Instructions for Use Anchors

Dalbo®-Z, Pro-Snap, Eccentric, Mini-Gerber PLUS and Mini-Gerber PLUS Ring G

1 Scope of application of Instructions for Use

These Instructions for Use apply to the products listed under Point 29 in Table 1. 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 Point 29, Table 1.

3 Intended use

The components are intended for use in prosthetic restorations on root canal caps and to support procedures in the dental clinic or laboratory.

4 Expected clinical benefit

Restoration of chewing function and improved aesthetics.
The summaries of safety and clinical performance (SSCP) for the implantable devices covered by these Instructions for Use, are available on our homepage and accessible at this address: https://www.cmsa.ch/docs

5 Product description

Anchors

An anchor is a prosthetic retaining element consisting of a female (outer) part and a male (inner) part. The male part is soldered onto an individually fabricated root canal cap. The female part is bonded or directly polymerised into the removable denture. The root canal cap itself consists of a cast metal cap with a root canal post. As a high-quality solution, the prefabricated root canal post is integrated into the metal cap by cast-on. A more economical alternative is to cast a burn-out root canal post directly with the metal cap. There are fricative and retentive anchor concepts. Fricatively functioning restorations can be inserted and removed smoothly and without damaging the anchor teeth. Retentive restorations snap into place audibly and give the patient a secure feeling of a correctly fitting, removable denture.

Dalbo®-Z
The Dalbo®-Z is an activatable, fricative, rigid or vertical resilience anchor on root canal caps.

– The Elitor® (E) male part can be soldered or lasered onto root canal caps.

– The female part OSV (O) is integrated exclusively by polymerisation.

Pro-Snap
The Pro-Snap is an activatable, retentive resilience anchor on root canal caps. The ball head diameter of 2.22 mm is slightly smaller than that of the Dalbo® ball anchor system (Ø 2.25 mm).

The version TC. The Ceramicor (C) male part can be soldered on or cast-on during fabrication of the root canal cap. Casting-on saves time and eliminates the need for jointing materials. The titanium female part (T) can be polymerised or bonded into a metal housing.

The version TK. The male part made of special burn-out Korak (K) resin results in a high-quality surface after casting when used correctly.
The titanium female part (T) can be polymerised or bonded into a metal housing.

The retention inserts are made of Galak (G), a mouth-resistant plastic. Three force levels are available. Retention insert yellow for “soft”, red for “middle” and green for “strong”.

Eccentric
The Eccentric is an activatable, cylindrical, retentive rigid or resilient anchor. At only 1.1 mm construction height, the Eccentric is the anchor with the lowest insertion height.

– The male part in OSV (O) with integrated solder S.G 750 (melting point 750°C) can only be soldered onto root canal caps.

– The female part in Elasticor (EL) is integrated exclusively by polymerisation.

Mini-Gerber PLUS
The Mini-Gerber PLUS is an activatable anchor, which can be used either fricatively or retentively. By screwing in the threaded ring with hexagon socket, it is activated from frictional to retentive and thus also increases the holding force.

The **male part in Valor (V)** can be connected to the root canal cap by casting-on or soldering. Casting-on saves time and eliminates the need for jointing materials.

The **titanium female part (T)** can be polymerised or bonded into a metal housing.

The **retention insert** is made of Galak (G), a mouth-resistant plastic.

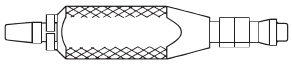
The **threaded ring in titanium (T)** secures the retention insert in the housing. By screwing it further into the housing, the retention insert is compressed and thus increases the retention force of the denture progressively.

The **ring made of Galak (G)** is supplied without a thread. This is only cut into the housing when it is screwed in. Application: in the case of fricatively set work with less than 200 g adhesion, it cannot be ruled out that the threaded titanium ring may become loose on its own accord. Using the G ring prevents becoming loose by itself.

The threaded ring T features a special thread which prevents it from becoming loose by itself.

Auxiliary parts and instruments

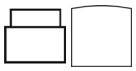
Elastomeric ring
Available for the Dalbo®-Z (Cat. No. 050273)



Instrument for mounting of elastomeric ring (Cat. No. 070205)
For the optimal function and protection of the lamellae of the Dalbo®-Classic and Dalbo®-B, the elastomer ring mounted on the female parts should not be removed.

Do not re-use elastomer rings once they have been slipped on.

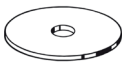
Duplicating aid G
Available for the Mini-Gerber-PLUS (Cat. No. 072466).
These “red” parts are slightly oversized with regard to the original components. This allows optimal bonding clearance for duplicating and bonding techniques. After being used as a duplication aid, the duplication auxiliary part can also be used as polishing protection.



Spacer G
Available for the Dalbo®-Z (Cat. No. 070439)
Protection cap G
Available for the Pro-Snap (Cat. No. 07050004)

Spacers/protection caps basically replace the anchor female parts during plastic polymerisation in the laboratory. These are then removed from the fully polymerised denture. The most optimal polymerisation or bonding of the original female parts is performed by the dentist directly in the patient's mouth after cementation of the root canal caps. The spacer also proves to be an excellent protection cap for the male part.

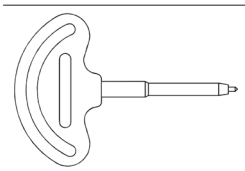
⚠ The duplicating aid, spacer and protection cap must not be used in place of the female part as a temporary replacement, nor for taking impressions in the mouth.

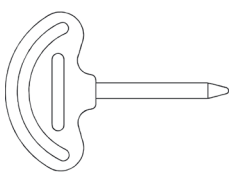


Spacer disc Z tin
Available for the Dalbo®-Z (Cat. No.. 050394) and Eccentric, spacer disc occlusal (Cat. No. 050393) and gingival (Cat. No. 050392).
The tin spacer disc supplied with each female part enables vertical resilience. This is incorporated in the laboratory prior to polymerisation, after which it is removed again.

⚠ The tin spacer disc must not be inserted in the mouth.

Stabilisation ring G
Available for the Pro-Snap.
Polymerisation aid (green) for insertion of the female part into the denture.

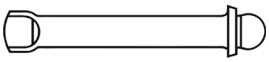




Activator/Deactivator
Dalbo®-Z
The activator (Cat. No. 070197) and deactivator (Cat. No. 070199) must not be sterilised. There is a risk that the resin handles will be destroyed during sterilisation in an autoclave. Please consider the published national guidelines when selecting a disinfection process and the Instructions for Use “Reprocessing of surgical and prosthetic products” (www.cmsa.ch/docs).

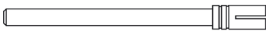
Pro-Snap
The fixation instrument (Cat. No. 07050008) is used for pressing the retention insert with stabilising ring into the housing.

Mini-Gerber PLUS
The special socket spanner (Cat. No. 072597) is used for tightening the threaded ring, activation and deactivation of the retention insert.



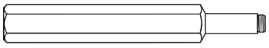
Transfer jig
Dalbo®-Z (Cat. No. 070157)
Pro-Snap (Cat. No. 07050005)
Eccentric (Cat. No. 070161) and for the male part with resilience (Cat. No. 070167)
Mini-Gerber PLUS (Cat. No. 072461)

Manipulation male part For fabricating the master model.



Parallelometer insert
Dalbo®-Z and Pro-Snap (Cat. No. 070131)
Mini-Gerber PLUS (Cat. No. 072460)

Used for the parallel setting of the male part in the parallelometer.



Heating rod
Mini-Gerber PLUS (Cat. No. 070605)

For extracting housings from the resin.

6 Indication

Removable, rigidly or resiliently anchored denture on root canal caps:
– Hybrid prosthetics
– Unilateral dentures, splinted transversally
– Partial and free-end dentures in combination

7 Contraindications

– Unilateral, partial and free-end dentures without transversal support.
– Restoration of severely periodontally damaged abutment teeth.
– Hybrid prostheses, which are restored with a single root canal cap.
– Lacking compliance of the patient with respect to correct follow-up / recall instructions.
– Patients with bruxism or other para-functional habits.
– In patients with allergies to one or more elements of the materials used in the product.
– Existing clinical picture in the patient's mouth does not permit the correct application of the products.

8 Compatible products

To fabricate the finished denture, a number of general laboratory supplies are required in addition to the products listed under Point 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 User qualification

The expertise of a professional dentist or dental technician is required. 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.

Only original tools and parts may be used for this work. For information and additional details, please contact your Cendres+Métaux SA representative.

Important information for the specialist

⚠ Warning symbol for increased caution

10 Prescription

Federal laws (USA) prohibit the use or sale by unlicensed dentists.

11 Side effects

⚠ This product may not be used in patients with allergies to one or more elements of the product materials. In patients with suspected allergy to one or more elements of the materials, this product may only be used following allergological clarification and proof of non-existence of an allergy.
Auxiliary instruments may contain nickel.
No known side effects if applied as intended.

12 Warnings

⚠ **Magnetic resonance 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

These Instructions for Use are sufficient for immediate application for the products described in this application area of the Instructions for Use. Dental or laboratory knowledge is required. Information: www.cmsa.ch/docs

14 Preventive measures

– Only original tools and parts may be used for this work.
– The product components are supplied non-sterile. For more information see Section 16 Reprocessing.
– Secure parts against aspiration.
– Before any procedure, ensure that all required product components are available in sufficient quantity.
– For your safety, always wear suitable protective clothing.
– The mechanical cleaning of the product using a toothbrush and toothpaste may lead to premature wear of the functional parts.
– It is essential to block out undercuts prior to polymerising the female part.
– No pre-treatment required, such as sandblasting or silanisation.of the housing of the female part.

15 Single use

Unless labelled otherwise, the product components are only intended for single use.
Products that are labelled for single-use are subject to a certain load during use, which can lead to wear, loss of function and/or malfunctions.

⚠ Re-use of products labelled as single-use products may compromise safety, function and performance.
Products for single-use have not been tested for re-use/reprocessing, which increases the risk of infection transmission.

16 Reprocessing

After any fabrication or modification and prior to use, the prosthetic work, including all system components, must be cleaned, disinfected and, if appropriate, sterilised. Materials made of metal alloys, high-performance polymers (Pekkton®) and ceramics are suitable for steam sterilisation, whereas components made of plastic other than Pekkton® are not suitable. 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 anchors are designed to fixate partial and full dentures on root canal caps in the maxilla and mandible.

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.

18 Procedure

18.1 Fabrication of the primary reconstruction

Work preparation
Wax-up of the root canal cap with the root canal post. In the case of several root canal caps, prepare the solder/laser surface at right angles to the direction of insertion. Use prefabricated, cast-on precious metal pins.

Twin caps
In the case of two consecutive root canal caps in the posterior region of a quadrant, the combined use of a rigid anchor and a resilient anchor is recommended. As a rule, the rigid anchor is placed on the anterior abutment and the resilient anchor on the posterior abutment, whereby the root canal caps must not be blocked. This effectively prevents rocking effects and overloading of individual abutments.

18.1.1 Inserting the male part by casting-on

Pro-Snap and Mini-Gerber PLUS
Using the parallelometer insert, set the male parts parallel to each other and as centrally as possible and wax it cleanly to the root canal cap. Then embed and cast. Allow to cool to room temperature (self-tempering). After devesting, the male part must not be blasted (dimensional changes). Clean in ultrasonic bath. Check functionality on the master model.

Only precious metal alloys may be used for casting-on.

18.1.2 Inserting the male part by soldering

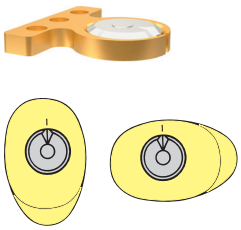
For soldering, separate the male part from the female part and, if multi-part, disassemble into its individual parts.

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

After thermal treatment (e.g. soldering, cast-on), slowly allow to cool to room temperature. The optimal mechanical properties are achieved allowing it to bench-cool to room temperature. Fit a duplication aid or spacer to protect the male part during sandblasting and processing.

Acid-treated parts glide better again if they are briefly placed in soapy water (ultrasound) after stripping.

Dalbo®-Z, Pro-Snap and Mini-Gerber PLUS
Using the parallelometer insert, set the male parts parallel to each other and as centrally as possible on the already cast and face-milled root canal cap and fix it with wax (take aesthetics into account). The solder gap should be continuous and between 0.05 – 0.20 mm wide. Design the soldering block, such that the male part is securely held and good flame access is ensured (angle by approx. 45°).
Recommended solders: S.G 810 (Cat. No. 01000348) and S.G 750 (Cat. No. 01000345).



Eccentric
The low construction height of this anchor allows positioning of the male parts without a parallelometer. The solder incorporated in the centre of the male part is sufficiently dimensioned to ensure a solder connection on the root canal cap.
Due to the slight protrusion of the pressed-in solder on the underside of the male part, the soldering process is additionally simplified by direct contact with the cap.
Place the male part on the root canal cap so that the marking points to occlusal and is aligned anteriorly at the same time. (Fig. 1). In case of several male parts in the same jaw, these must be aligned parallel to the median axis. A mark is now made on each root canal cap before soldering, which determines the position of the mark on the male part. Then remove the male part and apply a thin layer of soldering paste to the root canal cap. Replace the male part on the root canal cap, hold the root canal post with soldering tweezers and carefully solder over a soft Bunsen burner flame. After soldering, allow the work to cool to room temperature, then pickle, finish and polish. Functional check with the female part.

Alloy OSV
OSV must not be soft annealed or tempered after the soldering process (risk of fracture due to embrittlement of the alloy). If individual parts made of OSV are heated strongly, the oxide layer formed is quite difficult to remove by pickling. In such cases, the alloy is restored to its original appearance by treatment with the glass brush. Under no circumstances should the objects be treated with abrasive agents such as blasting sand or polishing pastes.

18.1.3 Inserting male part K by casting

Pro-Snap
Fill the cavity of the male part K with wax. Using the parallelometer insert, set the male part K as centrally as possible and wax it cleanly to the waxed-up root canal cap. After casting, polish the male part extremely carefully and set to the desired frictional power with the female part.

18.2 Fabrication of the secondary reconstruction (denture)

General information

Occlusal metal surfaces over the female parts ensure that they remain in the resin. As in the case of framework retentions which enclose the female parts like a basket, the female part is never soldered in place, even in the case of occlusal metal surfaces.

Block out the interpapillary spaces with cement, wax or Flexistone. Before polymerising the female part, protect the inside of the female part by applying some Vaseline to prevent resin from penetrating.

Dalbo®-Z, Eccentric
The tin spacer disc supplied with each female part enables vertical resilience. The soft spacer disc is placed over the entire root canal cap or anchoring element and adapted prior to polymerisation of the resin. After completion of the resin work, the spacer disc is removed again. Current clinical experience shows that the minimal vertical resilience disappears once the denture is placed. The greatest advantage is that the denture base is not overloaded on the root canal cap.

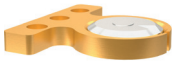
Dalbo®-Z
For the optimal function and protection of the lamellae, the mounted elastomer ring should not be removed in case of the Dalbo®-Z. If necessary, the elastomeric ring can be changed using the instrument for mounting of elastomeric ring (Cat. No. 070205) as follows:
1) Remove blue sleeve from the punch
2) Slip on several elastomer rings
3) Mount sleeve
4) By pushing the sleeve, the elastomer rings are pressed over the lamellae of the female part.
Do not re-use elastomer rings once they have been slipped on.

Fit the elastomer ring flush with the rim of the female part, so that the maximum retention can be used for the resin.

18.2.1 Inserting the female parts in the laboratory by polymerisation

Dalbo®-Z and Mini-Gerber PLUS
Block out the undercuts and interpapillary spaces with impression plaster, wax, Flexistone or a rubber dam.

Pro-Snap
To ensure unhindered rotational movement, place the green stabilising ring on the retention stud. The stabilising ring holds the housing in the most favourable position. Place the housing on the stud so that the edge is perfectly flush with the stabilising ring. The retention element of the Pro-Snap housing must not come into contact with monomer. Otherwise, the retention element must be replaced after completion. This also applies to relinings of the denture base.



Eccentric

The female parts must not be soldered under any circumstances.

All female parts in the same jaw must be aligned such that simultaneous opening and closing of the arms of the female part is ensured during insertion and removal of the denture. Prior to polymerisation, it is recommended to fix the female parts along the perforated retention with some autopolymerisate. Here, the opening of the retention arms must be at the position where the occlusal marking of the male part is located. Then block out the centre of the male part as well as the retention arms of the female part with a 1 mm thick layer of soft cement, wax or Flexistone. The occlusal surface, however, does not need to be covered.

Inserting of the female part with resilience:
To ensure resilience of the removable denture, the gingival tin spacer disc must be adapted to the root canal cap before polymerisation, the female part must be placed on the male part and finally the occlusal spacer disc must be bonded to the male part. Then block out the retention arms.

18.2.2 Inserting the female parts by bonding in the laboratory

Mini-Gerber PLUS
Place the duplication aid G on the male part, block out undercuts and duplicate the model (silicone type). After casting and finishing, clean the inner surface of the retention housing. Blast the outer surface of the female part as well as the model cast housing with Al_2O_3. Wax the female parts on the male parts and bond them into the framework. Use only suitable bonding agents.

18.2.3 Inserting the female part in the patient's mouth

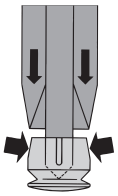
Dalbo®-Z and Mini-Gerber PLUS
Create sufficient space prior to inclusion in the denture body. Fixate the female parts in the mouth and block out the undercuts. If possible, drill an additional drainage canal through the denture body. With hybrid dentures, ensure that the root canal cap is not loaded. This prevents the denture from rocking after insertion.

Pro-Snap
The Pro-Snap housings can also be polymerised into the finished denture after cementing the root canal caps in the dental practice. For polymerisation of the denture in the laboratory, the protection cap (Cat. No. 07050004) is used instead of the female part. This leaves enough space in the denture for the housing. However, a hole must be drilled to lingual through the denture to allow the excess resin to drain off when polymerising in the mouth. Place the Pro-Snap housings with the green stabilising ring on the stud and seal at the base with wax so that no resin can penetrate. Also cover the root canal cap surface with a wax film and check that this does not interfere with the perfect fit of the denture. Fill the recess with cold polymer (not too thin) and insert the denture. After curing, remove the excess resin and polish.

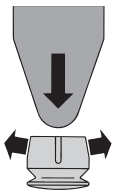
Make sure that no resin has flowed into the housing of the female part. If necessary, remove the resin carefully and without damaging it so as not to impair the function of the female part.

18.3 Activation and deactivation

18.3.1 Dalbo®-Z



Activation:
Press the four lamellae together evenly by applying light pressure with the activator provided for this purpose (Cat. No. 070197).



Deactivation:
Apply light pressure with the deactivator provided for this purpose (Cat. No. 070199) to spread the lamellae evenly without the female part breaking out of the resin.

18.3.2 Pro-Snap

The retention force is adjusted by exchanging the retention inserts. Three force levels are available. Retention insert yellow for “soft” red for “middle” and green for “strong”.

Changing the retention elements
The retention inserts are easy to replace by using a probe to pry them out of the Pro-Snap housing and then using the fixation instrument (Cat. No. 07050008) to reinsert the new retention inserts.

1. Place the blue fixation ring on the fixation instrument.
   Ensure that the wider edge of the ring rests on the step of the instrument.
2. Place the retention inserts (yellow, red or green) on the positioned blue ring and press lightly.
3. Firmly press the instrument with the attached plastic parts axially parallel into the empty housing. The click is clearly audible.

18.3.2 Eccentric

No product-specific instrument is available for adjusting the holding force of the female part. Use a suitable laboratory instrument for this purpose.

18.3.4 Mini-Gerber PLUS

Insert the special socket spanner (072597) into the threaded ring with hexagon socket. The retention force is increased continuously by approx. 300 grams per ¼ turn. The female part is set fricative by default with a retention force of approx. 300 g.
Note: The threaded ring features a special thread which prevents it from becoming loose by itself.

Replacing the retention insert G
Unscrew the threaded ring T from the housing using the special socket spanner, then carefully remove the retention insert G using a pointed probe. The internal thread of the female part must not be damaged in this process. Carefully reposition the new retention insert into the housing of the female part, insert the threaded ring T and readjust the desired retention force with the special socket spanner.

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

18.4 Follow-up

Retaining elements in prosthetic work are subject to considerable stress in the mouth in a constantly changing environment, and thus more or less subjected to signs of wear. Wear is omnipresent in daily routine 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 carried out if required to prevent rocking movement (overload). We recommend checking the denture at intervals of approx. 3 months initially and to replace the retention inserts if necessary.

18.5 Modifications, relining

Before taking the impression, preferably remove the old female part from the denture.

Mini-Gerber PLUS
The heating rod (072605) enables quick removal of a female part polymerised into the denture without damaging the denture. This is screwed into the housing of the female part and heated on the opposite end over the flame of a Bunsen burner until the resin around the female part becomes soft. When done, use pliers to pull the heating rod together with the female part out of the denture. In the case of a bonded female part housing, the temperature required to neutralise the adhesive's bonding strength is many times higher than that of female parts fixated with resin.

18.5.1 Impression taking

Always use the original female part for this purpose. Place the female part on the male part.
Block out the space between the female part and the male part with a little soft wax before taking the impression. Ensure an exact fit, parallelism of the insertion direction and correct alignment with the occlusal plane of the female part. Take a functional impression. Use a solid impression silicone. Check that the material is distributed completely around the female part and that no impression material has flowed into the female part, otherwise clean the male part and female part and repeat impression taking.

18.5.2 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.

18.5.3 Inserting the female parts

Details on this are described in Section 18.2 (Fabrication of the secondary reconstruction (denture)).

18.5.4 Insufficient denture retention – what to do:

1. Remove the denture and clean thoroughly. In particular, make sure that the anchoring elements are absolutely clean and free of contamination.
2. Check the denture to see if 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 a maximally activated female part, the primary reconstruction with the male part must be replaced.

18.6 Mini-Gerber PLUS, application of ring G

Initial situation:
In the case of fricatively set work with less than 200 g adhesion with the Mini-Gerber PLUS anchor, it cannot be ruled out that the threaded titanium ring may become loose on its own accord. Micro-movements in the patient's mouth can be considered as being the reason. To exclude this, ring G (Cat. No. 055759) made of Galak plastic can be used instead of the threaded titanium ring.
Note: Ring G is supplied without a thread. This is only cut into the housing when it is screwed in. This prevents becoming loose by itself.

Procedure:
First remove the titanium threaded ring using the special socket spanner (Cat. No. 072597). Then place ring G on the special socket spanner up to the stop. Then place in the opening of the housing and screw ring G into the housing while applying slight pressure. Ensure that a full turn is always performed clockwise and half a turn anticlockwise. If ring G comes to rest at the level of the inner edge of the housing, one can expect friction starting at approx. 100 g. Ring G can also be screwed deeper into the housing depending on the desired friction strength. The retention force of the female part can be checked by means of the transfer jig (Cat. No. 072461).
Note: If the ring is activated or deactivated several times, then a new ring G should be inserted.

19 Materials

C = Ceramicor; Au 60.0 %, Pt 19.0 %, Pd 20.0 %, Ir 1.0 %.
T_S – T_L 1400 – 1490°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

EL = Elasticor; Au 61.0 %, Pt 13.5 %, Ag 16.5 %, Cu 9.0 %.
T_S – T_L 950 – 1050°C

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

S.G 750; Au 75.0%, Pt 1.0%, Ag 11.7%, Zn 12.1%
T_S – T_L 700 – 745°C

V = Valor; Au 10.0%, Pt 89.0%, Ir 1.0%.
T_S – T_L 1660 – 1710°C

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

G = Galak; Mouth-resistant plastic

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

Detailed information on the materials and their classification is given in the specific material data sheets, the catalogue as well as the product list given in Table 1 in Point 29. See website www.cmsa.ch/docs or the Cendres+Métaux SA Dental Documentation (available free of charge from all Cendres+Métaux SA subsidiaries, branches and dealers).

20 Notes on storage

The product must be stored in a dry place in its original packaging, at room temperature and without direct sunlight, unless otherwise stated on the packaging. 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 patients are motivated and instructed according to their own abilities such as manual dexterity and vision with regard to the handling and care of their teeth and dentures.

Permanent and removable dentures are subject to considerable stress in the mouth in a constantly changing environment, and thus more or less subjected to signs of wear. Wear is omnipresent in daily routine 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

Ensure that the dentures do not tilt, as any tilting can lead to damage. Never insert dentures by biting the teeth together. This can lead to damage or even breakage of the connecting element. Further information on handling and aftercare of dentures is available in the patient information brochure at www.cmsa.ch/docs.

Insertion

Hold the dentures between the thumb and forefinger, and place them back into the mouth on the anchors. Search or feel for the correct insertion position and push the dentures onto the anchors with gentle, steady pressure. Carefully close your jaws and check whether the dentures are in the correct final position.

Removal

Hold the dentures between the thumb and forefinger, and slowly, carefully and steadily pull them off the anchors and remove them from the mouth.

21.3 Cleaning and care

We recommend cleaning your teeth and your dentures after every meal. Cleaning of dentures includes cleaning of the connecting element. The gentlest cleaning is achieved by cleaning the connecting element under running water with a soft toothbrush. The most intensive cleaning is achieved when cleaning the dentures in a small ultrasonic device and adding a suitable cleaning agent. Never clean the high precision connecting elements with toothpaste. This could lead to damage. Caution should also be exercised in the case of unsuitable cleaning agents or tablets. This could also damage the high quality connecting element or impair its function. Only clean the connecting parts on the other teeth or implants with water and a soft toothbrush as well as an interdental brush. Do not use toothpaste to avoid damage.

Pay attention to regular cleaning of the anchorage to prevent any inflammation of the soft tissue.
For information and additional tips on caring for the instruments see the website (www.cmsa.ch/docs).

For information and additional details, please contact your Cendres+Métaux SA representative.

22 Ordering information

More detailed information on the catalogue numbers, the number of products and their classification can be found in the product list under Point 29 in Table 1, the specific product catalogue, the packaging and, in the case of individual products, also directly on the product itself. You can find further information on the website www.cmsa.ch/docs or the Cendres+Métaux SA Dental Documentation (available free of charge from all Cendres+Métaux SA subsidiaries, branches and dealers).
For information and additional details, please contact your Cendres+Métaux SA representative.

23 Availability

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

24 Traceability batch number

The batch numbers of all parts used must be documented to ensure traceability. If different batch numbers are used for the products described in this application area of the Instructions for Use for the fabrication of dentures, all the batch numbers concerned must be recorded to ensure traceability.

25 Complaint

Cendres+Métaux SA must be notified immediately of any incident that has occurred with regard to the product to all branches, offices and dealers of Cendres+Métaux SA and, in case of serious cases, to the competent authority where the user is registered.

26 Safe disposal

The product 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:

Dalbo® / Elitor®

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. This product is part of an overall concept and may only be used or combined with the corresponding original components and instruments. Otherwise, the manufacturer rejects any responsibility and liability. In case of complaints, please always include the batch number.

The use of third party products not distributed by Cendres+Métaux SA in connection with the products listed in Table 1 will void any warranty or other express or implied obligations of Cendres+Métaux SA.

The user of Cendres+Métaux SA products is responsible for determining whether or not a product is suitable for a specific patient and a specific situation.

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 or installation of Cendres+Métaux SA products.

The user is also obliged to regularly study the latest developments of the Cendres+Métaux SA products listed in Table 1 and their applications.

Please note: the descriptions contained in this document are not sufficient for the immediate application of Cendres+Métaux SA products. Specialist knowledge of dentistry, dental technology and instructions in handling the products listed in Table 1 by an operator with appropriate experience is always required.

29 Product list

Table 1

Cat. No.	Product name	Material	Single use	Labelling	UDI-DI	Basic UDI-DI
	Dalbo®-Z					
050398	Dalbo®-Z OE	OSV / Elitor®	Yes	CE 0483	07640166513766	764016651000050DW
051507	Female part O	OSV	Yes	CE 0483	07640166513988	764016651000053E4
050273	Elastomeric ring (5 pcs.)	Elastomer	Yes	CE 0483	07640173091684	764016651000053E4
050394	Spacer disc Z tin (5 pcs.)	Tin	Yes	CE	07640166513759	764016651000028E5
050272	Male part E	Elitor®	Yes	CE 0483	07640166513698	764016651000050DW
070439	Spacer G	Galak	Yes	CE	07640173093619	764016651000026DZ
070157	Transfer jig	Steel	Yes	CE	07640166514404	764016651000032DU
070131	Parallelometer insert	Steel	No	CE	07640166514312	764016651000018E2
070205	Instrument for mounting of elastomeric ring	Steel	No	CE	07640166514534	764016651000016DW
070197	Activator	Steel	No	CE	07640166514497	764016651000003DM
070199	Deactivator	Steel	No	CE	07640166514503	764016651000003DM
070222	Attachment tweezers	Steel	No	CE	07640166514565	764016651000035E2
	Pro-Snap					
05050033	Pro-Snap TC yellow	Titanium / Ceramicor®	Yes	CE 0483	07640173090311	764016651000050DW
05050060	Housing T yellow	Titanium	Yes	CE 0483	07640173090694	764016651000053E4
05050034	Pro-Snap TC red	Titanium / Ceramicor®	Yes	CE 0483	07640173090328	764016651000050DW
05050061	Housing T red	Titanium	Yes	CE 0483	07640173090700	764016651000053E4
05050035	Pro-Snap TC green	Titanium / Ceramicor®	Yes	CE 0483	07640173090335	764016651000050DW
05050037	Male part C	Ceramicor®	Yes	CE 0483	07640173090564	764016651000050DW
05050062	Housing T green	Titanium	Yes	CE 0483	07640173090717	764016651000053E4
05050036	Pro-Snap TK yellow	Titanium / Korak	Yes	CE 0483	07640173090557	764016651000053E4
05050038	Male part K	Korak	Yes	n/a	07640173090571	n/a
05050060	Housing T yellow	Titanium	Yes	CE 0483	07640173090694	764016651000053E4
070131	Parallelometer insert	Steel	No	CE	07640166514312	764016651000018E2
07050004	Protection cap	Galak	Yes	CE	07640173090991	764016651000007DV
07050005	Transfer jig	Steel	Yes	CE	07640173091004	764016651000032DU
07050006	Stabilisation ring G (3 pcs.)	Galak	Yes	CE 0483	07640173091011	764016651000031DS
05050042	Retention insert G yellow (6 pcs.)	Galak	Yes	CE 0483	07640173090588	764016651000053E4
05050043	Retention insert G red (6 pcs.)	Galak	Yes	CE 0483	07640173090601	764016651000053E4
05050044	Retention insert G green (6 pcs.)	Galak	Yes	CE 0483	07640173090625	764016651000053E4
07050008	Fixation instrument	Galak	No	CE	07640173091547	764016651000001DH
	Eccentric					
050345	Eccentric ELO	Elasticor / OSV	Yes	CE 0483	07640173091172	764016651000050DW
050397	Eccentric ELO (with resilience)	Elasticor / OSV	Yes	CE 0483	07640173092100	764016651000050DW
050306	Female part EL	Elasticor	Yes	CE 0483	07640173091707	764016651000053E4
051002	Male part O with integrated solder (solder S.G.750)	OSV	Yes	CE 0483	07640173091189	764016651000050DW
051003	Male part O (resilience) with integrated solder (solder S.G 750)	OSV	Yes	CE 0483	07640173092117	764016651000050DW
050393	Spacer disc occlusal (5 pcs.)	Tin	Yes	CE	07640173092087	764016651000028E5
050392	Spacer disc gingival (5 pcs.)	Tin	Yes	CE	07640173092063	764016651000028E5
070161	Transfer jig	Steel	Yes	CE	07640173090007	764016651000032DU
070167	Transfer jig (with resilience)	Steel	Yes	CE	07640173090014	764016651000032DU
	Mini-Gerber PLUS					
055646	Mini-Gerber PLUS TV	Titanium / Valor	Yes	CE 0483	07640173093251	764016651000050DW
055686	Female part T	Titanium	Yes	CE 0483	07640173090885	764016651000053E4
055508	Retention insert G (5 pcs.)	Galak	Yes	CE 0483	07640173093183	764016651000053E4
055507	Threaded ring T	Titanium	Yes	CE 0483	07640173093176	764016651000053E4
055506	Male part V	Valor	Yes	CE 0483	07640173093169	764016651000050DW
055759	Ring G (3 pcs.)	Galak	Yes	CE 0483	07640173093312	764016651000053E4
072466	Duplicating aid G	Galak	Yes	CE	07640173093893	764016651000006DT
072461	Transfer jig	Steel	Yes	CE	07640173091073	764016651000032DU
072460	Parallelometer insert	Steel	No	CE	07640173091066	764016651000018E2
072597	Special socket key	Steel	No	CE	07640173091219	764016651000002DK
072605	Heating rod	Steel	No	CE	07640173091240	764016651000010DJ
070222	Attachment tweezers	Steel	No	CE	07640166514565	764016651000035E2

30 Symbols

	Important information for the specialist
	Warning symbol for increased caution

Labelling on packaging / symbols

	Date of manufacture
	Manufacturer
REF	Catalogue number
LOT	Batch code
QTY	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.
CE 0483 CE	Cendres+Métaux products with CE marking meet the requirements of the relevant European requirements.
	Do not re-use
	Non-sterile
	Keep away from sunlight
	Attention, observe accompanying documents
UDI 	Unique Device Identification – UDI
EC REP	European Authorised Representative
	Importer in EU
MD	Medical device

CENDRES+ MÉTAUX

Cendres+Métaux SA
Rue de Boujean 122
CH-2501 Biel/Bienne

Phone +41 58 360 20 00
Fax +41 58 360 20 15
info@cmsa.ch

Rx only

www.cmsa.ch

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