# The Swiss Dalbo®-System



Instructions for use for

**Dalbo® Abutment**
**Dalbo®-Classic** **Dalbo®-Classic elliptic**
**Dalbo®-PLUS** **Dalbo®-PLUS elliptic**

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

**Traceability of lot numbers**
The lot numbers of all components must be recorded to ensure that they can be traced.

**Sterilization/disinfection**
After any fabrication or modification and prior to use, the prosthetic work, including the female part components, must be cleaned, disinfected and, if appropriate, sterilized. Metal and Pekkton® components are suitable for steam sterilization (see below), while components made of plastic other than Pekkton® are not. Consider published national guidelines when selecting a disinfection and sterilization process. For re-usable surgical and prosthetic instruments, consult the dedicated documentation Care and Maintenance Surgical and Prosthetic Instruments (available for download on www.cmsa.ch/Dental/Download-Center), which provides detailed instructions and recommendations (partly instrument-specific) regarding, maintenance, cleaning, disinfection and sterilization.

**Recommendation: Disinfection**
All the parts must be disinfected before use with a high-level disinfectant. Follow the instructions of the manufacturer regarding dosage and exposure time.
When choosing the disinfectant, ensure that:
– it is suitable for the cleaning and disinfection of dental prosthetic components,
– it is compatible with the materials of the products to be cleaned and disinfected, and
– it has proven efficacy in disinfection.
We recommend using an ortho-phthaldehyde (OPA) solution like the Cidex® OPA Solution. Strictly follow the manufacturer's instructions.

**Sterilization**
After cleaning and disinfection, and prior to use, all metal and Pekkton® components must be sterilized. Plastic parts, except those made of Pekkton®, are not suitable for steam sterilization and are processed as indicated in the section Sterilization/Disinfection above.

**Sterilization method**
The original packaging shall not be used for the sterilization process. Steam sterilization for sterilization of system components was validated with the following parameters:
– Temperature of saturated steam: 132 °C (270° F)
– Flash-gravity (gravity displacement according to ANSI/AAMI ST79: 2010)
– Sterilization time 10 min (components unwrapped in an unclosed container)
– Drying time: 1 min

According to material properties, metal and Pekkton® components are also compatible with prevacuum steam sterilization at 134°C (273°F) for 18 minutes. Do not exceed 140°C (284°F).

Allow system components to cool before use. Only use approved sterilizers, sterilization containers, sterilization pouches, biological indicators, chemical indicators and other sterilization accessories appropriately identified and recommended for sterilization and the sterilization cycle.

**Disinfection of activators/deactivators**
070197 Activator (for Dalbo®-Classic and Dalbo®-B), 070199 Deactivator (Dalbo®-Classic and Dalbo®-B), must not be sterilised. When sterilising the above activators and 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.

**Hints**
for processing precious metal alloys are available in the Dental documentation of Cendres+Métaux (April 99 edition) and in the Internet by visiting **www.cmsa.ch/dental.**

All female parts of the Dalbo®-System fit the spherical male parts of other manufacturers and spherical ball attachments (∅ 2.25 mm) on implants.

Diverging abutments can be compensated:
**Dalbo®-PLUS**
On rootcaps up to 8°–16° depending on activation.
On implants up to 40° depending on the system.
**Dalbo®-Classic**
On rootcaps 10°
**Dalbo®-B**
On rootcaps 9°

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

# The Swiss Dalbo®-System

**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.

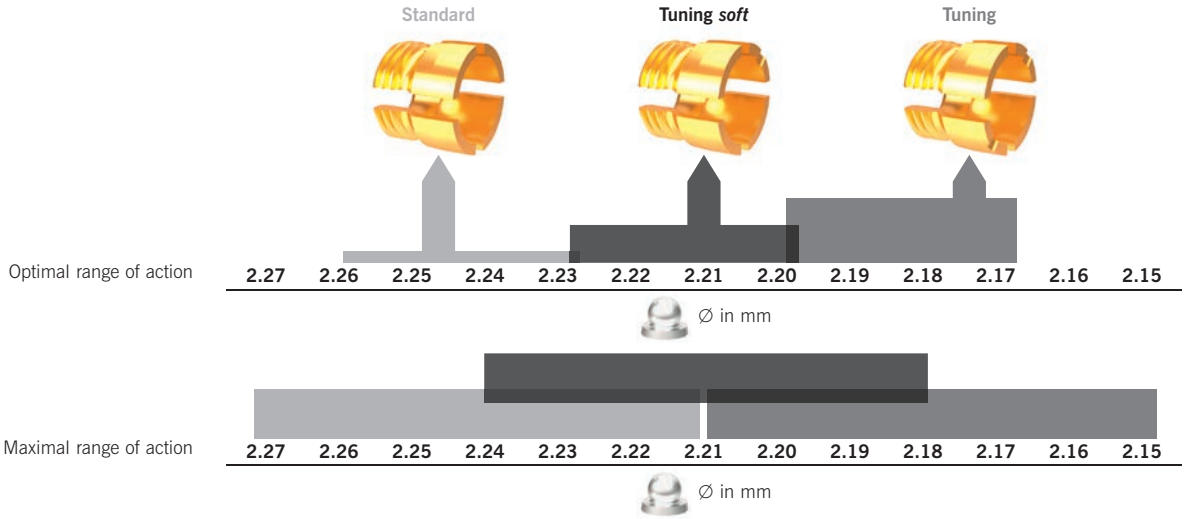
These operating instructions are not sufficient for immediate use of the attachment. Knowledge of dentistry and dental technology as well as instruction on the handling of the Cendres+Métaux attachments by an experienced person are required. Training courses are regularly provided by Cendres+Métaux, 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.

**Fitting**
**Dalbo®-Classic / Dalbo®-Classic elliptic**
**Female part** **E = Elitor®**
Polymerising into place
**Male part** **V = Valor®**
Integration: casting-on or soldering to precious metal alloy
**(Cannot be laser welded)**
**Male part** **E = Elitor®**
Laser welding or soldering
**Male part** **K = Korak**
Cast with precious, non-precious or titanium alloys with a minimum proof stress (Rp 0.2 %) exceeding 500 N/mm²
**Dalbo®-PLUS / Dalbo®-PLUS elliptic**
**Female housing** **T = Pure titanium (grade 4)**
The Dalbo®-PLUS is resin-bonded or polymerized into place and the Dalbo®-PLUS elliptic is polymerized into place
**Lamellae retention insert** **E = Elitor®**
Winding into the female housing
**Male part** **V = Valor®**
Integration: casting-on or soldering to precious metal alloy
**(Cannot be laser welded)**
**Male part** **E = Elitor®**
Laser welding
**Dalbo® Abutment** **S = Syntax**
Insertion: screw in at recommended torque

**General information**
– We recommend to design the clinical case in such a way that the largest possible support polygon can be achieved. Small distances between consecutive implants and long free-end saddles can cause undesirable effects, such as increased wear of the system components.
– The correct seating of the prosthesis on the mucous membrane must be checked at least once a year, if necessary it must be relined to prevent swinging movements (overloads). We recommend checking the prosthesis at regular intervals of approximately three months and replacing the retention inserts if necessary.

**Materials used and processing**
Description and abbreviations for materials:
Detailed information about the materials and their classification can be found in the specific material data sheets and the catalogue.
See website www.cmsa.ch/dental or the dental documentation from Cendres+Métaux (available free of charge from all subsidiaries, branch offices and agencies of Cendres+Métaux).



**S = Syntax**
– Dalbo® Abutment (male part)
– Dalbo® CAD/CAM retention element (male part)

**T = Pure titanium (grade 4)**
Ti > 98.9375 %
– Female part

**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
– Retention insert

**V = Valor®**
Pt 89.0 %, Au 10.0 %, Ir 1.0 %
$T_S$ – $T_L$ 1660–1710 °C
– Male part

**K = Korak**
Burnout plastic for use when casting

**X = Steel**
– Auxiliary instruments

**Indications**
Removable, rigidly or resiliently restorations supported on implants and root caps:
– Hybrid dentures
– Unilateral free-end dentures locked transversally
– Insertion/free-end dentures in combination

**Contraindication**
– The Dalbo® Abutments are to be used exclusively with the implant systems listed explicitly for this purpose in the web list www.cmloc.ch.
– Unilateral free-end dentures without transversal support
– Restoration of severely periodontally damaged abutment teeth.
– Hybrid prostheses, which are restored with a single root canal cap.
– In patients with a pre-existing allergy to one or more elements of the attachment element materials.
– Lacking cooperation of the patient with respect to correct follow-up/recall instructions.
– Patients with bruxism or other para-functional habits.
– Implant divergences > 20°.
- Not suitable if a fixed connection is required.
– Existing clinical picture in the patient's mouth does not permit the correct use of the Dalbo® System.
– Unilateral free-end prosthesis without transversal support.
– If immediate loading is not indicated for the implant.
– Implant system is not approved for the application. http://www.cmsa.ch/docs

– For additional contraindications, please refer to the instructions for use from the implant manufacturer.

**Equipment and parts required for correct processing**
Dalbo® Abutment Screw Driver (Order No. 07000266)
Parallelometer (if the abutments are less than 10° out of parallel, they do not have to be paralleled).
Special paralleling insert (Order No. 072637) or paralleling insert (Order No. 070131) and attachment tweezers (Order No. 070222). **Dalbo®-Classic / elliptic:** Plunger for fitting the elastomeric ring (Order No. 070205), activator (Order No. 070197), deactivator (Order No. 070199) and spacer (Order No. 072625). **Dalbo®-PLUS / elliptic:** Screwdriver/activator (Order No. 072609).

**Technique for using the auxiliary parts (Galak)**
Here the spacers generally replace the anchor female parts during resin-polymerization in the dental laboratory. These are then removed from the finished polymerized denture. The polymerization or resin-bonding of the original female parts is done by the dental surgeon directly in the mouth of the patient after cementing of the root canal caps. The spacers are also an excellent by the dental surgeon directly in the mouth of the patient after cementing of the root canal caps. The spacers are also an excellent protection for the male parts during polishing.

**Duplicating aids**
These red parts are slightly overdimensioned compared to the original parts. The result is an optimal gap for the resin-bonding technique.
**Note:** The duplication aid must not be used instead of the female part as a temporary replacement and also must not be placed in the mouth for impression-taking.

**Impression taking**
Use small amount of soft wax to block out the space between the female part and the male part or the abutment prior to the impression. Place the original female part on the male part or the abutment. After create a functional impression. Use a solid impression material (e.g., Impregum™).

**Spacer disc**
The tin spacer supplied with this attachment provides for vertical resilience. The soft spacer is placed over the entire root cap and adapted prior to polymerizing the resin. Once the resin has been finished, the spacer is removed. Current clinical experience shows that the minimal vertical resilience is eliminated once the denture has been placed. The greatest advantage is that the denture base is not overloaded on the root cap.
**Note:** Do not put the spacer in tin in the mouth.

**Auxiliary instruments**
The auxiliary instruments to be used are listed in the main catalogue of Cendres+Métaux under the heading for the particular attachment. See website www.cmsa.ch/dental or the dental documentation from Cendres+Métaux (available free of charge from all subsidiaries, branch offices and agencies of Cendres+Métaux).

**Processing Dalbo® Abutment**
The implant must already have been placed beforehand.
Please refer to the instructions for use from the relevant implant manufacturer in this case.
Determining the abutment height:
Choose the gingival height of the abutment height with a probe (1mm graduation). The lower edge of the abutment should lie 1mm above the gingiva. (Fig. 1) Various heights are available.
Please observe the information on the packaging specific to the system.

**Inserting the Dalbo® Abutment:**
First, place the Dalbo® Abutment on the Dalbo® Abutment Screw Driver (order no. 07000266) and screw it into the implant by hand. (Fig. 2)
Then tighten with a standard commercial torque wrench or contra-angle handpiece using the corresponding torque (observe information on the packaging).
Check correct fit of the abutment. (Fig. 3)
Secure all parts against aspiration.

**In case of a new prosthesis, use a Dalbo® CAD/CAM Retention Element as an additional retention element on a milled bar.**
Impression of the clinical situation in the mouth and fabrication of the master model as specified by the implant manufacturer.
Then fabricate the prosthesis using a conventional wax setup. The bar is then fabricated using CAD/CAM technology. Please follow the manufacturer's instructions of the respective system.
When modelling the bar in the CAD software, allow for the position of the Dalbo® CAD/CAM Retention Element.
A standard thread M2 is required for fixation of the Dalbo® CAD/CAM Retention Element in the CAD/CAM dental bar.
After fabricating the CAD/CAM dental bar, the Dalbo® CAD/CAM Retention Element can be mounted to the milled bar with a torque of 35Ncm using the Dalbo® Abutment Screw Driver.
After assembly of the milled bar with mounted Dalbo® CAD/CAM Retention Element and fixed female part on the master model, the prosthesis can be fabricated.

**In case of an existing prosthesis, use a Dalbo® CAD/CAM Abutment as an additional retention element on a milled bar.**

Take an impression of the relining with impression posts from the respective implant manufacturer and prosthesis.
Then pass to dental laboratory for fabrication of the model.
Fabrication of milled bar with mounted female part according to description; use of Dalbo® CAD/CAM Retention Element as an additional retention element on a milled bar for a new prosthesis.

**Preparatory procedures**
Wax up the root cap with root post
In cases with several root caps, the solder/laser surface should be prepared at **90° to the angle of insertion**
Use prefabricated precious metal posts for casting-on.

**General comments on fitting the male part**
After soldering/casting, bench cool to room temperature. Thus the optimum mechanical properties are obtained without heat treatment. Fit the duplicating aid or spacer to protect the male part during sandblasting and trimming.

**Casting-on the Valor® male part**
Use the paralleling insert to position the male part as centrally as possible and wax it onto the root cap as neatly as possible. Invest and cast.

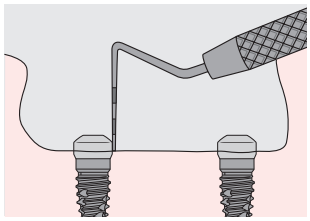


Fig. 1

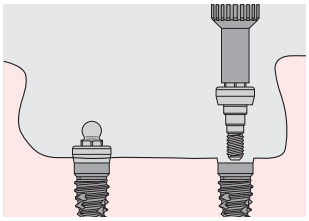


Fig. 2

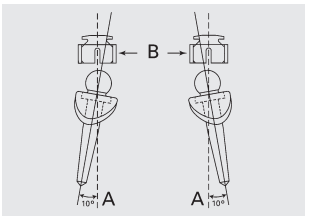


Fig. 4

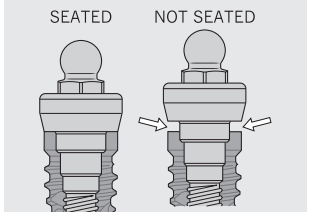


Fig. 3

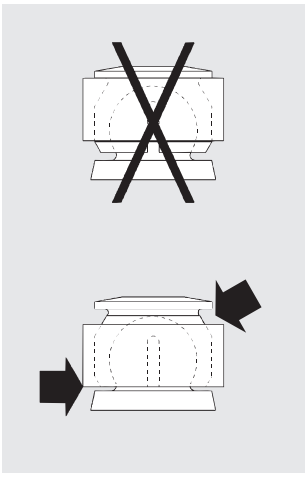


Fig. 5

**Laser-welding the Elitor® male part**
Basically only materials of the same composition may be joined. Subsequent failures are thus reduced to an absolute minimum. The Dalbo® Laser Male Part (order No. 055921) made of Elitor® (identical to Protor® 3) may only be processed with the corresponding laser welding wire Protor® 3 (order No. 010903) and the Cendres+Métaux casting alloy Protor® 3 (order No. 010654). Processing details can be found in the instructions for use for Cendres+Métaux laser welding wires (automatically supplied with the Dalbo® Laser Male Part).

**Soldering the Valor® male part**
Use the paralleling insert to position the male part as close to the centre of the root cap as possible – after casting and milling the cap smooth – (take the aesthetics into account). The soldering gap should be uniform and 0.05–0.2 mm wide. Design the soldering model to hold the male part firmly and provide good access with the flame.

**Casting-on the Korak male part**
Fill the indentation in the male part with wax. Use the paralleling mandrel to position the male part as centrally as possible and wax it onto the root cap as neatly as possible. After casting, polish the male extremely cautiously and set the desired friction with the female part.

**General comments on fitting the female part**
The **tin spacer** supplied with this attachment provides for vertical resilience. The soft spacer is placed over the entire root cap and adapted prior to polymerizing the resin. Once the resin has been finished, the spacer is removed. Current clinical experience shows that the minimal vertical resilience is eliminated once the denture has been placed. The greatest advantage is that the denture base is not overloaded on the root cap or the abutment.
**Elliptic version**
If necessary, the retainers can be slightly reduced. Each modification, however, will reduce the retention hold in the denture.
**Attention:** do not grind laser seam (weakening)!

**Polymerizing the female parts into place *in the laboratory***
Before fitting the female part, apply a coat of Vaseline inside it to prevent resin creeping in. When fitting several females, ensure that **they are positioned and waxed onto the male parts parallel** (Fig. 4/B). The elastomeric ring must be flush with the edge of the female (Fig. 5) to create maximum retention for the resin. Block out the undercuts and interpapillary spaces with impression plaster, wax, Flexistone or a rubber dam. Maximum deviation: 10° (Fig. 4/A). To ensure optimum functioning and protect the lamellae, the elastomeric ring should not be removed from the Dalbo®-Classic / elliptic female part. If necessary, the plunger can be used to replace the elastomeric ring as follows: 1) Remove the sleeve 2) slide on several elastomeric rings 3) fit the sleeve 4) slide the sleeve to press the elastomeric rings over the lamellae on the female part. elastomeric rings which have been pressed into place once must not be used again.

**Dalbo®-PLUS**

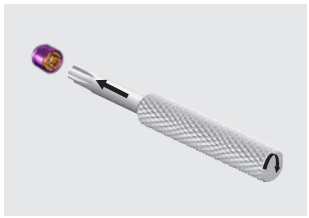


Fig. 6

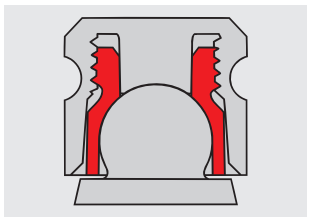


Fig. 7

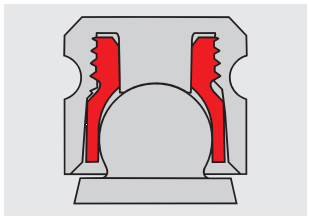


Fig. 8

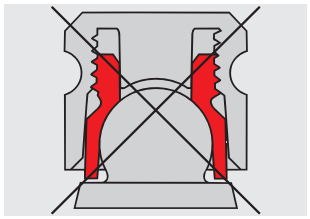


Fig. 9

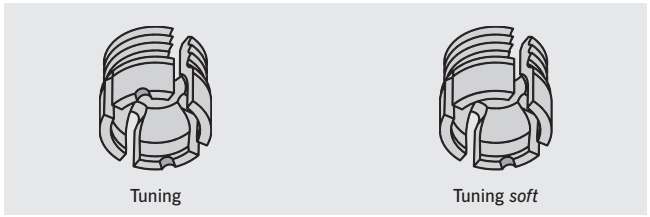



Fig. 12

**Dalbo®-Classic**

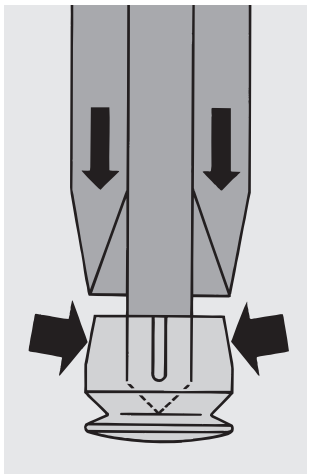


Fig. 10

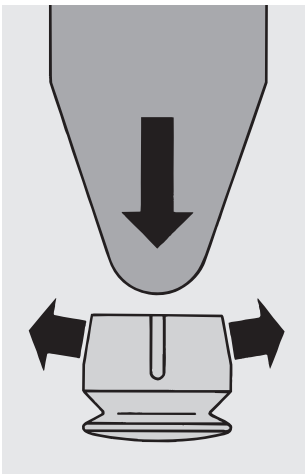


Fig. 11

**Resin-bonding the female parts into place *in the laboratory***
The red duplicating aid for the Dalbo®-PLUS is larger than the female to create an ideal gap for the resin after casting. Once the cap has been fabricated, place the duplicating aid, block out the undercuts and duplicate the model (silicone). After casting and trimming the interior of the retentive housing, sandblast the exterior of the Dalbo®-PLUS female using $Al_2O_3$.
**Wax up the females parallel on the male parts** and resin-bond them into the framework. Only use suitable bonding resins. For more details on resin-bonding, please refer to the «Cendres+Métaux resin-bonding» brochure at **www.cmsa.ch/dental.**

**Fitting the female part in the patient's *mouth***
Versions of the Elliptic with strengthened plastic retainers are available specifically for this purpose.
**Please note:** It is **essential** to read the instructions on fitting female parts in the laboratory!
Before fitting the female, create adequate space in the denture base. Fix the elliptic females **parallel in the mouth** and block out the undercuts. Where possible, drill an extra escape aperture through the denture base. With hybrid dentures, ensure that the root cap or the abutment are not loaded. This prevents the denture rocking after placement.

**Adjusting the retentive force**
**Dalbo®-Classic and Dalbo®-Classic elliptic:**
Use the appropriate instrument to exert gentle pressure and press the four lamellae together uniformly (Fig. 10) or spread them (Fig. 11) making certain not to break the female part out of the resin. After use, clean the instruments with water and disinfect.
**Do not sterilize.**
**Dalbo®-PLUS and Dalbo®-PLUS elliptic:**
The screwdriver/activator (Fig. 6) is required for activating, deactivating and removing the lamellae retention insert. This instrument has four lamellae and should be positioned correctly before pressing it as far as possible into the lamellae retention insert.
The retentive force is adjusted by turning the instrument – clockwise to increase the force and anti-clockwise to reduce it. The unit is supplied set to a retentive force of approx. 200 g., i.e. the minimum force which can be set (Fig. 7) – the maximum force is approx. 1200 g. (Fig. 8).
**Caution:** The lamellae retention insert must not protrude from the housing (Fig. 9).
**Indication:** if the activation does not allow proper retention force, check if the female part is well-sitted and if needed, repolimerize.

**Modifications and relines**
It is preferable to remove the original female part from the denture. A heating rod (Order No. 072 639) is available for the Dalbo®-PLUS / elliptic. Procedure:
1. Remove the lamellae retention insert
2. Wind the heating rod into the housing of the female
3. Heat the opposite end with a Bunsen burner until the resin surrounding the female softens.
4. Use pliers to pull the heating rod and female out of the denture.
Please note: If the housing of the female has been resin-bonded, a much higher temperature is required to debond it!
Prior to taking the impression, place each spacer on its male part. To fabricate the master model, insert the transfer pin (Order No. 070 157) into the spacer. Fit the female part as described.

**Tuning/Tuning soft lamellae retention insert**
Our stud anchor diameter of 2.25 mm is now standard for the majority of systems on the market. Experience and tests on other products indicate that very slight differences, e.g. choice of material, geometry or tolerance limits, can reduce the friction of the Dalbo®-PLUS. Two additional lamellae retention inserts are available for increasing friction. They can be easily distinguished from standard retention inserts by the different indentations (Fig. 7) on the lamellae.

| | |
|---|---|
| Dalbo®-PLUS (Standard) | normal friction |
| **Standard** | **normal friction** |
| Lamellae retention insert | |
| **Tuning soft** | |
| Lamellae retention insert | **strong friction** |
| **Tuning** | |
| Lamellae retention inserts | **extra strong friction** |

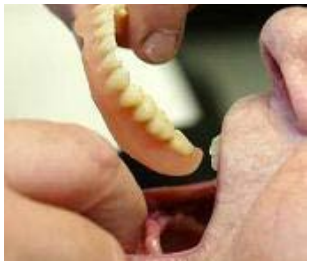
**Sales programme female parts basic:**
– with retention insert
**Standard**
Order No. 055752
**Tuning soft**
Order No. 05000214
**Tuning**
Order No. 055771
**Sales programme female parts elliptic:**
– with retention insert
Standard
Order No. 055890
**Tuning soft**
Order No. 05000215
**Tuning**
Order No. 055891
**Sales programme of lamellae retention inserts**
**Standard**
Order No. 055643
**Tuning soft**
Order No. 05000068
**Tuning**
Order No. 055687

**Handling / follow-up**
Retaining elements in prosthetic work are subject to considerable stress in the mouth in a constantly changing environment, and thus more or less subjected to signs of wear. Wear is omnipresent in daily routine and cannot be avoided, only reduced. The amount of wear depends on the overall system. Our endeavors 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 carried out if required to prevent tilting (overload). We recommend checking the prosthesis at intervals of approx. 3 months initially and to replace the retention inserts if necessary.

**Insertion and removal of the dentures**
Ensure that the dentures do not tilt, as any tilting can lead to damage. Never insert dentures by biting the teeth together. This can lead to damage or even breakage of the connecting element. Further information on handling / aftercare of dentures is available in the patient information brochure at www.cmsa.ch/dental.

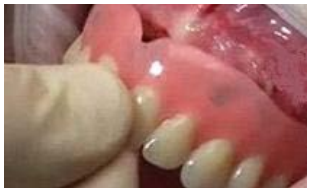
**Insertion**

Hold the dentures between the thumb and forefinger, and place them back into the mouth on the anchors. Search or feel for the correct insertion position and push the dentures onto the anchors with gentle, steady pressure. Carefully close your jaws and check whether the dentures are in the correct final position.



**Removal**

Hold the dentures between the thumb and forefinger, and slowly, carefully and steadily pull them off the anchors and remove them from the mouth.



**Cleaning and care**

It is best to clean your teeth and your dentures after every meal. Cleaning of dentures includes cleaning of the connecting element. The gentlest cleaning is achieved by cleaning the connecting element under running water with a soft toothbrush. The most intensive cleaning is achieved when cleaning the dentures in a small ultrasonic device and adding a suitable cleaning agent. Never clean the high precision connecting elements with toothpaste. This could lead to damage. Caution should also be exercised in the case of unsuitable cleaning agents or tablets. This could also damage the high quality connecting element or impair its function. Only clean the connecting parts on the other teeth or implants with water and a soft toothbrush as well as an interdental brush. Do not use toothpaste to avoid damage. Pay attention to regular cleaning of the anchorage to prevent any inflammation of the soft tissue. For information and additional tips on caring for the instruments. (www.cmsa.ch/dental).
For information and additional details, please contact your Cendres+Métaux representative.

**Traceability of the batch numbers**

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

**Disclaimer / disclaimer of liability**

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. This attachment element is part of an overall concept and may only be used or combined with the corresponding original components and instruments. Otherwise, the manufacturer rejects any responsibility and liability. In case of complaints, please always include the batch number.

**Copyrights and trademarks**



**Markings on the packaging / Symbols**

| | |
|---|---|
| | Date of manufacture |
| | Manufacturer |
| REF | Item number |
| LOT | Batch code |
| QTY | Quantity |
| | Consult instructions for use<br>URL: cmsa.ch/docs |
| Rx only | Attention: According to US federal law, this product may only be sold by or on behalf of a physician. |
| CE 1250 CE | Cendres+Métaux products with CE labeling meet the requirements of the Medical Device Directive 93/42/EEC. |
| | Do not re-use |
| NON STERILE | Non-sterile |
| | Keep away from sunlight |
| | Attention, observe accompanying documents |
| | Unique Device Identification – UDI |

CENDRES+
MÉTAUX
Medtech

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

Phone +41 58 360 20 00
Fax +41 58 360 20 15
info@cmsa.ch

www.cmsa.ch