

Instructions for use

Hinges

Application, activation, deactivation, repairs and regular servicing of attachments should only be carried out by trained personnel using original instruments and components. Mechanically cleaning attachments with a toothbrush and toothpaste can cause premature wear and tear of the functional components.

With the publication of these instructions for use all previous Editions are no longer valid.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

Hinges: general guidelines

Traceability of lot numbers

If attachments are assembled from components with different lot numbers, all relevant lot numbers have to be recorded to ensure that they can be traced.

Twin crowns

Two splinted abutment crowns per quadrant located on a mutual frontal plane are ideal for supporting and retaining hinged unilateral and bilateral free-end dentures.

Metal occlusal surfaces

Metal occlusal surfaces above female parts assure that they remain in the resin. As when using retainers which embrace the female, the female must never be soldered into place.

Dismantling the attachments

Separate the male and female parts before thermal treatment (casting-on, soldering, hardening and ceramic firing) and, if they consist of several components, dismantle them.

Precautions when soldering OSV

IMPORTANT!

OSV alloy must not be annealed or hardened after soldering. (Danger of fracture due to embrittlement of the alloy.) If components of OSV attachments are heated intensely, they oxidize severely and the oxide layer is not easily removed by pickling. In this case, remove the oxide layer with a glass brush. Do not use sandblasting or any other abrasive products such as prepolishing paste.

Pickling

Oxidation on soldered female parts made of Doral can be removed by pickling with warm 10 vol. % sulphuric acid (H₂SO₄). **Note:** Do not pickle with nitric acid (HNO₃), hydrochloric acid

Note: Do not pickle with nitric acid (HNO₃), hydrochloric acid (HCl) nor Neacid. These acids can destroy the alloy. Alternatively, oxidation can also be removed by careful blasting (1.5 bar pressure) with glass beads.

Pickled parts slide better, if they are placed in soapy water (ultrasonic bath) after pickling.

Disinfection

After any fabrication or modification, the prosthetic work, incl. female part component, must be cleaned and disinfected according to national guidelines. When selecting the disinfectant, it is essential to 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 tested efficacy in disinfection.

All parts made of plastic must be disinfected with a high EPAregistered disinfectant prior to use.

Recommended: Cidex® OPA Solution. Strictly follow manufacturer's instructions.

Further information

on processing precious metal alloys, soldering and casting-on are included in the Dental documentation of Cendres+Métaux and in the website www.cmsa.ch/dental.

Warnings

Allergies

This product must not be used for patients known to be allergic to one or several of the elements contained in the attachment materials. Should the patient be suspected of being allergic to one or several of the elements contained in any one attachment, this product can only be used after preliminary allergological testing and proof that no allergy exists.

Please contact your Cendres+Métaux sales representative for further information.

Auxiliary instruments may contain nickel.

The device has not been evaluated for safety and compatibility in the MR environment.

The device has not been tested for heating or migration in the MR environment

Precautions

- The parts are delivered non-sterile. Proper preparation of the parts before use in patients is explained in the section «Disinfection».
- Ensure the attachment is cleaned regularly to avoid soft tissue inflammation.
- During intraoral use, all products should generally be secured against aspiration.
- No cutting work should be performed in the patient's mouth.





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

Mini-Dalbo[®]

ΕO

Female part $E = Elitor^{\otimes}$

Integration: Polymerisation

Male part O = OSV

Integration: Soldering

EC

Female part $E = Elitor^{\otimes}$

Integration: Polymerisation

Male part C = Ceramicor®

Integration: Casting-on or soldering

DK

Female part D = Doral

Integration: Polymerisation

Male part K = Korak

Non-residual burnout plastic for the casting technique

Indications

- Stress-broken unilateral and bilateral free-end dentures
- Short or long-span denture saddles with a transverse framework

Contraindications

- Where patients have an existing allergy to one or more elements of the attachment materials.
- Unwillingness of the patient to correctly follow the aftercare/ recall instructions.
- Patients with bruxism or further uncontrolled para-functional habits.
- Unilateral dentures without transverse bracing
- Insertion dentures

Characteristics

The simple design of the Mini-Dalbo® is impressive and easy for the dentist and patient to handle.

Equipment and components required for correct processing

Parallelometer, accessories and instruments. Refer to the Dental documentation of Cendres+Métaux.

Please note

When casting Korak K male parts, only use alloys with an $0.2\,\%$ proof stress of at least 500 N/mm².

E = Elitor

Au $68.60\,\%,$ Pt $2.45\,\%,$ Pd $3.95\,\%,$ Ag $11.85\,\%,$ Cu $10.60\,\%,$ Ir $0.05\,\%,$ Zn $2.50\,\%$

D = Doral

Ag 49.3 %, Pd 20.0 %, Au 15.0 %, Cu 13.7 %, Ru 2.0 %

C = Ceramicor®

Au 60.0%, Pt 19.0%, Pd 20.0%, Ir 1.0% $\rm T_{\rm S} - \rm T_{\rm L}$ 1400–1490°C

0 = OSV

Au $60.0\,\%,$ Pt $10.5\,\%,$ Ag $7.0\,\%,$ Pd $6.5\,\%,$ Cu $14.0\,\%,$ Zn $2.0\,\%$

 $T_{s} - T_{L} 960 - 1065 ^{\circ}C$





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Instructions for use

Important! Three-dimensional parallelism

To guarantee the rotational movement of the removable denture, the Mini-Dalbo® attachments must be parallel to one another in all three dimensions (vertical, sagittal and horizontal).

In the **upper jaw**, the Mini-Dalbo® must be placed parallel to the **median line** (Figure 1).

In the **lower jaw**, the Mini-Dalbo® must be placed on the **bisecting line B** between the alveolar ridge **C** and median line **A** (Figure 2).

Fitting male parts C and K

Determine the angle of insertion taking the three-dimensional parallelism into account, place male part C or K on the wax pattern with the parallelometer insert (070146) and wax the male into place

Male part C: For casting onto with precious alloys

Male part K: For casting with precious or non-precious alloys. After casting, place the female part in position and check for correct hinge movement (Figure 3).

Fitting male part O

When furnace-soldering OSV male parts to metal-ceramic crowns, as OSV oxidizes severely when heated, it is advisable to pre-solder the OSV male (freehand) on the stop plate with a solder after firing. Then use a parallelometer insert (070 146) to align the male with the angle of insertion, wax it into place and fabricate a soldering model. The same solder and flux as used for pre-soldering can be used for furnace-soldering the male and crown.

Fitting female parts E and D to a removable denture

To retain their mechanical properties, neither female versions must ever be soldered into place. Place the females in their rest positions on the balls in the male parts (Figure 4). Block out all undercuts, the slots in the activation lamellae and the exterior surface in close proximity to the activation slots with wax. This prevents denture acrylic creeping into the female housing during polymerization and provides clearance for activating/deactivating the lamellae. The retainer on the end of the housing ensures that it is retained properly in the denture saddle.

Activation

Friction can be increased by carefully bending the lamellae inwards with a flat instrument.

Modifications / relines

When modifying or relining the denture, the transfer jigs (070176) should be placed on the working model for the reconstruction of the position of the male parts.

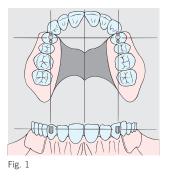




Fig. 3

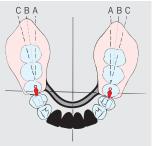


Fig. 2



Fig. 4

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Aftercare

Inside the mouth, retainers for prosthetic work are more or less exposed to stresses in a constantly changing environment, and hence wear. Wear occurs everywhere in everyday situations and cannot be avoided, only reduced. The intensity of wear depends on the system as a whole. Our endeavour is to use materials that are optimally matched to one another, in order to reduce wear to an absolute minimum. The good fit of the denture on the mucosa has to be checked at least once a year and a lining may have to be provided in order to eliminate swinging movements (overloads), especially in the case of free-end prostheses. We recommend replacing the friction insert (wearing part) at the annual check-up as a precaution.

Patients can obtain information and recommendations about the use, removal and care of prostheses on the patient website at www.cmsa.ch/dental/infos.

Care & cleaning

Ideally you should clean your teeth and your denture after every meal. Cleaning your denture also involves cleaning the connecting element. The gentlest method is to clean the connecting element under running water with a soft toothbrush. For the most thorough cleaning, the denture has to be placed in a small ultrasonic device with a suitable cleaning additive. High-precision attachments must never be cleaned with toothpaste because this can cause damage. You should also be wary of unsuitable cleaning solutions or tablets. These can also damage the high-quality connecting element or interfere with its functioning. The connecting elements fixed in your mouth, e.g. on remaining teeth or on implants, must be cleaned only by using water and a soft toothbrush as well as an interdental brush. Do not use toothpaste in order to avoid premature damage to the connecting element.

Ensure the attachment is cleaned regularly to avoid soft tissue inflammation.

Please contact your Cendres+Métaux agency for advice and additional information

Disclaimer

Upon publication, these instructions for use supersede all previous editions.

The manufacturer is not liable for any damages due to the user disregarding the instructions for use below.

This attachment is part of a comprehensive conception and may only be used or be combined with the corresponding original components and instruments. If this is not the case, any responsibility by the manufacturer will be refused.

In case of complaints the lot number must always be specified.

Markings on the packaging / Symbols

V.

Manufacturer

REF

Catalogue number

LOT

Batch code

QTY

Quantity

 $\prod_{\mathbf{i}}$

Consult instructions for use

Rx only

Caution: US Federal law restricts this device to sale by or on the order of a licensed (healthcare)

practitioner.





Cendres+Métaux products with the CE mark fulfill the requirements of the Medical Device Directive 93/42/EEC.



Do not re-use



Non-sterile



Keep away from sunlight



Caution, consult accompanying documents