

Anchors

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 anchors manufactured by Cendres+Métaux serve as connectors for tooth-supported removable dental prosthesis.

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.

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

Technique for using the auxiliary parts (Galak)

Here the spacers generally replace the anchor female parts during resin-polymerization in the dental laboratory. These are then removed from the finished polymerized denture. The polymerization or resin-bonding of the original female parts is done by the dental surgeon directly in the mouth of the patient after cementing of the root canal caps. The spacers are also an excellent by the dental surgeon directly in the mouth of the patient after cementing of the root canal caps. The spacers are also an excellent protection for the male parts during polishing.

Duplicating aids

These red parts are slightly overdimensioned compared to the original parts. The result is an optimal gap for the resin-bonding technique.

Note: The duplication aid must not be used instead of the female part as a temporary replacement and also must not be placed in the mouth for impression-taking.

Spacer disc

The tin spacer supplied with this attachment provides for vertical resilience. The soft spacer is placed over the entire root cap and adapted prior to polymerizing the resin. Once the resin has been finished, the spacer is removed. Current clinical experience shows that the minimal vertical resilience is eliminated once the denture has been placed. The greatest advantage is that the denture base is not overloaded on the root cap.

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

Twin crowns

With two root canal caps in succession in the posterior region of a quadrant the combined use of a rigid anchor with a resilient anchor is recommended. Normally the rigid anchor will be placed on the anterior and the resilient one on the posterior abutment. The two root canal caps must **not be** blocked. Thus rocking movements and overloads can be prevented.

Occlusal metal surfaces

Occlusal metal surfaces above female parts assure that they remain in the resin. The female parts must never be soldered, but must be polymerized directly into the removable denture in the patients mouth by the dental surgeon.

Denture framework

For bilateral insertion and free-end dentures cast transversal connections such as plates in the upper, sublingual connectors in the lower jaw are used. It is important that these constructions are absolutely rigid (no springiness).

Transversal blocking

Rigid unilateral dentures must be blocked transversally, generally with Cendres+Métaux attachments (see chapter «Slide attachments» in the Dental documentation of Cendres+Métaux).

Precautions when soldering OSV**IMPORTANT!**

The alloy OSV must not be annealed or hardened after soldering (Danger of fracture due to embrittlement of the alloy.)

If components of anchors oxidize strongly during soldering, the oxide layer may not easily be 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.

Dismantling of the attachment

Separate the male and female parts before soldering and, if they are made up of components, dismantle them.

Pickling

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

Thread

If desired, thread cutters and tap dies are available for specific attachments.

Auxiliary instruments

The auxiliary instruments to be used are listed in the main catalogue of Cendres+Métaux under the heading for the particular attachment. See website www.cmsa.ch/dental or the dental documentation from Cendres+Métaux (available free of charge from all subsidiaries, branch offices and agencies of Cendres+Métaux).

Further indications

For processing of precious metal alloys, soldering and casting-on see Dental documentation of Cendres+Métaux.

Allergies

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.

Materials used and processing**Description and abbreviations for materials:**

Detailed information about the materials and their classification can be found in the specific material data sheets and the catalogue.

See website www.cmsa.ch/dental or the dental documentation from Cendres+Métaux (available free of charge from all subsidiaries, branch offices and agencies of Cendres+Métaux).

E = Elasticor

Au 61.0%, Pt 13.5%, Ag 16.5%, Cu 9.0%

O = OSV

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

$T_s - T_L$ 960–1065°C

SG 750

Au 75.0%, Pt 1.0%, Ag 11.8%, Zn 12.2%

$T_s - T_L$ 700–745°C

050345 EI.O

anterior

051277 EI.O

posterior

050397 EI.O

anterior resilience

051278 EI.O

posterior resilience

Female part

EI = Elasticor hardened

Integration: Polymerization

Male part

O = OSV

with integrated solder

S.G 750 Cd-free

Integration: soldering

Mounting parts for 050397/051278

Spacer disc, occlusal

Spacer disc, gingival

Indications

Removable, retention-grip, rigidly or resiliently restorations supported on devitalized roots:

- Rigid hybrid dentures
- Rigid hybrid dentures combined with resilient Eccentric
- Insertion and free-end dentures in combination

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 components required for correct processing

Accessories. Refer to the Dental documentation of Cendres+Métaux.

Characteristics

As this attachment is not very high, the male part can be positioned without using a parallelometer.

The quantity of the solder integrated into the centre of the male part is large enough to solder it to the root post cap.

Instructions for use

Fabricating the root post cap

The occlusal surface of the root post cap must be waxed up at right-angles to the intended angle of insertion of the removable denture. After casting, cut the head off the root post and mill the occlusal surface perpendicular to the angle of insertion.

Male parts O 050345/051277 are identical.

Male parts O 050397/051278 are identical.

Soldering male part O into place

Note: Soldering is simplified thanks to the slight extension of the solder on the underside of the male part giving direct contact on the root cap (Fig. 3/A).

Position male part O on the root post cap so that the marking is visible on the occlusal and aligned with the anterior aspect (Figure 1). If several males are being fitted to the same arch, they must be placed parallel with the median plane (Figure 2). Prior to soldering, record the position of the marking on the male on every root post cap. Remove the male part and apply CM soldering paste (order No. 080229) in a thin layer onto the root cap. Then replace the male part as described onto the root cap, hold the root canal post with the tweezers and carefully solder over a softly regulated bunsen flame (Fig. 3). After soldering, allow the unit to cool to room temperature – pickle, trim and polish it. Check that it functions correctly with the female part in place.

Two different versions of female part are available.

Females 050345/051277 and 050397/051278 have a crosswise retainer for retaining them in the anterior region. The retainer on females 050345/051277 and 050397/051278 is positioned lengthwise for retaining them in the posterior region (Figure 2).

Fitting female part EI to the denture

These female parts are simply polymerized into the denture acrylic. They must never be soldered.

Please note

All female parts in the same arch must be aligned so that their arms can be opened and closed simultaneously when the denture is inserted or removed from the mouth (Figure 2). Before polymerizing the females into the denture, it is advisable to fix them into place by applying a small amount of self-curing resin to their perforated retainers (Figure 4). Process the acrylic denture using standard dental techniques.

Polymerizing female part EI 050345 or 051277 into the denture

Replace the root post cap and anchor on the master model and place the female on the male. The aperture in the retaining arm must be positioned where the occlusal mark on the male is (Figure 2). Block out the centre of the male and the retaining arm of the female with a 1 mm coat of cement, wax or Flexistone. The occlusal surface must remain exposed.

050345/051277

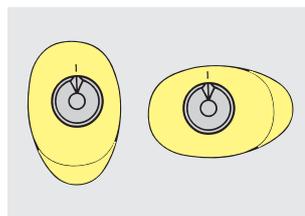


Fig. 1

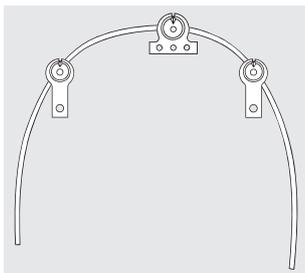


Fig. 2

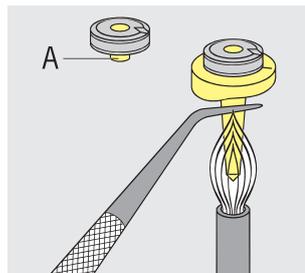


Fig. 3

050397/051278

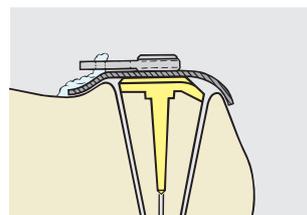


Fig. 4

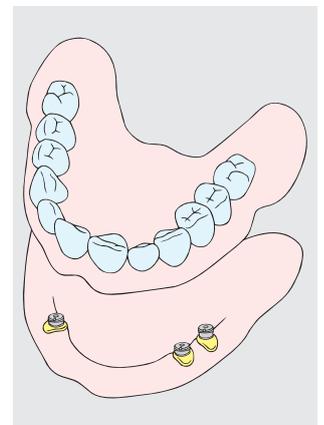


Fig. 5

Polymerizing female part EI 050397 or 051278 into the denture

To ensure that the removable denture is resilient, the tin gingival spacer must be adapted to the root post cap prior to polymerization, placed on the male and the occlusal spacer adhered to the male (Figure 4). Block out the retaining arms as described for version 050345/051277.

Processing the denture

Once the denture has been released from the master model, all the blocking out material must be removed from the retaining arms to ensure that they are fully mobile when the denture is inserted/removed. The occlusal spacer must also be removed from the denture.

Modifications / relines

When modifying or relining the denture, the transfer jigs (070161 or 070167) should be placed on the new working model in place of the male parts.

When using 050345/051277 attachments, the impression can either be taken with the females placed on the males or without the females.

When using resilient 050397/051278 attachments, the impression must be taken with the female placed on the male.

Please note: The functional section of transfer jig 070167 is not identical with the original male part. This transfer jig is used for positioning the female parts exactly along the vertical axis.

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.
	Do not re-use
	Non-sterile
	Keep away from sunlight
	Caution, consult accompanying documents