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Slide attachments

M-SG® Star 1, M-SG® Star 2, Mini-SG®, Mini-SG® F/R,
Mini-SG® PLUS, Mini-SG® Tuning Matrice and SG Geschiebe

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Instructions for Use Slide Attachments

M-SG® Star 1, M-SG® Star 2, Mini-SG®, Mini-SG® F/R, Mini-SG® PLUS, Mini-SG® Tuning female part and SG slide attachment

1 Scope of application of Instructions for Use

These Instructions for Use apply to the products listed under Section 29. The issuing of these Instructions for Use renders all previous versions invalid. The manufacturer rejects any liability for damages resulting from non-compliance with these Instructions for Use.

2 Trade name

See Section 29.

3 Intended use

The products are intended for prosthetic restorations and to support procedures in the dental clinic or laboratory.

4 Expected clinical benefit

Restoration of chewing function and improved aesthetics.

The Summary of Safety and Clinical Performance, SSCP for the implantable devices covered by these Instructions for Use, is available on our website and accessible at this address: www.cmsa.ch/docs.

5 Product description

Slide attachments

A slide attachment is a prosthetic retaining element consisting of a female (outer) part and a male (inner) part. The male part is firmly connected to an abutment tooth, the female part is inserted into the removable denture.

If implant prosthetics are out of the question, this type of prosthesis is suitable. The restoration with a slide attachment is successful for smaller and larger gaps between teeth, provided that there are still enough stable teeth available which can be crowned as abutment teeth. As a rule, several abutment teeth are required; this protects the retaining teeth from leverage and pressure forces acting on the dentures when worn.



M-SG® Star 1

The fricatively functioning attachment has an integrated stress distributor and, compared to the Mini-SG® versions, has an additional occlusal support on the stress distributor. This increases stability and protects the attachment from overloading. The compact design with rounded edges saves space for insertion into the denture.

Activation is achieved by exchanging friction inserts.
Four force levels are available.

Three material versions are available:

M-SG® Star 1 TC: male part C for casting-on, housing T can be bonded

M-SG® Star 1 TK: for casting male part C, housing T can be bonded

M-SG® Star 1 MK: for casting male part K, housing X can be bonded

Mounted with friction insert G red (055356), also included one friction insert each yellow (055691) and red(055356), as well as a duplicating aid G (07000040).



M-SG® Star 2

The only difference to the M-SG® Star 1 version is the activation principle.

By turning the activating screw in and out, retention in the mouth can be varied infinitely. In addition, this activation screw fixates the friction insert in the slide attachment.

Two force levels are available.

Two material versions are available:

M-SG® Star 2 TC: male part C for casting-on, housing T can be bonded

M-SG® Star 2 TK: for casting male part K, housing T can be bonded

A friction insert orange (055774) is mounted, and a friction insert orange (055774) and violet (055811) are enclosed, as well as a duplicating aid G (07000041).

⚠ The female part X (steel) contains nickel.



Mini-SG®

Introduced to the market in 1996, the Mini-SG® was the first slide attachment of its kind with a primary and secondary integrated stress distributor.

Activation is achieved by exchanging friction inserts.
Four force levels are available.

Three material versions are available:

Mini-SG® DK: for casting male part K, female part D can be bonded

Mini-SG® XC: male part C for casting-on, female part X can be soldered, bonded

Mini-SG® XK: for casting male part K, female part X can be soldered, bonded

Mounted with friction insert red (055356), the friction insert green (055357) is included
Delivery unit version XC: pack of 2 pieces.



Variante Frikativ



Variante Retentiv

Mini-SG® F/R

The Mini-SG® F/R is a further development of the Mini-SG®. This Mini-SG® version was specifically designed for the duplicating and bonding technique. The Mini-SG® F/R can be used either frictional F or retentive R by using the friction insert or the retention insert.

Activation is by exchanging the friction and retention inserts:
Friction inserts, four force levels are available.
Retention inserts, two force levels are available.

Five material versions are available:
Mini-SG® F/R TV: male part V for casting-on (Pd-free), female part T can be bonded
Mini-SG® F/R TC: male part C for casting-on, female part T can be bonded
Mini-SG® F/R TK: for casting male part K, female part T can be bonded
Mini-SG® F/R CC: male part C for casting-on, cast-on female part C, can be bonded
Mini-SG® F/R CK: for casting male part K, cast-on female part, can be bonded

Mounted with friction insert red (055356). In addition, a friction insert yellow (055691) and red (055356) as well as a retention insert orange (055718) and violet (055766) are included. For the TV, TC and TK versions, the duplicating aid G (Art. no. 072600) is also included in the scope of delivery.



Mini-SG® PLUS

The difference to the Mini-SG® F/R version is the activation principle. By turning the activating screw in and out, retention in the mouth can be varied infinitely. In addition, this screw fixates the friction insert in the attachment. Two force levels are available.

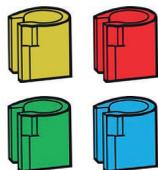
2 material versions are available:
Mini-SG® PLUS TV: male part V for casting-on (Pd-free), female part T can be bonded
Mini-SG® PLUS TK: for casting male part K, female part T can be bonded

Includes housing T, an activation screw T (055775), one friction insert G each orange (055774) and violet (055811), incl. duplicating aid G (072649).



Mini-SG® F/R, Mini-SG® PLUS

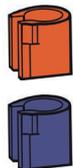
The Valor male part is marked occlusally on the cylindrical part with a depression.



Friction insert G

Can be used with M-SG® Star 1, Mini-SG®, Mini-SG® F/R and Mini-SG® tuning female part

Yellow (smooth friction): approx. 300 g
Red (normal friction): approx. 600 g
Green (strong friction): approx. 900 g
Blue (extra-strong friction): > 1200 g



Retention insert G

Can be used with Mini-SG® F/R and Mini-SG® tuning female part

Orange (normal retention): 500 - 800 g
Violet (strong retention): > 800 g



Friction insert G

Can be used with M-SG® Star 2 and Mini-SG® PLUS

Orange (normal friction): 100 - approx. 600 g
Violet (strong friction): 500 - approx. 1000 g



Activating screw T

Can be used with M-SG® Star 2 and Mini-SG® PLUS.

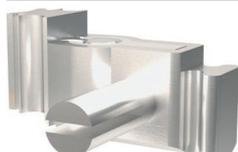
Retains the friction insert in the housing.
For fine adjustment of friction.



Friction insert G

Can be used with M-SG® Star 1, Mini-SG®, Mini-SG® F/R and Mini-SG® tuning female part

Yellow (smooth friction): approx. 300 g
Red (normal friction): approx. 600 g
Green (strong friction): approx. 900 g
Blue (extra-strong friction): > 1200 g



Retention insert G

Can be used with Mini-SG® F/R and Mini-SG® tuning female part

Orange (normal retention): 500 - 800 g
Violet (strong retention): > 800 g

**Friction insert G**

Can be used with M-SG® Star 2 and Mini-SG® PLUS

Orange (normal friction): 100 - approx. 600 g

Violet (strong friction): 500 - approx. 1000 g

**Activating screw T**

Can be used with M-SG® Star 2 and Mini-SG® PLUS.

Retains the friction insert in the housing.

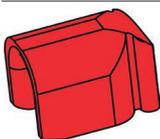
For fine adjustment of friction.

**Montageschraube X**

Verwendbar für SG Geschiebe.

Erleichtert die Kunststoffpolymerisation.

Wird bei der Bestellung der kompletten Teile automatisch mitgeliefert.

Auxiliary parts and instruments**Duplicating aid G**

M-SG® Star 1 (Art No. 07000040)

M-SG® Star 2 (Art No. 07000041)

Mini-SG® F/R (Art. No. 072600)

Mini-SG® PLUS (Art. No. 072649)

SG slide attachment (Art. No. 072502)

The duplicating aid made of red plastic is slightly oversized with regard to the original components. This allows optimal bonding clearance for duplicating and bonding techniques. After being used as a duplicating aid, the duplicating auxiliary part can also be used as polishing protection.

 The duplicating aid must not be used in place of the female part as a temporary replacement, nor for taking impressions / placeholder technique in the mouth.

**Transfer jig**

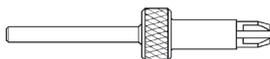
M-SG® Star 1 and M-SG® Star 2 (Art. No. 07000042)

Mini-SG®, Mini-SG® F/R, Mini-SG® PLUS (Art. No. 072616)

SG slide attachment (Art. No. 070566)

Manipulation male part for fabricating the master model.

 Due to the varying wear of the male part, a prefabricated transfer jig is not available for the Mini-SG® tuning female part. If necessary, the transfer jig (Art. No. 072616) must be readjusted.

**Special parallelometer insert** (Art. No. 072627)

Universal instrument for all M-SG® Star, Mini-SG® and SG slide attachment variants.

Is mounted in a parallelometer device.

Is used to set the male part in the correct position and in parallel.

**Insert remover**

M-SG® Star 1 (Art No. 07000056)

Mini-SG®, Mini-SG® F/R and Mini-SG® tuning female part (Art. No. 072483)

For detaching the friction and retention insert.

**Tweezers** (Art. No. 070347)

Universal instrument for all M-SG® Star, Mini-SG® and SG variants.

For integration and detaching the friction and retention insert.

**Screwdriver/activator** (Art. No. 072653)

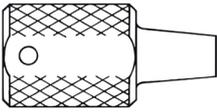
Can be used with M-SG® Star 2 and Mini-SG® PLUS.

Multifunctional; is used to screw the activation screw in and out and to activate and deactivate the friction insert.

**Screwdriver insert** (Art. No. 070293)

Can be used with SG slide attachment.

Blade insert and coupling sleeve. Fits precisely into the activation screw without pressing on and blocking the lamellae of the screw when screwing in and out.



Thomas spanner key (Art. No. 070221)
Firmly secures the screwdriver insert (Art. No. 070293).

6 Indications

Dental and dental-gingival supported dentures:

- Insertion dentures
- Rigidly anchored, uni- and bilateral free-end dentures
- Dentures combined with an insertion denture and a free-end section

Mini-SG® tuning female part

- Upgrading of dentures which are no longer retained adequately on worn Mini-SG® male parts.

7 Contraindications

- Unilateral, partial and free-end dentures without transversal support.
- Restoration of severely periodontally damaged abutment teeth.
- Patients who are unable to keep the regularly required check-up appointments for health reasons.
- Patients with bruxism or other para-functional habits.
- Patients with allergies to materials used in the product, see Section 19.
- Existing clinical picture in the patient's mouth does not permit the correct application of the products.

Mini-SG® tuning female part

- Use on non-worn Mini-SG® male parts.

8 Compatible products

To fabricate the finished denture, a number of general laboratory supplies are required in addition to the products listed under Section 29. The following gives a selection of materials that Cendres+Métaux SA offers in its portfolio.

08052138	Polyurock Kit
08052135	Polyurock Catalyst
08052136	Polyurock Release Spray
08052137	Polyurock Mixer
08052566	Polyurock Colour yellow
08052149	ABF Wax Universal
08052150	ABF Wax Creativ light
08052151	ABF Wax Creativ dark
08052154	ABF Wax Special
08052148	ABF Wax Margin
08052153	ABF Wax Position
08052152	ABF Wax Tecno
08055014	Livento® invest Powder (50 x 100 g)
083739	Livento® invest Liquid (1000 ml)
08052160	uniVest® Plus Powder (30 x 150 g)
08052161	uniVest® Plus Liquid (1000 ml)
08052162	uniVest® Rapid Powder (30 x 150 g)
08052163	uniVest® Rapid Liquid (1000 ml)
080181	CM soldering investment (4 kg)
080229	CM soldering paste
08052307	Legabril Diamond (50 g)

9 Qualification of the specialist

Expertise in professional dentistry and dental technology is assumed. The current Instructions for Use must be available at all times and be completely read and understood before the first application. The fabrication of dentures and their maintenance may only be performed by qualified specialists.



Important information for the specialist



Warning symbol for increased caution

10 Prescription

Federal laws in the USA prohibit the use by or sale to unlicensed dentists.

11 Side effects



This product must not be used in patients with allergies or suspected allergies to materials used in the product (see Section 19), or only after prior allergological clarification.

Auxiliary instruments may contain nickel.

If applied as intended, side effects can be excluded.

12 Warnings



Magnetic resonance (MR) environment

The device has not been evaluated for safety and compatibility in the MR environment.

The product has not been tested for heating or migration in the MR environment.

13 General information

When working with design elements in which friction and retention inserts are used, it is essential to ensure that the denture is supported as stably and rigidly as possible in the mouth. If this is not observed, irreparable damage to the male part can occur due to tiny movements, which have a cumulative effect over the course of several years. Reasons are often insufficient cleaning of the denture, lack of follow-up, poor fit of the denture, incorrect handling, too high load of masticatory force, e.g. due to unbalanced equilibrated tooth set-up and too large denture saddles with insufficient alveolar ridge support.

14 Preventive measures

- The product components are supplied non-sterile. For more information see Section 16 "Reprocessing".
- Only original tools and parts may be used for this work. For information and additional details, please contact your Cendres+Métaux SA representative.
- Before any procedure, ensure that all required product components are available in sufficient quantity.
- For your own safety, always wear suitable protective clothing. In particular when grinding, we recommend wearing protective goggles and a dust mask as well as the use of a suction unit.
- Secure parts against aspiration.
- The mechanical cleaning by patients with a toothbrush and toothpaste may lead to premature wear.

15 Single use

Products that are intended for single use and are labelled "single-use" accordingly are subject to a certain amount of stress, increased wear, and even loss of functionality during their use.

Multiple application of products labelled «single use» was not tested. This can impair the safety, function and performance of the products as well as increase the risk of transmitting infections.

16 Reprocessing

The prosthetic work, including all system components, must be cleaned, disinfected and, if appropriate, sterilised prior to each work step. Materials made of metal alloys, high-performance polymers (Pekkton®) and ceramics are suitable for steam sterilisation. With the exception of Pekkton®, components made of plastics are not suitable for steam sterilisation. Consider published national guidelines when selecting a disinfection and sterilisation process and the Instructions for Use "Reprocessing of surgical and prosthetic products" (www.cmsa.ch/docs).

17 Scope of application

The slide attachments are designed to fixate partial dentures on crowns or bridges in the maxilla and mandible.

18 Procedure**Tooth preparation**

Extracoronary design elements do not require a special procedure for preparation. Minimally invasive crown preparation can be performed.

Denture design

We recommend that the denture be designed such that the largest possible support polygon can be achieved. Small distances between consecutive anchor teeth and long free-end saddles can cause undesirable effects such as increased wear of the system components.

Circumferential milling (stress distributor)

Due to the design of the M-SG® Star, Mini-SG® and SG slide attachments, there is no need for circumferential milling with stabiliser to protect the attachments.

Denture frameworks

Cast transpalatal plates, bands and sublingual brackets are used as transversal connectors. Here it is important that such prosthetic frameworks are absolutely rigid and not elastic.

Thermal treatment

The male and female parts must be separated prior to thermal treatment (casting-on, soldering, lasering, curing and ceramic firing) and, if consisting of several parts, disassembled into their individual parts. Subsequently allow to cool slowly to room temperature. Thus the optimal mechanical properties are achieved without a tempering process.

Cleaning

Fit a duplicating aid or spacer to protect the male part during sandblasting and processing.

18.1 Fabrication of the primary reconstruction**Work preparation**

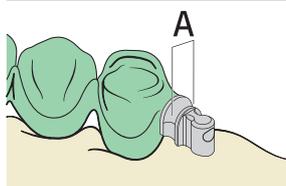
Preparation of the master model.

When modelling the wax frameworks, make sure that the framework thickness is at least 0.5 mm to achieve sufficient stability.

A simple parallelometer is required for parallel setting of the male part.

The male parts must not be ground or cleaned with abrasive blasting media.

Only use precious metal alloys for casting-on.

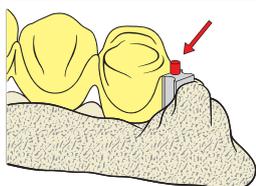
18.1.1 Inserting the male part by casting-on

After modelling the wax framework, the degreased male part (M-SG® Star, Mini-SG® or SG attachment) is positioned and waxed down with the special parallelometer insert (Art. No. 072627) in the most ideal insertion direction for the patient and in parallel to each other. The guide grooves A, which take on the function of the stress distributor, must be free of wax.

Invest, cast and allow to cool slowly to room temperature without any tempering process.

18.1.2 Inserting the male part by soldering

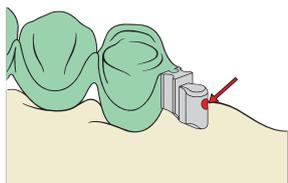
 Applies to Mini-SG® designs.



Proceed as described under Point 18.1.1.
The ideal soldering gap lies between 0.05 - 0.20 mm and must be parallel to the insertion direction of the attachment. Clean the soldering surface well before soldering, it must be free of grease. The soldering process is simplified by the soldering groove in the back wall of the male part. The soldering rod S.G 1055, Cat. No. 01000353, is inserted into the groove. Apply sufficient CM soldering paste (Art. No. 080229) to protect against oxide formation during the heating process. After soldering, allow to cool slowly to room temperature without any tempering process.

 The flame must be aligned such, that not only the relatively small male part reaches working temperature during soldering, but also the framework and the entire soldering block.

18.1.3 Inserting male part K by casting



Proceed as described under Point 18.1.1.
After devesting, the male part must not be blasted (dimensional changes). Clean the cast ultrasonically and polish the male part carefully with a rotary brush without changing the profile of the male part. For the retention insert to snap into place, the notch in the upper third of the male part must only be machined with extreme care. Check and adjust functionality on the master model.

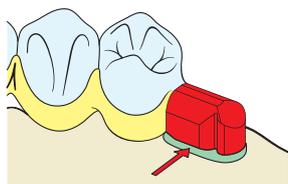
 The quality of the male part fabricated in the dental manufacturing process depends on the choice of material and processing technique. It has a decisive influence on the functional capability and durability of the denture. To obtain sufficient strength in the cast male part, the casting alloy used must have a 0.2 % yield strength of at least 500 N/mm².

18.2 Fabrication of the secondary reconstruction (denture)

18.2.1 Integration of the female part by bonding
(duplicating and bonding technique)

Applies to M-SG® Star, Mini-SG® F/R, Mini-SG® PLUS and SG slide attachment designs.

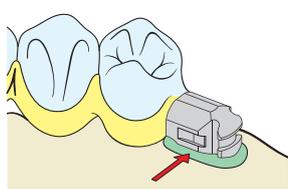
 A duplicating aid adapted to the respective shape is available for each type of slide attachment.



Place the duplicating aid. Block out the undercuts and interpapillary spaces with wax. Duplicate with a dimensionally stable duplicating material (silicone or polyether) and make a duplicate model.



Modelling of the framework including box for bonding the female part. If space is limited, a metal masticatory surface can be modelled over the attachment as additional protection. Casting and finishing.



Blast the bonding seam of the model casting (CoCr) with 250 µm and the female part with 50 µm Al₂O₃. To avoid damaging the functional section of the female part, fit the transfer jig matching the female part for protection. Thoroughly clean the surfaces to be bonded with the steam jet and do not touch again. Before bonding the female part, protect the inside of the female part by applying some Vaseline to prevent adhesive from penetrating. Mount the female part and block out the undercuts with wax. Apply a thin layer of adhesive to both surfaces to be bonded without bubbles and join them together. Please observe the information provided by the manufacturer of the adhesive.

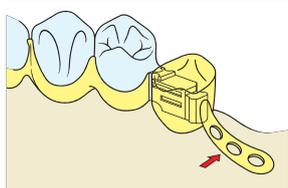
18.2.2 Inserting the female part by polymerisation

Before polymerising the female part, protect the inside of the female part by applying Vaseline to prevent resin from penetrating. Mount the female part and block out the undercuts with wax.

 Make sure that no resin has flowed into the housing of the female part. If necessary, remove the resin carefully and without damaging it so as not to impair the function of the female part.

18.2.3 Inserting the female part by casting-on

 Only applies to Mini-SG® F/R, female part in C (Ceramicor®)



With the cast-on technique on the female part, a retention must also be modelled. This allows the finished abutment to be securely anchored in the denture resin. As the coefficient of thermal expansion (CTE) of Ceramicor® is lower than that of the burn-out alloy, the housing should be covered circularly with a wax layer at least 0.7 mm thickness. This ensures that the ceramic does not come into contact with the female part in Ceramicor®. This prevents cracks from forming in the ceramic.

Separate the female part with the wax-up from the male part and remove the friction insert before investing. The inner surfaces of the female part must be free of wax. We recommend using an instrument to make a fine groove at the transition of the wax to the female part, so that an inflow of alloy can be practically ruled out during casting.

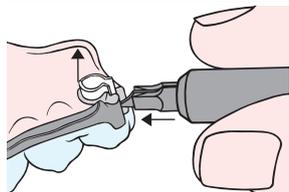
Divesting and cleaning

For reasons of safety, blasting is not allowed in the area of the inner housing of the female part. Cleaning in ultrasonic bath. Insert the slide insert and check functionality on the master model.

-  Acid-treated parts glide better again if they are briefly placed in soapy water (ultrasound) after stripping.
-  The friction insert used for processing must be replaced with a new one after completion of the denture.

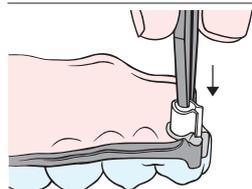
18.3 Activation and deactivation

18.3.1 M-SG® Star 1, Mini-SG® F/R and Mini-SG®



Removing the friction insert

Press both ends of the lamella together with tweezers. By disengaging from the retention, the friction or retention insert can be removed easily. If the slide insert remover is used, the lamella cams are automatically released from retention when inserted.



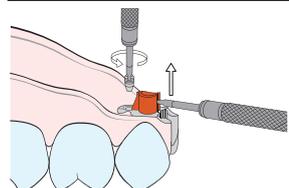
Inserting the friction insert

Using tweezers, grasp one of the two lamellae on the rounded side of the friction or retention insert and carefully press against the opposite inner wall of the housing. Using slight pressure, the friction or retention insert is pushed into its final position. The click is audible. If not, the friction or retention insert has been inserted from the wrong side.

18.3.2 M-SG® Star 2 and Mini-SG® PLUS

Activation occurs when the activator screw is screwed in clockwise using a screwdriver/activator. Deactivation is performed in reverse order. The desired friction can be adjusted continuously from 100 to 600 g with the orange friction insert. For increased friction from approx. 500 to 1000 g, the violet friction insert should be used.

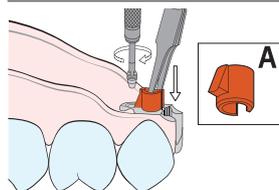
-  If the respective friction play of the two friction inserts is exceeded by activation, this returns to the maximum adjustable values after approx. 3 - 5 months.



Removing the friction insert

Unscrew the activation screw completely with the screwdriver and lift the friction slide insert with the screwdriver.

-  The activation screws of the M-SG® Star 2 and Mini-SG® PLUS are identical.



Inserting the friction insert

Using tweezers, grasp one of the two lamellae on the rounded side of the friction insert and carefully press against the opposite inner wall of the housing. Here, care must be taken that the wider part of the wedge lies occlusally (A). Then screw the activating screw back in.

-  Counter-pressure of the friction insert on the screw prevents the screw from loosening by itself.

18.3.3 SG Slide attachment

Activation is by turning the activation screw clockwise using the Thomas spanner key and the mounted screwdriver insert. Deactivation is performed in reverse order. The margin of activation is not very large.

Removing the friction insert

Fully unscrew the activation screw with the Thomas spanner key and mounted screwdriver insert and remove the friction insert from the housing.

Inserting the friction insert

Grasp the friction insert with the tweezers and carefully push into the housing. Here, care must be taken that the flat part of the friction insert lies occlusally. Then screw the activating screw back in.

-  After use, clean instruments with water and proceed as described in Section 16 (Reprocessing).

18.4 Modifications, relining

18.4.1 Impression taking

Provided that the fit of the female part on the male part is correct, use some soft wax or silicone to block out the cavity between the gingiva and the underside of the male part before taking the impression. Take a functional impression. Use a solid impression silicone.

18.4.2 Model fabrication

To fabricate the model, the respective transfer axis of the system is used by inserting it into the female part and fixating it securely. Then proceed with fabrication of the master model.

18.5 Insufficient denture retention – what to do:

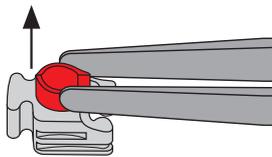
1. Remove the denture and clean thoroughly. In particular, make sure that the slide attachment elements are absolutely clean and free of contamination.
2. Check whether the female part or its components are damaged, replace if necessary and readjust denture retention.
3. Check whether the incorporated female part is correctly positioned on the male part. If this is not the case, the retention force is reduced and wear is very high. It is essential to insert the female part afresh. The correct seating of the female part can be checked by using an easy-flowing silicone.
4. Check in the mouth to see if there are any signs of wear on the male part, which could be the cause of insufficient retention. If sufficient denture retention can no longer be achieved with the maximum activated female part, then a tuning female part is available for the Mini-SG®. This option is not available for the M-SG® Star and SG slide attachment systems.

18.5.1 Mini-SG® tuning female part, procedure

Option 1

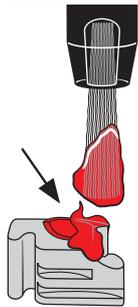
(direct method – in the dental practice)

1. Remove the denture.



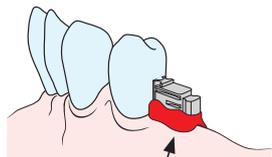
2. Adjust the grip of the Mini-SG® tuning female part in the patient's mouth by replacing the friction inserts. The Mini-SG® tuning female part is supplied with the yellow friction insert (= lowest friction force). The three other friction levels are included. The friction inserts can be replaced using tweezers.

3. Grind the Mini-SG® female part out of the denture. Milling cutter recommendation: cross-toothed carbide cutter, parallel-walled, face-cutting, Ø up to 2.25 mm.



4. Insulate the inside of the Mini-SG® tuning female part with Vaseline (protection against penetrating plastic).

5. Mount the Mini-SG® tuning female part on the male part in the patient's mouth.



6. Block out attachment undercuts, e.g. with soft wax.

7. Before fitting the Mini-SG® tuning female part, check that the denture can be inserted and removed properly in the patient's mouth.



8. If possible, drill a drainage canal for the resin through the denture body.

9. Mix the denture resin, apply to denture and Mini-SG® tuning female part, carefully insert denture and remove excess.

10. After curing, remove the denture, finish, use a rubber wheel and polish.

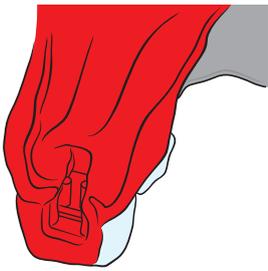
11. Final check: check denture retention and, if necessary, fit a different slide insert.

Option 2

(indirect method, impression-taking – integration in dental laboratory)

Steps 1 - 7 are analogous to the direct method.

8. Temporarily connect the Mini-SG® tuning female part to the denture with resin.



9. Take the impression. If it is not possible to remove the Mini-SG® female part from the denture, then as an alternative, remove the friction side insert and fill the female part with impression material and then take the overall impression with the inserted denture.



10. Working model: due to the varying wear of the male part, a prefabricated transfer jig is not available. Procedure: when using the Mini-SG® tuning female part, insulate the inner surface with Vaseline, carefully fill the female part with suitable stump/model material, e.g. epoxy, and provide a retention for the plaster model, e.g. with a wire loop. Fabricate working model.

11. Insertion of the Mini-SG® tuning female part is performed as described in Section 18.2.

19 Materials

C = Ceramicor®; Au 60.0 %, Pt 19.0 %, Pd 20.0 %, Ir 1.0 %.

$T_s - T_L$ 1400 – 1490°C

D = Doral; Au 15.0%, Pd 22.0%, Ag 49.3%, Cu 13.7%

$T_s - T_L$ 930 – 1015°C.

E = Elitor®; Au 68.6%, Pt 2.4%, Pd 3.9%, Ag 11.8%, Cu 10.6%, Zn 2.5%.

$T_s - T_L$ 880 – 940°C

G = Galak; Mouth-resistant resin.

K = Korak; Residue-free burn-out resin for the casting technique.

M = Med steel; special alloy for medical use. Contains nickel.

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

T = Pure titanium (Grade 4); Ti > 98.9375 %.

V = Valor; Au 10.0%, Pt 89.0%, Ir 1.0%.

$T_s - T_L$ 1660 – 1710°C

X = Steel; stainless steel, corrosion-resistant.

More detailed information on the materials as well as their compositions can be found in the product-specific material data sheets, the product information as well as the product list compiled in Section 29. All relevant documents can be found on the website www.cmsa.ch/docs by entering the relevant product name.

20 Notes on storage



Insofar as no specific information on storage is given on the packaging of the product, we recommend storing the product in its original packaging, in a dry place, at room temperature and without direct sunlight. Improper storage can influence the product properties and lead to failure of the restoration.

21 Patient information

21.1 Handling / follow-up

On the day of insertion of the dentures at the latest, the patient must be informed that regular follow-up care is necessary to maintain the health of the entire masticatory system and the functionality of the denture. Ensure that the patients are motivated and instructed with regard to caring for their teeth as well as dentures.

Permanent and removable dentures are subject to considerable stress. Signs of wear are normal and cannot be avoided, only reduced. The amount of wear depends on the overall system.

Our endeavours are aimed at using materials that are as optimally matched as possible in order to reduce wear to an absolute minimum. Proper seating of the dentures on the mucosa must be checked at least once each year, and relining must be performed if required to prevent rocking movement (overload). We recommend checking the dentures at intervals of approx. 3 months initially and to replace the auxiliary parts such as retention inserts if necessary.

21.2 Insertion and removal of the dentures

It should be ensured that the dentures do not tilt, as any tilting can lead to damage. The denture should never be inserted by clenching the teeth, as this can damage or even break the connecting element.

Insertion

The denture can be placed on the anchor elements in the mouth using the thumb and index finger. Then it is correctly positioned on the anchoring elements applying gentle, even pressure. By carefully closing the jaws, it is possible to check whether the denture is in its correct final position.

Removal

For removal, the denture can be grasped with the thumb and index finger and carefully pulled from the anchor elements and taken out of the mouth.

21.3 Cleaning and care**Material Doral (D)**

Do not use cleaning agents which contain corrosive components.

This could lead to discolouration, stress corrosion cracks and fracture of the female part D.

We recommend cleaning teeth and dentures after every meal. Cleaning of dentures includes cleaning of the connecting element. Gentlest cleaning can be achieved by cleaning the restoration under running water with a soft toothbrush and the connecting element in the mouth with an interdental brush. The most intensive cleaning of the restoration is achieved with the aid of an ultrasonic device and a cleaning additive suitable for dentures.

Never clean the high precision connecting elements with toothpaste as this could lead to damage. Caution should also be exercised in the case of aggressive cleaning agents or tablets as this could damage the high-quality connecting element or impair its function.

Regular cleaning of the anchorage can prevent inflammation of the soft tissue.

22 Ordering information

The information relevant to your order can be found in the product list in Section 29 of this document. The product information is also helpful. This and other relevant documents can be found on the website www.cmsa.ch/docs by entering the relevant product name.

23 Availability

Some of the products described in this document may possibly not be available in all countries.

24 Traceability of the lot number

The lot numbers of all parts used must be documented to ensure traceability.

25 Complaint

Cendres+Métaux SA must be notified immediately of any incident that has occurred with regard to the product. To do this, please contact your customer advisor or send us your message by e-mail to the address complaints-cmbrand@cmsa.ch. In serious cases, also send a report to the competent authority where you are domiciled.

26 Safe disposal

The products must be disposed of in accordance with local laws and environmental regulations, taking into account the level of contamination. Cendres+Métaux Lux SA would be very pleased to accept precious metal waste. For information and additional details, please contact your Cendres+Métaux SA representative.

27 Trademarks

Registered trademarks of Cendres+Métaux Holding SA, Biel/Bienne, Switzerland include:

Ceramicor®, Elitor®, Mini-SG® and M-SG® Star

Unless explained specifically, all products marked with "®" are not registered trademarks of Cendres+Métaux Holding SA, but registered trademarks of the respective manufacturer.

28 Disclaimer

The manufacturer rejects any liability for damages resulting from non-compliance with these Instructions for Use. Cendres+Métaux SA products are parts of an overall concept and may only be used or combined with the appropriate original components and instruments. Otherwise, the manufacturer rejects any responsibility and liability. In case of complaints, please always include the lot number.

The use of third party products not distributed by Cendres+Métaux SA in connection with the products mentioned in the product list in Section 29 will void any warranty or other express or implied obligation of Cendres+Métaux SA.

Responsibility regarding the suitability of a product for the specific patient case is at the discretion of the specialist.

Cendres+Métaux SA disclaims any express or implied liability and shall not be responsible for any direct, indirect, punitive or other damages arising from or in connection with errors in professional judgement or practice in the use of Cendres+Métaux SA products.

The specialist is obliged to regularly study the latest developments of the products mentioned in the product list in Section 29 and their applications.

It should be noted that the descriptions contained in this document are not sufficient for the immediate application of Cendres+Métaux SA products. Expertise in dentistry, dental technology and instructions by an experienced specialist in the use of the products mentioned in the product list under Section 29 is always necessary.

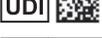
In case of inconsistencies in translations, the English language version shall prevail.

29 Product list

Cat. No.	Product name	Material	Single use	Labelling	UDI-DI	Basic UDI-DI
M-SG® Star 1						
05000429	M-SG® Star 1 TC for casting-on	Titanium / Ceramicor®	Yes	CE 0483	07640166515067	764016651000051DY
05000432	M-SG® Star 1 TK for casting	Titanium / Korak	Yes	CE 0483	07640173091127	764016651000067EF
05000673	M-SG® Star 1 MK for casting	Med steel / Korak	Yes	CE 0483	07640173090441	764016651000067EF
05000433	Female part T	Titanium	Yes	CE 0483	07640166515098	764016651000067EF
05000674	Female part M	Med steel	Yes	CE 0483	07640173090458	764016651000067EF
055691	Friction insert G yellow (smooth friction) 5 pcs.	Galak	Yes	CE 0483	07640173093268	764016651000067EF
055356	Friction insert G red (normal friction) 5 pcs.	Galak	Yes	CE 0483	07640173093121	764016651000067EF
055357	Friction insert G green (strong friction) 5 pcs.	Galak	Yes	CE 0483	07640166516125	764016651000067EF
055358	Friction insert G blue (extra-strong friction) 5 pcs.	Galak	Yes	CE 0483	07640173093145	764016651000067EF
05000407	Male part C for casting-on	Ceramicor®	Yes	CE 0483	07640166515005	764016651000051DY
05000410	Male part K	Korak	Yes	n/a	07640173093855	n/a
07000040	Duplicating aid G	Galak	Yes	CE	07640166515173	764016651000006DT
07000042	Transfer jig	Steel	Yes	CE	07640166515180	764016651000032DU
072627	Special parallelometer insert	Steel	No	CE	07640166514930	764016651000018E2
07000056	Insert remover	Steel	No	CE	07640166515197	764016651000001DH
070347	Tweezers	Steel	No	n/a	07640166511854	n/a
M-SG® Star 2						
05000411	M-SG® Star 2 TC for casting-on	Titanium / Ceramicor®	Yes	CE 0483	07640166515036	764016651000051DY
05000413	M-SG® Star 2 TK for casting	Titanium / Korak	Yes	CE 0483	07640173093862	764016651000067EF
05000414	Female part T	Titanium	Yes	CE 0483	07640166515050	764016651000067EF
055774	Friction insert G orange (normal friction) 5 pcs.	Galak	Yes	CE 0483	07640173093350	764016651000067EF
055811	Friction insert G violet (strong friction) 5 pcs.	Galak	Yes	CE 0483	07640173093411	764016651000067EF
055775	Activating screw T	Titanium	Yes	CE 0483	07640166514206	764016651000067EF
05000407	Male part C for casting-on	Ceramicor®	Yes	CE 0483	07640166515005	764016651000051DY
05000410	Male part K	Korak	Yes	n/a	07640173093855	n/a
07000041	Duplicating aid G	Galak	Yes	CE	07640173093503	764016651000006DT
07000042	Transfer jig	Steel	Yes	CE	07640166515180	764016651000032DU
072627	Special parallelometer insert	Steel	No	CE	07640166514930	764016651000018E2
072653	Screwdriver/activator	Steel	No	CE	07640173091295	764016651000002DK
070347	Tweezers	Steel	No	n/a	07640166511854	n/a
Mini-SG® F/R						
055534	Mini-SG® F/R TV	Titanium / Valor	Yes	CE 0483	07640173090359	764016651000051DY
055543	Mini-SG® F/R TC	Titanium / Ceramicor®	Yes	CE 0483	07640173093237	764016651000051DY
055532	Mini-SG® F/R TK	Titanium / Korak	Yes	CE 0483	07640173090878	764016651000067EF
055675	Mini-SG® F/R CC	Ceramicor® / Ceramicor®	Yes	CE 0483	07640173090366	764016651000051DY
055699	Mini-SG® F/R CK	Ceramicor® / Korak	Yes	CE 0483	07640173093282	764016651000067EF
055531	Female part T	Titanium	Yes	CE 0483	07640173090342	764016651000067EF
055677	Female part C	Ceramicor®	Yes	CE 0483	07640173090373	764016651000067EF
055925	Tuning female part E	Elitor®	Yes	CE 0483	07640173093480	764016651000067EF
055691	Friction insert G yellow (smooth friction) 5 pcs.	Galak	Yes	CE 0483	07640173093268	764016651000067EF
055356	Friction insert G red (normal friction) 5 pcs.	Galak	Yes	CE 0483	07640173093121	764016651000067EF
055357	Friction insert G green (strong friction) 5 pcs.	Galak	Yes	CE 0483	07640166516125	764016651000067EF
055358	Friction insert G blue (extra-strong friction) 5 pcs.	Galak	Yes	CE 0483	07640173093145	764016651000067EF
055718	Retention insert G orange (normal friction) 5 pcs.	Galak	Yes	CE 0483	07640173093299	764016651000067EF
055766	Retention insert G violet (strong friction) 5 pcs.	Galak	Yes	CE 0483	07640173093336	764016651000067EF
055517	Male part V	Valor	Yes	CE 0483	07640173093206	764016651000051DY
055544	Male part C	Ceramicor®	Yes	CE 0483	07640173093244	764016651000051DY

Cat. No.	Product name	Material	Single use	Labelling	UDI-DI	Basic UDI-DI
055529	Male part K	Korak	Yes	n/a	07640173093220	n/a
072600	Duplicating aid G	Galak	Yes	CE	07640173091226	76401665100006DT
072616	Transfer jig	Steel	Yes	CE	07640173091257	764016651000032DU
072627	Special parallelometer insert	Steel	No	CE	07640166514930	764016651000018E2
072483	Insert remover	Steel	No	CE	07640173091776	76401665100001DH
070347	Tweezers	Steel	No	n/a	07640166511854	n/a
Mini-SG® PLUS						
055802	Mini-SG® PLUS TV	Titanium / Valor	Yes	CE 0483	07640173090380	764016651000051DY
055804	Mini-SG® PLUS TK	Titanium / Korak	Yes	CE 0483	07640173090922	764016651000067EF
055807	Female part T	Titanium	Yes	CE 0483	07640173090397	764016651000067EF
055774	Friction insert G orange (normal friction) 5 pcs.	Galak	Yes	CE 0483	07640173093350	764016651000067EF
055811	Friction insert G violet (strong friction) 5 pcs.	Galak	Yes	CE 0483	07640173093411	764016651000067EF
055775	Activating screw T	Titanium	Yes	CE 0483	07640166514206	764016651000067EF
055517	Male part V	Valor	Yes	CE 0483	07640173093206	764016651000051DY
055529	Male part K	Korak	Yes	n/a	07640173093220	n/a
072649	Duplicating aid G	Galak	Yes	CE	07640173091288	76401665100006DT
072616	Transfer jig	Steel	Yes	CE	07640173091257	764016651000032DU
072627	Special parallelometer insert	Steel	No	CE	07640166514930	764016651000018E2
072653	Screwdriver/activator	Steel	No	CE	07640173091295	764016651000002DK
070347	Tweezers	Steel	No	n/a	07640166511854	n/a
Mini-SG®						
055364	Mini-SG® DK	Doral / Korak	Yes	CE 0483	07640173090830	764016651000067EF
055919	Mini-SG® XC (2 pcs.)	Steel / Ceramicor®	Yes	CE 0483	07640173093718	764016651000051DY
055487	Mini-SG® XK	Steel / Korak	Yes	CE 0483	07640173090861	764016651000067EF
055371	Female part D	Doral	Yes	CE 0483	07640173090847	764016651000067EF
055489	Female part X	Steel	Yes	CE 0483	07640166517702	764016651000067EF
055925	Tuning female part E	Elitor®	Yes	CE 0483	07640173093480	764016651000067EF
055691	Friction insert G yellow (smooth friction) 5 pcs.	Galak	Yes	CE 0483	07640173093268	764016651000067EF
055356	Friction insert G red (normal friction) 5 pcs.	Galak	Yes	CE 0483	07640173093121	764016651000067EF
055357	Friction insert G green (strong friction) 5 pcs.	Galak	Yes	CE 0483	07640166516125	764016651000067EF
055358	Friction insert G blue (extra-strong friction) 5 pcs.	Galak	Yes	CE 0483	07640173093145	764016651000067EF
055544	Male part C	Ceramicor®	Yes	CE 0483	07640173093244	764016651000051DY
055529	Male part K	Korak	Yes	n/a	07640173093220	n/a
072616	Transfer jig	Steel	Yes	CE	07640173091257	764016651000032DU
072627	Special parallelometer insert	Steel	No	CE	07640166514930	764016651000018E2
072483	Slide insert remover	Steel	No	CE	07640173091776	76401665100001DH
070347	Tweezers	Steel	No	n/a	07640166511854	n/a
SG Slide attachment						
052157	SG DC	Doral / Ceramicor®	Yes	CE 0483	07640173090809	764016651000051DY
052158	SG DK	Doral / Korak	Yes	CE 0483	07640173090816	764016651000067EF
052159	Female part D	Doral	Yes	CE 0483	07640173090823	764016651000067EF
052163	Friction insert G white (normal friction) 5 pcs.	Galak	Yes	CE 0483	07640173092018	764016651000067EF
05000057	Friction insert G violet (strong friction) 5 pcs.	Galak	Yes	CE 0483	07640173091158	764016651000067EF
052161	Activating screw O	OSV	Yes	CE 0483	07640173092049	764016651000067EF
052164	Mounting screw X	Steel	Yes	CE	07640166519324	764016651000008DX
052160	Male part C	Ceramicor®	Yes	CE 0483	07640173092032	764016651000051DY
052162	Male part K	Korak	Yes	n/a	07640173092056	n/a
072502	Duplicating aid G	Galak	Yes	CE	07640173091783	76401665100006DT
070566	Transfer jig	Steel	Yes	CE	07640173091509	764016651000032DU
072627	Special parallelometer insert	Steel	No	CE	07640166514930	764016651000018E2
070293	Screwdriver insert	Steel	No	CE	07640173093572	764016651000002DK
070221	Thomas spanner key	Steel	No	CE	07640166511861	764016651000013DQ
070222	Attachment tweezers	Steel	No	CE	07640166514565	764016651000035E2

30 Labelling on packaging/symbols

	Date of manufacture
	Manufacturer
	Catalogue number
	Lot number
	Quantity
 www.cmsa.ch/docs	Observe the Instructions for Use, which are available in electronic form at the address specified.
Rx only	Attention: According to US federal law, this product may only be sold by or on behalf of a physician.
	Cendres+Métaux products with CE labelling meet the requirements of the relevant European requirements.
	Do not re-use
	Non-sterile
	Protect from sunlight
	Attention, observe accompanying documents
	Clear product identification
	European Authorised Representative
	Importer
	Medical device