M-SG® Star 2

Instructions for use

Slide attachments

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With the publication of these instructions for use all previous Editions are no longer valid.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 trans-palatal 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, laser welding, 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 EPA-registered disinfectant prior to use.
Recommended: Cidex® OPA Solution. Strictly follow manufacturer's instructions.

Further hints
Further information on soldering, casting on, laser welding etc. can be accessed on our website at www.cmsa.ch/dental in the section **Clinic**.

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 con-tained 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 Mark.
See packaging for details.

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M-SG® Star 2

Materials
Female part T = Pure titanium
Fitting: Polymerized or resin-bonded

Male parts C = Ceramicor®
Fitting: **Cast-on**

Y = Yelor
Fitting: **Laser welding**

K = Korak
Fitting: Non-residual burnout plastic for the **casting technique**

Friction 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

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, product-specific processing aids and instruments

Instructions for use

Function of the M-SG® Star 2
The M-SG® Star 2 (2 for screw-activated friction) is an attachment for retaining a removable restoration in the mouth using friction. Intraoral retention can be adjusted smoothly by turning the activation screw.

Milled brace support (stress breaker)
Due to the design of the M-SG® Star 2 a milled brace support with a stabilizing arm does not have to be fabricated to protect the attachment. Information on relevant scientific studies can be accessed on our web-site at www.cmsa.ch/dental in the **Clinic** section.

Fitting the male parts
The male parts must be placed parallel to each other.
They should not be ground or cleaned with sandblast-ing abrasive.
Note: No risk of using the wrong male part! Male parts manufactured from different materials and in different designs depending on their application are easily distinguished visually (Fig. 1).

Version TC: Cast-on
Only precious metal alloys should be used for casting on. After contouring the wax framework, place the degreased male part to the ideal path of insertion for the patient using the special paralleling mandrel (Order No. 072 627) and wax it in position. The guide grooves A, which assume the function of a stress breaker, must be kept free of wax (Fig. 2). Cast and then allow the casting to cool to room temperature (to ensure optimal mechanical properties).

T = Pure titanium

C = Ceramicor®
Au 60.0 %, Pt 19.0 %, Pd 20.0 %, Ir 1.0 %
$T_S - T_L$ 1400–1490 °C
CTE (25–500 °C) 11.9 x 10^{-6} K^{-1}
(25–600 °C) 12.2 x 10^{-6} K^{-1}

Y = Yelor
Au 75.1 %, Pd 18.85 %, Ag 1 %, Cu 0.5 %, Sn 2 %, In 2 %, Zn 0.5 %, Ir 0.05 %
$T_S - T_L$ 1120–1250 °C

K = Korak

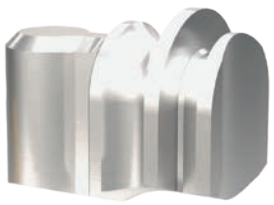
Fig 1 Cast-on


Fig 1 Laser weld

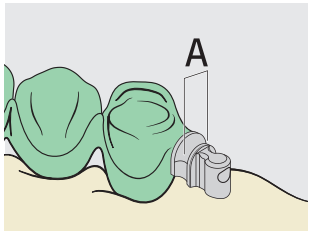

Fig. 2

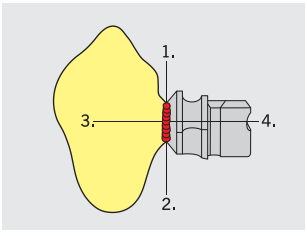

Fig. 3

Version TY Laser welding
Always laser weld materials that are as similar as possible. This will reduce the failure rate to an absolute minimum. A brief description of the technique (Fig. 3):
Mill the crown wall parallel to the interface of the male part (prepare an X seam)
Place the male part in the correct position for laser welding using a parallelometer or jig
Secure the male part over the cross to avoid stresses
Laser weld the male part circumferentially by adding filler material (same as the crown alloy). Fill the X seam from the centre to the outside and smooth the laser weld joint.

Version TK: Casting
Prepare and position the male part K (Order No. 05000410) 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 attachment 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.

Fitting the female part
The female part T (Order No. 05000410) can either be polymerized directly into the framework or duplicated and resin bonded.

Duplicating and resin-bonding technique
Position the duplicating aid G (Order No. 07000041). Block out any undercuts or papilla gaps with wax (Fig. 4). Duplicate with a dimensionally stable duplicating compound (silicon or polyether type) make the duplicat-ing model. Model the framework with a box for the female part. With constricted places model a metallic oc-clusal surface for additional protection (Fig. 5). Cast and finish using standard dental laboratory procedures.

Resin-bonding technique
Sandblast the bonding surfaces, using 250 micron Al_2O_3 abrasive for the cobalt chrome denture base and 50 micron Al_2O_3 abrasive for the female part.
Please note: To prevent damage to the functional part of the female, fit the system transfer jig (Order No. 07000042). 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.

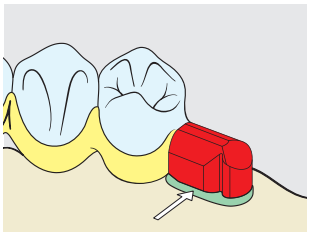
Fig. 4

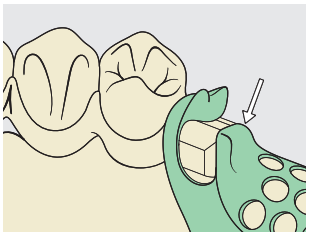
Fig. 5

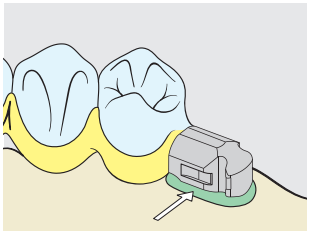
Fig. 6

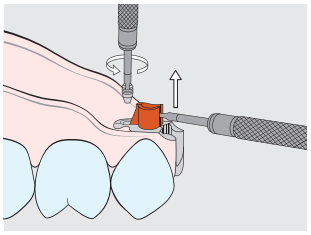
Fig. 7

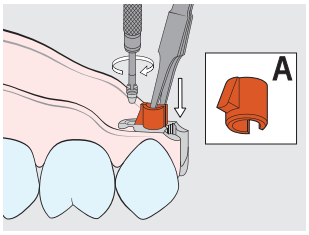

Fig. 8

Finishing the denture
Before polymerizing the female part into the denture, we recommend sandblasting the outer surface with 50 μm Al_2O_3 to increase retention in the denture acrylic (protect the functional areas with the transfer pin!), clean the sandblasted surfaces thoroughly and do not handle again. Prior to fitting the female part 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. The friction insert used for laboratory work should be replaced by a new insert after the denture is finished.

Removing the friction insert
Unscrew activating screw T (Order No. 055775) fully with the screwdriver (Order No. 072653) and raise friction insert G (Order No. 055774 or 055811) with the screwdriver (Order No. 072653) (Fig. 7).

Inserting the friction insert
Use tweezers (Order No. 070347) to grip the insert on one of its lamellae and press it carefully into the housing (Fig. 8). Ensure that the wider part of the wedge is positioned toward the occlusal aspect (Fig. 8/A). Replace activating screw T.
Please note: The insert exerts counterpressure on the screw to prevent it loosening on its own.

Aftercare
Retentive units in prosthetic restorations are subjected to very high loading intraorally in a continually chang-ing milieu and consequently to a varying degree of wear and tear. Though wear and tear occurs during nor-mal use and cannot be avoided, it can be reduced. The extent to which it can be reduced depends on the system. Our aim is to use optimally coordinated materials so that wear is reduced to an absolute minimum.
The denture should be checked at least once a year to ensure it fits optimally on the mucosa and should be relined if necessary to eliminate rocking (overloading), particularly in the case of free-end dentures. We rec-ommend replacing the friction insert (unit subject to wear) at the annual checkup as a precautionary measure.

Patients can obtain information and recommendations about the use, removal and care of prostheses on the patient website at www.cmsa.ch/dental/infos.

Activation / deactivation
Wind in activating screw T clockwise with the screwdriver/activator (Order No. 072653). Deactivation is achieved by unwinding the screw. The desired friction can be adjusted progressively from 100–600 g with the orange insert (Order No. 055774). To achieve increased friction of approx. 500–1000 g, use the violet insert (Order No. 055811).
Please note: Should the range of friction of the two inserts be exceeded when activating the slide attachment, it will revert to the maximum adjustable friction after approximately 3–5 months.

Modifications / Relines
Should the denture require modifying or relining, place the system transfer jig (Order No. 07000042) on the working model to take the place of the male part.

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