

Dolder® System female parts (for bar attachment and resilient bar)

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06.2015

Instructions for use

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 bars manufactured by Cendres+Métaux SA serve as connectors for tooth- or implant-supported removable dental prostheses.

In general

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.

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: Cidex® OPA Solution. Strictly follow manufacturer's instructions.

Disinfection of deactivators

070200 Deactivator (Dolder® micro) und 070201 Deactivator (Dolder® macro) must not be sterilised. When sterilising the above deactivators in the autoclave, there is a possibility that their plastic handles may be destroyed.

It is therefore advisable to disinfect according to the section «Disinfection» of these instructions for use.

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.

Further hints

Further information on soldering, casting on, laser welding etc. can be accessed on our website at www.cmsa.ch/dental in the **Products/Shop, Information** section.

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

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The 5 female parts concept

- Female part micro and macro (Fig. 1a) E = Elitor®**
Version: **standard**
Fitting: polymerized
Lengths: 25 and 50mm
Indication: bar attachment and resilient bar
Female part micro and macro (Fig. 1b) D = Doral
Version: **standard**
Fitting: polymerized
Lengths: 50mm
- Female part asymmetrical micro and macro (Fig. 2) E = Elitor®**
Version: **asymmetrical**
Integration: polymerized or resin-bonded
Length: 30mm
Indication: bar attachment and resilient bar
- Female part asymmetrical micro and macro (Fig. 3) T = Pure titanium**
Version: **asymmetrical**
Integration: polymerized or resin-bonded
Length: 30mm
Indication: bar attachment and resilient bar
- Female part micro and macro (Fig. 4) T = Pure titanium**
Version: **standard**
Integration: polymerized or resin-bonded
Length: 50mm
Indication: bar attachment and resilient bar
- Female part micro (Fig. 5) T = Pure titanium**
Version: **comfort, with replaceable retention inserts** G = Galak
Integration: polymerized or resin-bonded
Length: 47.5mm (space for 12 friction inserts)
Indication: bar attachment

Auxiliary parts

Friction inserts

G = Galak

Brass spacer

Micro 50x0.75mm (Order No. 052080)

Macro 50x1.05mm (Order No. 052081)

Indication: ensures vertical resilience of the denture and discharges bar extensions.

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

Contraindication

- 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 after-care/recall instructions.
- Patients with bruxism or further uncontrolled para-functional habits.

E = Elitor®

Au 68.60 %, Pt 2.45 %, Pd 3.95 %, Ag 11.85 %, Cu 10.60 %, Ir 0.05 %, Zn 2.50 %
T_s – T_L 880–940°C

D = Doral

Au 15.00 %, Pd 22.00 %, Ag 49.30 %, Cu 13.70 %
T_s – T_L 930–1015°C

T = Pure titanium

G = Galak

mouth-resistant plastic

Note: Not all components/materials are available in all countries. Please contact your sales agent for information about the availability of the products.

Dolder® System female parts (for bar attachment and resilient bar)

Instructions for use

Female parts 1, 2, 3, and 4

The female parts can be used on prefabricated bars in gold, titanium and cast materials. Gold alloys, titanium and non-precious metal alloys are suitable as casting materials. The casting alloy used should have a 0.2% proof stress of at least 500 N/mm² to ensure that the cast male part has adequate strength.

1. Female part E, micro and macro (Fig. 1a, 1b)

The bar sleeve is adjusted throughout the length of the bar to achieve maximum possible retention force (Fig. 6). Remove flash inside and outside. So that the bar sleeve can be securely anchored in the plastic, it must not be shorter than 5 mm. Mount bar sleeve onto male part, then block out the space between bar and gingiva as well as implant caps or root caps. Half of the lamella height should remain free-moving. This allows access for the activation instrument and reduces premature wear (Fig. 7). The retention wings of the bar sleeve can only be bent once and with extreme caution in order to avoid breaking them off. Polymerize bar sleeve into the denture or into the cast reinforcement.

2. Female part asymmetrisch E, micro and macro (Fig. 2)

3. Female part asymmetrisch T, micro and macro (Fig. 3)

The bar sleeve is adjusted throughout the length of the bar to achieve maximum possible retention force (Fig. 6). Remove flash inside and outside. So that the bar sleeve can be securely anchored in the plastic, it must not be shorter than 5 mm. Mount bar sleeve onto male part, then block out the space between bar and gingiva as well as implant caps or root caps. Half of the lamella height should remain free-moving. This allows access for the activation instrument and reduces premature wear (Fig. 7). The asymmetric retention of the bar sleeve can be ground back, e.g. for insertion of a cast reinforcement (Fig. 8). Polymerize bar sleeve into the denture or bond into the cast reinforcement.

4. Female part T, micro and macro (Fig. 3)

The bar sleeve is adjusted throughout the length of the bar to achieve maximum possible retention force (Fig. 6). Remove flash inside and outside. So that the bar sleeve can be securely anchored in the plastic, it must not be shorter than 5 mm. Mount bar sleeve onto male part, then block out the space between bar and gingiva as well as implant caps or root caps. Half of the lamella height should remain free-moving. This allows access for the activation instrument and reduces premature wear (Fig. 7). The retention wings of the bar sleeve can be ground back only for sectioning. Polymerize bar sleeve into the denture or bond into the cast reinforcement.

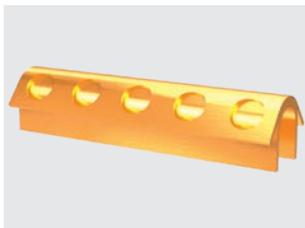


Fig. 1a



Fig. 1b

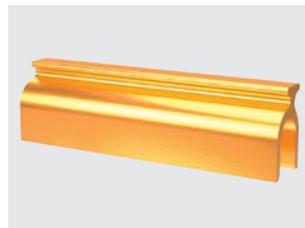


Fig. 2



Fig. 3



Fig. 4

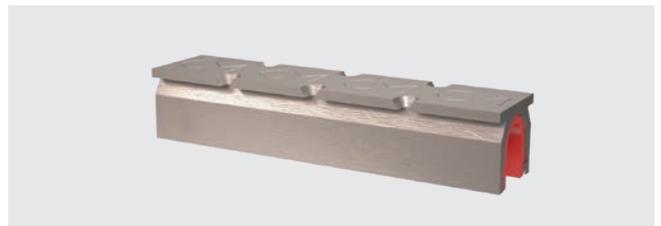


Fig. 5

Dolder® System female parts (for bar attachment and resilient bar)

Female parts 1, 2, 3 and 4

Activation / Deactivation bar sleeve

The posterior lamella, which is subjected to greater loading, is activated (Fig. 9). The anterior lamella acts as a guide surface. The relevant activator from the Activation Set (Order No. 070198) is used to push the sleeve carefully inwards for activation. The deactivator (Order No. 070200 micro sleeve, 070201 macro sleeve) is pushed into the sleeve to deactivate an excessively tight bar sleeve until the required friction is attained (Fig. 10).

5. Female part T (with replaceable friction inserts G) (Fig. 5)

Six yellow (light friction) and six red (normal friction) friction inserts are supplied with the bar female part. The length of the bar female part can be shortened every 3.5 mm using the separating groove. The groove is also used as a guide for the cut-off wheel when separating (Fig. 11). Remove any flash (Fig. 12) with a rubber polisher after separating. After fitting the friction inserts, place the female part on the bar and block out the space between the bar and the gingiva as well as the root and implant caps (Fig. 13) and then resinbond or polymerise into place.

Fitting the plastic insert

Place the friction insert G on the insert positioner (Order No. 07000034) (Fig. 14). Apply a little pressure by pressing on the female part to find the correct position of the friction insert (Fig. 15). As soon as the insert engages in the groove (clearly audible), push the friction insert in to its final position (Fig. 16). The insert makes an audible click when it engages. Several inserts, even inserts with different degrees of friction, can be used depending on the amount of retention force required (Fig. 17). Only a few inserts, the ones with minimum friction, should be used for 2–4 weeks so that the patient can quickly become accustomed to handling the new restoration.

Note:

- Do not use the friction inserts used for laboring the denture for the patient.
- Newly fitted friction inserts:
- The inserts may become displaced laterally after fitting. After a day in situ they adjust to their correct position and can no longer become displaced.
- The correct retention force is attained after about two weeks. The retention force is slightly higher initially.
- Do not re-use friction inserts once they have been used.

Removing the plastic insert

Press the two ends of the lamella together with tweezers (Order No. 070347). This disengages the insert from the retention and allows it to be easily removed.

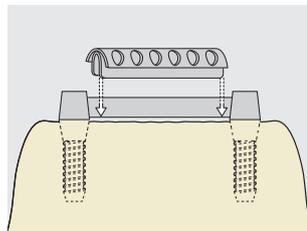


Fig. 6

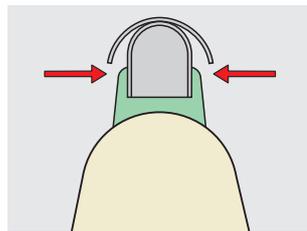


Fig. 7

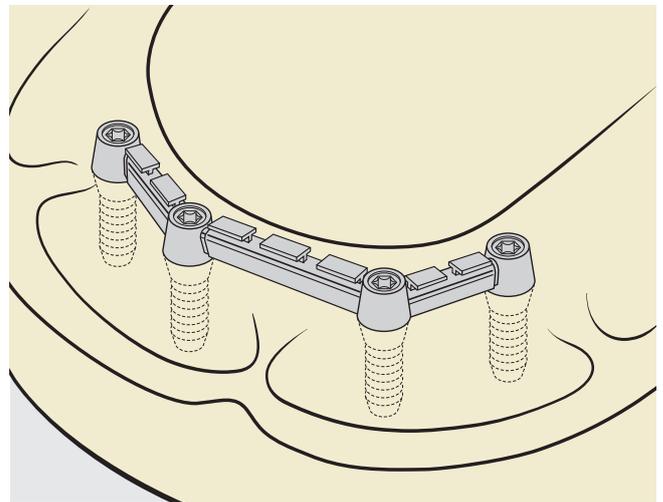


Fig. 8

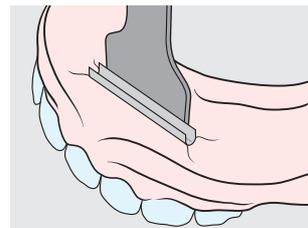


Fig. 9

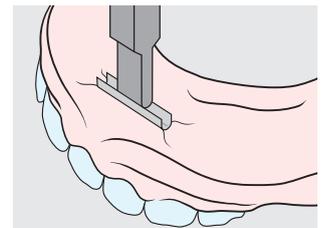


Fig. 10

Dolder® System female parts (for bar attachment and resilient bar)

Activation

Three different sizes of friction inserts are available for adjusting the friction.

Yellow (Order No. 05000394) **Smooth friction**

Red (Order No. 05000395) **Normal friction**

Green (Order No. 05000396) **Strong friction**

Note: The retention force depends on the number of friction inserts used.

Aftercare

Retentive units in prosthetic restorations are subjected to very high loading intraorally in a continually changing milieu and consequently to a varying degree of wear and tear. Though wear and tear occurs during normal use and cannot be avoided, it can be reduced. The extent to which it can be reduced depends on the system. Our aim is to use optimally coordinated materials so that wear is reduced to an absolute minimum.

The denture should be checked at least once a year to ensure it fits optimally on the mucosa and should be relined if necessary to eliminate rocking (overloading), particularly in the case of free-end dentures. We recommend replacing the friction insert (unit subject to wear) at the annual checkup as a precautionary measure.

Modifications / Relines

Should the denture require modifying or relining, place the transfer jig (Order No. 070171 micro or 070173 macro) on the working model to take the place of the bar.

Relining procedure

1. Block out any undercuts on the bar
2. Coat the denture with adhesive for silicone impressions
3. Take the impression
4. Position the transfer jig in the female part
5. Cast the models (plane line articulator)
6. Remove the silicone from the denture. Check the female part for damage and replace it with a new female part if necessary
7. Roughen the underside of the denture
8. Place the female part on the transfer jig
9. Block out any undercuts on the bar and the adjustable lamellae of the female part (Fig. 7)
10. Apply separating agent to the model
11. Pack the acrylic
12. Trim the denture

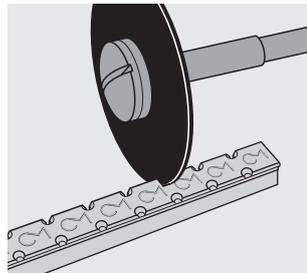


Fig. 11

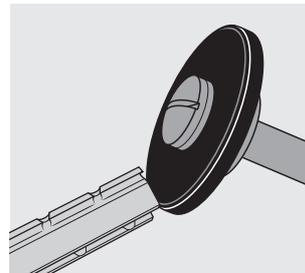


Fig. 12

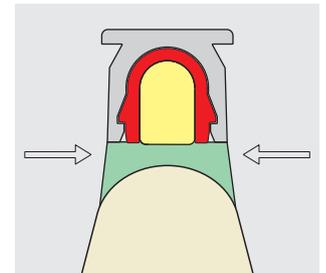


Fig. 13

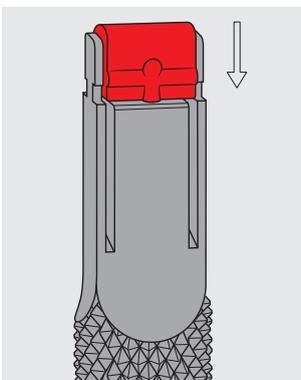


Fig. 14

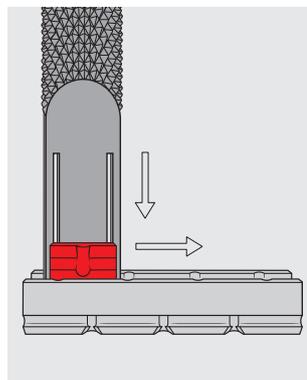


Fig. 15

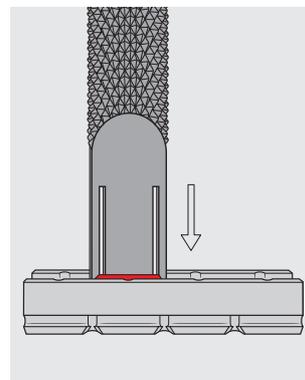


Fig. 16

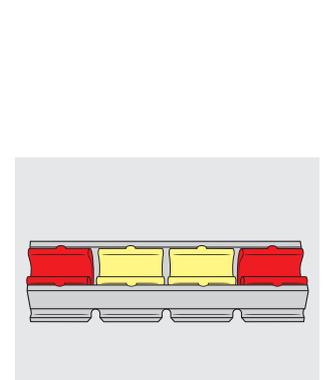


Fig. 17

Dolder® System female parts (for bar attachment and resilient bar)

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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. |
|  | |
|  | Non-sterile |
|  | Keep away from sunlight |
|  | Caution, consult accompanying documents |