Roach ball joint

Instructions for use

Hinges

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With the publication of these instructions for use all previous Editions are no longer valid.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 lots numbers, all relevant lots 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 parts made of plastic must be disinfected with a high EPA-registered disinfectant prior to use.

Recommended: $\mathsf{Cidex}^\circledast$ OPA Solution. Strictly follow manufacturer's instructions.

Further information

on processing precious metal alloys, soldering and casting-on are included in the Dental documentation of Cendres+Métaux and in the website www.cmsa.ch/dental.

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.

The following items contain nickel:

070196 Activator 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.



Phone +41 58 360 20 00 Fax +41 58 360 20 11 info@cmsa.ch The products carry the CE Mark. See packaging for details.

Roach ball joint

Female part Integration: Casting-on Male part Integration: Casting-on C = Ceramicor[®]

C = Ceramicor®

Indications

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

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 dentures without transverse bracing
- Insertion dentures

Characteristics

The simple design and minimal space requirements of the Roach ball joint are impressive and indicate it especially for transverse blocking.

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 joints must be placed parallel to

the **median line** (Figure 1). In the **lower jaw**, the Roach ball joints must be placed on the **bisecting line B** between the alveolar ridge **C** and median line **A** (Figure 2).

Important!

To enable the friction to be adjusted as required (Figure 3), the male parts must always be positioned so that their activation slots and holes are upright.

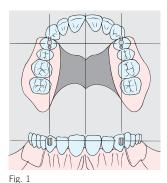
Fitting male part to a fixed restoration

Determine the angle of insertion taking the three-dimensional parallelism into account, place male part C on the wax pattern with the parallelometer insert (070145), wax the male into place and cast precious alloy onto it.

Fitting the female part to a removable denture

The female part must be polymerized into the removable denture. To provide for adequate retention, solder a spade-shaped, curved wire retainer to the back of the female in advance. A casting can also be used to fabricate an occlusal stop for the male.





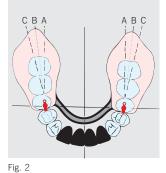






Fig. 3

 $\begin{array}{l} \textbf{C} = \textbf{Ceramicor}^{\$} \\ \text{Au } 60.0\,\%, \, \text{Pt } 19.0\,\%, \, \text{Pd } 20.0\,\%, \, \text{Ir } 1.0\,\% \\ \text{T}_{\text{s}} - \text{T}_{\text{l}} \,\, 1400 {-} 1490^{\circ}\text{C} \end{array}$

Roach ball joint

Fitting the female part for use as a transverse brace for unilateral free-end saddles

Determine the angle of insertion taking the three-dimensional parallelism into account and use a parallelometer insert (070121) to integrate the female part into the wax pattern of the fixed restoration and wax the female into place. Female should be located interdentally, opposite the free-end saddle. To provide for adequate self-cleansing, the underside of the female must not be closed off. Cast precious alloy onto the female.

Fitting the male part for use as a transverse brace

Once the inner framework has been cast onto the female part and finished, insert male part into it and block out all undercuts. Ensure that the stop plate remains free of wax. Duplicate the master model and complete the wax pattern of the chrome cobalt restoration, taking the male into account. Once the chrome cobalt restoration has been trimmed, the male

part can be soldered to the upright intended for it.

Activation

The friction can be increased by carefully activating the male part with the activator (070196). To do so, insert the two tips into the holes at the top and bottom of the activation slots and turn the knurled screw clockwise to tighten them.

Modifications / relines

When modifying or relining the denture, the transfer jigs (070222) should be placed on the working model for the reconstruction of the position of the female parts.

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
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

Non-sterile

Keep away from sunlight

Caution, consult accompanying documents