Instructions for Use Dalbo®-System
Dalbo® Abutment, Dalbo®-PLUS, Dalbo®-Classic, Dalbo®-B and Dalbo®-PLUS Gauge set

1 Scope of application of Instructions for Use
These Instructions for Use apply to the products listed under Point 29 in Table 1 and Table 2. 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 and Table 2

3 Intended use
The components are intended for use in prosthetic restorations on dental implants and root canal caps and to support procedures in the dental clinic or laboratory.

4 Expected clinical benefit
Restoration of chewing function and improved aesthetics.

5 Product description
Dalbo® System
The Dalbo® System is an anchorage for retentive, rigid or resilient use on implants and root canal caps. When restoring with one or two ball anchors, there is a certain degree of resilience; with three or more ball anchors, the denture is rigid.

Dalbo®-PLUS
Dalbo®-PLUS Female part TE basic
Is intended for assembly in the laboratory. It can be polymerised directly or bonded into a metal housing. The red duplicating aid enclosed with the product considerably simplifies the fabrication process of a bonding box in the laboratory: attach – block out undercut – duplicate – model – embed – cast – divest – blast – bond – finished!
**Dalbo®-PLUS Female part TE elliptic**

Is intended for placement directly in the patient’s mouth. Experience has shown that the quality of the resin deteriorates with direct placement and that the female part can break from the denture under high loads. The elliptical design of the resin retention increases the retention force in the denture body.

**Tuning system for female parts**

The ball anchor is the oldest and most used anchoring principle. Minute differences in ball diameter, material selection, geometry and tolerance ranges influence the friction clearance. Two Dalbo®-PLUS Tuning female parts with different inner diameters of the lamellae retention inserts allow the retention force to be restored, regardless of the system used or even age-related wear.

### Tuning system for female parts

**Standard**

- Lamellae retention insert (basal: no groove)

**Tuning soft**

- Tuning lamellae retention insert soft (basal: 1 groove)

**Tuning**

- Tuning lamellae retention insert (basal: 2 grooves)

The following abutment divergences can be compensated:

- root canal caps, depending on the activation of between 4° – 8°.
- on implants, depending on the activation, up to 20°.
Dalbo®-Classic basic (a) / Dalbo®-Classic elliptic (b)
The elliptic (b) version differs in the design of the female part from the basic (a) version by a massively pronounced, elliptically shaped resin retention, but without changing the popular, low insertion height. This design is indicated for direct placement in the mouth or quite simply where an extra strong retention force of the female part in the denture body is desired.

Version EV. The male part in the Valor (V) can be connected to the root canal cap by casting-on or soldering. Casting-on saves time and eliminates the need for jointing materials. The attached retention of both designs with an additional anti-rotation mechanism ensures a secure hold in the resin.

The EK version. The male part made of special burn-out Korak (K) resin results in a high-quality surface after casting when used correctly. The two female part designs are identical to the EV versions.

The following abutment divergences can be compensated:
– on root canal caps 10°
– on implants up to 20°

The Elitor® (E) female part is integrated exclusively by polymerisation.

Dalbo®-B
Was the world’s first ball anchor and formed the basis for the development of the Dalbo®-PLUS and the Dalbo®-Classic.

The following abutment divergences can be compensated:
– on root canal caps 6°
– on implants up to 18°

The female part is integrated exclusively by polymerisation.

Auxiliary parts and instruments

Elastomer ring
Dalbo®-Classic (Cat. No. 055 688)
Dalbo®-B (Cat. No. 051 005)

Duplication aid G (Cat. No. 072 626)
Can only be used for the Dalbo®-PLUS female part!
These «red» parts are slightly oversized with regard to the original components. This allows optimal bonding clearance for duplicating and bonding techniques. After being used as a duplication aid, the duplication auxiliary part can also be used as polishing protection.

Spacer G
Dalbo®-Classic (Cat. No. 072 625)
Dalbo®-B (Cat. No. 070 440)
Spacers basically replace the anchoring female parts during resin polymerisation in the laboratory. These are then removed from the fully polymerised denture. The most optimal polymerisation or bonding of the original female parts is performed by the dentist directly in the patient’s mouth after cementation of the root canal caps. The spacer also proves to be an excellent polishing protection for the male part.

⚠️ The duplicating aid and the spacer must not be used in place of the female part as a temporary replacement, nor for taking impressions in the mouth.

Spacer disc Z (Cat. No. 050394)
The tin spacer supplied with each female part enables vertical resilience. This is incorporated prior to polymerisation, after which it is removed again.

⚠️ The tin spacer disc must not be inserted in the mouth.

Activator / deactivator
The activator (Cat. No. 070197) and deactivator (Cat. No. 070199) for the Dalbo®-Classic and Dalbo®-B must not be sterilised. There is a risk that the resin handles will be destroyed during sterilisation in an autoclave.
Please consider the published national guidelines when selecting a disinfection process and the Instructions for Use «Preparation of surgical and prosthetic products» (www.cmsa.ch/docs).
Instructions for Use Dalbo®-System

Punch for elastomer ring mounting (Cat. No. 070205)
For the optimal function and protection of the lamellae of the Dalbo®-Classic/elliptic and Dalbo®-B, the elastomer ring mounted on the female parts should not be removed.

Do not re-use elastomer rings once they have been slipped on.

Transfer axis (Cat. No. 070157): for fabricating the master model.

Dalbo® Abutment Analog (Cat. No. 07000312): for master model fabrication for implant work.

Dalbo® Abutment Screwdriver (Cat. No. 07000266): Screwdriver for Dalbo® Abutment.

Special-Parallelometer Insert (Cat. No. 072 637): Is used for the parallel setting of several Dalbo® Male parts in the parallelometer.

Screwdriver / Activator (Cat. No. 072 609): Is used to screw in and activate the lamellae retention insert for the Dalbo®-PLUS.

Heating Rod (Cat. No. 072 639): For extracting housings (only Dalbo®-PLUS) from the resin.

6 Indication
Removable, rigidly or resiliently anchored denture on implants and root canal caps:
– Hybrid prosthetics
– Unilateral dentures, splinted transversally
– Partial and free-end dentures in combination

7 Contraindications
– Unilateral, partial and free-end dentures without transversal support.
– Compensation of abutment divergences outside the respective application area of the system for male part and female part (see Point 5 Product Description)
– Restoration of severely periodontally damaged abutment teeth.
– Use on implant systems which are not approved for ball anchorages (see Point 29, Table 2)
– Use for the immediate restoration of implants if the manufacturer has not approved this indication.
– Lacking compliance of the patient with respect to correct follow-up / recall instructions.
– Patients with bruxism or other para-functional habits.
– In patients with allergies to one or more elements of the materials used in the product.
– Existing clinical picture in the patient’s mouth does not permit the correct application of the products.

8 Compatible products
The Dalbo® Abutments have been designed for conventional implant interfaces. Approved systems are listed under Point 29, Table 2.
The Dalbo® Female parts are compatible with
– Dalbo®-Rotex
– Implant ball anchorage with a ball head diameter of 2.25 mm.
– Ball anchorage with a ball head diameter of 2.25 mm.

The retention force of the Dalbo® Female parts on the male parts of other manufacturers can vary due to their manufacturing tolerances and surface qualities.

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 fabrication of dentures and their maintenance may only be performed 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 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 Section 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.
- The mechanical cleaning of the product using a toothbrush and toothpaste may lead to premature wear of the functional parts.
- It is essential to block out undercuts prior to polymerising the female part.
- No pre-treatment required, such as sandblasting or silanisation of the housing of the female part.

15 Single use
Unless labelled otherwise, the product components are only intended for single use.
Products that are labelled for single-use are subject to a certain load during use, which can lead to wear, loss of function and/or malfunctions.
⚠️ Re-use of products labelled as single-use products may compromise safety, function and performance.
Products for single-use have not been tested for re-use/preparation, 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, sterilised. Materials made of metal alloys, high-performance polymers (Pekkton®) and ceramics are suitable for steam sterilisation, whereas components made of plastic other than Pekkton® are not suitable. Consider published national guidelines when selecting a disinfection and sterilisation process and the Instructions for Use “Preparation of surgical and prosthetic products” (www.cmsa.ch/docs).

17 Scope of application
The Dalbo® System components are designed to fixate partial and full dentures on implants and root canal caps in the maxilla and mandible.
⚠️ We recommend that the denture be designed such that the largest possible support polygon can be achieved. Small distances between consecutive implants and long free-end saddles can cause undesirable effects such as increased wear of the system components.

18 Procedure
18.1 Fabrication of the primary reconstruction
18.1.1 Dalbo® Abutment
Before using the Dalbo® Abutment, follow the Instructions for Use of the implant manufacturer.

Determining the abutment height
Choose the required gingival height of the abutment height with a probe (1 mm graduation). The lower edge of the abutment should lie 1 mm above the gingiva. Various heights are available.

Inserting the Dalbo® Abutment
First, place the Dalbo® Abutment on the Dalbo® Abutment Screwdriver (Cat No. 07000266) and screw it into the implant by hand.
Then tighten with the torque ratchet with the corresponding torque (see information on the packaging). Make sure that the screwdriver is seated correctly on the abutment. Secure all parts against aspiration. After assembly, the screwdriver can be removed again by lifting it slightly.
– Screw in the abutment only once using the torque specified for this purpose.
– In case of immediate loading (observe indication of the implant manufacturer), ensure that the tightening torque of the abutment does not exceed that of the screwed-in implant. Recommendation, at least 5 Ncm less than the implant tightening torque.

The screwdriver features an ISO connection and fits onto the coupling inserts for the corresponding torque ratchets.

18.1.2 Dalbo® CAD/CAM Retention element
When modelling the bar in the CAD software, allow for the position of the Dalbo® CAD/CAM Retention element. A standard thread M2.0 is required for fixation of the Dalbo® CAD/CAM Retention element on the bar.

Inserting the Dalbo® CAD/CAM Retention element
After fabricating the milled bar, the Dalbo® CAD/CAM Retention element can be mounted on the bar using the Dalbo® Screwdriver (Cat. No. 0700 0266). Make sure that the screwdriver is seated correctly on the retention element. Secure all parts against aspiration. Then tighten with the torque ratchet with a torque of > 35 Ncm. After assembly, the screwdriver can be removed again by lifting it slightly.

The screwdriver features an ISO connection and fits onto the coupling inserts for the corresponding torque ratchets.

18.1.3 Dalbo® Male parts

Work preparation
Wax-up of the root canal cap with the root canal pin. In the case of several root canal caps, prepare the solder/laser surface at right angles to the direction of insertion. Use prefabricated, cast-on precious metal pins.

Inserting the Dalbo® Male part V by casting-on
Using the special parallelometer insert (Cat. No. 072 637) set the male part V as centrally as possible and wax it cleanly to the root canal cap. Then embed and cast.

Inserting the Dalbo® Male part V by soldering
Using the special parallelometer insert (Cat. No. 072 637) set the male part V as centrally as possible on the already cast and face-milled root canal cap and fix it with wax (take aesthetics into account). The solder gap should be continuous and between 0.05 – 0.20 mm wide. Design the soldering block, such that the male part V is securely held and good flame access is ensured. Recommended solders: S.G 810 (Cat. No. 010916) and S.G 750 (Cat. No. 010895).

Inserting the Dalbo® Male part E by laser welding
In principle, only identical materials of the same composition should be joined together. Later failures can thus be reduced to an absolute minimum. We recommend using the Dalbo® Laser male part E (identical with Protor® 3) with the laser welding wire LW No. 5 (Cat. No. 0105 0041) and the casting alloy Protor® 3 (Cat. No. 010654) from Cendres+Métaux. Details on processing can be found in the Instructions for Use of the laser welding wires.

After thermal treatment (e.g. soldering, cast-on) slowly allow to cool down to room temperature to achieve the optimum mechanical properties without a tempering process. Fit a duplicating aid or spacer to protect the male part during sandblasting and processing.

Inserting the Dalbo® Male part K by casting
Fill the cavity of the male part K with wax. Using the special parallelometer insert (Cat. No. 072 637) set the male part K as centrally as possible and wax it cleanly to the waxed-up root canal cap. After casting, polish the Dalbo® Male part extremely carefully and set to the desired frictional power with the female part.

18.2 Fabrication of the secondary reconstruction (denture)

General information
The tin spacer (Cat. No. 050 394) supplied with the female part enables vertical resilience. The soft spacer disc is placed over the entire root canal cap or anchoring element and adapted prior to polymerisation of the resin. After completion of the resin work, the spacer disc is removed again. Current clinical experience shows that the minimal vertical resilience disappears once the denture is placed. The greatest advantage is that the denture base is not overloaded on the root canal cap or the abutment.

For optimal function and protection of the lamellae, the elastomer ring mounted on the Dalbo®-Classic basic, Dalbo®-Classic elliptic and Dalbo®-B female parts should not be removed. If necessary, the elastomer ring can be changed using the punch (Cat. No. 070 205) as follows:
1) Remove blue sleeve from the punch
2) Slip on several elastomer rings
3) Mount sleeve
4) By pushing the sleeve, the elastomer rings are pressed over the lamellae of the female part.
Do not re-use elastomer rings once they have been slipped on.

Before fitting, protect the inside of the female part with Vaseline or soft silicone to prevent resin from penetrating.

When fitting several female parts, make sure that they are positioned parallel to each other on the male parts and waxed firmly.

When fitting several female parts, make sure that they are positioned parallel to each other on the male parts and waxed firmly.

Fit the elastomer ring flush with the rim of the female part, so that the maximum retention can be used for the resin. Block out the undercuts and interpapillary spaces with impression plaster, wax, Flexistone or a rubber dam. Observe maximum abutment divergence. For the optimal function and protection of the lamellae the elastomer ring mounted on the Dalbo®-Classic and Dalbo®-B Female parts should not be removed.
Inserting the female parts in the laboratory by polymerisation
Block out the undercuts and interpapillary spaces with impression plaster, wax, Flexistone or a rubber dam.

Inserting the Dalbo®-PLUS basic female parts by bonding in the laboratory
The red duplicating aid G (Cat. No. 072 626) enclosed with the product is oversized in relation to the female part such that it creates an ideal bonding gap after casting the framework. After fabricating the primary construction, place the duplication aid G on the ball anchor, block out undercuts and duplicate the model (silicone type). After casting and finishing, clean the inner surface of the retention housing. Blast the outer surface of the Dalbo®-PLUS basic female part as well as the model cast housing with Al₂O₃. Wax the female parts parallel to each other on the male parts and bond them into the framework. Use only suitable bonding agents.

Inserting the female part in the patient's mouth
To this end, the elliptic versions with reinforced resin retention are available specifically for Dalbo®-PLUS and Dalbo®-Classic. Create sufficient space prior to inclusion in the denture body. Fixate the elliptic female part in the mouth in parallel and block out the undercuts. If possible, drill an additional drainage canal through the denture body. With hybrid dentures, ensure that the root canal cap or the abutment are not loaded. This prevents the denture from rocking after insertion.

Make sure that no resin has flowed into the housing of the female part. If necessary, remove the resin carefully and without damaging it so as not to impair the function of the female part.

18.3 Activation and deactivation

18.3.1 Dalbo®-Classic, Dalbo®-B

**Activation:**
Press the four lamellae together evenly by applying light pressure with the activator provided for this purpose (Cat. No. 070 197).

**Deactivation:**
Apply light pressure with the deactivator provided for this purpose (Cat. No. 070199) to spread the lamellae evenly without the female part breaking out of the resin.

18.3.2 Dalbo®-PLUS
The Dalbo®-PLUS has three retention inserts, the lamellae retention insert E (Cat. No. 055643), the tuning lamellae retention insert soft E (Cat. No. 0500068) and the tuning lamellae retention insert E (Cat. No. 055687).
For new work, the lamellae retention insert E (Cat. No. 055643) is used. Our ball anchor diameter 2.25 mm has become the standard for most systems in the market. Experience and studies with third-party products have shown that minute differences, such as the choice of material, the geometry or the tolerance range, can reduce the frictional clearance of the Dalbo®-PLUS Lamellae retention insert. Two additional lamellae retention inserts are available to increase the clearance and for the after-care of already worn ball head male parts. Different notches on the lamellae make them easy to distinguish from «normal» retention inserts.

| Standard Lamellae retention insert (without notches) | normal friction |
| Tuning soft Lamellae retention insert (one notch) | high friction |
| Tuning Lamellae retention insert (two notches) | extra high friction |

The screwdriver / activator (Cat.-No.072 609) is required to activate, deactivate and remove the lamellae retention insert. The instrument with four cams is pushed into the lamellae retention insert in its correct position up to the stop. The retention force is adjusted by turning clockwise to increase the retention force and vice versa to reduce the retention force.

The basic setting on delivery is approximately 200 g, which also represents the minimum retention force to be set (lamellae retention insert is flush with the lower edge of the housing).
The retention force is adjusted by turning clockwise to increase the retention force and vice versa to reduce the retention force. The maximum retention force is approx. 1200 g (lamellae retention insert cannot be screwed in any further).

The lamellae retention insert must not protrude from the housing, otherwise it could become detached from the housing by itself.

After use, clean instruments with water and proceed as described in Section 16 (Preparation).

18.4 Follow-up

Retaining elements in prosthetic work 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 carried out if required to prevent rocking movement (overload). We recommend checking the denture at intervals of approx. 3 months initially and to replace the retention inserts if necessary.

18.4.1 Modifications, relining

Before taking the impression, preferably remove the original female part from the denture.

**Dalbo®-Classic / Dalbo®-B**

Carefully remove the old female part from the denture.

**Dalbo®-PLUS**

1. Removing the lamellae retention insert
2. Screw the heating rod (Cat. No. 072 639) into the housing of the female part
3. Heat the opposite end over the flame of a Bunsen burner until the resin around the female part becomes soft.
4. Using pliers, pull the heating rod together with the female part out of the denture.
5. Before taking the impression, place the existing or a new Dalbo® Female part on the male part, the abutment. Place the master model analogue/transfer axis in the Dalbo® Female part to fabricate the master model.

In the case of a bonded Dalbo®-PLUS Female part housing, the temperature required to neutralise the adhesive's bonding strength is many times higher!

18.4.2 Impression taking

Always use the original Dalbo® Female part for this purpose.

Place the Dalbo® Female part on the Dalbo® Male part or the Dalbo® Abutment.

Block out the space between the female part and the male part/abutment with a little soft wax before taking the impression. Ensure an exact fit, parallelism of the insertion direction and correct alignment with the occlusal plane of the female part. Take a functional impression. Use a solid impression silicone. Check that the material is distributed completely around the female part and that no impression material has flowed into the female part, otherwise clean the male part and female part and repeat impression taking.

18.4.3 Model fabrication

To fabricate the model, the implant analogue (Cat. No. 0700 0312) is used for an implant restoration, and the transfer axis (Cat. No. 070157) is used for root canal pin restorations by inserting it into the female part and fixating it securely. Then proceed with fabrication of the master model.

18.4.4 Insufficient denture retention – what to do:

1. Remove the denture, clean it and check which anchor system was used.
2. Check the denture to see if the female part or its components are damaged, replace if necessary and readjust denture retention.
3. Check whether the incorporated female part is correctly positioned on the male part. If this is not the case, the retention force is reduced and wear is very high. It is essential to insert the female part afresh.
4. Check in the mouth to see if there are any signs of wear on the ball of the male part, which could be the cause of insufficient retention. If yes, use the Dalbo®-PLUS Gauge set to check the level of wear in the patient's mouth. If the Dalbo®-PLUS was used, then denture retention can be easily readjusted by replacing the lamellae retention insert, which is available in 3 different force levels, in the housing. If a different ball anchor system was used, we recommend changing to the Dalbo®-PLUS when the ball male parts are worn out.
18.4.5 Dalbo®-PLUS Gauge set

With the Dalbo®-PLUS Gauge set it is possible to check in the mouth whether the ball male part shows signs of wear.

<table>
<thead>
<tr>
<th>Gauge set (Cat. No. 0700 0026).</th>
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<tbody>
<tr>
<td>Scope of delivery: male part gauge (Cat.-No. 0700 0027), female part gauge (Cat.-No. 0700 0024), lamellae retention insert (Cat.-No. 055 643), tuning lamellae retention insert soft (Cat.-No. 0500 0068), tuning lamellae retention insert (Cat.-No. 055 687), screwdriver / activator (Cat.-No. 072 609).</td>
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</table>

Male part gauge (Cat. No. 0700 0027).
Allows checking the set retention force in the denture outside the mouth. The nominal dimension of the ball diameter of the male part gauge is 2.245 mm and corresponds to the most commonly used systems on the market.

Female part gauge (Cat. No. 0700 0024)
Supplied without mounted lamellae retention insert.
Serves to check and determine the desired Dalbo®-PLUS Female part retention force in the patient's mouth and selection of the ideal lamellae retention insert.

Adjusting the retention force with the gauge set
1. Screw in the lamellae retention insert (Cat no. 055 643) with the screwdriver/activator (Cat no. 072 609) into the female part gauge (Cat no. 0700 0024) up to the 0-position (flush with the lower edge of the housing).

Repeated screwing and unscrewing of the lamellae retention insert reduces the protection against becoming loose by itself!

2. Check and adjust the retention force in the mouth with the female part gauge, which is secured with a thread, by increasing the retention force stepwise with ¼ turns. Adjustment is a matter of feeling. The recommended retention force lies between 600 – 900 g, but may vary depending on the number of anchors used and the patient situation.

3. If sufficient retention cannot be achieved with the lamellae retention insert, the tuning lamellae retention insert soft (Cat. No. 0500 0068) and later, the tuning lamellae retention insert (Cat. No. 055 687) are screwed into the female part gauge and the procedure is repeated.

4. Once the desired retention force has been reached, note the number of revolutions.

Unscrew the lamellae retention insert and adjust it again with the same number of turns in the original housing.

5. Note the type of lamellae retention insert used and the batch number in the patient file.

19 Materials

| S = Syntax; TIA16V4 ELI (Grade5) |
| T = Pure titanium (Grade 4); Ti > 98.9375 % |
| E = Elior®; Au 68.60 %, Pt 2.45 %, Pd 3.95 %, Ag 11.85 %, Cu 10.60 %, Ir 0.05 %, Zn 2.50 %, T₆ – T₇ 880 – 940 °C |
| V = Valor; Pt 89.0 %, Au 10.0 %, Ir 1.0 %, T₆ – T₇ 1660 – 1710 °C |
| K = Korak; Residue-free burn-out resin for the casting technique. |
| G = Galak; Mouth-resistant resin |
| X = steel. |

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.

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 batch 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:

Dalbo® / Elitor®

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.
### Table 1

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Symbols

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Important information for the specialist

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Warning symbol for increased caution

Labelling on packaging/symbols

[Image of symbol]

Date of manufacture

[Image of symbol]

Manufacturer

[Image of symbol]

Catalogue number

[Image of symbol]

Batch code

[Image of symbol]

Quantity

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