Dalbo®-PLUS female part and Dalbo® Certain® Abutment

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.

04.2012
Manufacturer: Cendres+Métaux

Intended Use
The Dalbo®-PLUS female part and Dalbo® Certain® Abutment manufactured by Cendres+Métaux serve as connectors for implant-supported removable dental prosthesis.

In general:

Traceability of lot numbers
The lot numbers of all components must 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 the parts must be disinfected before use with a low or intermediate EPA-registered hospital disinfectant.
Recommended: Cidex® OPA Solution. Strictly follow manufacturer's instructions.

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.

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.

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.

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

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Dalbo®-PLUS female part and Dalbo® Certain® Abutment

Materials
Dalbo® Certain® Abutment S

Dalbo®-PLUS female part
Female housing T
Integration: Resin-bonded or polymerized into place
Lamellae retention insert E
Integration: Threads into the female housing Dalbo®-PLUS

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 / TiA6 V4 ELI
(grade 5) Ti > 89.478 %, Al 6.0 %, V 4.0 %

T = Pure titanium

E = Elitor®
Au 68.60 %, Ag 11.85 %, Cu 10.60 %, Pd 3.95 %, Pt 2.45 %, Zn 2.50 %, Ir 0.05 %
T_S – T_L 880–940 °C

Indications
Removable, rigid or resilient retained restorations supported on implants **placed as parallel as possible** and fully incorporated in the bone (essential to follow the instructions for BIOMET 3i™): Hybrid dentures, transverse splinted unilateral free-end dentures as well as insertion/free-end dentures.

Can be combined with the following types of the BIOMET 3i™ implant system **with internal connection:**
– **Certain® PREVAIL™ 4.1 mm (D)** (Order No. IIOS4585, IIOS4510, IIOS4511, IIOS4513 and IIOS4515).
– **OSSEOTITE® Certain® 4.1 mm (D)** (Order No. IOSS485, IOSS410, IOSS411, IOSS413, IOSS415, IOSS418, IOSS420, IFOS485, IFOS410, IFOS411, IFOS413 and IFOS415).
– **OSSEOTITE® NT Certain® 4.1 mm (D)** (Order No. INT485, INT410, INT411, INT413, INT415, IFNT485, IFNT410, IFNT411, IFNT413 and IFNT415).

Contraindication
– Implant divergences of more than 15°
– 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 aftercare/recall instructions.
– Patients with bruxism or further uncontrolled para-functional habits.
– For additional contraindications, please refer to the instructions for use from the implant manufacturer.

Equipment and parts required for correct processing
Available from Cendres+Métaux:
• Screwdriver/activator (Order No. 072 609) for threading-in and activation of the lamellae retention insert.
• Spacer disc in tin (Order No. 050 094) thickness 0.4 mm

Available from BIOMET 3i™:
• O-Ring/Dal-Ro screwdriver (Order No. PAD01)
• O-Ring/Dal-Ro driver tip for torque ratchet (Order No. RAOR1)
• Torque ratchet (Order No. RTI2035K)
• Dal-Ro Laboratory analogue (Order No. DRLAU)
• Pick-Up impression coping 4.1 mm (Order No. IIIC41)
• Hex screwdriver 17 mm (Order No. PHD02N)
• Certain™ Implant Lab Analogue 4.1 mm (Order No. IILA20)

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).

Dalbo®-PLUS female part and Dalbo® Certain® Abutment

Instructions for use

Indirect technique (integration of the female part in the laboratory)

1. (Fig. 1): Determine the correct height for each of the Dalbo® Certain® Abutments by measuring the height of the healing cap above the tissue, **without** curvature, using a probe (1 mm scale). Then subtract this from the overall height of the healing cap and add 1 mm to the result.
Three collar heights are available: 2 mm, 4 mm and 6 mm.
2. Remove the healing cap.
3. (Fig. 2): Manually insert the selected Dalbo® Certain® Abutment into the implant using the O-Ring/Dal-Ro screwdriver (PAD01).
4. (Fig. 3): Using an X-ray verify that the Dalbo® Certain® Abutment is seated correctly on the implant. Hold the film perpendicular to the interface of the Dalbo® Certain® Abutment and the implant.
5. (Fig. 4): Torque the Dalbo® Certain® Abutment into the implant using the O-Ring/Dal-Ro driver tip (RAOR1) and torque ratchet set at 20 Ncm. (If the surgeon is only inserting the Dalbo® Certain® Abutment, the existing denture must be relieved accordingly around it.)
6. (Fig. 5): A custom tray or stock tray can be used for making the impression. The area around the Abutment should be relieved by 2 mm.
7. (Fig. 6): A medium or high viscosity impression material is recommended, e.g. vinyl polysiloxane or polyether rubber. Syringe the Dalbo® Certain® Abutment bubble free and then insert the impression tray loaded with impression material.
8. (Fig. 7): After the impression material has set (adhere to manufacturer's instructions!), remove the impression tray from the mouth and insert the **Dal-Ro laboratory analogue** into the moulded ball abutment and check that it is seated **correctly.**
Instead of the impression of the Dalbo® Certain® Abutment, transfer can be done with the impression coping Pick-Up 4.1 mm. The Certain™ Implant Lab Analogue 4.1 mm and the appropriate Dalbo® Certain® Abutment are needed for model fabrication.
9. Fabricate a master model. Depending on the situation, the existing denture is adapted or a new denture is fabricated in the laboratory.
10. **Version A) Polymerizing the female housing Dalbo®-PLUS into place**
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** (Fig. 8) **and waxed onto the male parts parallel.**
Block out the undercuts and interpapillary spaces with impression plaster, wax, Flexistone or a rubber dam.

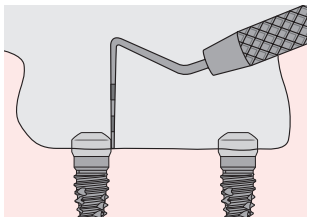


Fig. 1

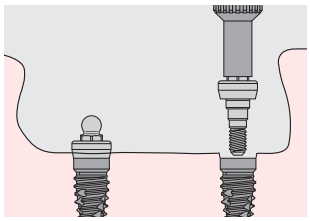


Fig. 2

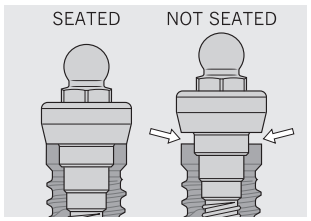


Fig. 3

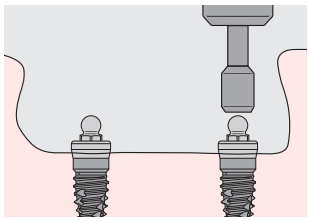
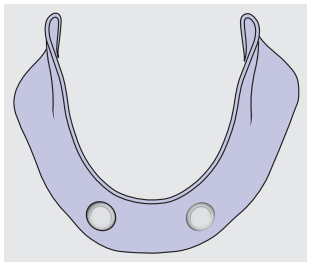


Fig. 4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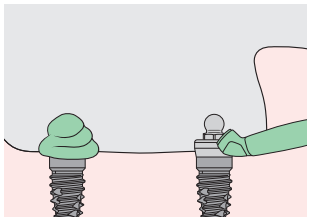


Fig. 6

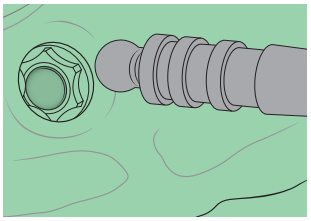
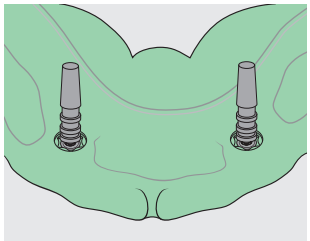


Fig. 7



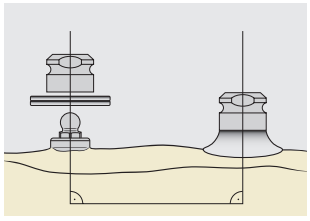


Fig. 8

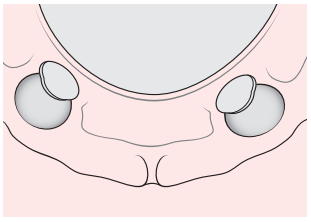
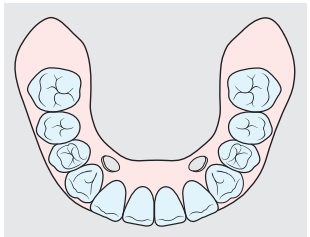


Fig. 9



Dalbo®-PLUS female part and Dalbo® Certain® Abutment

Please note:

- (Fig. 8): Before polymerizing the female part into the denture, we recommend using **two tin spacers** (Order No. 050094) to compensate for the seating of the denture so that subsequent overloading of the denture and female part on the ball abutments is avoided. Place the flexible spacer over the ball abutment and adapt it before polymerizing the acrylic. Remove the spacer after finishing the denture.

10. Version B) Resin-bonding the female housing Dalbo®-PLUS into a reinforcing framework (recommended!)

The **red duplicating/spacer** aid is larger than the female to create an ideal gap for the resin after casting of the reinforcing framework. 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 «CM resin-bonding» brochure at **www.cmsa.ch/dental.**

Direct technique (Fitting the female part in the patient's mouth)

Follow steps **1 – 5 of the indirect technique.**

6. (Fig. 9): Before fitting the female, create adequate space in the denture base. Fix the elliptic females **parallel in the mouth** (Fig. 8) and block out the undercuts (e.g. with soft wax or impression plaster).

With hybrid dentures, ensure that the implant is not loaded (e.g. with a rubber dam). This prevents the denture rocking after placement.

Important: Increased wear and service expense may be expected if the female parts are not aligned in parallel.

Adjusting the retentive force

The screwdriver/activator (Order No. 072609) 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 «Zero Position» corresponds when the lamellae retention insert is flush with the opening of the housing. The retention strength increases by approx. 200 g with each ¼ rotation (Fig. 11). If needed, the lamellae retention insert can be exchanged, or in case of advanced wear of the sphere, replaced with a tuning lamellae retention insert without removing the female part from the denture's body.

Caution: The lamellae retention insert must **not** protrude from the housing (Fig. 12).

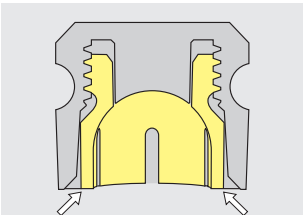


Fig. 10

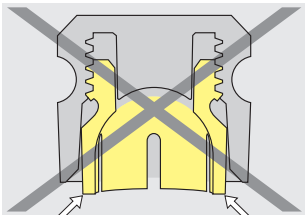


Fig. 12

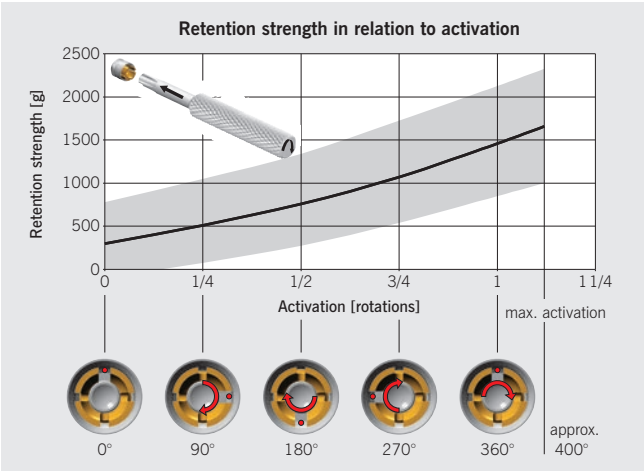


Fig. 11

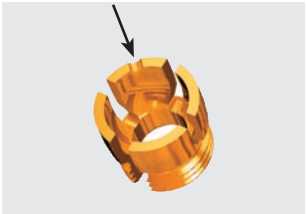


Fig. 13

Lamellae retention inserts Tuning *soft*

Tuning soft version
(1 indentation)

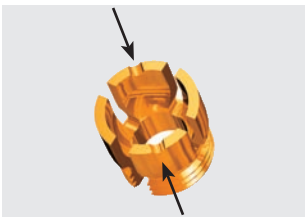


Fig. 14

Lamellae retention inserts Tuning

Tuning version
(2 indentations)

Dalbo®-PLUS female part and Dalbo® Certain® Abutment

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. 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!
5) Widen the resulting cavity with a spherical bur.
6) Take an impression
7) To fabricate the master model, use the **Dal-Ro Laboratory analogue.**
8) To fit the female part, proceed as described above.

Two additional lamellae retention inserts are available for increasing friction: Tuning and Tuning soft. They can be easily distinguished from standard retention inserts by the different indentations (Fig. 13 + 14) on the lamellae.

Lamellae retention inserts:

Standard	**normal friction** (Order No. 055 643)
Tuning *soft*	**high friction** (Order No. 0500 0068)
Tuning	**extra high friction** (Order No. 055 687)

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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.
	Do not re-use
	Non-sterile
	Keep away from sunlight
	Caution, consult accompanying documents