Instructions for use for

spherical ball 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.

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- or implant-supported removable dental prostheses.

Traceability of lot numbers

The lot numbers of all components must be recorded to ensure that they can be traced.

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.

Further hints

for processing precious metal alloys are available in the Dental documentation of Cendres+Métaux and in the Internet by visiting www.cmsa.ch/dental.



Pro-Snap



Profix



Pro-Snap TC



Pro-Snap TK



Profix EE



Profix EK

Rx only

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



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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.

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.

Pro-Snap

Housing Pro-Snap S = Syntax
Integration: resin-bonded or polymerized into place
Male part C = Ceramicor®
Integration: casting-on or soldering to precious metal alloy
Male part K = Korak
Cast with precious, non-precious or titanium alloys with a

minimum proof stress (Rp 0.2%) exceeding 500 N/mm²

Profix

Female part E = Elitor®

Integration: polymerising into place

Male part E = Elitor®

Integration: soldering

Male part K = Korak

Cast with precious, non-precious or titanium alloys with a minimum proof stress (Rp 0.2 %) exceeding 500 N/mm 2

Indications

Removable, rigidly or resiliently restorations supported on implants and root caps:

- Hybrid dentures
- Unilateral free-end dentures locked transversally
- Insertion/free-end dentures in combination

Contraindications

- 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.

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).

$E = Elitor^{\circ}$

Au 68.60 %, Pt 2.45 %, Pd 3.95 %, Ag 11.85 %, Cu 10.60 %, Ir 0.05 %, Zn 2.50 % $T_{\rm S}-T_{\rm I}$ 880 – 940 $^{\circ}{\rm C}$

C = Ceramicor®

Au 60.00%, Pt 19.00%, Pd 20.00%, Ir 1.00%

 $T_s - T_L 1400 - 1490 \,^{\circ}C$

TE (25-500°C) 11.9 x 10-6 K-1 (25-600°C) 12.2 x 10-6 K-1

S = Syntax TiAl6V4 (grade 5)

Ti > 89.478%, AI 6.00%, V 4.00%

K = Korak

Non-residual burnout plastic for use when casting

Instructions

Integration of the male part

Take an index of the temporarely set up denture teeth. After wax removal determine the most favorable position to place the retention knob. Incorporate the retention knob into the waxedup overdenture coping and cast. A guiding pin, available on request, facilitates properly linedup ball-sockets. After trimming, protect the knob with the special protection cap (Order No. 070131) during polishing (enclosed), the surface thus stays unaltered and ensures the retention strength within the housing.

Soldering

For soldering, embed in a block of soldering investment and border the knob only slightly, in order that the solder can pass without hindrance. To avoid getting solder on the knob's base, apply some antiflux paste Stopor (Order No. 08052181) during preheating and soldering only heat the metal coping. Cool at room temperature; afterwards pickle the object.

Casting-on the Korak male part

Use the paralleling mandrel to position the male part as centrally as possible and wax it onto the root cap as neatly as possible. After casting, polish the male extremely cautiously and set the desired friction with the female part.

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 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

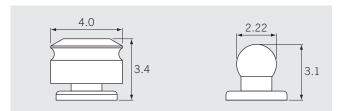
These red parts are slightly overdimensioned compared to the original parts. The result is an optimal gap for the resin-bonding technique.

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.

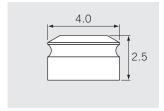
Spacer disc

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.

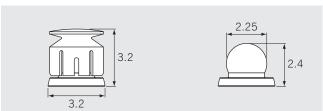
Note: Do not put the spacer in tin in the mouth.



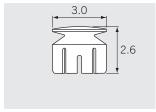
Pro-Snap



Housing Pro-Snap



Profix



Female part Profix

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).

Polishing

After trimming, protect the knob with the special protection cap (Pro-Snap Order No. 07050004, Profix Order No. 070440) during polishing (enclosed), the surface thus stays unaltered and ensures the retention strength within the housing.

Pro-Snap:

Preparing for processing

Place housings on to the Snap polymerisation accesory using the enclosed green stabilizing ring. Remove enough wax to allow for a recess large enough in order to position the housing and refit the waxed up denture on to the model. In case the nylon retention element come in contact with acrylic monomer, it is recommended they be replaced with new ones. Use the transfer jig to prepare the master model (Order No. 07050005).

Note: A detailed, partiallike frame, reinforced around the housings may be caste in chrome to add strengh to the prosthesis.

Sucorporations or exchanging the housing in the mouth

The housings, even after cementing the overdenture copings can be mounted chairside by the practitioner on to an existing prosthesis. In cases such as this a new denture would have been preprocessed in the lab. with the protection cap (Order No. 07050004) mounted to provide the needed space to later incorporate the housing. A drainage, providing an escape for excess resin, is drilled lingually into the housing. Mount the housing (using the green stabilizing ring) on to the retention knob. Continue with the application of a thin film of wax to the overdenture copings to prevent the resin from penetrating. The applied wax coating should pose no hindrance to the proper seating of the denture. Fit the denture onto the housing using a selfcuring resin (not to liquid). After setting of the resin trim and polish as usual.

Exchange of retention elements

The used retention elements are easily removed from the housing with an explorer and replaced with new ones using the seating tool (Order No. 07050008).

- 1. Place blue retaining ring on the seating tool, ensuring that the larger diameter is set against the shoulder of the seating tool.
- 2. Place the retention element (yellow, red or green) on top of the blue retaining ring exerting moderate pressure.
- 3. Press the seating tool squarely into the female housing until it snaps into position.

Profix

Preparation for resin mounting

To ensure unimpeded rotational movement, adjust the 0.40 mm spacer (Order No. 050394) as it will keep the housing in the best position. Place the housing with plastic ring on the knob so that the edge ends perfectly with the foil. To prevent resin penetration, the housing can be sealed with a thin layer of silicone or similar material. When packing on the duplicate model, place the housing on the transfer jig (Order No. 070157) (when fabricating the duplicate model, reposition the transfer jig in the housing remaining in the impression). This should also be done when relining the denture base. After curing, remove silver foil and trim any resin residues from the housing. The plastic ring (Order No. 055688) should not be removed.

Sucorporations or exchanging the housing in the practice

The housings, even after cementing the overdenture copings can be mounted chairside by the practitioner on to an existing prosthesis. In case such as this a new denture would have been preprocessed in the lab. With the Spacer G (Order No. 070440) mounted to provide the needed space to later incorporate the housing. A drainage, providing an escape for excess resin, is drilled lingually into the housing. Mount the housing with plastic ring on to the retention knob. Continue with the application of a thin film of wax to the overdenture copings to prevent the resin from penetrating. The applied wax coating should pose no hindrance to the proper seating of the denture. Fit the denture onto the housing using a self-curing resin (not to liquid). After setting of the resin trim and polish as usual.

Adjusting the retentive force

Use the appropriate instrument (Order No. 070197 or 070199) to exert gentle pressure and press the eight lamellae together uniformly or spread them making certain not to break the female part out of the resin. After use, clean the instruments with water and disinfect.

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

REF

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 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