

Instructions for use

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.

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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.

Intended Use

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

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.

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.

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

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.

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.

Information

You can obtain more detailed information on subjects such as soldering, laser welding, etc. on our website under www.cmsa.ch/dental.

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).

Female part

Integration: Polymerisation, resin-bonding

Male part

Fitting: Soldered or cast-on, **cannot be laser-welded**

Male part

Fitting: Laser-welding

T = Pure titanium

V = Valor®

T = Pure titanium

Components

Threaded ring

T = Pure titanium (grade 4)

Retention insert

G = Galak

Mouthresistant plastic

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).

T = Pure titanium (grade 4)

Ti > 98.9375 %

V = Valor®

Pt 89.0%, Au 10.0%, Ir 1.0%

T_s – T_L 1660–1710 °C

Indications

Removable, friction or retention-grip, rigidly restorations supported on devitalized tooth:

- Friktion or retention-grip constructions on periodontally damaged teeth
- Unilateral free-end dentures locked transversally
- Insertion/free-end dentures in combination
- Hybrid dentures

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 necessary for correct processing

Parallelometer, auxiliary parts and instruments specific to the product.

Instructions for use

Integration of the male part V by soldering

Model the surface of the root canal post cap at right angles to the direction of insertion. Mill the cast surface horizontally. Place the male part V using the parallelometer insert (072 460) parallel to the direction of insertion and fix it with wax. Make a small soldering block (incline by about 45°) and allow for good flame access. After soldering benchcool to room temperature (have optimal mechanical properties).

Inserting male part T by laser welding

As a rule, materials being joined should always be identical. **Subsequent failures can thus be reduced to an absolute minimum.** You can obtain detailed information about this on our website under www.cmsa.ch/dental.

Integration of the male part V by casting-on

Model the surface of the root canal post cap at right angles of the direction of insertion. Shorten the root canal post to this height. Place the male part using the parallelometer insert (072 460) parallel to direction of insertion and finish modelling around the base. Invest, cast and benchcool to room temperature. After deinvesting do not sandblast the male part (danger of change of dimensions). Clean ultrasonically. Check the function on the master model.

Note: The Valor® male part can be identified by the mark on the occlusal surface.

Important: Only use precious metal alloys for casting-on!

Integration of the female part T into the denture

This female part is suited for direct polymerization into the denture or for resin-bonding.

Polymerization of the female part T

Place the root canal cap with the anchor on the master model and block out any undercuts or papilla gaps with cement, wax or Flexistone. Before polymerizing the female part it is recommended to protect the inside from penetration of resin by applying a little vaseline. Mount the female part and finish the resin work as usual. If any resin has penetrated between female part and the base, remove it with a pointed instrument.

Resin-bonding the female part T

If a model casting denture is to be constructed above the Mini-Gerber PLUS, it is recommended to use the red duplicating aid (072 466) instead of the original female part for the construction of the duplicate model. The use of form stable duplicating compounds (polyether or silicone) gives best accuracy of fit.

Activation

Insert the the special socket key (072 597) into the threaded ring with internal hexagon. By each $\frac{1}{4}$ turn the retention strength is increased by about 300g. The female part T is delivered with friction-grip and has a retention strength of about 300g.

Note: The threaded ring T has a special thread which prevents independant loosening.



Modifications / underlining

In the case of a transformation or an underlining of the denture use the transfer jigs (072 461) for the reconstruction of the position of the male part on the working model. The heating rod (072 605) allows fast removal of a female part from the denture without damaging it. It is introduced into the female part, the other end is heated over a bunsen flame until the resin surrounding the female part becomes soft. Then the female part can be removed from the denture by simply pulling out. Resin-bonded female parts cannot be removed with the heating rod, because the adhesive has a much higher temperature resistance.

Exchange of the retention insert G

Unscrew the threaded ring T with the special socket key (072 597) from the housing. Carefully remove the retention insert G with a pointed instrument. Take care not to damage the thread of the female part. Carefully introduce the new retention ring into housing. Mount the threaded ring T onto the special socket key (072 597) and tighten to the desired retention strength.

Working parts

Recommendation: Exchange working parts made of plastic (Galak) during the annual routine check-up.

Note

The female part T of the Mini-Gerber PLUS is compatible with the male part O of the Mini-Gerber 32.07.4.

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