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Root anchor

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Instructions for Use Root Anchor

(Rotex / Rotex-RD / Dalbo®-Rotex)

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

Product	Description
	<p>Rotex</p> <ul style="list-style-type: none"> – Conical profile of the endodontic part with rounded tip. – Self-tapping thread with drainage grooves for the cement. – Available in three different sizes. – For the root canal preparation, a reamer, a face-cutting drill and a trimmer are available for each size of root anchor. – For each anchor size there is a socket wrench for screwing the root anchor into the root canal.
	<p>Rotex-RD</p> <ul style="list-style-type: none"> – Based on the Rotex system (endodontic part identical). – Conical profile of the endodontic part with rounded tip. – Self-tapping thread with drainage grooves for the cement. – Available in three different sizes. – Reduced diameter (RD) of the retention head compared with Rotex. – For the root canal preparation, a reamer, a face-cutting drill and a trimmer are available for each size of root anchor. – For each of the three different root anchor sizes there is a socket wrench for screwing into the root canal.
<p>a) </p> <p>b) </p>	<p>Dalbo®-Rotex</p> <ul style="list-style-type: none"> – Based on the Rotex system (endodontic part identical). – Conical profile of the endodontic part with rounded tip. – Self-tapping thread with drainage grooves for the cement. – ball-head diameter: 2.25 mm – Female parts; the G female part is included in the system (Galak, mouth-compatible plastic). – Further, compatible female parts; Dalbo®-PLUS, Dalbo®-Classic and Dalbo®-B (information about the products can be found on our website www.cmsa.ch/docs). – Available in two designs, according to Dr. Dalla Bona and according to Prof. Brunner, each in two different sizes. – For the root canal preparation, a reamer, a face-cutting drill and a trimmer are available for each size of root anchor. – For each design there is a socket wrench for screwing the root anchor into the root canal. <p>The two designs:</p> <p>a) according to Dr. Dalla Bona; the insertion direction can deviate up to 6° from the anchor axis.</p> <p>b) according to Prof. Brunner; the insertion direction can deviate up to 18° from the anchor axis.</p>

Root canal instruments

- The instruments are standardised and have a depth mark or depth stop.
- All instruments are colour-coded. Mix-ups can thus be ruled out.
- The reamers and trimmers are identical for the Rotex, Rotex-RD and Dalbo®-Rotex system, only the face-cutting drills are different.
- A coupling piece is available to extend the instruments.

6 Indications

Rotex / Rotex-RD

- Direct abutments.
- Larger fillings with amalgam or composite

Dalbo®-Rotex

- Temporary fixation of hybrid and partial dentures.

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 marginal 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

N/A

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.

– Dalbo®-Rotex; as a preventive measure to protect against secondary caries, the root surface must receive a fluoride treatment at regular intervals.

Products made of titanium 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**Rotex / Rotex-RD:**

These products are inserted into the tooth roots 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.

– Direct abutments

– Larger fillings with amalgam or composite

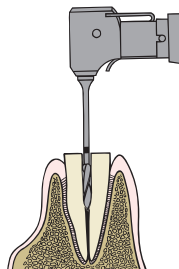
Dalbo®-Rotex:

The anchor system is used for the treatment of tooth roots with unfavourable long-term prognosis or as an economical solution for removable hybrid and partial dentures.

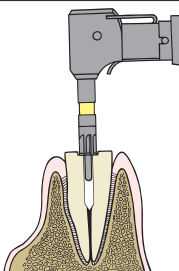
18 Procedure

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).

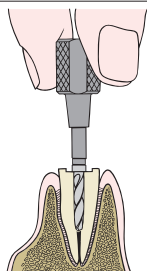
18.1 Rotex / Rotex-RD / Dalbo®-Rotex



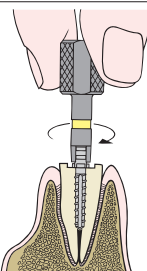
After successful completion of root canal treatment, the root canal is mechanically enlarged with the reamer of the corresponding size. The mark on the shaft of the reamer corresponds to the drilling depth.



Preparation of the support area for the retention head is carried out with the face-cutting drill (sinking depth into the root max. 0.5 mm). The entire base of the retention head should rest on a flat support area. This optimises distribution of forces.

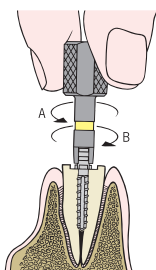


The final calibration of the root canal is prepared manually with the trimmer of the corresponding size. Preparation is done manually, using the Thomas socket wrench.

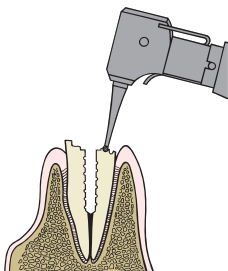


Using the socket wrench, insert the root canal anchor as far as possible into the root canal. The thread is now in contact with the canal wall. Then make one turn in clock-wise direction followed by a 1/2 turn in anti-clockwise direction to reduce the tensions acting on the root dentine during thread tapping. The final position is reached, when the retention head lies flat on the plane surface of the prepared root.

18.2 Rotex / Rotex-RD:

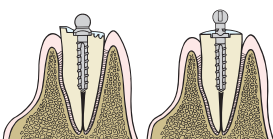


After thread tapping, unscrew the root anchor, remove chippings and fill the cement using a lentulo spiral filler. Reinsert the root canal anchor initially turning in an anti-clockwise direction (A) until the thread of the anchor engages in the preformed grooves (this can be clearly felt). Then tighten clockwise (B) until the final position is reached. Remove the surplus cement and build up the crown core with a plastic build-up material.

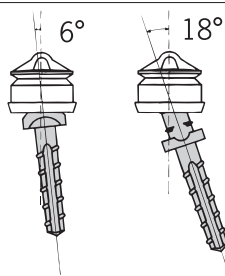
18.3 Dalbo®-Rotex:

Prior to cementing, in the case of irregular tooth surfaces the "sandwich" technique is indicated. The position of the anchor plate of the spherical head must be adapted to the clinical case or the root slope. After thread tapping, remove the Dalbo®-Rotex anchor from the canal again and cut small supplementary retentions onto the root surface with a small spherical drill. After finishing the root surface, remove the chippings and fill a glass ionomer cement into the root canal using a lentulo spiral filler.

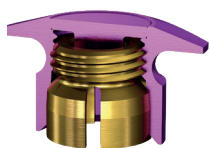
Reinsert the root canal anchor initially turning in an anti-clockwise direction (A) until the thread of the anchor engages in the preformed grooves (this can be clearly felt). Then tighten clockwise (B) until the final position is reached. Disperse the excess cement into the retentions and on the root 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 of the root with light curing resin and then polish.



The hermetic closure of the root canal is achieved with composite.



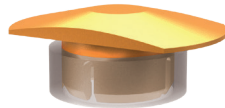
In the case of non-parallelism between two or more Dalbo®-Rotex, with the version according to Dr. Dalla Bona the direction of insertion of the denture can diverge from the anchor axis by max. 6°, for the version according to Prof. Brunner by max. 18°. The female parts must be positioned parallel to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



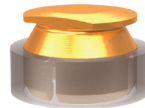
Dalbo®-PLUS elliptic



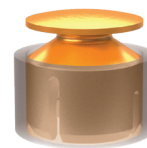
Dalbo®-PLUS basic



Dalbo®-Classic elliptic



Dalbo®-Classic basic



Dalbo®-B

Insertion of female parts for Dalbo®-Rotex:

Alternatively, Dalbo®-PLUS, Dalbo®-Classic and Dalbo®-B can be used as a high-quality anchoring solution instead of the G plastic female part supplied. Information on the insertion of the various Dalbo® female parts can be found in the respective instructions for use. Website www.cmsa.ch/docs.

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 Insertion and removal of the dentures

Dalbo®-Rotex:

It should be ensured that the dentures do not tilt, as any tilting can lead to damage. The denture should never be inserted by clenching the teeth, as this can damage or even break the connecting element.

Insertion

The denture can be placed on the anchor elements in the mouth using the thumb and index finger. Then it is correctly positioned on the anchoring elements applying gentle, even pressure. By carefully closing the jaws, it is possible to check whether the denture is in its correct final position.

Removal

For removal, the denture can be grasped with the thumb and index finger and carefully pulled from the anchor elements and taken out of the mouth.

21.3 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

Registered trademarks of Cendres+Métaux Holding SA, Biel/Bienne, Switzerland include:

Dalbo®

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	Basic UDI-DI
Dalbo®-Rotex (by Dr. Dalla Bona)					
051864	Dalbo®-Rotex GT (Size 1)	Galak/titanium	YES	CE 0483	764016651000049ED
051865	Dalbo®-Rotex GT (Size 2)	Galak/titanium	YES	CE 0483	764016651000049ED
051868	Female part G	Galak	YES	CE 0483	764016651000063E7
051511	Dalbo®-B Female part E	Elitor®	YES	CE 0483	764016651000053E4
051869	Male part T (Size 1)	Titanium	YES	CE 0483	764016651000049ED
051870	Male part T (Size 2)	Titanium	YES	CE 0483	764016651000049ED
070380	Root canal drill (White) Anchor size 1	Steel	NO	CE 0483	764016651000060DZ
070381	Root canal drill (Yellow) Anchor size 2	Steel	NO	CE 0483	764016651000060DZ
070499	Face cutting drill (White) Anchor size 1	Steel	NO	CE 0483	764016651000060DZ
072474	Face cutting drill (Yellow) Anchor size 2	Steel	NO	CE 0483	764016651000060DZ
070298	Reamer (White) Anchor size 1	Steel	NO	CE 0483	764016651000019E4
070299	Reamer (Yellow) Anchor size 2	Steel	NO	CE 0483	764016651000019E4
070498	Spanner key for spherical head	Steel	NO	CE	764016651000013DQ
070221	Thomas spanner key	Steel	NO	CE	764016651000013DQ
072414	Coupling piece	Steel	NO	CE	764016651000014DS
070205	Instrument for mounting of elastomeric ring	Steel	NO	CE	764016651000016DW
070197	Activator	Steel	NO	CE	764016651000003DM
070199	Deactivator	Steel	NO	CE	764016651000003DM
070440	Spacer G	Galak	YES	CE	764016651000026DZ
070511	Transfer jig	Steel	YES	CE	764016651000032DU
051904	Introduction set (Brunner/Dalla Bona)	Various	NO	CE 0483	764016651000059EG
08000002	Endobox Rotex / Rotex RD / Dalbo®-Rotex	Steel	NO	N/A	N/A
Dalbo®-Rotex (by Prof. Brunner)					
051866	Dalbo®-Rotex GT (Size 1) 5 pcs.	Galak/titanium	YES	CE 0483	764016651000049ED
051867	Dalbo®-Rotex GT (Size 2) 5 pcs.	Galak/titanium	YES	CE 0483	764016651000049ED
051868	Female G (5 pcs.)	Galak	YES	CE 0483	764016651000063E7
051511	Dalbo®-B Female part E	Elitor®	YES	CE 0483	764016651000053E4
051871	Male Part T (Size 1) 5 pcs.	Titanium	YES	CE 0483	764016651000049ED
051872	Male Part T (Size 2) 5 pcs.	Titanium	YES	CE 0483	764016651000049ED
070380	Root canal drill (White) Anchor size 1	Steel	NO	CE 0483	764016651000060DZ
070381	Root canal drill (Yellow) Anchor size 2	Steel	NO	CE 0483	764016651000060DZ
070295	Face cutting drill (White) Anchor size 1	Steel	NO	CE 0483	764016651000060DZ
072473	Face cutting drill (Yellow) Anchor size 2	Steel	NO	CE 0483	764016651000060DZ
070298	Reamer (White) Anchor size 1	Steel	NO	CE 0483	764016651000019E4
070299	Reamer (Yellow) Anchor size 2	Steel	NO	CE 0483	764016651000019E4
070500	Spanner key for spherical head	Steel	NO	CE	764016651000013DQ
070221	Thomas spanner key	Steel	NO	CE	764016651000013DQ
072414	Coupling piece	Steel	NO	CE	764016651000014DS
070205	Instrument for mounting of elastomeric ring	Steel	NO	CE	764016651000016DW
070197	Activator	Steel	NO	CE	764016651000003DM
070199	Deactivator	Steel	NO	CE	764016651000003DM
070440	Spacer G	Galak	YES	CE	764016651000026DZ
070512	Transfer jig	Steel	YES	CE	764016651000032DU
051904	Introduction set (Brunner/Dalla Bona)	Various	NO	CE 0483	764016651000059EG
08000002	Endobox Rotex / Rotex RD / Dalbo®-Rotex	Steel	NO	N/A	N/A
Rotex					
051289	Rotex T Size 1	Titanium	YES	CE 0483	764016651000049ED
051290	Rotex T Size 2	Titanium	YES	CE 0483	764016651000049ED
051291	Rotex T Size 3	Titanium	YES	CE 0483	764016651000049ED
070380	Root canal drill (White) Anchor size 1	Steel	NO	CE 0483	764016651000060DZ
070381	Root canal drill (Yellow) Anchor size 2	Steel	NO	CE 0483	764016651000060DZ
070382	Root canal drill (Red) Anchor size 3	Steel	NO	CE 0483	764016651000060DZ
070295	Face cutting drill (White) Anchor size 1	Steel	NO	CE 0483	764016651000060DZ
070296	Face cutting drill (Yellow) Anchor size 2	Steel	NO	CE 0483	764016651000060DZ
070297	Face cutting drill (Red) Anchor size 3	Steel	NO	CE 0483	764016651000060DZ
070298	Reamer (White) Anchor size 1	Steel	NO	CE 0483	764016651000019E4
070299	Reamer (Yellow) Anchor size 2	Steel	NO	CE 0483	764016651000019E4
070300	Reamer (Red) Anchor size 3	Steel	NO	CE 0483	764016651000019E4
070301	Spanner key (White) Anchor size 1	Steel	NO	CE	764016651000013DQ

Cat. No.	Product name	Material	Single use	Labelling	Basic UDI-DI
070302	Spanner key (Yellow) Anchor size 2	Steel	NO	CE	764016651000013DQ
070303	Spanner key (Red) Anchor size 3	Steel	NO	CE	764016651000013DQ
070221	Thomas spanner key	Steel	NO	CE	764016651000013DQ
072414	Coupling piece	Steel	NO	CE	764016651000014DS
051497	Introduction set	Various	NO	CE 0483	764016651000059EG
08000002	Endobox Rotex / Rotex RD / Dalbo®-Rotex	Steel	NO	N/A	N/A
Rotex-RD					
055195	Rotex-RD T Size 1 (5 pcs.)	Titanium	YES	CE 0483	764016651000049ED
055196	Rotex-RD T Size 2 (5 pcs.)	Titanium	YES	CE 0483	764016651000049ED
055197	Rotex-RD T Size 3 (5 pcs.)	Titanium	YES	CE 0483	764016651000049ED
070380	Root canal drill (White) Anchor size 1	Steel	NO	CE 0483	764016651000060DZ
070381	Root canal drill (Yellow) Anchor size 2	Steel	NO	CE 0483	764016651000060DZ
070382	Root canal drill (Red) Anchor size 3	Steel	NO	CE 0483	764016651000060DZ
072470	Face cutting drill (White) Anchor size 1	Steel	NO	CE 0483	764016651000060DZ
072471	Face cutting drill (Yellow) Anchor size 2	Steel	NO	CE 0483	764016651000060DZ
072472	Face cutting drill (Red) Anchor size 3	Steel	NO	CE 0483	764016651000060DZ
070298	Reamer (White) Anchor size 1	Steel	NO	CE 0483	764016651000019E4
070299	Reamer (Yellow) Anchor size 2	Steel	NO	CE 0483	764016651000019E4
070300	Reamer (Red) Anchor size 3	Steel	NO	CE 0483	764016651000019E4
072459	Spanner key Anchor size 1-3	Steel	NO	CE	764016651000013DQ
070221	Thomas spanner key	Steel	NO	CE	764016651000013DQ
072414	Coupling piece	Steel	NO	CE	764016651000014DS
055236	Introduction set	Various	NO	CE 0483	764016651000059EG
08000002	Endobox Rotex / Rotex RD / Dalbo®-Rotex	Steel	NO	N/A	N/A

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