

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 Point 29 in Table 1. 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 Point 29, Table 1.

3 Intended use

The components are intended for use for prosthetic restoration on natural teeth and to support procedures in the dental clinic or laboratory.



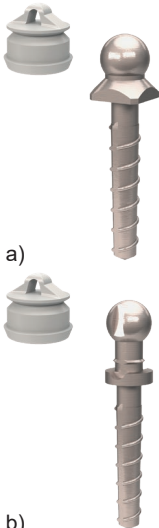
4 Expected clinical benefit

Restoration of chewing function and improved aesthetics.

For implantable products, link to "Summary of safety and clinical performance".

The summaries of safety and clinical performance (SSCP) for the implantable devices covered by these instructions for use, are available in the European database on medical devices EUDAMED, accessible at this address: <https://ec.europa.eu/tools/eudamed>

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 Indication

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.
- Lacking compliance of the patient with respect to follow-up / recall instructions.
- Patients with bruxism or other para-functional habits.
- In patients with a pre-existing allergy to one or more elements of the attachment element materials.
- Existing clinical picture in the patient's mouth does not permit the correct application of the products.

8 Compatible products

Not applicable.

9 User qualification

The expertise of a professional dentist or dental technician is required. The current instructions for use must be available at all times and be completely read and understood before the first application. The manufacturing work and its maintenance must be carried out by qualified specialists.

Only original tools and parts may be used for this work. For information and additional details, please contact your Cendres+Métaux SA representative.


 Important information for the specialist

 Warning symbol for increased caution

10 Prescription

Federal laws (USA) prohibit the use or sale by unlicensed dentists.

11 Side effects

 This product may not be used in patients with allergies to one or more elements of the product 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.

Auxiliary instruments and products made of steel may contain nickel.

No known side effects if applied as intended.

12 Warnings

Magnetic resonance 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

These instructions for use are sufficient for immediate application for the products described in this application area of the instructions for use. Dental or laboratory knowledge is required. Information: www.cmsa.ch/docs

14 Preventive measures


-  – Only original tools and parts may be used for this work.
- The product components are supplied non-sterile. For more information see Point 16 Preparation.
- Secure parts against aspiration.
- Before any procedure, ensure that all required product components are available in sufficient quantity.
- For your safety, always wear suitable protective clothing.
- 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

– Unless labelled otherwise, the product components are only intended for single use.

Products that are marked for single-use are subject to a certain load during use, which can lead to wear, loss of function and/or malfunctions.

 Reuse of products marked as single-use products may compromise safety, function and performance. Products for single-use have not been tested for reuse/reprocessing, which increases the risk of infection transmission.

16 Preparation

 After any fabrication or modification and prior to use, the prosthetic work, including all system components, must be cleaned, disinfected and, if appropriate, sterilized. Materials made of metal alloys, high-performance polymers (Pekkton®) and ceramics are suitable for steam sterilization, whereas components made of plastic other than Pekkton® are not suitable. Consider published national guidelines when selecting a disinfection and sterilization process and the Instructions for Use "Preparation 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.

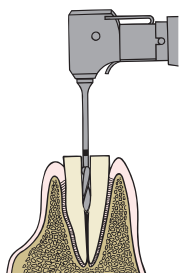
- Direct abutments
- Larger fillings with amalgam or composite

Dalbo®-Rotex®:

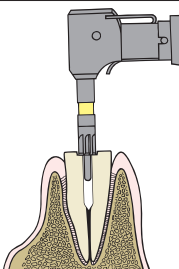
The anchor system is used for the treatment of tooth roots with unfavourable long-term prognosis or as an economical solution for removable hybrid and partial dentures.

18 Procedure

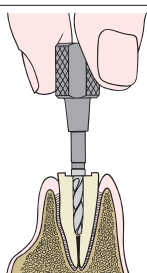
The tooth root must first be treated endodontically. The tooth or root is then prepared based on the specific indication. The choice of prosthetic products to be used depends on the X-ray, anatomy and root canal situation (length and diameter).

18.1 Rotex® / Rotex®-RD / Dalbo®-Rotex®

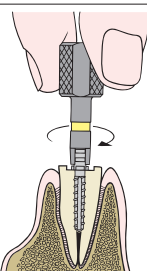
After successful completion of root canal treatment, the root canal is mechanically enlarged with the reamer of the corresponding size. The mark on the shaft of the reamer corresponds to the drilling depth.



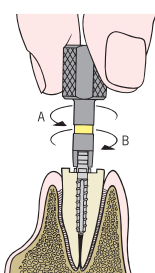
Preparation of the support area for the retention head is carried out with the face-cutting drill (sinking depth into the root max. 0.5 mm). The entire base of the retention head should rest on a flat support area. This optimises distribution of forces.



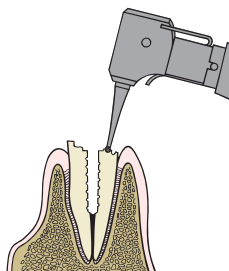
The final calibration of the root canal is prepared manually with the trimmer of the corresponding size. Preparation is done manually, using the Thomas socket wrench.



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.

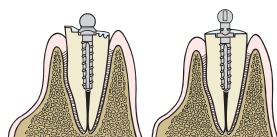
18.2 Rotex® / Rotex-RD®:

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.

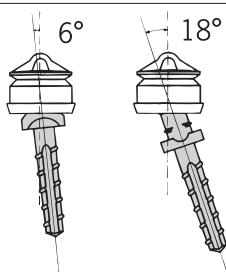
18.3 Dalbo®-Rotex®:

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.

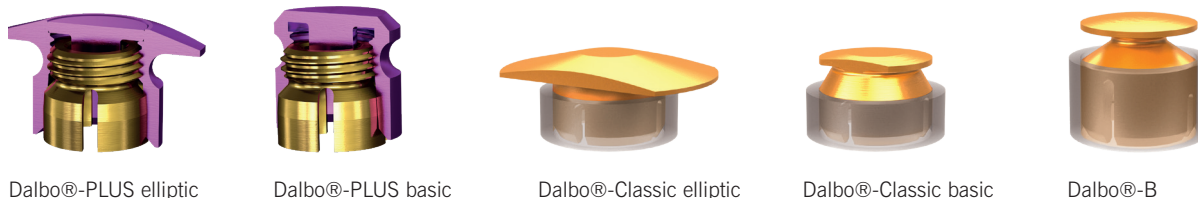
Reinsert the root canal anchor initially turning in an anti-clockwise direction (A) until the thread of the anchor engages in the preformed grooves (this can be clearly felt). Then tighten clockwise (B) until the final position is reached. Disperse the excess cement into the retentions and on the root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

Detailed information on the materials and their classification is given in the specific material data sheets, the catalogue as well as the product list given in Table 1 in Point 29. See website www.cmsa.ch/docs or the Cendres+Métaux SA Dental Documentation (available free of charge from all Cendres+Métaux SA subsidiaries, branches and dealers).

20 Notes on storage

 The product must be stored in a dry place in its original packaging, at room temperature and without direct sunlight, unless otherwise stated on the packaging. 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 patients are motivated and instructed according to their own abilities such as manual dexterity and vision with regard to the handling and care of their teeth and dentures.

Permanent and removable dentures are subject to considerable stress in the mouth in a constantly changing environment, and thus more or less subjected to signs of wear. Wear is omnipresent in daily routine 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

Ensure that the dentures do not tilt, as any tilting can lead to damage. Never insert dentures by biting the teeth together. This can lead to damage or even breakage of the connecting element. Further information on handling and aftercare of dentures is available in the patient information brochure at www.cmsa.ch/docs.

Insertion

Hold the dentures between the thumb and forefinger, and place them back into the mouth on the anchors. Search or feel for the correct insertion position and push the dentures onto the anchors with gentle, steady pressure. Carefully close your jaws and check whether the dentures are in the correct final position.

Removal

Hold the dentures between the thumb and forefinger, and slowly, carefully and steadily pull them off the anchors and remove them from the mouth.

21.3 Cleaning and care

We recommend cleaning your teeth and your dentures after every meal. Cleaning of dentures includes cleaning of the connecting element. The gentlest cleaning is achieved by cleaning the connecting element under running water with a soft toothbrush. The most intensive cleaning is achieved when cleaning the dentures in a small ultrasonic device and adding a suitable cleaning agent. Never clean the high precision connecting elements with toothpaste. This could lead to damage. Caution should also be exercised in the case of unsuitable cleaning agents or tablets. This could also damage the high quality connecting element or impair its function. Only clean the connecting parts on the other teeth or implants with water and a soft toothbrush as well as an interdental brush. Do not use toothpaste to avoid damage.

Pay attention to regular cleaning of the anchorage to prevent any inflammation of the soft tissue.
For information and additional tips on caring for the instruments see the website (www.cmsa.ch/docs).
For information and additional details, please contact your Cendres+Métaux SA representative.

22 Ordering information

More detailed information on the catalogue numbers, the number of products and their classification can be found in the product list under Point 29 in Table 1, the specific product catalogue, the packaging and, in the case of individual products, also directly on the product itself. You can find further information on the website www.cmsa.ch/docs or the Cendres+Métaux SA Dental Documentation (available free of charge from all Cendres+Métaux SA subsidiaries, branches and dealers).
For information and additional details, please contact your Cendres+Métaux SA representative.

23 Availability

Some of the products described in this document may possibly not be available in all countries.

24 Traceability Lot number

The batch numbers of all parts used must be documented to ensure traceability. If different batch numbers are used for the products described in this application area of the instructions for use for the fabrication of dentures, all the batch numbers concerned must be recorded to ensure traceability.

25 Complaint

Cendres+Métaux SA must be notified immediately of any incident that has occurred with regard to the product to all branches, offices and dealers of Cendres+Métaux SA and, in case of serious cases, to the competent authority where the user is registered.

26 Safe disposal

The product 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:

Rotex® / Rotex®-RD / Dalbo®-Rotex®

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. This product is part of an overall concept and may only be used or combined with the corresponding original components and instruments. Otherwise, the manufacturer rejects any responsibility and liability. In case of complaints, please always include the batch number.

The use of third party products not distributed by Cendres+Métaux SA in connection with the products listed in Table 1 will void any warranty or other express or implied obligations of Cendres+Métaux SA.

The user of Cendres+Métaux SA products is responsible for determining whether or not a product is suitable for a specific patient and a specific situation.

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 or installation of Cendres+Métaux SA products.

The user is also obliged to regularly study the latest developments of the Cendres+Métaux SA products listed in Table 1 and their applications.

Please note: the descriptions contained in this document are not sufficient for the immediate application of Cendres+Métaux SA products.

Specialist knowledge of dentistry, dental technology and instructions in handling the products listed in Table 1 by an operator with appropriate experience is always required.

29 Product list

Cat. No.	Product name	Material	Single use	Multiple use	Basic UDI-DI
Rotex					
051289	Rotex T size 1	Titanium	YES	NO	764016651000049ED
051290	Rotex T size 2	Titanium	YES	NO	764016651000049ED
051291	Rotex T size 3	Titanium	YES	NO	764016651000049ED
070380	Reamer (white) anchor size 1	Steel	NO	YES	764016651000060DZ
070381	Reamer (yellow) anchor size 2	Steel	NO	YES	764016651000060DZ
070382	Reamer (red) anchor size 3	Steel	NO	YES	764016651000060DZ
070295	Face-cutting drill (white) anchor size 1	Steel	NO	YES	764016651000060DZ
070296	Face-cutting drill (yellow) anchor size 2	Steel	NO	YES	764016651000060DZ
070297	Face-cutting drill (red) anchor size 3	Steel	NO	YES	764016651000060DZ
070298	Trimmer (white) anchor size 1	Steel	NO	YES	764016651000060DZ
070299	Trimmer (yellow) anchor size 2	Steel	NO	YES	764016651000060DZ
070300	Trimmer (red) anchor size 3	Steel	NO	YES	764016651000060DZ
070301	Socket wrench (white) anchor size 1	Steel	NO	YES	764016651000013DQ
070302	Socket wrench (yellow) anchor size 2	Steel	NO	YES	764016651000013DQ
070303	Socket wrench (red) anchor size 3	Steel	NO	YES	764016651000013DQ
070221	Thomas socket wrench	Steel	NO	YES	764016651000013DQ
072414	Coupling piece	Steel	NO	YES	764016651000014DS
051497	Basic range	Various	NO	YES	764016651000059EG
08000002	Endo box	Steel	NO	YES	N/A
Rotex-RD					
055195	Rotex-RD T size 1	Titanium	YES	NO	764016651000049ED
055196	Rotex-RD T size 2	Titanium	YES	NO	764016651000049ED
055197	Rotex-RD T size 3	Titanium	YES	NO	764016651000049ED
070380	Reamer (white) anchor size 1	Steel	NO	YES	764016651000060DZ
070381	Reamer (yellow) anchor size 2	Steel	NO	YES	764016651000060DZ
070382	Reamer (red) anchor size 3	Steel	NO	YES	764016651000060DZ
072470	Face-cutting drill (white) anchor size 1	Steel	NO	YES	764016651000060DZ
072471	Face-cutting drill (yellow) anchor size 2	Steel	NO	YES	764016651000060DZ
072472	Face-cutting drill (red) anchor size 3	Steel	NO	YES	764016651000060DZ
070298	Trimmer (white) anchor size 1	Steel	NO	YES	764016651000060DZ
070299	Trimmer (yellow) anchor size 2	Steel	NO	YES	764016651000060DZ
070300	Trimmer (red) anchor size 3	Steel	NO	YES	764016651000060DZ
072459	Socket wrench anchor size 1-3	Steel	NO	YES	764016651000013DQ
070221	Thomas socket wrench	Steel	NO	YES	764016651000013DQ
072414	Coupling piece	Steel	NO	YES	764016651000014DS
055236	Basic range	Various	NO	YES	764016651000059EG
08000002	Endo box	Steel	NO	YES	N/A
Dalbo®-Rotex (according to Dr. Dalla Bona)					
051864	Dalbo®-Rotex GT (size 1)	Galak/titanium	YES	NO	764016651000049ED
051865	Dalbo®-Rotex GT (size 2)	Galak/titanium	YES	NO	764016651000049ED
051868	Female part G	Galak	YES	NO	764016651000063E7
051511	Dalbo®-B female part E	Elitor®	YES	NO	764016651000053E4
051869	Male part T (size 1)	Titanium	YES	NO	764016651000049ED
051870	Male part T (size 2)	Titanium	YES	NO	764016651000049ED
070380	Reamer (white) anchor size 1	Steel	NO	YES	764016651000060DZ
070381	Reamer (yellow) anchor size 2	Steel	NO	YES	764016651000060DZ
070499	Face-cutting drill (white) anchor size 1	Steel	NO	YES	764016651000060DZ
072474	Face-cutting drill (yellow) anchor size 2	Steel	NO	YES	764016651000060DZ
070298	Trimmer (white) anchor size 1	Steel	NO	YES	764016651000060DZ
070299	Trimmer (yellow) anchor size 2	Steel	NO	YES	764016651000060DZ
070498	Socket wrench for ball-head anchor	Steel	NO	YES	764016651000013DQ
070221	Thomas socket wrench	Steel	NO	YES	764016651000013DQ
072414	Coupling piece	Steel	NO	YES	764016651000014DS
070205	Punch for elastomer ring mounting	Steel	NO	YES	764016651000016DW
070197	Activator	Steel	NO	YES	764016651000003DM
070199	Deactivator	Steel	NO	YES	764016651000003DM
070440	Spacer G	Galak	NO	YES	764016651000026DZ
070511	Transfer axis	Steel	NO	YES	764016651000032DU
051904	Basic range	Various	NO	YES	764016651000059EG
08000002	Endo box	Steel	NO	YES	N/A

Cat. No.	Product name	Material	Single use	Multiple use	Basic UDI-DI
Dalbo®-Rotex (according to Prof. Brunner)					
051866	Dalbo®-Rotex GT (size 1)	Galak/titanium	YES	NO	764016651000049ED
051867	Dalbo®-Rotex GT (size 2)	Galak/titanium	YES	NO	764016651000049ED
051868	Female part G	Galak	YES	NO	764016651000063E7
051511	Dalbo®-B female part E	Elitor®	YES	NO	764016651000053E4
051871	Male part T (size 1)	Titanium	YES	NO	764016651000049ED
051872	Male part T (size 2)	Titanium	YES	NO	764016651000049ED
070380	Reamer (white) anchor size 1	Steel	NO	YES	764016651000060DZ
070381	Reamer (yellow) anchor size 2	Steel	NO	YES	764016651000060DZ
070295	Face-cutting drill (white) anchor size 1	Steel	NO	YES	764016651000060DZ
072473	Face-cutting drill (yellow) anchor size 2	Steel	NO	YES	764016651000060DZ
070298	Trimmer (white) anchor size 1	Steel	NO	YES	764016651000060DZ
070299	Trimmer (yellow) anchor size 2	Steel	NO	YES	764016651000060DZ
070500	Socket wrench for ball-head anchor	Steel	NO	YES	764016651000013DQ
070221	Thomas socket wrench	Steel	NO	YES	764016651000013DQ
072414	Coupling piece	Steel	NO	YES	764016651000014DS
070205	Punch for elastomer ring mounting	Steel	NO	YES	764016651000016DW
070197	Activator	Steel	NO	YES	764016651000003DM
070199	Deactivator	Steel	NO	YES	764016651000003DM
070440	Spacer G	Galak	YES	NO	764016651000026DZ
070512	Transfer axis	Steel	YES	NO	764016651000032DU
051904	Basic range	Various	NO	YES	764016651000059EG
08000002	Endo box	Steel	NO	YES	N/A

30 Symbols



Important information for the specialist



Warning symbol for increased caution

Labelling on packaging/symbols



Date of manufacture



Manufacturer



Catalogue number



Batch code



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



Keep away from sunlight



Attention, observe accompanying documents



Unique Device Identification – UDI



European Authorised Representative



Importer in EU



Medical device