

Instructions for use

Extracoronary attachment

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With the publication of these instructions for use all previous Editions are no longer valid.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

The three main points leading to success:

- Mount the male parts parallel to one another in all three dimensions
- Close the lateral recesses of the female part with wax before polymerization
- Mount the female part in the neutral position

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.

Twin crowns

When fabricating stress-broken restorations, 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.

Duplicating aid

Duplicating aids are slightly larger than the originals creating an optimum gap for duplicating and resin-bonding.

Please note: The duplicating aid **must** not be placed in the mouth to replace the female part temporarily.

Pickling

Pickled parts slide better if they are placed in soapy water (ultrasonic unit) 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 the parts must be disinfected before use with a low or intermediate EPA-registered hospital disinfectant.

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

Further hints

for 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. With patients suspected of being allergic to one or several of the elements contained in any one of the attachment materials, 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 sign.
See packaging for details.

TV

Female part T = Titanium (grade 2)
Fitting: Polymerized or resin-bonded into the restoration
Male part V = Valor®
Fitting: Soldered or cast-on, **cannot be laser-welded**

DK

Female part D = Doral
Fitting: Soldered, polymerized or resin-bonded into the restoration
Male part K = Korak
 Burnout plastic for use when casting

Detachable parts for both versions

Sliding insert G = Galak
 Mouth-resistant plastic (POM)

Indications

Removable dental-gingival-supported dentures:
 – Hinged unilateral and bilateral free-end dentures
 – Short or long-span denture saddles with a transverse framework
 – Restorations can be planned in advance

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

Equipment and parts required for correct processing

– Simple parallelometer, processing aids, instruments (further details are included in the Dental documentation of Cendres+Métaux and in the website www.cmsa.ch/dental).

Milled brace support

To ensure that the Mini-SG® hinge really functions as a stress breaker, **do not** mill a brace support. For this reason, unlike the other Mini-SG® versions, the Mini-SG® hinge female part does not have an integral bracing unit.

Fitting male part V / Casting-on

Please note: Only precious alloys can be cast-on! Wax-up the framework using standard dental techniques. Degrease male V (055 517) and use a special paralleling mandrel (072 627) or paralleling mandrel (070 567) to position and wax it into place. **Important:** To ensure that the removable restoration really hinges, the V male parts must be aligned **parallel in three dimensions** (vertical, sagittal and horizontal), in the upper jaw parallel to the median plane (Fig. 1) and in the lower jaw along line **B** bisecting the alveolar ridge **C** and median plane **A** (Fig. 2). Keep wax out of guiding grooves **A** (Fig. 3). Cast and bench cool the casting to room temperature (optimum mechanical properties).

Soldering male part V into place

Align the male part as described for casting on. The groove in the back of the male part simplifies soldering. Insert the soldering rod into the groove (Fig. 4). After soldering, bench cool the restoration to room temperature **without hardening** it (optimum mechanical properties).

T = Pure titanium (grade 2) Ti > 98.9375%	
V = Valor® Pt 89.0%, Au 10.0%, Ir 1.0% T _s – T _L 1660–1710°C CTE (25–500°C) 10.1 10 ⁻⁶ K ⁻¹ (25–600°C) 10.3 10 ⁻⁶ K ⁻¹	
D = Doral Ag 49.3%, Pd 20.0%, Au 15.0%, Cu 13.7%, Ru 2.0% T _s – T _L 930–1015°C	

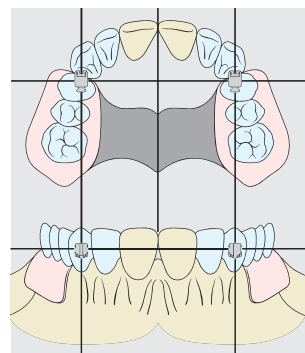


Fig. 1

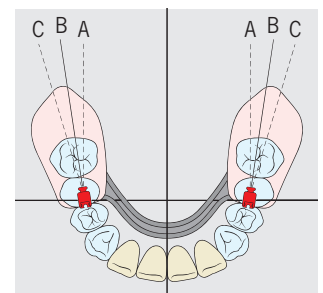


Fig. 2

Fitting male part K / Casting

Wax-up and position male part K (055529) as described above. Invest and cast. To ensure that the cast male is sufficiently strong, the alloy must exhibit an 0.2% proof stress (Rp 0.2%) of at least 500 N/mm². Do not sandblast the male after deinvesting (dimensional changes). Clean ultrasonically and polish with a brush in a handpiece. Assemble the female part and check that it functions properly.

Fitting female part T

Female part T (055848) of the Mini-SG® hinge can either be polymerized into the denture or resin-bonded directly into the framework using the duplicating and resin-bonding techniques.

Fitting female part D

Female part D (055847) of the Mini-SG® hinge can either be polymerized into the framework, resin-bonded (duplicating and resin-bonding techniques) or soldered into place.

Please note: To differentiate between female part D and female part T, female part D has an indentation on its retainer (Fig. 13 A).

Duplicating technique for use when resin-bonding or soldering

Place the duplicating aid (072600) in position. Block out the undercuts and interpapillary spaces with wax (Fig. 5). Duplicate with a dimensionally stable duplicating material (silicone or polyether) and cast a duplicate model. Wax-up the framework including the bracing unit and housing for resin-bonding the female part into place (Fig. 6).

Please note: When soldering, only the rear section of the female part is embraced by the framework – this is where the solder joint is placed later (Fig. 7). Should only limited space be available, a metal occlusal surface can be waxed up above the slide attachment to provide additional protection. Invest, cast and finish using standard dental laboratory techniques.

Resin-bonding technique

Sandblast that area of the cobalt chrome framework to be resin-bonded with 250µm Al₂O₃ and the distal retainer on the female part with 50µm Al₂O₃.

Please note: The system transfer jig (072616) must be fitted to prevent the functional section of the female part becoming damaged. Thoroughly steam clean the areas to be resin-bonded and do not touch them again.

Important: Fit the female part in the neutral position (see note) and block out the undercuts and side openings with wax (Fig. 8). Apply a thin coat of adhesive to both surfaces, ensuring that no bubbles are entrapped, and press them together. For further details, refer to the adhesive manufacturer's instructions.

Note: The neutral position is reached when the female part mounted on the male part are perpendicular to each other (see Fig. 9)

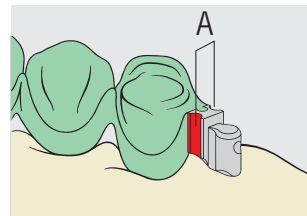


Fig. 3

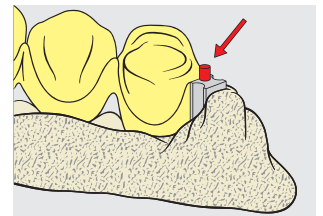


Fig. 4

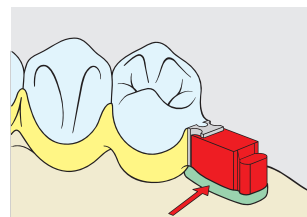


Fig. 5

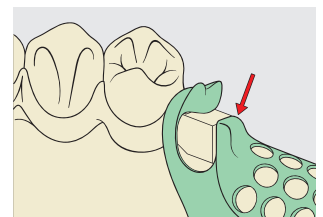


Fig. 6

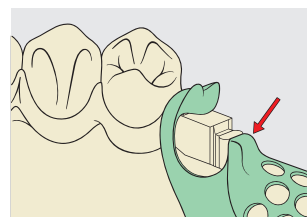


Fig. 7

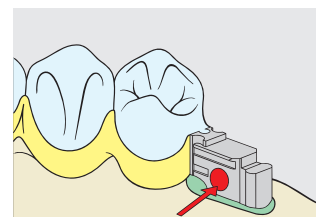


Fig. 8

Soldering

To ensure that the soldered joint is strong, it is advisable to apply S.W 925 solder to the removable section of the denture in advance. Then position female part D in the neutral position (see note resin-bonding) and fix it to the chrome cobalt framework with sticky wax or resin. Remove the sliding insert, fabricate a soldering model and solder the joint properly with S.W 870 solder.

Important: To prevent solder creeping into the housing, the two side openings must be filled with soldering investment (Fig. 8). The oxide which forms on the Doral female part can be removed with 10% (by volume) sulphuric acid (H₂SO₄).

Please note: Never use nitric acid (HNO₃), hydrochloric acid (HCL) or Neacid for pickling as these acids may destroy the alloy. Alternatively, the oxide can be blasted off carefully with glass beads at a pressure of less than 1.5 bars.

Adding the resin

Before polymerizing the female part into the denture, it is advisable to apply a small amount of Vaseline inside the female to prevent resin creeping in. Position the female part in the neutral position (see note resin-bonding). To allow for freedom of movement, the occlusal juncture between the female part and male part must be blocked out with wax. The undercuts and two side openings in the housing must also be blocked out (Fig. 8). Process the resin using standard dental laboratory techniques.

Important: To ensure that hinge insert G functions perfectly, the wax sealing the side openings must be removed after polymerizing.

Removing hinge insert G

Cut the hinge insert G with a scalpel along its full length and remove it (see Figs. 10 and 11).

Inserting hinge insert G

Use tweezers (070347) to squeeze the thicker end of the new hinge insert (Fig. 10 A) together gently and slide it into the housing carefully (Fig. 10). The first lamella is heard to click into place and the second lamella is then pressed into place gently (Fig. 11).

Activation

Hinge insert G is available in 2 different sizes for adjusting the friction.

Orange (055 799): Normal friction

Violet (055 800): Strong friction

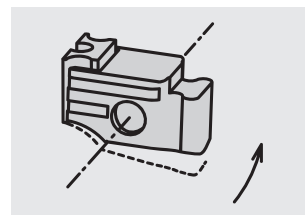


Fig. 9

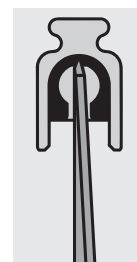


Fig. 10



Fig. 11

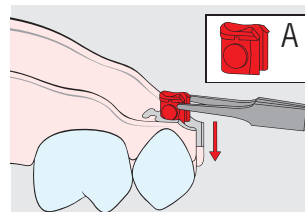


Fig. 12

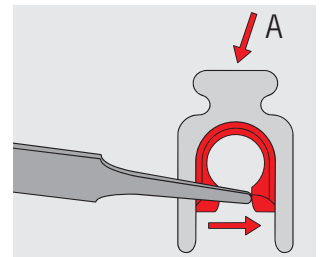


Fig. 13

Follow-up treatment

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.

Modifications / Relines

Should the denture require modifying or relining, place the system transfer jig (072 616) or transfer pin (072 481) on the working model to take the place of the male part.

Please also note: The male part of this system is compatible with all Mini-SG® attachment female parts.

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

	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