

prosthetic.line

Bars

Dolder® System, round bar with rider
and Ackermann-Bar

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Instructions for Use Bars

Dolder® System, round bar with rider and Ackermann-Bar

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

Bar

A bar is a prosthetic retaining element consisting of a female (outer) part and a male (inner) part. The male part is fixated on at least two anchor elements, tooth and/or implant. The female part is polymerised into the removable denture. One can distinguish between round, oval and parallel-walled bar male parts according to their cross-sectional shape. Round, and to a lesser extent oval bars, allow their bar riders to rotate around the bar axis so that good stability is ensured and the masticatory pressure is transferred to the alveolar ridge by the rotation, thus reducing the load on the anchor elements. Parallel-walled bars, on the other hand, do not allow rotation and are selected if at least three anchor elements are available or if purely tooth/implant-supported borne superstructures are desired.

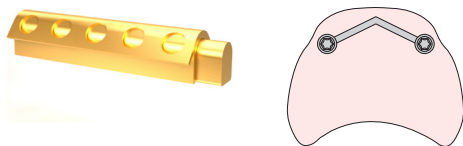
Bar-splinted, well-fitting implants can be restored immediately with the denture without having to wait for osseointegration, provided that the implant manufacturer permits this application. By splinting periodontally weakened teeth, the burden on the roots is reduced by downsizing the lever arm. Dentures on bars are extremely stable.

5.1 Dolder® System

The Dolder® bar system according to Prof. Dr. E Dolder comprises two bar concepts, the bar attachment and the bar joint. Available in two sizes, micro and macro. The Dolder® bar is the original and the reference in bar prosthetics.

Dolder® Bar

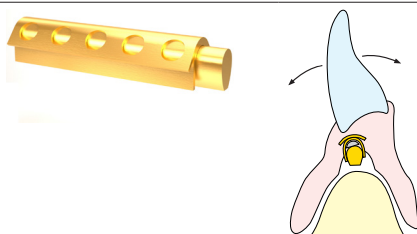
The bar can be soldered or lasered onto root caps, anchor crowns or implant superstructures, or cast in a cast alloy with sufficient strength using a fully burn-out mould.



Dolder® Bar Attachment

The bar attachment is a rigid anchoring element without any degrees of freedom.

The cross-sectional shape is parallel-walled for a rigidly supported denture on anchor elements. The bar attachment is applied when several teeth are joined together or when two teeth cannot be joined together by a straight bar (see diagram).

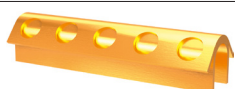


Dolder® Bar Joint

The bar joint with an oval cross-section is a dynamic anchorage element for hybrid dentures, which enables three degrees of freedom (translational and rotational movements). The fabrication of the bar joint denture requires that two teeth or implants in the anterior zone (mandible and maxilla) can be connected via a straight bar. This is the only way to guarantee function of the joint. In addition, vertical translation of the removable denture can be incorporated. For this purpose, the spacer for polymerisation is placed between the bar and the female part.

Dolder® Female Parts

The female parts on the Dolder® bar joint and Dolder® bar attachment are of identical construction. Three material variants are available. They can be individually cut to the desired length of the male part.



Dolder® Bar Female Part in Elitor® (E)

The original form and the classic for bar restorations.

The high-quality, durable yellow-gold precious metal alloy Elitor® features optimal properties tailored to the function.

The female part can be activated.

Available in the lengths 25 mm and 50 mm.

Insertion: polymerisation.



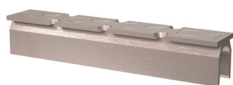
Dolder® Female Part in Doral (D)

The precious metal alloy Doral is a slightly less expensive alternative to the alloy Elitor®, and features comparable properties.

The female part can be activated.

Available in a length of 50 mm.

Insertion: polymerisation.



Dolder® Female Part in Pure Titanium (T)

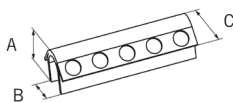
The cost-effective female part solution made of high-quality titanium.

The female part can be activated.

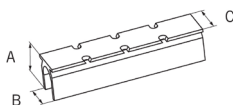
Available in a length of 50 mm.

Insertion: polymerisation or bonding.

Variant E, D



Variant T



Dimensions						
Material	Variant	L = overall length	A = height	B = width	C = width of retention	
		mm	mm	mm	mm	
E	macro L25	25.00	3.30	2.80	4.60	
E	micro L25	25.00	2.75	2.10	3.60	
E	macro L50	50.00	3.30	2.80	4.60	
E	micro L50	50.00	2.75	2.10	3.60	
D	macro L50	50.00	3.30	2.80	4.60	
D	micro L50	50.00	2.75	2.10	3.60	
T	macro L47.5	47.50	3.60	2.90	3.60	
T	micro L47.5	47.50	2.80	2.20	2.80	

Dolder® Male Parts (Bar Attachment, Bar Joint)

Elitor (E)

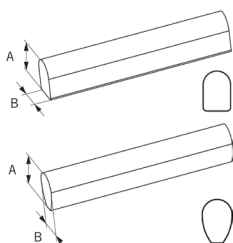


Each available in two material versions:

Male part E: can be soldered or lasered.

Male part K: burn-out (delivery unit: pack of 2)

Korak (K)



Dimensions				
Material	Variant	L = overall length	A = height	B = width
		mm	mm	mm
E	macro L50	50.00	3.00	2.20
E	micro L50	50.00	2.30	1.60
K	macro L75	75.00	3.00	2.20
K	micro L75	75.00	2.30	1.60



Casting to Elitor® is not possible.



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/mm².

5.2 Round Bars

The round bar profile permits space-saving, individual adaptation to the contour of the alveolar ridge. The bar can be soldered or lasered to implant caps, root caps or anchor crowns.

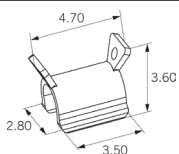


Round Bar with Rider

The diameter of the male part of the round bar is 1.9 mm.

Female Parts (Rider)

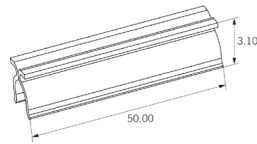
Two female part concepts are available in the alloy Elitor®. The high-quality, durable yellow-gold precious metal alloys feature optimal properties tailored to the function.



Female Parts E

This female part has a length of 3.5 mm. The female part can be activated, but not shortened.

Insertion: polymerisation.



Female Parts E L50

This female part is available in a length of 50 mm and can be individually cut to the desired length of the male part.
The female part can be activated.

Insertion: polymerisation.

Elitor® E



Korak (K)



Male Parts

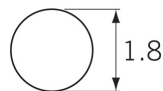
Two material versions are available:

Male part E: can be soldered or lasered. Available in the lengths 50 mm and 200 mm.
Male part K: burn-out. Available in a length of 75 mm. (Delivery unit: pack of 2 pieces)



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/mm².

5.3 Ackermann-Bar

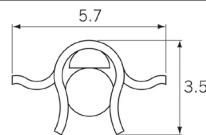
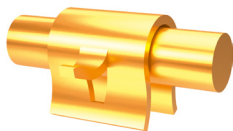


The diameter of the male part of the round bar is 1.8 mm.

Female Parts (Rider)

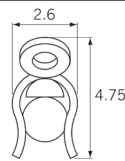
Two different female part concepts are available in the precious metal alloy Elitor®.

The female part can be activated.



Female Part Ackermann-Bar A

The two retentions for fixation in the denture resin are aligned anteriorly and posteriorly in cases where little space is available occlusally.



Female Part Ackermann-Bar B

The two retentions for fixation in the denture resin are generously dimensioned and designed occlusally.



Male part

Available in one material version:
Male part P3: can be soldered.

Available in the lengths 50 mm and 200 mm.

5.4 Auxiliary parts and instruments



Spacer

- Enables vertical resilience of the denture.
- Compensates for the sinking in of dental-supported dentures when storing after new fabrication or relining.
- Relieves the load on the male part of the bar in the case of bar extensions.

Integration between female part and bar during polymerisation of the resin, the spacer is then removed again.

Dolder® System

- macro 50 x 1.05 mm (Cat. No. 052081)
- micro 50 x 0.75 mm (Cat. No. 052080)

Material: Brass

Round Bar with Rider

- 50 x 0.60 mm (Cat. No. 052082)
- 200 x 0.60 mm (Cat. No. 052085)

Material: Tin

Ackermann-Bar

- micro 50 x 0.75 mm (Cat. No. 052080)

Material: Brass



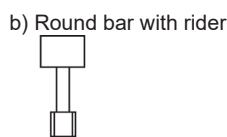
The spacer must not be used intraorally to insert the female part.



The spacer is included with the male part of the Dolder® bars.
For the two round bars, the spacer is included with the female parts.



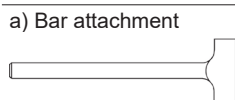
Transfer jig
Manipulation male part for fabricating the master model.



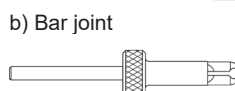
a) Dolder® System
– macro L50 (Cat. No. 070173)
– micro L50 (Cat. No. 070171)

b) Round bar with rider (Cat. No. 072293)

Ackermann-Bar
Not available.

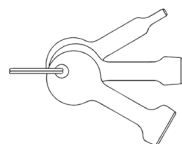


Parallelometer insert
Is mounted in a parallelometer device.
Is used to set the male part in the correct position and in parallel.

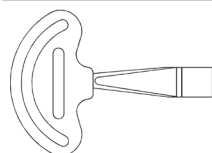


a) Dolder® Bar Attachment
– macro (Cat. No. 070144)
– micro (Cat. No. 070143)
b) Dolder® Bar Joint
– macro (Cat. No. 072517)
– micro (Cat. No. 072515)

Round bar with rider and Ackermann-Bar
Not available.



Activator set (Cat. No. 070198)
Serves to activate the lamellae of the female parts of the Dolder® system, the round bar with rider and Ackermann-Bar.



Deactivator
Serves to deactivate the female parts of the Dolder® system.
– macro (Cat. No. 070201)
– micro (Cat. No. 070200)

6 Indications

- Removable dental prostheses (definitely)**
- Tooth and combined tooth-mucosa supported dentures
 - Implant and implant-mucosa supported dentures
 - Combined implant-tooth supported dentures
 - Dolder® bar attachments and round bars:
 - Removable partial denture
 - Free-end removable partial denture
 - Hybrid denture
 - Dolder® bar joint:
 - Hybrid denture

7 Contraindications

- Partial denture without transversal support.
- Hybrid denture supported on a single anchor element (crown, root canal cap or implant).
- 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	08055014	Livento® invest powder (50 x 100 g)
08052135	Polyurock Catalyst	083739	Livento® invest liquid (1000 ml)
08052137	Polyurock Mixer	080181	CM soldering investment (4 kg)
08052149	ABF Wax Universal	080229	CM soldering investment
08052150	ABF Wax Creativ light	08052307	Legabril Diamond (50 g)
08052151	ABF Wax Creativ dark		
08052154	ABF Wax Special		
08052148	ABF Wax Margin		
08052153	ABF Wax Position		
08052152	ABF Wax Tecno		

The female parts of the bar may also be used on CAD/CAM fabricated bars, provided that the dimensions of the male parts of the bar specified in Section 5 are adhered to within a tolerance of +/-0.02 mm.

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

A bar is designed to fixate a removable denture in the maxilla or mandible on splinted implants, root caps or crowns.

18 Procedure**18.1 Fabrication of the primary reconstruction**

The male part of the bar is already soft annealed when delivered.



Soldering or lasering of prefabricated bars to abutment crowns made of non-precious metal alloys is not recommended (risk of corrosion).



The male and female parts of bars must be separated prior to thermal treatment.

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.

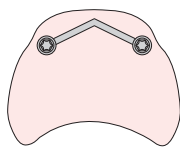
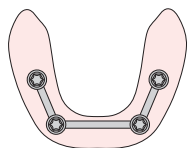
Screw on implant caps for work on the bar. For natural teeth, fabricate a root canal cap and/or anchor crown. In the case of crowns, sufficient space must be provided for correct soldering or lasering.

We recommend that the teeth are already set up before the bar is fabricated so that placement can be realised under optimal aesthetic and functional conditions.

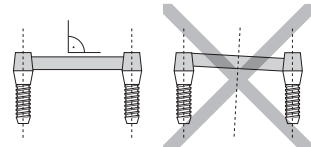
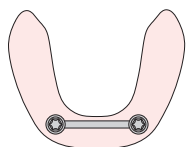
18.1.1 Fitting the bar

Dolder® System

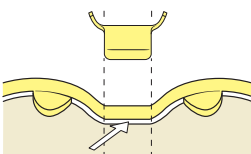
Using the parallelometer insert matching the bar profile, the male part of the bar is fixated tension-free parallel to the occlusal plane, the abutments and the contour of the alveolar ridge in the physiologically most favourable position to the abutment elements with adhesive wax or burn-out autopolymerisate. Minimum distance to the gingiva is 1.00 mm. The solder gap should be in the range of 0.05 - 0.20 mm. Check with overcast.

**Dolder® Bar Attachment**

If an angle is desired, proceed as follows: saw first, file the angle, bend and fixate with adhesive wax.


**Dolder® Bar Joint**

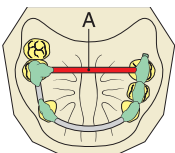
To maintain the function of rotation, this bar must not be bent or placed at an angle under any circumstances.

**Round bar**

Adapt the round bar individually to the contour of the alveolar ridge. The distance between the bar and the mucosa should be large enough so that a fitted rider does not come into contact with the mucosa. Check with overcast.

When adapting the round bar by bending, straight zones with a minimum length of 4 mm must be left to be able to position the bar riders.


 To avoid damage to the round bar, do not use sharp-edged bending pliers and bend the bar slowly.

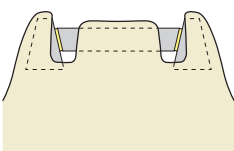
18.1.2 Fabrication of the soldering block

Fixate the finished adapted male part of the bar on or to the abutment elements with adhesive wax or burn-out autopolymerisate. Check position of the bar with the overcast. Ensure that the connections of the bar to the primary parts are adequately dimensioned. In the case of U-shaped bar constructions, a small wooden stick (toothpick / A) can be waxed on in the posterior area for additional stabilisation. Carefully lift the bar splinted with the abutment elements from the model and make a soldering block with solder investment material.

18.1.3 Soldering

 For abutments made of burn-on alloys or for large spans, we recommend furnace brazing in a ceramic furnace.

 Observe the instructions of the ceramic manufacturer with regard to cooling in the case of burn-on alloys.



Wash out the adhesive wax or remove the autopolymerisate. While the soldering block is still warm, apply sufficient CM soldering paste (Cat. No. 080229) to the soldering point and preheat the soldering block at 500°C in a preheating furnace for 10 - 15 min.

Solder recommendation:

First solder: S.G 810 (Cat. No. 01000348)

Second solder: S.G 750 (Cat. No. 01000345)

Furnace soldering

After preheating in the preheating furnace and while the soldering block is still warm, wet the soldering point again with sufficient CM soldering paste. Immediately place the soldering block in the preheated (500°C) ceramic furnace. The heating rate should be 50°C/min. so that the entire soldering block is heated evenly. The final temperature must be set 50 - 70°C higher than the liquid temperature of the solder. Maintain the final temperature for 1 minute so that the solder can wet the base material properly. Then allow the work to cool slowly in the soldering block (optimum mechanical properties).

Flame soldering

After preheating in the preheating furnace and while the soldering block is still warm, wet the soldering point again with sufficient CM soldering paste. Then heat the solder object with the flame to the working temperature of the solder. The flame must not be removed from the solder object (risk of oxidation). Apply the solder coated with solder paste to the solder gap and hold the flame on the opposite side. This allows the solder to flow towards the warmer zone. After soldering is completed, heat the entire soldering block again evenly and allow the work to cool slowly (optimum mechanical properties).

Soldering of crowns

To prevent the solder joint from becoming a vulnerable point, we recommend modelling the end of the bar approx. 0.5 mm into the wax crown wall or placing it on a small protrusion. If neither are given, a gold wire bent into a U-shape can be brought into contact with the cast crown wall via the bar before soldering to enlarge the soldering area.

Soft annealing and curing

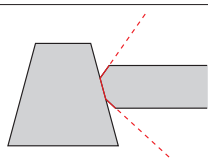
If the soldering block is cooled slowly to room temperature, this process is not necessary.

However, if required, the work can be quenched and tempered retrospectively as follows:

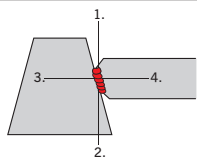
1. Soft annealing: 700°C / 10 min / then quench with H₂O
2. Hardening: 400°C / 15 min / cool slowly

18.1.4 Laser welding

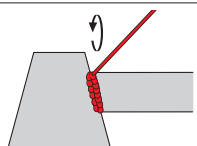
Ideally, only identical materials should be joined together as a matter of principle. Later failures can thus be reduced to an absolute minimum. A parallelising and fixation device for the laser technique as well as the respective parallelometer insert can be used to align the bar profile.



To create a stable laser welded seam, the connecting surface of the corresponding bar profile must be adapted in a V-shape using a carbide cutter.



To avoid stress in the welding area, fixate the bar crosswise beforehand. Then weld the bar in a circular manner. Always make sure to alternate with a counterpoint on the opposite side. Each bar is first connected to only one implant abutment. Only then come the remaining ends.



Fill the connecting area from the centre towards the outside when adding the jointing material. Then smooth the laser welding spot.
Male part of the bar E (Elitor®) with laser welding wire LW N°5 (Cat. No. 01000361)

Thermal treatment after laser welding

The bar made of Elitor® is soft annealed when delivered. The hardness of the laser weld is approx. 190 HV5 as it is an extremely fast cooling material. To ensure that the laser welding spots and the bar achieve optimum mechanical properties after laser welding, the workpieces must be thermally treated after laser welding as follows:

1. Soft annealing: 700°C / 10 min / quenching with H₂O
2. Hardening: 400°C / 15 min / cool slowly

18.1.5 Etching

Oxidation resulting from soldering or laser welding can be etched with 10 vol. % warm sulphuric acid (H₂SO₄). Do not etch with nitric acid (HNO₃) or hydrochloric acid (HCL), as these acids can destroy the alloy. Alternatively, the oxide can be cleaned mechanically using a glass brush. To avoid dimensional changes, the bars must not be blasted.

18.1.6 Inserting male part K by casting

Proceed as described under Point 18.1.1.



Applying the necessary care, the round bar can be deformed plastically by heating, e.g. over the Bunsen burner, and individually adapted to the contour of the alveolar ridge. However, it is also possible to optimally adapt the bar to the alveolar ridge by cutting and waxing together. Ideally, a wedge-shaped cut is made without having to separate the bar completely. For the rider to function well for many years, it must be seated perfectly on the bar profile. To achieve this, sections of 4 mm in length must remain intact.



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/mm².

Tips for a successful and as perfect as possible cast:

- Attach sufficient casting channels.
- Wax the casting channels to prevent creating sharp edges and corners.
- Do not use any aggressive wetting agents that can dissolve the resin.
- Use of high-strength, shock-resistant investment material.
- Burn-out: cylinder opening facing downwards so that as much material as possible can burn out outside the die, heating rate < 4°C per minute, maintain at 250 - 300°C for 30 - 60 min.
- Final temperature: heating rate < 7°C per minute, maintain at desired final temperature for 30 - 50 min.
- Devest with care, if possible without blasting and clean the cast ultrasonically. In case of blasting, only with glass beads, 50 µm, at low pressure.
- Finish the cast only to the extent necessary, e.g. remove casting defects such as blisters. The profile must be retained.

18.1.7 Polishing

Polish the bar profile with extreme care using conventional polishing agents and, if possible, without abrading any material. Keep abrasion of the material to a minimum to maintain stability of the connection. The function of the bar sleeve must be assured.

18.2 Fabrication of the secondary reconstruction (denture)

Due to the heavy stress on a bar-anchored denture in the mouth, we recommend fabricating the bar denture with a reinforced base made of metal. If space is limited, a metal surface can be modelled over the female part for additional protection and to reduce the volume of the denture.

18.2.1 Inserting the female part (rider)



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.



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



Make sure that no resin has flowed into the housing of the female part. If necessary, remove the resin carefully and without causing damage so as not to impair the function of the female part.



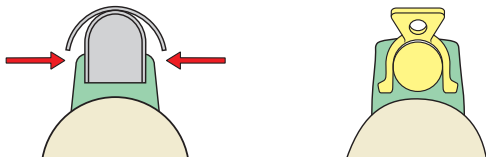
If a female part is placed on more than one bar segment, the denture is retained without degrees of freedom, independent of the bar profile.



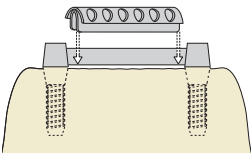
In the case of a resilient construction, the spacer is adjusted occlusally along the entire length of the bar and the female part is mounted on top. Following polymerisation, the spacer is removed again.



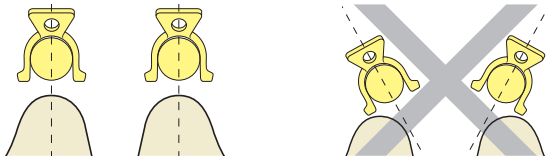
The retention wings of the female part may only be bent once and with extreme caution to avoid breaking off. Repeated bending back and forth can lead to the retention wings breaking off.

**Placement of the female part**

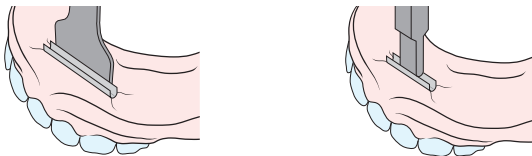
Block out the space between the bar and the gingiva slightly conical with wax. In the case of the Dolder® female part, ½ of the lamella height must remain free to move. Make sure that the legs of the round female part are blocked out sufficiently thick. This enables unrestricted spring travel of the lamellae during insertion and removal, as well as access of the instrument to activate/deactivate the lamellae (reduces premature wear). Furthermore, this prevents denture resin from penetrating into the female part during polymerisation. The retention attached to the female part guarantees perfect fixation in the denture saddle.

18.2.2 Dolder® System

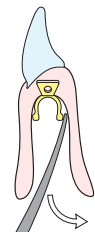
The female part is adjusted over the entire length of the bar to achieve the maximum possible holding force. After separation, remove burrs inside and outside. To ensure that the female part can be securely anchored in the resin, it must not be shorter than 5 mm. Polymerise the female part into the denture or into the cast reinforcement.

18.2.3 Round bar (round bar with rider, Ackermann-Bar)

To avoid premature deactivation of the lamellae and to ensure simultaneous insertion and removal of the denture, the female parts must be aligned parallel to each other.

18.3 Activation and deactivation**18.3.1 Dolder® Female Parts**

The more heavily loaded posterior lamella is activated. The anterior lamella assumes the function of a guide surface. Activation is via the corresponding activator from the activation set (Cat. No. 070198) by carefully pressing inwards. To deactivate a bar sleeve that is too tight, press the deactivator (Cat. No. 070200 female part micro, 070201 female part macro) into the female part until the desired friction is set.

18.3.2 Round bar female parts

To activate, carefully press the legs of the female part inwards with the small activator from the activation set (Cat. No. 070198).

18.4 Modifications, relining

When modifying or relining the denture, use the transfer jig of the respective system to reconstruct the position of the bar female part on the new working model.

18.4.1 Impression taking

Provided that the seating of the female part on the male part is correct, the female part does not need to be removed.

18.4.2 Relining

1. Block out undercut areas of the bar in the patient's mouth (e.g. with soft wax)
2. Coat denture with bonding agent for silicone impressions
3. Perform impression taking
4. Position transfer jig in the female part
5. Model fabrication (in the occludator)
6. Remove silicone material from the denture. Check the female part for damage, remove if necessary and replace with a new one
7. Roughen denture base
8. Insofar as the female part had to be replaced, position a new female part on the transfer jig
9. Block out undercut areas of the bar as well as activatable lamellae of the female part (as described in Section 18.2.1)
10. Insulate the model
11. Press denture
12. Finishing

19 Materials

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.
 Condition: cold-formed.

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

P3 = Protor 3; 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.
 Condition: soft annealed.

T = Pure titanium

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:

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
Dolder® System						
Female parts						
054747	Female part E macro L25	Elitor®	Yes	CE 0483	07640166514121	764016651000055E8
054746	Female part E micro L25	Elitor®	Yes	CE 0483	07640166514114	764016651000055E8
052046	Female part E macro L50	Elitor®	Yes	CE 0483	07640166514084	764016651000055E8
052043	Female part E micro L50	Elitor®	Yes	CE 0483	07640166514077	764016651000055E8
05001125	Female part D macro L50	Doral	Yes	CE 0483	07640173091622	764016651000055E8
05001201	Female part D micro L50	Doral	Yes	CE 0483	07640173091639	764016651000055E8
05000681	Female part T macro L47.5	Pure titanium	Yes	CE 0483	07640173091394	764016651000055E8
05000680	Female part T micro L47.5	Pure titanium	Yes	CE 0483	07640173091387	764016651000055E8
052081	Spacer macro L50	Brass	Yes	CE	07640166514107	764016651000030DQ
052080	Spacer micro L50	Brass	Yes	CE	07640166514091	764016651000030DQ
070198	Activator set	Steel	No	CE	07640166511830	764016651000002DK
070201	Deactivator macro	Steel/plastic	No	CE	07640166511847	764016651000003DM
070200	Deactivator micro	Steel/plastic	No	CE	07640166514510	764016651000003DM
Male part bar attachment						
052053	Male part E macro L50	Elitor®	Yes	CE 0483	07640173091974	764016651000052E2
05000289	Male part E micro L50	Elitor®	Yes	CE 0483	07640173091110	764016651000052E2
05000559	Male part K macro L75 (2 pcs.)	Korak	Yes	n/a	07640173091134	n/a
05000266	Male part K micro L75 (2 pcs.)	Korak	Yes	n/a	07640173091103	n/a
Male part bar joint						
052061	Male part E macro L50	Elitor®	Yes	CE 0483	07640173091998	764016651000052E2
052057	Male part E micro L50	Elitor®	Yes	CE 0483	07640173091981	764016651000052E2
05000563	Male part K macro L75 (2 pcs.)	Korak	Yes	n/a	07640173091370	n/a
05000561	Male part K micro L75 (2 pcs.)	Korak	Yes	n/a	07640173091363	n/a
070173	Transfer jig macro L50	Steel	Yes	CE	07640166514442	764016651000033DW
070171	Transfer jig micro L50	Steel	Yes	CE	07640166514435	764016651000033DW
070144	Parallelometer insert macro (bar attachment)	Steel	No	CE	07640166514350	764016651000018E2
070143	Parallelometer insert micro (bar attachment)	Steel	No	CE	07640166514343	764016651000018E2
072517	Parallelometer insert macro (bar joint)	Steel	No	CE	07640166514909	764016651000018E2
072515	Parallelometer insert micro (bar joint)	Steel	No	CE	07640166514893	764016651000018E2

Cat. No.	Product name	Material	Single use	Labelling	UDI-DI	Basic UDI-DI
Round Bar with Rider						
050527	Female part E	Elitor®	Yes	CE 0483	07640166513797	764016651000055E8
055801	Female part E (5 pcs.)	Elitor®	Yes	CE 0483	07640166514213	764016651000055E8
05000679	Female part E L50	Elitor®	Yes	CE 0483	07640166515111	764016651000055E8
052082	Spacer (tin) 50 x 0.60 mm	Tin	Yes	CE	07640166511809	764016651000029E7
052085	Spacer (tin) 200 x 0.60 mm	Tin	Yes	CE	07640173093077	764016651000029E7
052030	Male part P3 L50	Protor	Yes	CE 0483	07640173093046	764016651000052E2
052028	Male part P3 L200	Protor	Yes	CE 0483	07640173093039	764016651000052E2
055881	Male part K L75 (2 pcs.)	Korak	Yes	n/a	07640173093466	n/a
072293	Transfer jig	Steel	Yes	CE	07640166514831	764016651000033DW
070198	Activator set	Steel	No	CE	07640166511830	764016651000002DK
Ackermann-Bar						
05050010	Ackermann-Bar A female part E	Elitor®	Yes	CE 0483	07640166515142	764016651000055E8
05050011	Ackermann-Bar B female part E	Elitor®	Yes	CE 0483	07640166515159	764016651000055E8
052080	Spacer micro L50	Brass	Yes	CE	07640166514091	764016651000030DQ
05050014	Male part P3 L60	Protor	Yes	CE 0483	07640173092162	764016651000052E2
070198	Activator set	Steel	No	CE	07640166511830	764016651000002DK

30 Labelling on packaging/symbols

	Date of manufacture
	Manufacturer
	Catalogue number
	Lot number
	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.
	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
	Clear product identification
	European Authorised Representative
	Importer
	Medical device