

Instructions for use

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.

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.

Intended Use

The bars manufactured by Cendres+Métaux SA serve as connectors for tooth- or implant-supported removable dental prostheses.

In general

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.

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 EPA-registered disinfectant prior to use.

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

Warnings

With patients having an existing allergy to one or several elements of the materials contained in any one attachment, this particular product must not be used. With patients suspected of having an allergy to one or several of these elements contained in any one attachment, this product can only be used after preliminary allergological testing and proof of a non-existing allergy.

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.

These operating instructions are not sufficient for immediate use of the attachment. Knowledge of dentistry and dental technology as well as instruction on the handling of the Cendres+Métaux attachments by an experienced person are required. Training courses are regularly provided by Cendres+Métaux, among others. The activation, deactivation, repair and periodic maintenance of attachments should be carried out solely by specialists. Only original auxiliary tools and parts should be used for this work.

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 male parts must be placed parallel to the direction of insertion.
- Undercuts must be blocked out.

Further hints

for processing precious metal alloys, soldering and casting-on are available in the Dental documentation of Cendres+Métaux or in the internet by visiting www.cmsa.ch/dental.

Round bar with rider

Female part E /

Female part E L50

E = Elitor®

Supplied: **Hardened**

Fitting: Polymerized into place

Male part P3

P3 = Protor® 3

Supplied: **Annealed**

Fitting: soldering or **Laser welding:** Refer to the instructions for use «Cendres+Métaux wires for laser welding»

Lengths: 50, 100 and 200 mm

Male part K

K = Korak

Fitting: Burnout plastic for the casting technique

Length: 75 mm

Individual components

Tin spacer

Ensures vertical translational movement of the denture

Note: Do not put the tin spacer in tin in the mouth.

E = Elitor®

Au 68.60 %, Pt 2.45 %, Pd 3.95 %, Ag 11.85 %, Cu 10.60 %, Ir 0.05 %, Zn 2.50 %
T_S-T_L 880-940 °C

P3 = Protor® 3

Au 68.6 %, Pt 2.4 %, Pd 4.0 %, Ag 11.8 %, Cu 10.6 %, Ir 0.1 %, Zn 2.5 %
T_S-T_L 880-940 °C

K = Korak

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

Indications

Tooth and tooth/gingival supported dentures
Implant-supported dentures, partial dentures and coverdentures, especially in cases of severe partial edentulousness, partial dentures and coverdentures on extremely weak abutment teeth

Contraindication

- Unilateral dentures without transverse support.
- Restoration of abutment teeth with severe periodontal damage.
- Hybrid dentures which are fitted with a single root cap.
- 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.

Equipment and parts required for correct processing

Bending pliers, processing aids and instruments (further details are available in the Dental documentation of Cendres+Métaux or in the internet by visiting www.cmsa.ch/dental).

Brief description

The round bar can be adapted to the anatomy of the alveolar ridge, which saves space. The bar can be soldered or laser welded to implant caps, root caps or crowns. The casting-on technique cannot be employed.

Preparation

To ensure that the teeth are positioned to provide for optimum aesthetics and functioning, we recommend setting them up before fitting the bar.

Instructions for use for the round bar P3

Adapting the round bar

Bend and adapt the bar to the anatomy of the alveolar ridge, either in contact with the gingiva or not.

Please note: The bar is supplied **annealed**.

It is not advisable to solder bars to non-precious abutment crowns (risk of corrosion).

Check with an overcast. When bending the round bar to adapt it, ensure that straight sections of at least 4 mm remain for positioning the riders (example with female part E) (Fig. 1).

Important: To prevent damage to the bar, do not use sharp pliers and bend the bar slowly.

Heat treatment

The male part and female part must be separated prior to being heat treated.

Annealing and hardening

If the restoration is not bench cooled after soldering, it can be tempered afterwards.

1. Annealing: 700°C, 10 min./quench in H₂O
2. Hardening: 400°C, 15 min./bench cool

Fabricating the soldering model

Once the bar has been adapted, fix it to the abutment units with sticky wax or self-curing burnout resin. Use the overcast to check the position of the bar. Ensure that the connectors between the primary parts and bar are of adequate dimensions. When using «U» shaped bars, a wooden stick (e.g. toothpick) can be waxed to the posterior region to provide additional stability (Fig. 2 A). Carefully release the combined bar/abutment units from the model and fabricate the soldering model with soldering investment.

Furnace-soldering the round bar

Please note: It is advisable to solder ceramic alloy abutments or long-span restorations in a porcelain furnace.

Remove the sticky wax and stabilizer. While the soldering model is still warm, apply adequate amounts of flux C (Order No.: 080227) to the joint and preheat the soldering model at 500°C in a preheating furnace for 10–15 minutes. Cut the solder to size, place it in the gap and coat all joints with flux C again. Heat the porcelain furnace to 500°C and place the soldering model in it immediately. The heating rate should be 50°C/min. to ensure that the entire soldering model is heated thoroughly. The final temperature must be set 50–70°C higher than the liquidus of the solder. Hold the final temperature for 1 minute to ensure that the solder wets the alloy fully. Bench cool the restoration on the soldering model (to achieve optimum mechanical properties).

Please note: Ceramic alloys should be cooled as described in the manufacturer's instructions.

Soldering the round bar with a torch

Remove the sticky wax and stabilizer. While the soldering model is still warm, apply adequate amounts of CM flux paste (Order No.: 080229) to the joint and preheat the soldering model at 500°C in a preheating furnace for 10–15 minutes. Apply more flux. Use the torch flame to heat the restoration to the working temperature of the solder. The flame must not be removed from the restoration (risks oxidation). Coat the solder with flux and place it on the gap – hold the flame on the opposite side to ensure that the solder flows toward the warmer area. After soldering, heat the entire soldering model again uniformly and bench cool the restoration (to achieve optimum mechanical properties).

Pickling

The oxide produced during soldering can be pickled off with 10% by volume warm sulphuric acid (H₂SO₄).

Please note: Never pickle with nitric acid (HNO₃) or hydrochloric acid (HCL) as they may destroy the alloy. Alternatively, the oxide may be cleaned off with a glass-fibre brush. To rule out dimensional changes, the bars must not be sandblasted.

Laser-welding

Basically only materials of the same composition may be joined. Subsequent failures are thus reduced to an absolute minimum. Processing details can be found on our website at www.cmsa.ch/dental in the **Interesting facts about alloys** under **Laser welding technique**, and in the instructions for use for Cendres+Métaux laser welding wires (automatically supplied with the product).

Polishing

Polish the bar extremely carefully with standard types of polish, making certain not to reduce its cross-section.

Instructions for use for the round bar K

Adapting the round bar

The plastic bar can be plastically shaped and individually adapted to the alveolar ridge by carefully heating, eg. over a bunsen. Alternatively, adaption of the bar to the alveolar ridge can also be done by cutting and waxing-up. Ideally cut a V-shape without completely separating the bar. For the rider to function properly for years it must fit accurately onto the round bar. Therefore, straight lengths of 4 mm must be left **untouched** (Fig. 1).

Casting technique for the round bar

Tips for a successful, perfect casting:

- Use a casting alloy having a 0.2 % proof stress (Rp 0.2 %) of min. 500 MPa.
- Attach sufficient sprues.
- Wax-up the sprues without any sharp edges or acute angles.
- Do not use any aggressive wetting agents which could dissolve the plastic.
- Use a high strength, phosphate-bonded investment compound (e.g. Ceramicor).
- Burnout: Place the cylinder with the opening down, so that as much material as possible can burn outside the cylinder, heating rate < 4 °C/min., keep for 30–60 min. at 250–300 °C.
- Final temperature: heating rate < 7 °C/min., keep at the final temperature for 30–50 min.
- Devest carefully, blast with 50 μm glass beads only, use low pressure.
- Trim the casting only as much as needed, e.g. removal of casting faults such as bubbles. The profile must be retained.
- Carefully polish using rotating brushes and polishing paste.

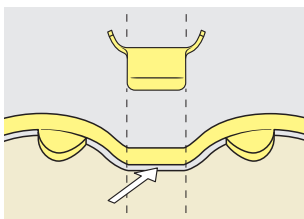


Fig. 1

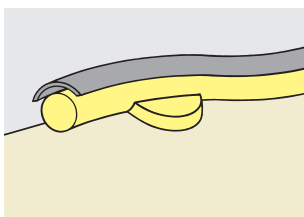


Fig. 3

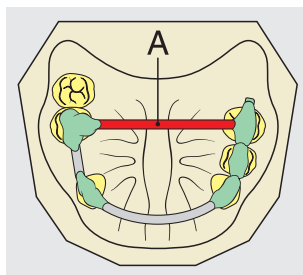


Fig. 2

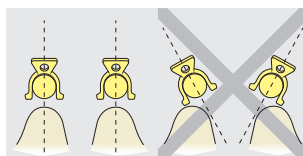


Fig. 4

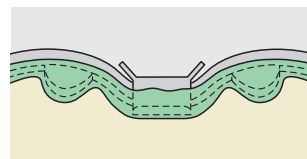


Fig. 5

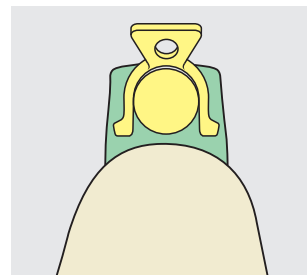


Fig. 6

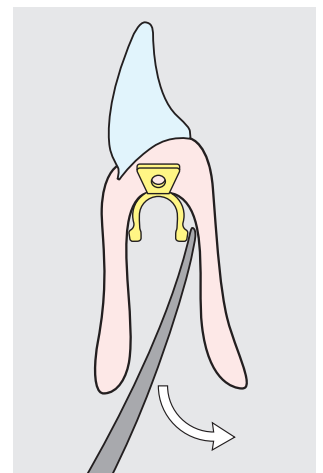


Fig. 7

Mounting the female parts E and E L50 on the bar P3 or K

As the bar rider is supplied with the perfect properties enabling it to function long-term, it must not be heat treated, e.g. soldered. The two bar riders must be absolutely clean before being polymerized into place.

Please note:

- For resilient restorations, the tin spacer groove is adapted occlusally along the entire length of the bar (Fig. 3). Once the acrylic has been packed, the spacer can be removed. Fit the desired number of bar riders.
- To prevent the lamellae being deactivated prematurely and ensure that the denture can be fitted and removed simultaneously, the bar riders must be positioned parallel to each other (Fig. 4).

Female part E (Order No. 050 527 / package of 5 055 801)

To prevent the retainers on the bar rider breaking, they must only be bent once and extremely carefully. The retainers may break if bent backwards and forwards several times.

Female part E L50 (Order No. 0500 0679)

The female part can be reduced individually to the bar length. Adapt the female part to the entire length of the bar. Remove flash inside and outside after shortening. An optimal function and a long term life quality of the female part can only be obtained on straight bar sections.

Then block out the gingival aspects of the abutment units circumferentially and occlusally as well as the bar and rider on the model (Fig. 5). Ensure that the lamellae of the riders are blocked out adequately (Fig. 6) so that they remain fully flexible while being fitted and removed. If necessary, position the cast strengthener over the bar rider and complete the acrylic using standard dental technical methods.

Activation

To activate the lamellae of the rider, carefully press them inwards with the correct activator from the activator set (Order No. 070 198) (Fig. 7).

Modifications / Relines

Should the denture require modifying or relining, place the transfer jig (Order No. 072 293) on the working model to take the place of the bar rider.

Relining procedure for dentists

1. Remove the female part from the denture
2. Trim the underside of the denture
3. Place the new female part on the bar
4. Block out any undercuts on the bar (Fig. 5)
5. Coat the denture with adhesive for silicone impressions
6. Take the impression

Relining procedure for dental technicians

1. Position the transfer jig in the female part
2. Cast the models (plane line articulator)
3. Remove the silicone from the denture
4. Roughen the underside of the denture
5. Place the female part on the transfer jig
6. Block out any undercuts on the bar and the lamellae of the rider (Figs. 5 and 6)
7. Apply separating agent to the model
8. Pack the acrylic
9. Trim the denture

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












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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

	Manufacturer
	Catalogue number
	Batch code
	Quantity
	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.
	
	Non-sterile
	Keep away from sunlight
	Caution, consult accompanying documents