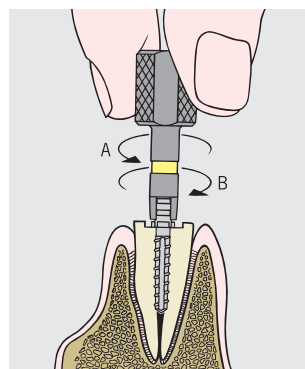


Fig. 4

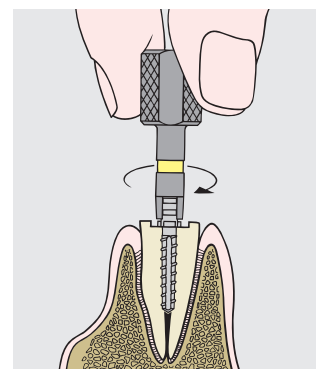


Fig. 5

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)