

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With the publication of these instructions for use all previous Editions are no longer valid.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

General information

Traceability of item numbers

The item numbers of all components used should be recorded to ensure traceability.

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.

Warnings

Allergies

This product should not be used for patients with a known allergy to one or more components of the attachment materials. If a patient has a suspected allergy to one or more components of these materials, the product should not be used until allergy tests have been completed and it has been established that the patient does not have an allergy to the product.

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.

Mini-SG® F/R instructions for use

These instructions for use are based on those for the Mini-SG® F/R and assume that the user is familiar with those instructions.

The latest version can be downloaded from our website at www.cmsa.ch/dental or obtained from our local representative.

Important

Ensure that you read through these instructions carefully. Please send an e-mail to mini-sg@cmsa.ch or simply call us to give us your assessment and experience of the product. We would like to thank you very much for your cooperation and valued custom.

Preparation

Introduction

Rigid attachments with replaceable, biocompatible plastic inserts that allow optimum adjustment of the retention of a removable restoration provide advantages which have led to an increase in their clinical use. Cendres+Métaux was one of the pioneers of this type of attachment and has had great success with it since putting it on the market in the 1980s.

In rare cases the male part showed signs of wear and tear.

A special Mini-SG® tuning female part has been developed for restoring retention.

Mini-SG® tuning female part

The Mini-SG® tuning female part, which has a smaller inner diameter, enables greater friction to be attained using the **existing friction inserts**.

The Mini-SG® tuning female part is easily distinguished from the standard Mini-SG® female part by its gold-coloured alloy material.

Basic requirement

It is essential to ensure that restorations with attachments, which use plastic inserts, have a stable support that is as rigid as possible in the mouth. If there is not stable, rigid support, very slight movements over the years can result in irreparable damage to the male part. Causes are often inadequate cleaning of the restoration, lack of aftercare, poor fit of the restoration, improper handling, high masticatory loading, e.g. due to an unbalanced set-up, a large denture saddle with little alveolar support etc.

Note: If this basic requirement is not met, there is the risk that use of the Mini-SG® tuning female part will only restore retention temporarily.

Refund guarantee

As wear and tear varies greatly, it cannot be guaranteed that retention will be restored with every denture. A possible reason could be that there is still insufficient retention or the Mini-SG® tuning female part cannot be fitted to the Mini-SG® male part. In such cases a used female part will be refunded.

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

Plastic inserts in G = Galak

Biocompatible, orally stable plastic

Insertion

Tuning female part

E = Elitor®

Insertion: polymerisation, soldering or adhesive retention

Indications

Restoring retention to restorations with reduced retention due to wear and tear on Mini-SG® male parts

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.
- Use on **fully functioning** Mini-SG® male parts

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.

Instructions for use

Replacing the Mini-SG® female part with the Mini-SG® tuning female part

Method 1

(Direct method – chairside)

1. Remove the denture.
2. Set the retention of the Mini-SG® tuning female part in the patient's mouth by replacing the friction inserts.
Note: The Mini-SG® tuning female part is supplied with the yellow insert (= minimum friction). The other three inserts are enclosed. The friction inserts can only be replaced using tweezers (Fig. 1 / Order no. 070347)!
3. Cut the Mini-SG® female part out of the denture.
4. Coat the inside of the Mini-SG® tuning female part (Fig. 2) with Vaseline (to prevent acrylic flowing into it).
5. Fit the Mini-SG® tuning female part onto the male part in the patient's mouth.
6. Block out undercuts on the attachment, e.g. with soft wax (Fig. 3).
7. Before incorporating the Mini-SG® tuning female part, check that the denture can be easily inserted into and removed from the patient's mouth.
8. If possible, drill an escape channel in the denture for the acrylic (Fig. 4).
9. Mix the denture acrylic, apply it to the denture and the Mini-SG® tuning female part, carefully fit the denture and remove any excess.
10. Remove the denture after curing. Then prepare, rubber polish and high-lustre polish it.

Tuning female part in E = Elitor®

Au 68.60 %, Pt 2.45 %, Pd 3.95 %, Ag 11.85 %, Cu 10.60 %, Ir 0.05 %, Zn 2.50 %
T_s – T_L 880–940 °C

G = Galak

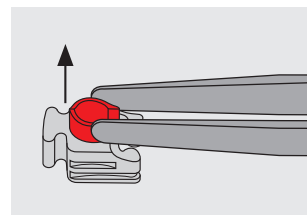


Fig. 1

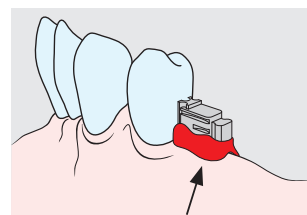


Fig. 3

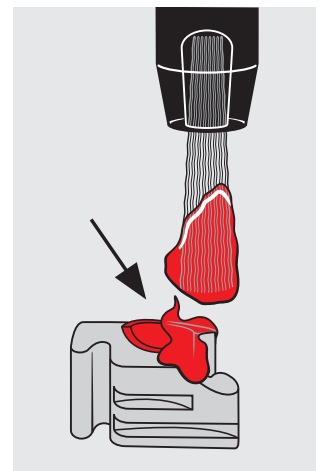


Fig. 2

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

Method 2

(Indirect method, impression taken – tuning female part inserted in the dental laboratory)

1. Remove the denture.

2. Set the retention of the Mini-SG® tuning female part in the patient's mouth by replacing the friction inserts.

Note: The Mini-SG® tuning female part is supplied with the yellow insert (= minimum friction). The other three inserts are enclosed. The friction inserts can only be replaced using tweezers (Fig. 1)!

3. Cut the Mini-SG® female part out of the denture. (Type B tungsten carbide cutter / Order no. 080461)

4. Coat the inside of the Mini-SG® tuning female part (Fig. 2) with Vaseline (to prevent acrylic flowing into it).

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

6. Block out undercuts on the attachment, e.g. with soft wax (Fig. 3).

7. Before incorporating the Mini-SG® tuning female part, check that the denture can be easily inserted into and removed from the patient's mouth.

8. Connect the Mini-SG® tuning female part to the denture provisionally with acrylic.

9. Take the impression.

Note: If the Mini-SG® female part cannot be removed from the denture, the friction insert is removed (Fig. 5), the female part filled with impression material and then a full impression taken with the denture in situ (Fig. 6).

10. Working model: a prefabricated transfer pin is not available due to variations in wear and tear on the male part.

a) Fabrication technique if the impression is taken with the existing Mini-SG® female part without the sliding insert: Carefully fill the female part with a suitable die/model material, e.g. epoxy resin, and provide retention for the stone model, e.g. with looped wire (Fig. 7).

b) Fabrication technique if the impression is taken with the Mini-SG® tuning female part: Coat the inside with Vaseline, carefully fill the female part with a suitable die/model material e.g. epoxy resin, and provide retention for the stone model, e.g. using looped wire.

11. Incorporate the Mini-SG® tuning female part using standard procedures. Follow the instructions in the Mini-SG® F/R instructions for use.

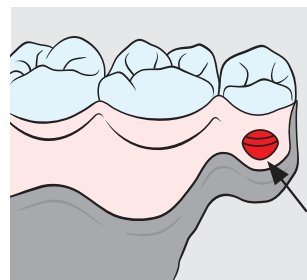


Fig. 4

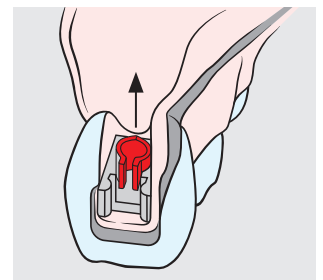


Fig. 5

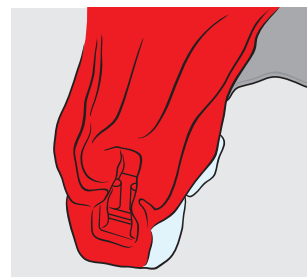


Fig. 6

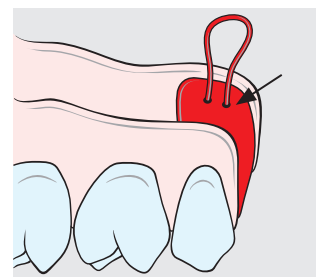


Fig. 7

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
	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