CENDRES+ MÉTAUX

prosthetic.line

# Hinged Joints

Mini-Dalbo® and Tecnoroach

# Instructions for Use Hinged Joints
## Mini-Dalbo® and Tecnoroach

### 1 Scope of application of Instructions for Use

These Instructions for Use apply to the products listed under Section 29. 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 Section 29.

### 3 Intended use

The products are intended for prosthetic restorations and to support procedures in the dental clinic or laboratory.

### 4 Expected clinical benefit

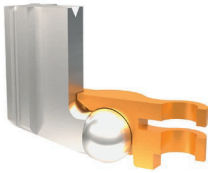
Restoration of chewing function and improved aesthetics.

The Summary of Safety and Clinical Performance, SSCP for the implantable devices covered by these Instructions for Use, is available on our website and accessible at this address: https://www.cmsa.ch/docs.

### 5 Product description

**Hinged Joint**

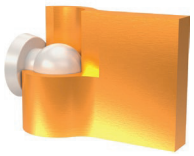
A hinged joint (from the group of attachments) is a prosthetic retaining element consisting of a female (outer) part and a male (inner) part. The male part is firmly connected to an abutment tooth, the female part is inserted into the removable denture. In contrast to an attachment, which creates a fixed connection of the denture with the remaining teeth, the hinge joint with a free-end denture allows rotational movement in a dorsal direction and thus prevents a possible damaging load on the abutment teeth.



**Mini-Dalbo®**
The Mini-Dalbo® is an extracoronal, retentive snap hinge joint with the option of retention force adjustment.

Activation is performed by pressing the two lateral lamellae of the female part together.

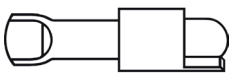
Two material versions are available:
Mini-Dalbo® EC: cast-on male part C, housing E can be polymerised
Mini-Dalbo® DK: male part K castable, housing D can be polymerised



**Tecnoroach**
The Tecnoroach is an extracoronal hinge joint with the option of retention force adjustment. The male part is only available in burn-out resin, which is burned out in the laboratory during fabrication of the crown.

Available in one material version:
Tecnoroach EK: male part K burn-out, housing E can be polymerised, bonded or soldered.

**Auxiliary parts and instruments**



**Transfer jig**
Mini-Dalbo® (Cat. No. 070176)
Tecnoroach, not available.

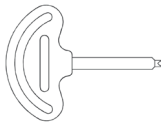
Manipulation male part for fabricating the master model.

a)

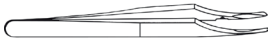
b)


**Parallelometer insert**
a) Mini-Dalbo® (Cat. No. 070146)
b) Tecnoroach (Cat. No. 072507)

Is mounted in a parallelometer device.
Is used to set the male part in the correct position and in parallel (3D parallelism).



**Activator**
Mini-Dalbo®, not available
Tecnoroach (Cat. No. 072505).



**Tweezers** (Cat. No. 070222)

Simplifies separation and mounting of the attachment.

### 6 Indications

Dental-gingival supported dentures:
– Free-end denture

## 7 Contraindications

– Unilateral free-end denture
– Unilateral free-end dentures without hinged transversal support
– Combined partial denture with an insertion denture and a free-end section
– Patients who are unable to keep the regularly required check-up appointments for health reasons.
– Patients with bruxism or other para-functional habits.
– Patients with allergies to materials used in the product, see Section 19.
– 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 Section 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 stain 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 investment |
| 08052307 | Legabril Diamond (50 g) |

## 9 Qualification of the specialist

Expertise in professional dentistry and dental technology is assumed. 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.

Important information for the specialist

⚠ Warning symbol for increased caution

## 10 Prescription

Federal laws in the USA prohibit the use by or sale to unlicensed dentists.

## 11 Side effects

⚠ This product must not be used in patients with allergies or suspected allergies to materials used in the product (see Section 19), or only after prior allergological clarification.
Auxiliary instruments may contain nickel.
If applied as intended, side effects can be excluded.

## 12 Warnings

⚠ **Magnetic resonance (MR) 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

N/A

## 14 Preventive measures

– The product components are supplied non-sterile. For more information see Section 16 "Reprocessing".
– Only original tools and parts may be used for this work. For information and additional details, please contact your Cendres+Métaux SA representative.
– Before any procedure, ensure that all required product components are available in sufficient quantity.
– For your own safety, always wear suitable protective clothing. In particular when grinding, we recommend wearing protective goggles and a dust mask as well as the use of a suction unit.
– Secure parts against aspiration.
– The mechanical cleaning by patients with a toothbrush and toothpaste may lead to premature wear.

## 15 Single use

Products that are intended for single use and are labelled "single-use" accordingly are subject to a certain amount of stress, increased wear, and even loss of functionality during their use.

⚠ Multiple application of products labelled "single use" was not tested. This can impair the safety, function and performance of the products as well as increase the risk of transmitting infections.

## 16 Reprocessing

The prosthetic work, including all system components, must be cleaned, disinfected and, if appropriate, sterilised prior to each work step.
Materials made of metal alloys, high-performance polymers (Pekkton®) and ceramics are suitable for steam sterilisation. With the exception of Pekkton®, components made of plastics are not suitable for steam sterilisation.
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 hinged joint is designed to fixate a free-end denture on crowns or bridges in the maxilla and mandible. The hinge function protects the abutment teeth against overloading.

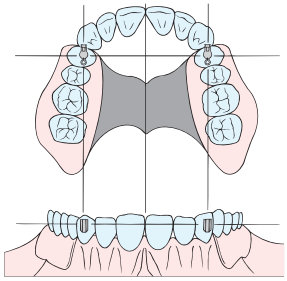
## 18 Procedure

**Tooth preparation**
A hinged joint does not require a special procedure for preparation. Minimally invasive crown preparation can be performed.

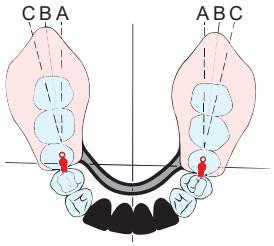
**Denture design**
We recommend that the denture be designed such that the largest possible support can be achieved on the alveolar ridge.

**Double crowns**
In joint prosthetics, two splinted abutment crowns (double crowns) form an ideal prerequisite for supporting and fixating the free-end denture.

**3D parallelism**
To ensure joint movement of the denture, the male parts must be aligned with each other in three-dimensional parallelism (vertical, sagittal and horizontal).



In the maxilla, the male parts are set parallel to the median plane.




In the mandible, the male parts are placed on the bisector B between the alveolar ridge C and the median plane A.

**Denture frameworks**
Cast transpalatal plates, bands and sublingual brackets are used as transversal connectors. Here it is important that such prosthetic frameworks are absolutely rigid and not elastic.

**Thermal treatment**
The male and female parts must be separated prior to thermal treatment (casting-on, soldering, lasering, curing and ceramic firing) and, if consisting of several parts, disassembled into their individual parts. Subsequently allow to cool slowly to room temperature. Thus the optimal mechanical properties are achieved without a tempering process.

## 18.1 Fabrication of the primary reconstruction

**Work preparation**
Preparation of the master model.
When modelling the wax frameworks, make sure that the framework thickness is at least 0.5 mm to achieve sufficient stability.

A simple parallelometer is required for 3D parallel setting of the male part.

The male parts must not be ground or cleaned with abrasive blasting media.

### 18.1.1 Inserting the male part by casting-on Mini-Dalbo®

Only use precious metal alloys for casting-on.

After modelling the wax framework, the degreased male part is positioned and waxed down with the respective parallelometer insert in the most ideal insertion direction for the patient and considering 3D parallelism to each other.
Invest, cast and allow to cool slowly to room temperature without any tempering process.

### 18.1.2 Inserting male part K by casting Tecnoroach

Proceed as described under Point 18.1.1.
After devesting, the male part must not be blasted (dimensional changes). Clean the cast ultrasonically and polish the male part carefully with a rotary brush without changing the profile of the male part. Check and adjust functionality on the master model.

The quality of the male part fabricated in the dental manufacturing process depends on the choice of material and processing technique. It has a decisive influence on the functional capability and durability of the denture. To obtain sufficient strength in the cast male part, the casting alloy used must have a 0.2% yield strength of at least 500 N/mm$^2$.

## 18.2 Fabrication of the secondary reconstruction (denture)

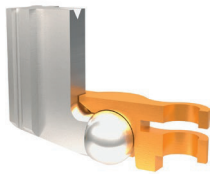
Before polymerising the female part, protect the inside of the female part by applying Vaseline to prevent resin from penetrating.

Before polymerising the female part, block out the lamellae of the female part on the outside (in the activation area) in such a manner that access is possible with the activator or instrument.

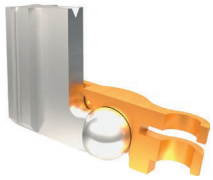
**Tecnoroach**
The female part can be shortened basally by max. 1⁄3 of its total length to adapt to the contour of the alveolar ridge.

### 18.2.1 Inserting the female part by polymerisation

**Mini-Dalbo®**



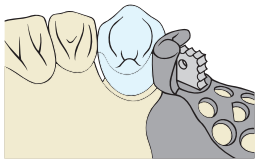
Position at rest



Hinge movement

Under no circumstances should the female part be soldered on, so that the properties of the alloy, which are tailored to optimum lamella function, are not altered. The female part is placed on the balls of the male part in the resting position. Block out all undercuts, the slots of the activation lamellae as well as the outside in the area of the activation slots with wax. This prevents denture resin from penetrating the housing of the female part during polymerisation, thus providing lamella clearance as well as enabling activation/deactivation of the lamellae. The retention attached to the end of the housing guarantees perfect fixation in the denture saddle. Modelling of the framework. If space is limited, a metal masticatory surface can be modelled over the female part as additional protection.
Casting and finishing.

**Tecnoroach**

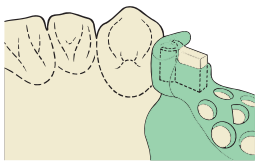


Place the female part, which may, if necessary, be adapted to the alveolar ridge contour, and block out the legs along their entire length and the undercuts. Creating the duplicate model. When modelling the framework, place an occlusal stop on the ball to prevent the denture from sinking. After fabrication of the denture framework, the retention of the female part must be fitted with notches and a hole for additional splinting before the female part is polymerised into the denture saddle.

### 18.2.2 Inserting the female part by soldering

**Mini-Dalbo®**
The female part must not be soldered on.

**Tecnoroach**



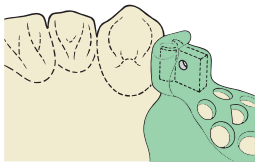
Place the female part, block out the legs along their entire length and the undercuts. Creating the duplicate model. The retention of the female part is included in the wax-up from the basal side so that 1⁄3 of the occlusal retention still remains free for later soldering. When modelling the framework, place an occlusal stop on the ball to prevent the denture from sinking.

**Divesting and cleaning**
For reasons of fit, blasting is not allowed in the area of the inner housing of the female part. Cleaning in ultrasonic bath.

### 18.2.3 Inserting the female part by bonding

**Mini-Dalbo®**
The female part may only be bonded to the housing retention.

**Tecnoroach**



Place the female part, block out the legs along their entire length and the undercuts. Creating the duplicate model. The finely blocked-out retention is fully incorporated into the wax-up to obtain an adhesive housing. A self-drilled hole through the retention of the female part and the model cast housing allows additional splinting of the connection. When modelling the framework, place an occlusal stop on the ball to prevent the denture from sinking.

**Bonding**
Blast the bonding seam of the model casting (CoCr) with 250 µm and the female part with 50 µm $Al_20_3$. Do not blast the inside of the female part so as not to impair the function. Thoroughly clean the surfaces to be bonded with the steam jet and do not touch again. Before bonding the female part, protect the inside of the female part by applying some Vaseline to prevent adhesive from penetrating. Mount the female part and block out the undercuts with wax. Apply a thin layer of adhesive to both surfaces to be bonded without bubbles and join them together.
Please observe the information provided by the manufacturer of the adhesive.

## 18.3 Activation and deactivation

### 18.3.1 Mini-Dalbo®

No product-specific instrument is available for adjusting the holding force of the female part. For this purpose, use a suitable, flat laboratory instrument by carefully bending the two lateral lamellae inwards or outwards to increase or reduce retention.

### 18.3.2 Tecnoroach

An activator specifically developed for the Tecnoroach (Cat. No. 072505) is available for activation. The activator is placed at the front, on the open side of the female part. The two lamellae of the female part are carefully pressed together. As the lamellae are solid, this requires a certain amount of pressure. Due to the extremely stable design of the female part, deactivation in the mouth is practically impossible.

## 18.4 Modifications, relining

### 18.4.1 Impression taking

Provided that the fit of the female part on the male part is correct, use some soft wax or silicone to block out the cavity between the gingiva and the underside of the male part before taking the impression. Take a functional impression. Use a solid impression silicone.

### 18.4.2 Model fabrication

**Mini-Dalbo®**
To fabricate the model, the transfer jig (Cat. No. 070176) is used for reconstructing the position of the male part by inserting it into the female part and fixating it securely. Then proceed with fabrication of the master model.

**Tecnoroach**
No auxiliary part is available for model making.
Coat the inside of the female part with a very thin layer of wax before making the model. Use a fracture-resistant model material, e.g. a polyurethane resin.

## 19 Materials

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

**D = Doral**; Au 15.0%, Pd 22.0%, Ag 49.3%, Cu 13.7%
$T_S$ – $T_L$ 930 – 1015°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.

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

More detailed information on the materials as well as their compositions can be found in the product-specific material data sheets, the product information as well as the product list compiled in Section 29. All relevant documents can be found on the website www.cmsa.ch/docs by entering the relevant product name.

## 20 Notes on storage

Insofar as no specific information on storage is given on the packaging of the product, we recommend storing the product in its original packaging, in a dry place, at room temperature and without direct sunlight. 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 the patients are motivated and instructed with regard to caring for their teeth as well as dentures.

Permanent and removable dentures are subject to considerable stress. Signs of wear are normal 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

It should be ensured that the dentures do not tilt, as any tilting can lead to damage. The denture should never be inserted by clenching the teeth, as this can damage or even break the connecting element.

**Insertion**

The denture can be placed on the anchor elements in the mouth using the thumb and index finger. Then it is correctly positioned on the anchoring elements applying gentle, even pressure. By carefully closing the jaws, it is possible to check whether the denture is in its correct final position.

**Removal**

For removal, the denture can be grasped with the thumb and index finger and carefully pulled from the anchor elements and taken out of the mouth.

## 21.3 Cleaning and care

**Material Doral (D)**
Do not use cleaning agents which contain corrosive components.
This could lead to discolouration, stress corrosion cracks and fracture of the female part D.

We recommend cleaning teeth and dentures after every meal. Cleaning of dentures includes cleaning of the connecting element. Gentlest cleaning can be achieved by cleaning the restoration under running water with a soft toothbrush and the connecting element in the mouth with an interdental brush. The most intensive cleaning of the restoration is achieved with the aid of an ultrasonic device and a cleaning additive suitable for dentures.
Never clean the high precision connecting elements with toothpaste as this could lead to damage. Caution should also be exercised in the case of aggressive cleaning agents or tablets as this could damage the high-quality connecting element or impair its function.

Regular cleaning of the anchorage can prevent inflammation of the soft tissue.

## 22 Ordering information

The information relevant to your order can be found in the product list in Section 29 of this document. The product information is also helpful. This and other relevant documents can be found on the website www.cmsa.ch/docs by entering the relevant product name.

## 23 Availability

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

## 24 Traceability of the lot number

The lot numbers of all parts used must be documented to ensure traceability.

## 25 Complaint

Cendres+Métaux SA must be notified immediately of any incident that has occurred with regard to the product. To do this, please contact your customer advisor or send us your message by e-mail to the address complaints-cmbrand@cmsa.ch. In serious cases, also send a report to the competent authority where you are domiciled.

## 26 Safe disposal

The products 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:

Ceramicor® and 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. Cendres+Métaux SA products are parts of an overall concept and may only be used or combined with the appropriate original components and instruments. Otherwise, the manufacturer rejects any responsibility and liability. In case of complaints, please always include the lot number.

The use of third party products not distributed by Cendres+Métaux SA in connection with the products mentioned in the product list in Section 29 will void any warranty or other express or implied obligation of Cendres+Métaux SA.

Responsibility regarding the suitability of a product for the specific patient case is at the discretion of the specialist.

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 of Cendres+Métaux SA products.

The specialist is obliged to regularly study the latest developments of the products mentioned in the product list in Section 29 and their applications.

It should be noted that the descriptions contained in this document are not sufficient for the immediate application of Cendres+Métaux SA products. Expertise in dentistry, dental technology and instructions by an experienced specialist in the use of the products mentioned in the product list under Section 29 is always necessary.

In case of inconsistencies in translations, the English language version shall prevail.

## 29 Product list

| Cat. No. | Product name | Material | Single use | Labelling | UDI-DI | Basic UDI-DI |
|---|---|---|---|---|---|---|
| | **Mini-Dalbo®** | | | | | |
| 050701 | Mini-Dalbo® EC | Elitor®/Ceramicor® | Yes | CE 0483 | 07640166513841 | 764016651000051DY |
| 051659 | Mini-Dalbo® DK | Doral/Korak | Yes | CE 0483 | 07640173090755 | 764016651000067EF |
| 050697 | Female part E | Elitor® | Yes | CE 0483 | 07640166513827 | 764016651000067EF |
| 051662 | Female part D | Doral | Yes | CE 0483 | 07640173092995 | 764016651000067EF |
| 050960 | Male part C | Ceramicor® | Yes | CE 0483 | 07640166513865 | 764016651000051DY |
| 051617 | Male part K | Korak | Yes | n/a | 07640173092926 | n/a |
| 070176 | Transfer jig | Steel | Yes | CE | 07640166514466 | 764016651000032DU |
| 070146 | Parallelometer insert | Steel | No | CE | 07640166514374 | 764016651000018E2 |
| 070222 | Attachment tweezers | Steel | No | CE | 07640166514565 | 764016651000035E2 |
| | **Tecnoroach** | | | | | |
| 055411 | Tecnoroach EK | Elitor/Korak | Yes | CE 0483 | 07640173090854 | 764016651000067EF |
| 055410 | Female part E | Elitor® | Yes | CE 0483 | 07640173092131 | 764016651000067EF |
| 055409 | Male part K | Korak | Yes | n/a | 07640173092124 | n/a |
| 072507 | Parallelometer insert | Steel | No | CE | 07640173091202 | 764016651000018E2 |
| 072505 | Activator | Steel/plastic | No | CE | 07640173091196 | 764016651000003DM |

## 30 Labelling on packaging / symbols

| | |
|---|---|
|  | Date of manufacture |
|  | Manufacturer |
| REF | Catalogue number |
| LOT | Lot number |
| 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 labelling meet the requirements of the relevant European requirements. |
|  | Do not re-use |
|  | Non-sterile |
|  | Protect from sunlight |
|  | Attention, observe accompanying documents |
| UDI  | Clear product identification |
| EC REP | European Authorised Representative |
|  | Importer |
| MD | Medical device |

CENDRES+ MÉTAUX


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

Phone +41-58-36020-00
Fax +41-58-36020-15
info@cmsa.ch

Rx only

www.cmsa.ch