# K 34

Instructions for use

**Anchors**

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**With the publication of these instructions for use all previous Editions are no longer valid.**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

– Dalbo®-Z
– Stepped Eccenter
– Gerber RZ
– Mini-Gerber
– Baer Cylindrical Anchor

Fig. 1

**Product description**
The anchors listed (in Fig. 1) are intended for dental prosthetics.

**Anchors**
– Dalbo®-Z (Supraradicular, cylindrical friction-grip anchor, adjustable)
– Stepped Eccenter (Supraradicular, cylindrical friction-grip or retention-grip anchor, adjustable)
– Gerber RZ (Supraradicular, cylindrical retention-grip anchor)
– Mini-Gerber (Supraradicular, cylindrical retention-grip anchor)
– Baer Cylindrical Anchor (Supraradicular, rigid, cylindrical anchor, adjustable)

**Intended Use**
The anchors manufactured by Cendres+Métaux serve as connectors for tooth- or implant-supported removable dental prostheses.

**Indication**
Dalbo®-Z
– Removable, friction-grip, rigidly or resiliently restorations supported on implants and devitalized roots.
– Resilient anchors as complementary elements of rigid anchors.

Stepped Eccenter
– Insertion dentures
– Rigid, unilateral, free-end dentures locked transversally
– Rigid, bilateral free-end dentures
– Rigid hybrid dentures

Gerber RZ
Removable, retention-grip, rigidly restorations supported on devitalized tooth:
– Retention-grip constructions on periodontally damaged teeth
– Unilateral free-end dentures locked transversally
– Insertion/free-end dentures in combination
– Hybrid dentures

Mini-Gerber
Removable, retention-grip, rigidly restorations supported on devitalized tooth:
– Retention-grip constructions on periodontally damaged teeth
– Unilateral free-end dentures locked transversally
– Insertion/free-end dentures in combination
– Hybrid dentures

Baer Cylindrical Anchor
Removable, friction-grip, rigidly hybrid dentures supported on devitalized roots:
– As complementary element to other rigid anchors

**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.

**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.

The following items contain nickel:
050315 Annular spring X (zu Gerber RZ)
055191 Spring X (zu Mini-Gerber)
070262 Sewdriver (zu Gerber RZ) .
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.

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

**Materials used and processing**
Description and abbreviations for materials:
E = Elitor®
O = OSV
X = Steel
Z =Tin
G=Galak

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).

Dalbo®-Z
Female part O = OSV
Fitting: Polymerization
Male part E = Elitor®
Fitting: Soldering
Elastomeric ring G = Galak
Distanzscheibe Z = Zinn

Stepped Eccenter
Female part O = OSV
Fitting: Polymerization
Male part O = OSV
Fitting: Soldering
Elastomeric ring G = Galak

Gerber RZ
Female part E = Elitor®
Fitting: Polymerization
Male part O = OSV
Fitting: Soldering
Threaded bush O = OSV
050315 Annular spring X = Steel
070262 Sewdriver X =Steel

Mini-Gerber
Female part E = Elitor®
Fitting: Polymerization
Male part O = OSV
Fitting: Soldering
Threaded bush = OSV
055191 Spring X = Steel

Baer Cylindrical Anchor
Female part E = Elitor®
Fitting: Polymerization
Male part O = OSV
Fitting: Soldering
Elastomeric ring G = Galak

**Procedure / Handling / Processing 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.

**Technique for using the auxiliary parts (Galak)**
Here the spacers generally replace the anchor female parts During resin-polymerization in the dental laboratory. These are then removed from the finished polymerized denture. The polymerization or resin-bonding of the original female parts is done by the dental surgeon directly in the mouth of the patient after cementing of the root canal caps. The spacers are also an excellent protection for the male parts during polishing.

**Duplicating aids**
These red parts are slightly overdimensioned compared to the original parts. The result is an optimal gap for the resin-bonding technique.
Note: The duplication aid must not be used instead of the female part as a temporary replacement and also must not be placed in the mouth for impression-taking.

**Spacer disc**
The tin spacer supplied with this attachment provides for vertical resilience. The soft spacer is placed over the entire root cap and adapted prior to polymerizing the resin. Once the resin has been finished, the spacer is removed. Current clinical experience shows that the minimal vertical resilience is eliminated once the denture has been placed. The greatest advantage is that the denture base is not overloaded on the root cap.
Note: Do not put the spacer in tin in the mouth

**Twin crowns**
With two root canal caps in succession in the posterior region of a quadrant, the combined use of a rigid anchor with a resilient anchor is recommended. Normally the rigid anchor will be placed on the anterior and the resilient one on the posterior abutment. The two root canal caps must **not be** blocked. Thus rocking movements and overloads can be prevented.

**Occlusal metal surfaces**
Occlusal metal surfaces above female parts assure that they remain in the resin. The female parts must never be soldered, but must be polymerized directly into the removable denture in the patients mouth by the dental surgeon.

**Denture framework**
For bilateral insertion and free-end dentures cast transversal connections such as plates in the upper, sublingual connectors in the lower jaw are used. It is important that these constructions are absolutely rigid (no springiness).

**Transversal blocking**
Rigid unilateral dentures must be blocked transversally, generally with Cendres+Métaux attachments.

**Precautions when soldering OSV**
**Important!**
**The alloy OSV must not be annealed or hardened after soldering** (Danger of fracture due to embrittlement of the alloy.)
If components of anchors oxidize strongly during soldering, the oxide layer may not easily be removed by pickling. In this case remove the oxide layer with a glass brush. Do not use sandblasting or any other abrasive products such as prepolishing paste.

**Dismantling of the attachment**
Seperate the male and female parts before soldering and, if the they are made up of components, dismantle them.

**Pickling**
Pickled parts slide better, if they are placed in soap water (ultrasonic bath) after pickling.
**Important note:** In-depth information on subjects such as soldering, casting, laser welding and much more can be accessed at our website www.cmsa.ch/dental under the heading Interesting Facts.

**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.

**Disinfection of activators/deactivators**
070197 Activator (for Dalbo®-Z), 070199 Deactivator (for Dalbo®-Z), 070480 Activator (for Baer Cylindrical Anchor) must not be sterilised. When sterilising the above activators and deactivators in the autoclave, there is a possibility that their plastic handles may be destroyed.
It is therefore advisable to disinfect according to the section «Disinfection» of these instructions for use.

**Transversal blocking**
Rigid unilateral dentures must be blocked transversally, generally with Cendres+Métaux attachments, 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).

**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**
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 CE labelling meet the requirements of the relevant European requirements. |
|  | Do not re-use |
|  | Non-sterile |
|  | Keep away from sunlight |
|  | Caution, consult accompanying documents |