

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.

Disinfection of deactivators

070200 Deactivator (Dolder® micro) und 070201 Deactivator (Dolder® macro) must not be sterilised. When sterilising the above deactivators in the autoclave, there is a possibility that their plastic handles may be destroyed.

It is therefore advisable to disinfect according to the section «Disinfection» of these instructions for use.

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

Further information on soldering, casting on, laser welding, burn-out plastic attachments etc. can be accessed on our website at www.cmsa.ch/dental in the section **Products/Shop, Informations**.

The 3 male part concepts

- 1. Male part micro and macro (Fig. 1)** **E = Elitor®**
Supplied: **warm straightened**
Fitting: soldering or **laser welded**
Lengths: 25, 50 and 200 mm
- 2. Male part micro and macro (Fig. 2)** **T = Pure titanium**
Supplied: **cold-drawn**
Fitting: **laser welded**
Lengths: 50 and 200 mm
- 3. Male part micro and macro (Fig. 3)** **K = Korak**
Fitting: **non-residual burn-out preformed male part**
Length: 75 mm

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

Auxiliary parts

Brass spacer (Fig. 11)

Micro 50x0.75mm, Order No. 052080

Macro 50x1.05mm, Order No. 052081

For vertical translation of the articulated denture

Note: Do not put the brass 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

T = Pure titanium

K = Korak

Non-residual burn-out plastic

Indications / Bar joint

Dolder® Resilient Bar

Removable dentures

Tooth/gingival supported resilient dentures (placed primarily in upper and lower anterior regions):

- Implant-supported dentures,
- Coverdentures

Contraindications

- 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

Simple parallelometer, product-specific processing aids and instruments

Brief description of the resilient bar

The resilient bar was designed by Prof. Dr. E. Dolder and is a dynamic connector with an oval cross-section specifically for coverdentures. In order to fabricate a denture with a resilient bar, two teeth or implants (upper or lower anterior) must be connected with a straight bar (Fig. 4). This ensures that the bar can function correctly. In addition, vertical translational movement of the removable denture can be allowed for by placing the brass spacer between the bar and sleeve prior to polymerization. The bar can be soldered, laser welded or cast in cast alloys with adequate strength by means of a fully burnout preformed part to root caps, crowns or implant suprastructures. The casting-on technique cannot be employed.

Preparing to fit the resilient bar

Screw on implant caps for bar restorations. With natural teeth, fabricate root post/caps and/or crowns. With crowns, adequate space must be provided for soldering/laser welding correctly. To ensure that the teeth are positioned to provide for optimum aesthetics and functioning, we recommend setting them up before fabricating the bar.

Please note: The bar (male part) is supplied warm straightened. It is not advisable to solder/laser weld prefabricated bars to non-precious abutment crowns (risk of corrosion).

Instructions for use

Fitting the resilient bar

Use the paralleling mandrel (Order No. 072515 micro bar, 072517 macro bar) to fix the bar section tension-free to the cast abutments with sticky wax or self-curing burnout resin parallel to the occlusal plane and abutments and in the correct physiological relationship (Fig. 5) to the alveolar ridge. Minimum gap from the gingiva is 1.00 mm. The soldering gap should be in the range of 0.05–0.20 mm. Check with an overcast.

Important: To ensure that the denture can rotate around the bar, it must never be bent or slanted.

1. Male part E (Fig. 1)

Soldering

Melt off the sticky wax or remove the self-curing resin (Fig. 6).

While the soldering model is still warm, apply adequate amounts of CM flux paste (Order No. 080229) to the bar 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).

Soldering to crowns

To prevent the soldered joint becoming a weak point, we recommend extending the end of the bar approx. 0.5 mm into the wax pattern of the crown or placing it on a small projection. Should neither of these be feasible, a «U» shaped gold wire can be placed over the bar and in contact with the crown before soldering, in order to increase the soldering area.

Furnace-soldering

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



Fig. 1

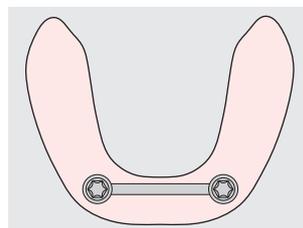


Fig. 4



Fig. 2

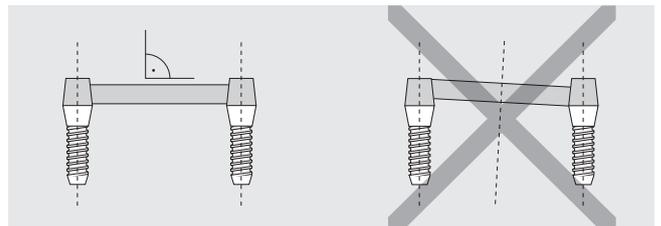


Fig. 5



Fig. 3

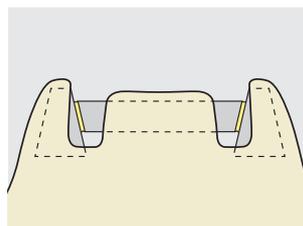


Fig. 6

Heat treatment

The male and female parts of bars must be separated prior to heat treatment.

Annealing and hardening

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

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

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 glassfibre brush. To rule out dimensional changes, the bars must not be sandblasted.

1. Male part E (Fig. 1)

2. Male part T (Fig. 2)

Laser welding

Integrity of the laser weld

Always laser weld materials that are as similar as possible. Subsequent failures are thus reduced to an absolute minimum. Use the special parallelometer and jig for laser welding (e.g. Paralas from Dentaurum / Order no. 090520) and the parallelometer attachment (Order no. 070143) for aligning the preformed bar. (Fig. 7)

To ensure a stable laser weld, prepare a V shape on the weld surface of the preformed bar using a tungsten carbide cutter. (Fig. 8) To avoid stresses in the weld joint, first weld the bar over the cross. Then weld the bar circumferentially.

Note: Ensure that the weld is uniform by alternately welding a counterpoint on each side. Each bar should be welded first to an implant abutment and then to the other ends. (Fig. 9)

Fill the surface from the centre to the outside (Fig. 10). Then smooth the laser weld joint.

Male part E with laser wire LW Protor® 3 (Order No. 010903)

Male part T with laser wire LW titanium (Order No. 01000081)

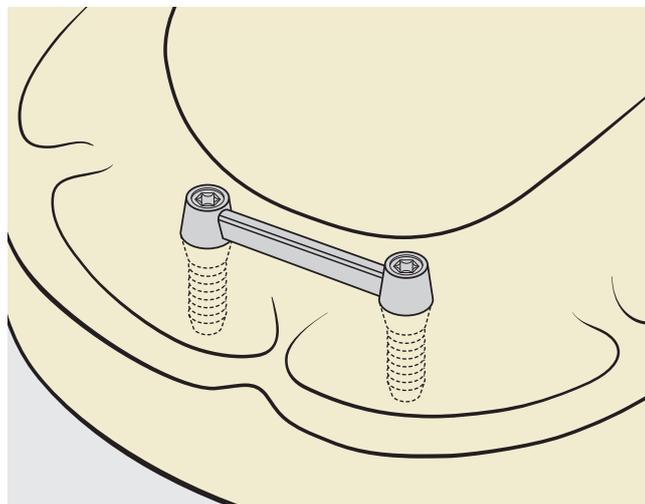


Fig. 7

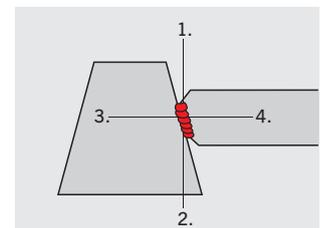


Fig. 9

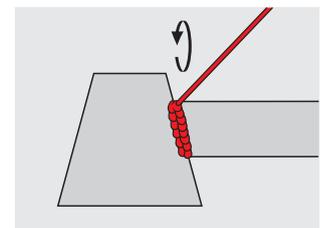


Fig. 10

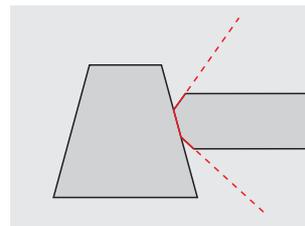


Fig. 8



Fig. 11

Polishing

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

Note: Material reduction should be kept to a minimum to ensure optimal stability of the weld joint. The function of the bar sleeve must be maintained.

Heat treatment

1. Male part E (Fig. 1)

The Dolder® System bar made of Elitor® are supplied warm straightened. As the material cools extremely quickly, the laser weld has a hardness of approx. 190 VH5. To ensure the laser weld joints and the bar have optimal mechanical properties after welding, the frameworks should be heat treated as follows after laser welding has been completed:

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

2. Male part T (Fig. 2)

Not necessary. The preset mechanical properties are unchanged during laser welding.

3. Male part K (Fig. 3)

Prepare and position the male part as described above. Invest and cast. Clean the casting in an ultrasonic unit and polish the male part carefully with a small rotary brush without altering its contour. Check and adjust the function on the master model.

Note: The quality of laboratory-fabricated male parts units depends on the choice of material and technique and has a crucial effect on the functionality and durability of the restoration.

The casting alloy used should have a 0.2% proof stress of at least 500 N/mm² to ensure that the cast male part has adequate strength.

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.

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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.



Do not re-use



Non-sterile



Keep away from sunlight



Caution, consult accompanying documents