

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.

With the publication of these instructions for use all previous editions are no longer valid.

The manufacturer refuses any liability for damages due to disregard of 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 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 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 self-cutting thread combined with prosthetic retainer.

Indication

Temporary fixation of partial and hybride dentures.

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.

In the case of a favorable long term prognosis of the teeth to be treated. Otherwise, based on today's scientific knowledge, there are no restrictions on indication after successful endodontic treatment.

Rx only

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

Material

The Dalbo®-Rotex® anchors are made of pure titanium (grade 4, standard ASTM F 67). Titanium is corrosion-resistant and exhibits mechanical strength.

The female parts are available in two different materials:

a. In special mouth and heat resistant plastic (Galak).

b. In the precious metal alloy Elitor®.

Composition in weight %:

Au 68.60, Pt 2.35, Pd 3.95, Ag 11.85, Cu 10.60, Zn 2.50, Ir 0.05.

Description

The Dalbo®-Rotex®-anchor system is intended as an economical solution in social and geriatric health care, e.g. in the case of roots with an unfavourable long term prognosis.

The Dalbo®-Rotex® anchors are available in two different versions and in two sizes each.

The endodontical part is identical for both versions. It has a self-cutting thread, a rounded point, two cement flow-off grooves and is slightly conical. These properties enable a nearly tension-free insertion of the Dalbo®-Rotex® anchor. The spherical diameter is identical for both versions and all sizes. The retention of the female part in plastic is guaranteed by the elasticity of the double walled construction.

The female part in precious metal is adjustable. The desired retention strength can be adjusted by means of the activator or deactivator.

The **root canal instruments** are standardized, colour-coded and have a depth mark resp. a depth stop. The root canal drills and the reamers are identical for both versions, only the face cutting drills are different.

For the extension of the instruments a coupling piece (11.01.129) is available.

Care and maintenance

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



Dalbo®-Rotex® 15.41

Dalbo®-Rotex® 15.42

Important information

The Dalbo®-Rotex® 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.

Additional information

The female parts of the new Dalbo®-Classic (43.02) und Dalbo®-PLUS (43.04) will also fit onto the male part of the Dalbo®-Rotex® by Dr. Dalla Bona/Prof. Brunner.

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.

Interaction

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

Instruction for use for Dalbo®-Rotex® 15.41

Fig. 1

a. Flat root surface

Mechanically enlarge the root canal with the root canal drill of the corresponding size. The mark on the shaft of the root canal drill corresponds to the drilling depth.

Fig. 2

Prepare the support area for the spherical anchor with the corresponding face cutting drill (sinking depth max. 0.5mm).

Fig. 3

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

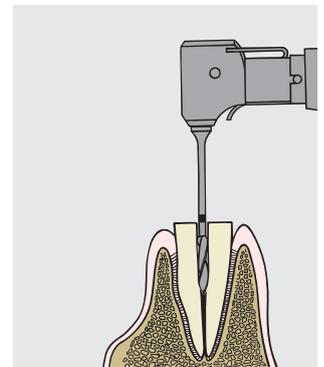


Fig. 1

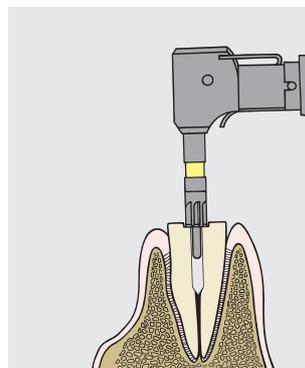


Fig. 2

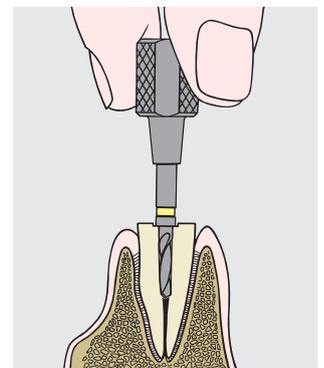


Fig. 3

Thread cutting

Insert the Dalbo®-Rotex®-anchor by means of the spanner key as far as possible into the root canal. The thread is now in contact with the root wall. Then make one turn in clock-wise direction followed by a ½ turn in anti-clockwise direction in order to reduce the tensions acting on the root dentine. The final position is reached, when the spherical head lies flat on the prepared root. After thread cutting remove the anchor and fill the canal with cement using a lentulo.

Reinsert the root canal anchor, initially turning in an anti-clockwise direction until the thread of the anchor engages in the preformed grooves (this can be clearly felt). Then tighten clockwise until the final position is reached. Remove the surplus cement.

b. With sloped root surfaces the «sandwich» technique is indicated.

The position of the anchor plate must be adapted to the clinical case or the root slope. (Root canal preparation and thread cutting see 15.41a).

Fig. 4

After thread cutting remove the Dalbo®-Rotex® from the canal and cut small supplementary retentions onto the root surface with a drill.

Fig. 5

Fix the Dalbo®-Rotex® with glass ionomer cement and disperse the excess of cement into the retentions and on the root surface. After hardening of the cement, etch the surface with an etching gel (approx. 30 sec.). Rinse and dry the surface well and remove the cement from the margin. Cover the surface with light curing resin and polish subsequently.

Instruction for use for Dalbo®-Rotex® 15.42

Root canal preparation, thread cutting and cementing see 15.41a.

Fig. 6

The hermetical closure of the root canal ensues with amalgam.

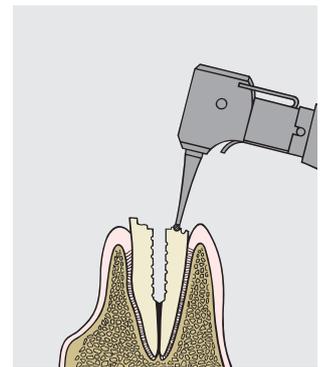


Fig. 4

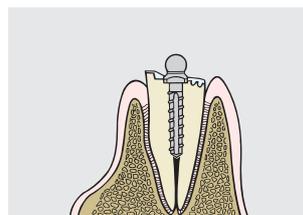


Fig. 5

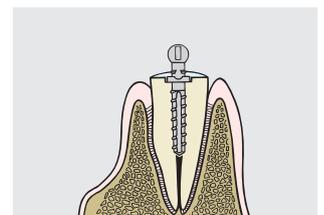


Fig. 6

Manufacture of the denture

The impression can be taken with or without the spacer. For the manufacture of the master model the transfer jig is placed into the spacer resp. into the impression.

Fig. 7

In the case of non-parallelism between two or more Dalbo®-Rotex®, the direction of insertion of the denture can diverge from the anchor axis by max. 6° for the version 15.41 and by max. 18° for the version 15.42. The female parts must be positioned parallel to each other on the spheres.

If the female part is polymerized by the dentist, the spacer with friction grip (43.02.824) in plastic must be used for the manufacture of the denture. This article may not be used in the patient's mouth and is for laboratory use.

This piece is drilled out by the dentist and replaced by a retentive original female part in plastic (051 868) or precious metal (051 511).

When using the precious metal female part, care must be taken that the PVC ring is flush with the lower edges of the female part to ensure that no resin flows between the lamellae. The female part must not be soldered because the thermal treatment would harm the elasticity of the lamellae. The required retention strength of the female part can be adjusted by means of the activator (31.02.85) or deactivator (31.02.855).

General information

As a preventive measure to protect against secondary caries a fluor treatment of the root surface must take place at regular intervals.

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.

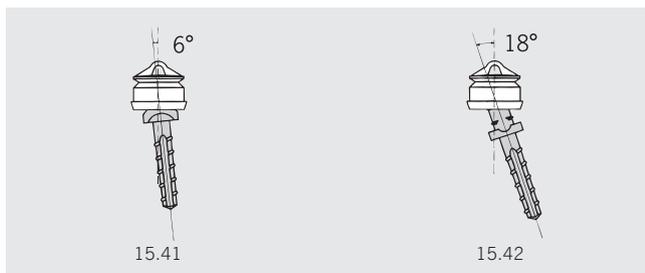


Fig. 7

Labeling on packaging / symbols

-  Date of manufacture
-  Manufacturer
-  Catalogue number
-  Batch code
-  Quantity
-  Consult instructions for use
-  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)