Mini-Gerber PLUS

Instructions for use

Ring G

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.

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.

Intended Use

The anchors manufactured by Cendres+Métaux serve as connectors for tooth-supported removable dental prosthesis.

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.

Warnings

With patients having an existing allergy to one or several elements of the materials contained in any one attachment, this particular product must not be used. With patients suspected of having an allergy to one or several of these elements contained in any one attachment, this product can only be used after preliminary allergological testing and proof of a non-existing allergy. 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.

These operating instructions are not sufficient for immediate use of the attachment. Knowledge of dentistry and dental technology as well as instruction on the handling of the Cendres+Métaux attachments by an experienced person are required. Training courses are regularly provided by Cendres+Métaux, among others. The activation, deactivation, repair and periodic maintenance of attachments should be carried out solely by specialists. Only original auxiliary tools and parts should be used for this work.

- 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 male parts must be placed parallel to the direction of
- insertion - Undercuts must be blocked out.

Indications

Removable, rigid dentures on root canal caps on devitalized roots: - Insertion dentures

- Unilateral free-end dentures, transversally blocked
- Combined insertion and free-end dentures- Bilateral free-end dentures
- Hybrid dentures
- Friction-grip constructions on periodontally damaged teeth.

Contraindication

- Unilateral dentures without transverse support.
- Restoration of abutment teeth with severe periodontal damage.
- Hybrid dentures which are fitted with a single root cap.
- 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
- For additional contraindications, please refer to the instructions for use from the implant manufacturer.

General instructions

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.

Materials used and processing

Description and abbreviations for materials:

Detailed information about the materials and their classification can be found in the specific material data sheets and the catalogue

See website www.cmsa.ch/dental or the dental documentation from Cendres+Métaux (available free of charge from all subsidiaries, branch offices and agencies of Cendres+Métaux).

Single parts

Ring G G = GalakPlastic-resistant to oral conditions



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Mini-Gerber PLUS Ring G

It cannot be ruled out that titanium threaded rings on friction retained restorations with Mini-Gerber PLUS attachments and a retentive force of less than 200g may loosen on their own. This is probably due to the micromovements in the patient's mouth. To eliminate this problem, the titanium threaded ring should be replaced with a Galak ring G (Order No. 055759).

Please note: Ring G is supplied without a thread. The thread is tapped when the ring is wound into the housing. This prevents its loosening inadvertently.

Procedure:

First, use a special key (Order No. 072 597) to remove the titanium threaded ring. Then press ring G (Order No. 055 759) up to the stop on the special key. Position ring G in the opening in the housing and wind it into the housing, applying gentle pressure. The ring must be rotated one turn clockwise and half a turn anti-clockwise. Once ring G coincides with the inner edge of the housing, the friction will be approximately 100g. Ring G can be wound further into the housing, depending on the degree of friction required. A transfer jig (Order No. 072 461) can be used to check the retentive force of the female part.

Please note: If the attachment is activated or deactivated several times, a new ring G should be fitted.

Auxiliary instruments

The auxiliary instruments to be used are listed in the main catalogue of Cendres+Métaux under the heading for the particular attachment. See website www.cmsa.ch/dental or the dental documentation from Cendres+Métaux (available free of charge from all subsidiaries, branch offices and agencies of Cendres+Métaux).

Aftercare

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.

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

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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 |
| REF | Catalogue number |
| LOT | Batch code |
| QTY | Quantity |
| ī | 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. |
| \otimes | Do not re-use |
| <u> </u> | NL |

Non-sterile

Keep away from sunlight

Caution, consult accompanying documents