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.

With the publication of these instructions for use all previous Editions are no longer valid.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

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.

Tooth preparation for extracoronal attachments

No special procedures required.

Metal denture base

As for bilateral interdental and free-end dentures, the transverse connector should consist of a cast transpalatal plate for uppers and a sublingual bar for lowers. It is important that the denture base is absolutely rigid (will not rebound).

Dismantling attachments

The male and female parts of attachments must be separated prior to heating (casting-on, soldering, tempering and firing porcelain) and – if they consist of several components – fully dismantled.

Duplicating aids

The duplicating aids are slightly larger than the original components to create an optimum gap for duplicating and resin-bonding.

Please note: The duplicating aid must **not** be placed in the patient's mouth as a temporary replacement for the female part.

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 EPAregistered disinfectant prior to use.

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

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.

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.

The following items contain nickel:

055916 Mini-SG® XC 055487 Mini-SG® XK 055489 Female part complete X 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 Mark. See packaging for details.

Mini-SG® F/R 06 2015

Materials

Female part T = Pure titanium

Fitting: Polymerized or resin-bonded into the restoration

C = Ceramicor®

Fitting: Polymerized, cast-on or resin-bonded

V = Valor® Fitting: Cast-on or soldered, cannot be laser-welded

C = Ceramicor®

Fitting: Cast-on or soldered

K = Korak

Fitting: Burnout plastic for use when casting

Plastic inserts G = Galak

Biocompatible, mouth-resistant plastic

Indications

Dental and dental-gingival supported dentures:

- Interdental insertion dentures
- Rigid unilateral and bilateral free-end dentures
- Dentures with one interdental saddle and one free-end situation/ Insertion denture and free-end parts in combination
- Restorations can be planned in advance

Contraindications

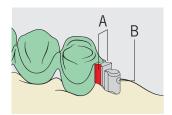
- Where patients have an existing allergy to one or more elements of the attachment materials.
- Unwillingness of the patient to correctly follow the aftercare/ recall instructions.
- Patients with bruxism or further uncontrolled para-functional habits.
- Unilateral dentures without transverse bracing

Equipment and parts required for correct processing

Simple parallelometer, 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).







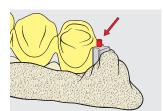
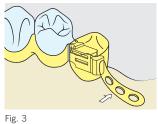


Fig. 1



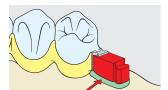


Fig. 4

Fig. 2

T = Pure titanium

Ti > 98.9375%

C = Ceramicor®

Au 60.0%, Pt 19.0%, Pd 20.0%, Ir 1.0%

T_s - T_L 1400-1490°C CTE

 $(25-500\,^{\circ}\text{C})\ 12.0\ 10^{-6}\,\text{K}^{-1}$ (25-600°C) 12.3 10-6 K-1

 $V = Valor^{\mathbb{R}}$

Pt 89.0%, Au 10.0%, Ir 1.0% T_s - T_L 1660-1710°C CTE

 $(25-500\,^{\circ}\text{C})\ 10.1\ 10^{-6}\,\text{K}^{-1}$ (25-600°C) 10.3 10-6 K-1

K = Korak

G = Galak

Mini-SG® F/R 66.2015

How the Mini-SG® F and Mini-SG® R function

The only difference between the Mini-SG® F (friction-fit) and Mini-SG® R (retentive) is the plastic insert. In cases with periodontally compromised abutment teeth, we recommend the use of a friction-fit insert due to the minimal, uniform loading. Where healthy preoperative conditions prevail, a click-in retentive insert can be used. As the female parts are identical, the functioning principle can be adapted to changing oral conditions at any time by replacing the insert.

Milled brace support (bracing unit)

The Mini-SG® F and Mini-SG® R are designed so as not to require a milled brace support and stabilizer to protect them.

Fitting male parts C and V / Casting-on

Important: Only precious alloys can be cast-on!
Wax-up the framework using standard dental techniques.
Degrease male part C (055544) or V (055517) and use a paralleling mandrel (072627) or (070567) to position and wax it along the correct path of insertion for the patient.

Please note: The Valor® male part can be identified by the mark on the occlusal surface of its cylinder.

Important: The guiding grooves A must be free of wax (Fig. 1). Cast, then bench cool the casting cylinder to room temperature (optimum mechanical properties).

Fitting male parts C and V / Soldering

If the male part is to be soldered to the crown, the soldering area of the crown must be parallel to the path of insertion of the slide attachment. The soldering groove on the back of the male part simplifies soldering.

The soldering rod is inserted into the groove (Fig. 2). After soldering, bench cool the restoration to room temperature, without tempering it (optimum mechanical properties).

Fitting plastic 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 of at least 500 MPa. Do not sandblast the male after devesting (dimensional changes). Clean the casting ultrasonically and polish with a brush in a handpiece. Check that it functions correctly on the master model. Please note – Mini SG® R: To ensure that the retentive sliding insert clicks into place, the groove in the upper third of the male part must only be trimmed extremely carefully (Fig. 1/B).

Fitting female part T

Female part T (055769) can either be polymerized directly into the framework or duplicated and resin-bonded.



Fig. 5



Fig. 7

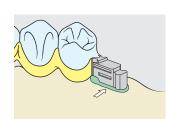


Fig. 6

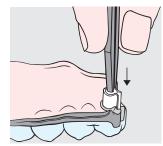


Fig. 8

Mini-SG® F/R 66.2015

Fitting female part C

Female part C (055770) can be polymerized into place, resinbonded (duplicating and resin-bonding) or cast-on (precious metal) to the outer section.

Please note:

When casting onto female part C an additional retainer has to be waxed up (Fig. 3) to allow the outer section to be retained securely in the denture acrylic.

As the coefficient of thermal expansion (CTE) of Ceramicor® is lower than that of the metal-ceramic alloy, the housing should be coated with at least 0.7 mm of wax. This prevents the ceramic contacting female C and precludes cracks in the ceramic.

Investing female part C

Separate the inner and outer sections and remove the sliding insert before investing.

Important: The interiors of the female parts must be free of wax. It is advisable to cut a narrow groove in the wax/housing C juncture with an instrument to virtually prevent the alloy creeping in while being cast on.

Devesting and cleaning

For safety reasons, the interior of the female part must not be sandblasted. Clean it with an ultrasonic cleaner. Fit the sliding insert and check that it functions properly on the master model.

Duplicating and resin-bonding technique

Position the duplicating aid (072600). Block out any undercuts or interpapillary spaces with wax (Fig. 4). Duplicate with a dimensionally stable duplicating material (silicone or polyether) and cast the duplicate model. Wax-up the framework with a box for resin-bonding the female part (Fig. 5). Where space is limited, a metal occlusal surface can be waxed up above the attachment to provide additional protection. Cast and finish using standard dental laboratory procedures.

Resin-bonding technique

Sandblast the bonding surfaces, using 250 micron AI_2O_3 abrasive for the cobalt chrome denture base and 50 micron AI_2O_3 abrasive for the female part.

Please note: To prevent damage to the functional part of the female, fit the system transfer jig (072616). Steam clean the bonding surfaces thoroughly and do not touch them again. Prior to bonding the female, apply a small amount of Vaseline inside it to prevent resin creeping in. Fit the female part and block out the undercuts with wax (Fig. 6). Apply a thin coat of resin to both surfaces, ensuring that no bubbles are trapped, and assemble them. For further details, please refer to the resin manufacturer's instructions.

Finishing the denture

Prior to polymerizing the female into the denture, apply a small amount of Vaseline inside the female to prevent resin creeping in. Fit the female and block out the undercuts with wax (Fig. 6). Complete the acrylic sections using standard dental laboratory procedures.

Removing the plastic insert

Press together both ends of the lamellae with tweezers (070 347) to disengage the retainers, and remove the insert. If the insert remover (072 483) is pressed in, the lamellae cams disengage the retainer automatically (Fig. 7).

Inserting the plastic insert

Hold one of the lamellae on the rounded side of the sleeve with the tweezers and carefully press it against the opposite inner surface of the housing. Continue exerting gentle pressure and press the sleeve into its correct position (Fig. 8). It can be heard to click into place. If not, the sleeve was inserted from the wrong side.

Activating the Mini-SG® F

The friction can be adjusted by using 4 different sizes of insert. Yellow (055 691): $150 - 500 \, \mathrm{g} \, \mathrm{friction}$ Red (055 356): $400 - 800 \, \mathrm{g} \, \mathrm{friction}$ Green (055 357): $700 - 1200 \, \mathrm{g} \, \mathrm{friction}$ Blue (055 358): $> 1200 \, \mathrm{g} \, \mathrm{friction}$

Activating the Mini-SG® R

The friction can be adjusted by using 4 different sizes of retentive insert.

Orange (055718): 500 800 g friction **Violet** (055766): > 800 g friction

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.

Mini-SG® F/R 66.2015

Modifications / Relines

Should the denture require modifying or relining, place the system transfer jig (072 616) 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

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Manufacturer

REF

Catalogue number



Batch code



Quantity

[i]

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