

Instructions for use

Roach ball joint

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With the publication of these instructions for use all previous Editions are no longer valid.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

Hinges: general guidelines

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.

Twin crowns

Two splinted abutment crowns per quadrant located on a mutual frontal plane are ideal for supporting and retaining hinged unilateral and bilateral free-end dentures.

Metal occlusal surfaces

Metal occlusal surfaces above female parts assure that they remain in the resin. As when using retainers which embrace the female, the female must never be soldered into place.

Dismantling the attachments

Separate the male and female parts before thermal treatment (casting-on, soldering, hardening and ceramic firing) and, if they consist of several components, dismantle them.

Pickling

Pickled parts slide better, if they are placed in soapy water (ultrasonic bath) after pickling.

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.

Further hints

For processing precious metal alloys, soldering and casting-on are included in the Dental documentation of Cendres+Métaux.

Warnings

Allergies

This product must not be used for patients known to be allergic to one or several of the elements contained in the attachment materials. Should the patient be suspected of being allergic to one or several of the elements contained in any one attachment, this product can only be used after preliminary allergological testing and proof that no allergy exists.

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.

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

DK

Female part

Integration: Polymerisation

Male part

Non-residual burnout plastic for the casting technique

D = Doral

K = Korak

Components

Plastic insert

Mouth resistant plastic

G = Galak

Indications

- Stress-broken unilateral and bilateral free-end dentures
- Short or long-span denture saddles with a transverse framework

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.
- Unilateral free-end dentures without transverse blocking

Characteristics

The Roach ball joint was developed specifically for unilateral or bilateral free-end, non-precious alloy appliances. As the male part burns out fully, any alloy can be selected.

Equipment and components required for correct processing

Parallelometer, accessories and instruments. Refer to the Dental documentation of Cendres+Métaux.

Instructions for use

Important! Three-dimensional parallelism

To guarantee the rotational movement of the removable denture, the Roach ball joints must be parallel to one another in all three dimensions (vertical, sagittal and horizontal).

In the **upper jaw**, the Roach ball joint must be placed parallel to the **median line** (Figure 1).

In the **lower jaw**, the Roach ball joint must be placed on the **bisecting line B** between the alveolar ridge **C** and median line **A** (Figure 2).

Fitting male part K

Wax up the fixed restoration. Use the parallelometer insert (070 146) to position the male.

The extension on the paralleling mandrel (Figure 3) serves three purposes:

The bottom edge of the extension indicates the predicted height of the female part (A), the bottom edge of the paralleling mandrel is 1 mm shorter than the original female which can be positioned as low as possible and its underside adapted to the contours of the gingivae. The extension also indicates the predicted length and position of the original female when placing the male (Figure 4). Invest and cast. To ensure that the cast male is sufficiently strong, the alloy must exhibit an 0.2% proof stress of at least 500 N/mm². Once the male has been devested, it must not be sandblasted (dimensional changes). Clean ultrasonically. Check that the ball joint functions properly on the master model.

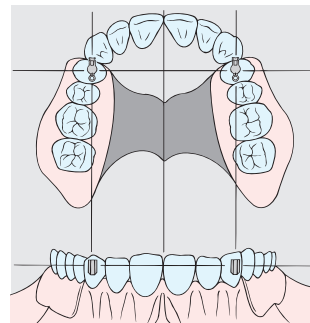
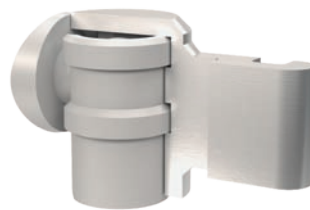


Fig. 1

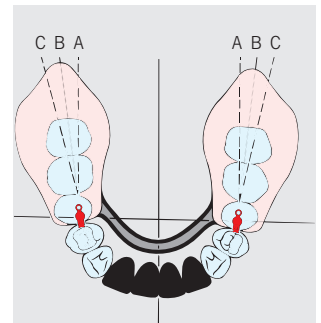


Fig. 2

D = Doral

Ag 49.3%, Pd 20.0%, Au 15.0%, Cu 13.7%, Ru 2.0%

Fitting female part D to removable dentures

To adapt the female part to the gingival contours, its underside can be reduced by up to 1.5 mm. The female must be on the ball (A) to ensure that the distance between it and the gingivae (B) can be adapted as required (Figure 5). The female should then be aligned using the rod (080363), taking the angle of insertion into account and either polymerized directly into the denture saddle or soldered to the chrome cobalt framework.

Replacing the friction insert

We recommend replacing the friction insert once a year at the routine checkup. Replacing the insert reduces the risk of damage to the male part by particle deposits in the plastic, e.g. from toothpaste.

Removing the friction insert

Place the scalpel blade between the plastic sleeve and the wall of the female part and lift up the friction insert towards the mesial opening. Once the friction insert has been removed, it should not be reused, as it may have been irreversibly damaged on removal.

Service Set Plastic-Roach

(Order no. 05000058)

In addition to the standard white insert (Order no. 051999), two other friction inserts are available as Service Set. Each Service Set contains 5 green (strong friction) and 5 blue (extra-strong friction) inserts. They are intended to restore the retentive function of the denture that has been lost through years of natural wear and tear. In case of premature wear and tear, it is essential to identify and solve the problem as early as possible in order to guarantee a durable restoration.

Modifications / relines

When modifying or relining the denture, the transfer jigs (070515) should be placed on the working model in place of the female parts.

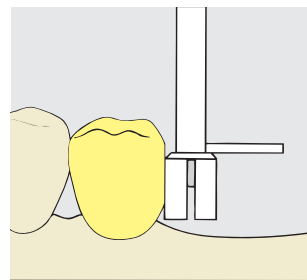


Fig. 3

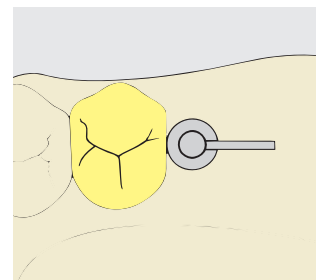


Fig. 4

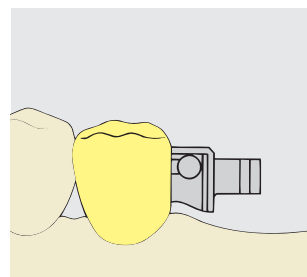


Fig. 5

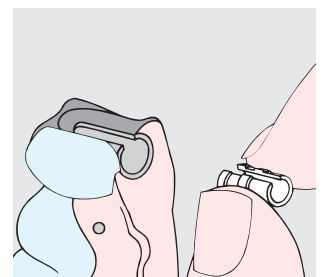


Fig. 6

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 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