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Dalbo®-System

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Instructions for Use Dalbo®-System

Dalbo® Abutment, Dalbo®-PLUS, Dalbo®-Classic and Dalbo®-B

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: www.cmsa.ch/docs.

5 Product description

Dalbo® System

The Dalbo® System is an anchorage for retentive, rigid or resilient use on implants and root canal caps. When restoring with one or two ball anchors, there is a certain degree of resilience; with three or more ball anchors, the denture is rigid.



Dalbo® Abutment

Implant ball anchorage with a ball head diameter of 2.25 mm. For available implant connections, see Section 29.



Dalbo® CAD/CAM Retention element

Ball anchorage with threaded pins and a ball head diameter of 2.25 mm for screwing into milled bar constructions.



Dalbo® Male parts

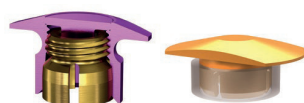
Ball head diameter: 2.25 mm.

- a) The Elitor® (E) male part can be soldered or lasered onto root canal caps
- b) The Valor (V) male part can be cast-on during fabrication of the root canal cap



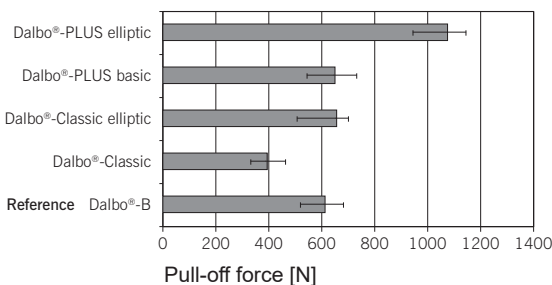
Dalbo® Female parts

All female parts of the Dalbo® System are suitable for ball male parts and implant ball head abutments with a diameter of 2.25 mm.



Elliptic variants

For an even stronger retention in the denture body. The elliptic retention wing can be reduced if necessary. However, any reduction leads to a loss of retention force.



Comparison of retention force of Dalbo® Female parts in the denture body

All ball female parts demonstrate sufficient retention in the denture body under laboratory conditions. Remarkable is the high value of the Dalbo®-PLUS Female part elliptic, which in part even exceeds the mechanical properties of the resin.

Dalbo®-PLUS



Dalbo®-PLUS Female part TE basic

Is intended for assembly in the laboratory. It can be polymerised directly or bonded into a metal housing. The red duplicating aid enclosed with the product considerably simplifies the fabrication process of a bonding box in the laboratory: attach – block out undercut – duplicate – model – embed – cast – divest – blast – bond – finished!



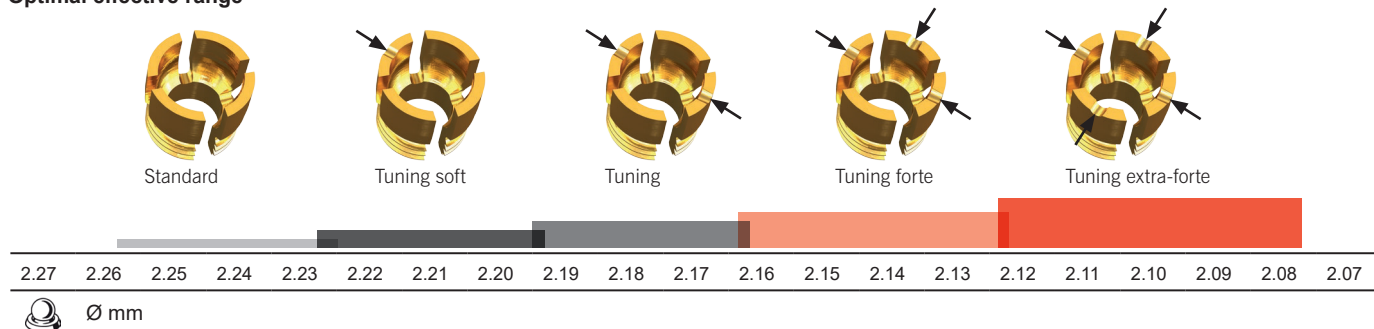
Dalbo®-PLUS Female part TE elliptic

Is intended for placement directly in the patient's mouth. Experience has shown that the quality of the resin deteriorates with direct placement and that the female part can break from the denture under high loads. The elliptical design of the resin retention increases the retention force in the denture body.

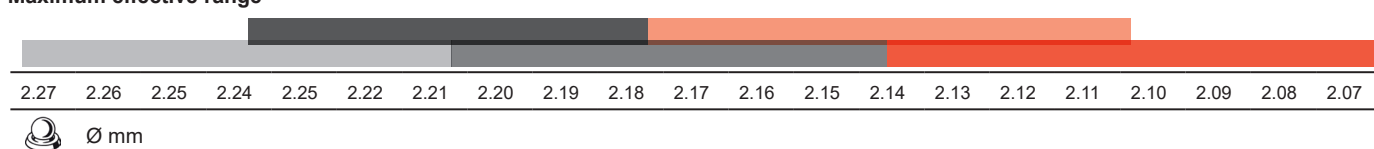
Tuning system for female parts

The ball anchor is the oldest and most used anchoring principle. Minute differences in ball diameter, material selection, geometry and tolerance ranges influence the friction clearance. Four different Dalbo®-PLUS Tuning lamellae retention insert with different inner diameters allow the retention force to be restored, regardless of the system used or even age-related wear.

Optimal effective range



Maximum effective range

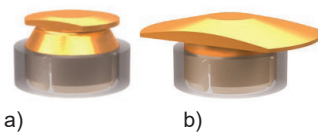


Lamellae retention inserts E

The lamellae retention insert is the actual retaining element of the system. It is made of Elitor® (E), a yellow precious metal alloy with ideal mechanical properties for a long-lasting and reliable function. Using a special screwdriver/activator (Cat. No. 072609), the insert can be turned out of the housing and re-inserted again without removing the female part from the denture body. The four special tuning retention inserts with a reduced inner diameter provide for an exceptionally broad frictional clearance range and for restoration of the retention force even in case of already worn male parts.

	Lamellae retention insert (basal: no groove)
	Tuning lamellae retention insert soft (basal: 1 groove)
	Tuning lamellae retention insert (basal: 2 grooves)
	Tuning lamellae retention insert forte (basal: 3 grooves)
	Tuning lamellae retention insert extra-forte (basal: 4 grooves)

The following abutment divergences can be compensated:
 – root canal caps, depending on the activation of between 4° – 8°.
 – on implants, depending on the activation, up to 20°.



Dalbo®-Classic basic (a) / Dalbo®-Classic elliptic (b)

The elliptic (b) version differs in the design of the female part from the basic (a) version by a massively pronounced, elliptically shaped resin retention, but without changing the popular, low insertion height. This design is indicated for direct placement in the mouth or quite simply where an extra strong retention force of the female part in the denture body is desired.

Version EV. The male part in the Valor (V) can be connected to the root canal cap by casting-on or soldering. Casting-on saves time and eliminates the need for jointing materials. The attached retention of both designs with an additional anti-rotation mechanism ensures a secure hold in the resin.

The EK version. The male part made of special burn-out Korak (K) resin results in a high-quality surface after casting when used correctly. The two female part designs are identical to the EV versions.

The following abutment divergences can be compensated:
 – on root canal caps 10°
 – on implants up to 20°

The Elitor® (E) female part is integrated exclusively by polymerisation.



Dalbo®-B

Was the world's first ball anchor and formed the basis for the development of the Dalbo®-PLUS and the Dalbo®-Classic.

The following abutment divergences can be compensated:
 – on root canal caps 6°
 – on implants up to 18°

The female part is integrated exclusively by polymerisation.

Auxiliary parts and instruments



Elastomer ring

Dalbo®-Classic (Cat. No. 055688)
 Dalbo®-B (Cat. No. 051005)



Duplication aid G (Cat. No. 072626)

Can only be used for the Dalbo®-PLUS female part!

These «red» parts are slightly oversized with regard to the original components. This allows optimal bonding clearance for duplicating and bonding techniques. After being used as a duplication aid, the duplication auxiliary part can also be used as polishing protection.



Spacer G

Dalbo®-Classic (Cat. No. 072625)
 Dalbo®-B (Cat. No. 070440)

Spacers basically replace the anchoring female parts during resin polymerisation in the laboratory. These are then removed from the fully polymerised denture. The most optimal polymerisation or bonding of the original female parts is performed by the dentist directly in the patient's mouth after cementation of the root canal caps. The spacer also proves to be an excellent polishing protection for the male part.

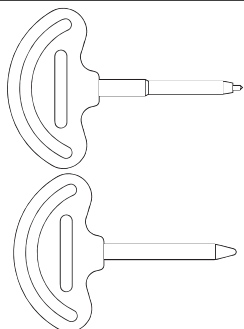
⚠ The duplicating aid and the spacer must not be used in place of the female part as a temporary replacement, nor for taking impressions in the mouth.



Spacer disc Z (Cat. No. 050394)

The tin spacer supplied with each female part enables vertical resilience. This is incorporated prior to polymerisation, after which it is removed again.

⚠ The tin spacer disc must not be inserted in the mouth.



Activator / deactivator

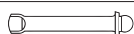
The activator (Cat. No. 070197) and deactivator (Cat. No. 070199) for the Dalbo®-Classic and Dalbo®-B must not be sterilised. There is a risk that the resin handles will be destroyed during sterilisation in an autoclave. Please consider the published national guidelines when selecting a disinfection process and the Instructions for Use «Preparation of surgical and prosthetic products» (www.cmsa.ch/docs).



Punch for elastomer ring mounting (Cat. No. 070205)

For the optimal function and protection of the lamellae of the Dalbo®-Classic/elliptic and Dalbo®-B, the elastomer ring mounted on the female parts should not be removed.

ⓘ Do not re-use elastomer rings once they have been slipped on.



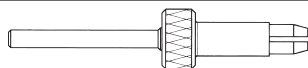
Transfer axis (Cat. No. 070157): for fabricating the master model.



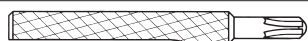
Dalbo® Abutment Analog (Cat. No. 07000312): for master model fabrication for implant work.



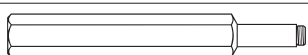
Dalbo® Abutment Screwdriver (Cat. No. 07000266):Screwdriver for Dalbo® Abutment.



Special-Parallelometer Insert (Cat. No. 072637) Is used for the parallel setting of several Dalbo® Male parts in the parallelometer.



Screwdriver / Activator (Cat. No. 072609): Is used to screw in and activate the lamellae retention insert for the Dalbo®-PLUS.



Heating Rod (Cat. No. 072639); For extracting housings (only Dalbo®-PLUS) from the resin.

6 Indications

- Removable, rigidly or resiliently anchored denture on implants and root canal caps:
- Hybrid prosthetics
 - Unilateral dentures, splinted transversally
 - Partial and free-end dentures in combination

7 Contraindications

- Unilateral, partial and free-end dentures without transversal support.
- Compensation of abutment divergences outside the respective application area of the system for male part and female part (see Section 5 Product Description).
- Restoration of severely periodontally damaged abutment teeth.
- Use on implant systems which are not approved for ball anchorages (see Section 29).
- Use for the immediate restoration of implants if the manufacturer has not approved this indication.
- 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

The Dalbo® Abutments have been designed for conventional implant interfaces. Approved systems are listed in Section 29.

The Dalbo® Female parts are compatible with

- Dalbo®-Rotex
- Implant ball anchorage with a ball head diameter of 2.25 mm.
- Ball anchorage with a ball head diameter of 2.25 mm.



The retention force of the Dalbo® Female parts on the male parts of other manufacturers can vary due to their manufacturing tolerances and surface qualities.

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	08052160	uniVest® Plus Powder (30 x 150 g)
08052149	ABF Wax Universal	08052161	uniVest® Plus Liquid (1000 ml)
08052150	ABF Wax Creativ light	08052162	uniVest® Rapid Powder (30 x 150 g)
08052151	ABF Wax Creativ dark	08052163	uniVest® Rapid Liquid (1000 ml)
08052154	ABF Wax Special	080181	CM soldering investment (4 kg)
08052148	ABF Wax Margin	080229	CM soldering paste
08052153	ABF Wax Position	08052307	Legabril Diamond (50 g)
08052152	ABF Wax Tecno		

9 Qualification of the specialist

Expertise in professional dentistry and dental technology is assumed. The current Instructions for Use must be available at all times and be completely read and understood before the first application. The fabrication of dentures and their maintenance may only be performed by qualified specialists.



Important information for the specialist



Warning symbol for increased caution

10 Prescription

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

11 Side effects

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

12 Warnings

- ⚠ **Magnetic resonance (MR) environment**
The device has not been evaluated for safety and compatibility in the MR environment.
The product has not been tested for heating or migration in the MR environment.

13 General information

N/A

14 Preventive measures

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

15 Single use

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

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

16 Reprocessing

- 📖 The prosthetic work, including all system components, must be cleaned, disinfected and, if appropriate, sterilised prior to each work step. Materials made of metal alloys, high-performance polymers (Pekkton®) and ceramics are suitable for steam sterilisation. With the exception of Pekkton®, components made of plastics are not suitable for steam sterilisation. Consider published national guidelines when selecting a disinfection and sterilisation process and the Instructions for Use "Reprocessing of surgical and prosthetic products" (www.cmsa.ch/docs).

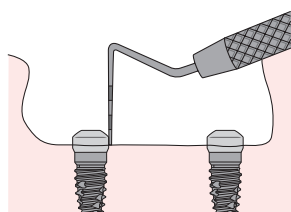
17 Scope of application

The Dalbo® System components are designed to fixate partial and full dentures on implants and root canal caps in the maxilla and mandible.

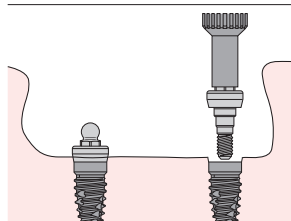
- 📖 We recommend that the denture be designed such that the largest possible support polygon can be achieved. Small distances between consecutive implants and long free-end saddles can cause undesirable effects such as increased wear of the system components.

18 Procedure**18.1 Fabrication of the primary reconstruction****18.1.1 Dalbo® Abutment**

- 📖 Before using the Dalbo® Abutment, follow the Instructions for Use of the implant manufacturer.

**Determining the abutment height**

Choose the required gingival height of the abutment height with a probe (1 mm graduation). The lower edge of the abutment should lie 1 mm above the gingiva. Various heights are available.

**Inserting the Dalbo® Abutment**

First, place the Dalbo® Abutment on the Dalbo® Abutment Screwdriver (Cat. No. 07000266) and screw it into the implant by hand.

Then tighten with the torque ratchet with the corresponding torque (see information on the packaging). Make sure that the screwdriver is seated correctly on the abutment. Secure all parts against aspiration. After assembly, the screwdriver can be removed again by lifting it slightly.

- 📖 – Screw in the abutment only once using the torque specified for this purpose.
– In case of immediate loading (observe indication of the implant manufacturer), ensure that the tightening torque of the abutment does not exceed that of the screwed-in implant. Recommendation, at least 5 Ncm less than the implant tightening torque.


- 📖 The screwdriver features an ISO connection and fits onto the coupling inserts for the corresponding torque ratchets.

18.1.2 Dalbo® CAD/CAM Retention element

When modelling the bar in the CAD software, allow for the position of the Dalbo® CAD/CAM Retention element. A standard thread M2.0 is required for fixation of the Dalbo® CAD/CAM Retention element on the bar.

Inserting the Dalbo® CAD/CAM Retention element

After fabricating the milled bar, the Dalbo® CAD/CAM Retention element can be mounted on the bar using the Dalbo® Screwdriver (Cat. No. 07000266). Make sure that the screwdriver is seated correctly on the retention element. Secure all parts against aspiration. Then tighten with the torque ratchet with a torque of > 35 Ncm. After assembly, the screwdriver can be removed again by lifting it slightly.

 The screwdriver features an ISO connection and fits onto the coupling inserts for the corresponding torque ratchets.

18.1.3 Dalbo® Male parts

Work preparation

Wax-up of the root canal cap with the root canal pin. In the case of several root canal caps, prepare the solder/laser surface at right angles to the direction of insertion. Use prefabricated, cast-on precious metal pins.

Inserting the Dalbo® Male part V by casting-on

Using the special parallelometer insert (Cat. No. 072637) set the male part V as centrally as possible and wax it cleanly to the root canal cap. Then embed and cast.

Inserting the Dalbo® Male part V by soldering

Using the special parallelometer insert (Cat. No. 072637) set the male part V as centrally as possible on the already cast and face-milled root canal cap and fix it with wax (take aesthetics into account). The solder gap should be continuous and between 0.05 – 0.20 mm wide. Design the soldering block, such that the male part V is securely held and good flame access is ensured.

Recommended solders: S.G 810 (Cat. No. 01000348) and S.G 750 (Cat. No. 01000345).

Inserting the Dalbo® Male part E by laser welding

In principle, only identical materials of the same composition should be joined together. Later failures can thus be reduced to an absolute minimum. We recommend using the Dalbo® Laser male part E (identical with Protor® 3) with the laser welding wire LW No. 5 (Cat. No. 01050041) and the casting alloy Protor® 3 (Cat. No. 010654) from Cendres+Métaux. Details on processing can be found in the Instructions for Use of the laser welding wires.


 After thermal treatment (e.g. soldering, cast-on) slowly allow to cool down to room temperature to achieve the optimum mechanical properties without a tempering process. Fit a duplication aid or spacer to protect the male part during sandblasting and processing.


Inserting the Dalbo® Male part K by casting

Fill the cavity of the male part K with wax. Using the special parallelometer insert (Cat. No. 072637) set the male part K as centrally as possible and wax it cleanly to the waxed-up root canal cap. After casting, polish the Dalbo® Male part extremely carefully and set to the desired frictional power with the female part.

18.2 Fabrication of the secondary reconstruction (denture)

General information

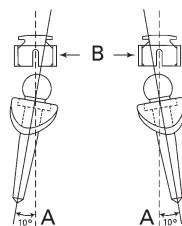
 The tin spacer (Cat. No. 050394) supplied with the female part enables vertical resilience. The soft spacer disc is placed over the entire root canal cap or anchoring element and adapted prior to polymerisation of the resin. After completion of the resin work, the spacer disc is removed again. Current clinical experience shows that the minimal vertical resilience disappears once the denture is placed. The greatest advantage is that the denture base is not overloaded on the root canal cap or the abutment.


 For optimal function and protection of the lamellae, the elastomer ring mounted on the Dalbo®-Classic basic, Dalbo®-Classic elliptic and Dalbo®-B female parts should not be removed. If necessary, the elastomer ring can be changed using the punch (Cat. No. 070205) as follows:

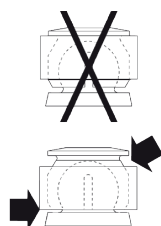
- 1) Remove blue sleeve from the punch
- 2) Slip on several elastomer rings
- 3) Mount sleeve
- 4) By pushing the sleeve, the elastomer rings are pressed over the lamellae of the female part.


Do not re-use elastomer rings once they have been slipped on.

 Before fitting, protect the inside of the female part with Vaseline or soft silicone to prevent resin from penetrating.



 When fitting several female parts, make sure that they are positioned parallel to each other on the male parts and waxed firmly.



 Fit the elastomer ring flush with the rim of the female part, so that the maximum retention can be used for the resin. Block out the undercuts and interpapillary spaces with impression plaster, wax, Flexistone or a rubber dam. Observe maximum abutment divergence. For the optimal function and protection of the lamellae the elastomer ring mounted on the Dalbo®-Classic and Dalbo®-B Female parts should not be removed.

Inserting the female parts in the laboratory by polymerisation

Block out the undercuts and interpapillary spaces with impression plaster, wax, Flexistone or a rubber dam.

Inserting the Dalbo®-PLUS basic female parts by bonding in the laboratory

The red duplicating aid G (Cat. No. 072626) enclosed with the product is oversized in relation to the female part such that it creates an ideal bonding gap after casting the framework. After fabricating the primary construction, place the duplication aid G on the ball anchor, block out undercuts and duplicate the model (silicone type). After casting and finishing, clean the inner surface of the retention housing. Blast the outer surface of the Dalbo®-PLUS basic female part as well as the model cast housing with Al₂O₃. Wax the female parts parallel to each other on the male parts and bond them into the framework. Use only suitable bonding agents.

Inserting the female part in the patient's mouth

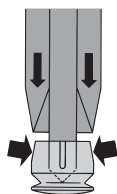
To this end, the elliptic versions with reinforced resin retention are available specifically for Dalbo®-PLUS and Dalbo®-Classic. Create sufficient space prior to inclusion in the denture body. Fixate the elliptic female part in the mouth in parallel and block out the undercuts. If possible, drill an additional drainage canal through the denture body. With hybrid dentures, ensure that the root canal cap or the abutment are not loaded. This prevents the denture from rocking after insertion.



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

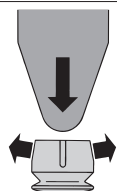
18.3 Activation and deactivation

18.3.1 Dalbo®-Classic, Dalbo®-B



Activation:

Press the four lamellae together evenly by applying light pressure with the activator provided for this purpose (Cat. No. 070197).



Deactivation:

Apply light pressure with the deactivator provided for this purpose (Cat. No. 070199) to spread the lamellae evenly without the female part breaking out of the resin.

18.3.2 Dalbo®-PLUS

The Dalbo®-PLUS has five retention inserts, the lamellae retention insert E (Cat. No. 055643), the tuning lamellae retention insert soft E (Cat. No. 05000068), the tuning lamellae retention insert E (Cat. No. 055687), tuning lamellae retention insert forte E (Cat. No. 05000081) and tuning lamellae retention insert extra-forte E (Cat. No. 05000083).

For new work, the lamellae retention insert E (Cat. No. 055643) is used.

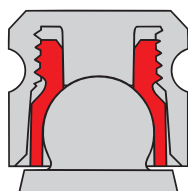
Our ball anchor diameter 2.25 mm has become the standard for most systems in the market. Experience and studies with third-party products have shown that minute differences, such as the choice of material, the geometry or the tolerance range, can reduce the frictional clearance of the Dalbo®-PLUS Lamellae retention insert. Two additional lamellae retention inserts are available to increase the clearance and for the aftercare of already worn ball head male parts. Different notches on the lamellae make them easy to distinguish from «normal» retention inserts.

Standard	Lamellae retention insert (without groove)	normal friction
Tuning soft	Lamellae retention insert (1 groove)	high friction
Tuning	Lamellae retention insert (2 grooves)	extra high friction
Tuning forte	Lamellae retention insert (3 grooves)	forte friction
Tuning extra-forte	Lamellae retention insert (4 grooves)	extra-forte friction

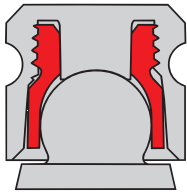


The screwdriver / activator (Cat.-No.072 609) is required to activate, deactivate and remove the lamellae retention insert. The instrument with four cams is pushed into the lamellae retention insert in its correct position up to the stop.

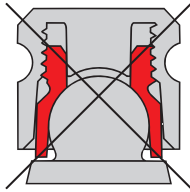
The retention force is adjusted by turning clockwise to increase the retention force and vice versa to reduce the retention force.





The basic setting on delivery is approximately 200 g, which also represents the minimum retention force to be set (lamellae retention insert is flush with the lower edge of the housing).




The retention force is adjusted by turning clockwise to increase the retention force and vice versa to reduce the retention force. The maximum retention force is approx. 1200 g (lamellae retention insert cannot be screwed in any further).



 The lamellae retention insert must not protrude from the housing, otherwise it could become detached from the housing by itself.

 After use, clean instruments with water and proceed as described in Section 16 (Preparation).

18.4 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 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 carried out if required to prevent rocking movement (overload). We recommend checking the denture at intervals of approx. 3 months initially and to replace the retention inserts if necessary.

18.4.1 Modifications, relining


Before taking the impression, preferably remove the original female part from the denture.

Dalbo®-Classic / Dalbo®-B

Carefully remove the old female part from the denture.

Dalbo®-PLUS

1. Removing the lamellae retention insert
2. Screw the heating rod (Cat. No. 072639) into the housing of the female part
3. Heat the opposite end over the flame of a Bunsen burner until the resin around the female part becomes soft.
4. Using pliers, pull the heating rod together with the female part out of the denture.
5. Before taking the impression, place the existing or a new Dalbo® Female part on the male part, the abutment. Place the master model analogue/transfer axis in the Dalbo® Female part to fabricate the master model.

 In the case of a bonded Dalbo®-PLUS Female part housing, the temperature required to neutralise the adhesive's bonding strength is many times higher!

18.4.2 Impression taking

Always use the original Dalbo® Female part for this purpose.

Place the Dalbo® Female part on the Dalbo® Male part or the Dalbo® Abutment.

Block out the space between the female part and the male part/abutment with a little soft wax before taking the impression. Ensure an exact fit, parallelism of the insertion direction and correct alignment with the occlusal plane of the female part. Take a functional impression. Use a solid impression silicone. Check that the material is distributed completely around the female part and that no impression material has flowed into the female part, otherwise clean the male part and female part and repeat impression taking.

18.4.3 Model fabrication

To fabricate the model, the implant analogue (Cat. No. 07000312) is used for an implant restoration, and the transfer axis (Cat. No. 070157) is used for root canal pin restorations by inserting it into the female part and fixating it securely.

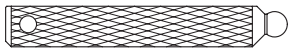
Then proceed with fabrication of the master model.

18.4.4 Insufficient denture retention – what to do:

1. Remove the denture, clean it and check which anchor system was used.
2. Check the denture to see if the female part or its components are damaged, replace if necessary and readjust denture retention.
3. Check whether the incorporated female part is correctly positioned on the male part. If this is not the case, the retention force is reduced and wear is very high. It is essential to insert the female part afresh.
The correct seating of the female part can be checked by using an easy-flowing silicone.
4. Check in the mouth to see if there are any signs of wear on the ball of the male part, which could be the cause of insufficient retention.
If yes, use the Dalbo®-PLUS Gauge to check the level of wear in the patient's mouth. If the Dalbo®-PLUS was used, then denture retention can be easily readjusted by replacing the lamellae retention insert, which is available in 3 different force levels, in the housing.
If a different ball anchor system was used, we recommend changing to the Dalbo®-PLUS when the ball male parts are worn out.

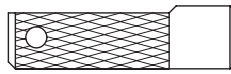
18.4.5 Dalbo®-PLUS Gauge

With the two instruments Male part gauge (Cat. No. 07000027) and Female part gauge (Cat. No. 07000024), it is possible to check in the mouth whether the ball male part shows signs of wear.



Male part gauge (Cat. No. 07000027).

Allows checking the set retention force in the denture outside the mouth. The nominal dimension of the ball diameter of the male part gauge is 2,245 mm and corresponds to the most commonly used systems on the market.



Female part gauge (Cat. No. 07000024)

Supplied without mounted lamellae retention insert.

Serves to check and determine the desired Dalbo®-PLUS Female part retention force in the patient's mouth and selection of the ideal lamellae retention insert.

Adjusting the retention force

1. Screw in the Standard lamellae retention insert (Cat. No. 055643) with the screwdriver/activator (Cat. No. 072609) into the female part gauge (Cat. No. 07000024) up to the 0-position (flush with the lower edge of the housing).



Repeated screwing and unscrewing of the lamellae retention insert reduces the protection against becoming loose by itself!

2. Check and adjust the retention force in the mouth with the female part gauge, which is secured with a thread, by increasing the retention force stepwise with ¼ turns. Adjustment is a matter of feeling. The recommended retention force lies between 600 – 900 g, but may vary depending on the number of anchors used and the patient situation.

3. If sufficient retention cannot be achieved with the Standard lamellae retention insert, first try the Tuning lamellae retention insert soft to see if denture retention can be achieved again. If this is not possible, start with the Tuning, then with the Tuning forte and finally repeat the procedure with the Tuning extra-forte until the denture finds sufficient hold on the ball anchors again. If even the strongest lamellae retention insert extra-forte cannot hold the denture, the ball anchor must be replaced.

4. Once the desired retention force has been reached, note the number of revolutions.

Unscrew the lamellae retention insert and adjust it again with the same number of turns in the original housing.

5. Note the type of lamellae retention insert used and the batch number in the patient file.

19 Materials

S = Syntax; TiAl6V4 ELI (Grade5)

T = Pure titanium (Grade 4); Ti > 98.9375 %

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

V = Valor; Pt 89.0 %, Au 10.0 %, Ir 1.0 %. $T_s - T_L$ 1660 – 1710 °C

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

G = Galak; Mouth-resistant resin

X = Steel

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

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:

Dalbo® / 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
See Implant system	Dalbo® Abutment	TiAl6V4 ELI, (Grade5)	Yes	CE 0483	See Implant system
05002599	Dalbo® CAD/CAM Retention element	TiAl6V4 ELI, (Grade5)	Yes	CE 0483	07640166517665
07000312	Dalbo® Abutment analogue	TiAl6 V4 ELI, (Grade5)	Yes	CE	07640166517672
07000266	Dalbo® Abutment screwdriver	Steel	No	CE	07640166517689
055750	Dalbo®-PLUS TEV basic	Ti / Elitor® / Valor	Yes	CE 0483	07640166514176
055889	Dalbo®-PLUS TEV elliptic	Ti / Elitor® / Valor	Yes	CE 0483	07640166514220
055752	Dalbo®-PLUS Female part TE basic	Ti / Elitor®	Yes	CE 0483	07640166514183
055890	Dalbo®-PLUS Female part TE elliptic	Ti / Elitor®	Yes	CE 0483	07640166514237
055643	Dalbo®-PLUS Lamellae retention insert E	Elitor®	Yes	CE 0483	07640166514145
05000214	Dalbo®-PLUS Tuning female part soft TE basic	Ti / Elitor®	Yes	CE 0483	07640166514985
05000215	Dalbo®-PLUS Tuning female part soft TE elliptic	Ti / Elitor®	Yes	CE 0483	07640166514992
05000068	Dalbo®-PLUS Tuning lamellae retention insert soft E	Elitor®	Yes	CE 0483	07640166514954
055771	Dalbo®-PLUS Tuning female part TE basic	Ti / Elitor®	Yes	CE 0483	07640166514190
055891	Dalbo®-PLUS Tuning female part TE elliptic	Ti / Elitor®	Yes	CE 0483	07640166514244
055687	Dalbo®-PLUS Tuning lamellae retention insert E	Elitor®	Yes	CE 0483	07640166514169
05000081	Dalbo®-PLUS Tuning lamellae retention insert forte E	Elitor®	Yes	CE 0483	07640239932098
05000083	Dalbo®-PLUS Tuning lamellae retention insert extra-forte E	Elitor®	Yes	CE 0483	07640239932104
050394	Dalbo®-PLUS /-Classic /-B /-Z Spacer disc Z	Tin	Yes	CE	07640166513759
055647	Dalbo®-PLUS /-Classic Male part V	Valor	Yes	CE 0483	07640166514152
055921	Dalbo®-PLUS /-Classic /-B Lasering male part E	Elitor®	Yes	CE 0483	07640166514251
055760	Dalbo®-PLUS Housing of the female part T basic	Ti	Yes	CE 0483	07640166517696
055886	Dalbo®-PLUS Housing of the female part T elliptic	Ti	Yes	CE 0483	07640173090939
072626	Dalbo®-PLUS Duplication aid / spacer G	Galak	Yes	CE	07640166514923
070157	Dalbo®-PLUS /-Classic /-B /-Z / Profix Transfer axis	Steel	Yes	CE	07640166514404
072637	Dalbo®-PLUS /Dalbo®-Classic Special parallelometer insert	Steel	No	CE	07640166514947
072609	Dalbo®-PLUS Screwdriver / activator	Steel	No	CE	07640166514916
072639	Dalbo®-PLUS Heating rod	Steel	No	CE	07640173091271
07000027	Dalbo®-PLUS Male part gauge	Steel	No	CE	07640173090984
07000024	Dalbo®-PLUS Female part gauge	Steel	No	CE	07640173090977
070222	KE forceps	Steel	No	CE	07640166514565
055689	Dalbo®-Classic EV basic	Elitor® / Valor	Yes	CE 0483	07640173090090
055701	Dalbo®-Classic EK basic	Elitor® / Korak	Yes	CE 0483	07640173090106
055892	Dalbo®-Classic EV elliptic	Elitor® / Valor	Yes	CE 0483	07640173090953
055893	Dalbo®-Classic EK elliptic	Elitor® / Korak	Yes	CE 0483	07640173090960
055698	Dalbo®-Classic Female part E basic	Elitor®	Yes	CE 0483	07640173090915
055887	Dalbo®-Classic Female part E elliptic	Elitor®	Yes	CE 0483	07640173090946
055688	Dalbo®-Classic Elastomer ring	Elastomer	Yes	CE 0483	07640173090892
055330	Dalbo®-Classic / Dalbo®-B Male part K	Korak	Yes	N/A	07640173093114
072625	Dalbo®-Classic Spacer G	Galak	Yes	CE	07640173091264
070205	Dalbo® / Baer cylinder anchor punch, for elastomer ring mounting	Steel	No	CE	07640166514534
070197	Dalbo®-Classic /-B /-Z / Profix activator	Steel	No	CE	07640166514497
070199	Dalbo®-Classic /-B /-Z / Profix deactivator	Steel	No	CE	07640166514503
050427	Dalbo®-B EE	Elitor®	Yes	CE 0483	07640166513780
055331	Dalbo®-B EK	Elitor® / Korak	Yes	CE 0483	07640173090113
051511	Dalbo®-B Female part E	Elitor®	Yes	CE 0483	07640166513995
051005	Dalbo®-B Elastomer ring	Elastomer	Yes	CE 0483	07640173092216
050423	Dalbo®-B Male part E	Elitor®	Yes	CE 0483	07640166513773
070440	Dalbo®-B Spacer G	Galak	Yes	CE	07640173090274
070131	Dalbo®-Z / Dalbo®-B / Profix / Pro-Snap Parallelometer insert	Steel	No	CE	07640166514312



















Implant system	Cat. No.	Product name	Platform	Torque (recom- mendation)	UDI-DI
Straumann®	05002446	Dalbo® Abutment	Straumann® RN 4.8, GH1	Torque 35Ncm	07640166516958
	05002447	Dalbo® Abutment	Straumann® RN 4.8, GH2	Torque 35Ncm	07640166516965
	05002448	Dalbo® Abutment	Straumann® RN 4.8, GH3	Torque 35Ncm	07640166516972
	05002456	Dalbo® Abutment	Straumann® RC 4.1/4.8, GH3	Torque 35Ncm	07640166516989
	05002457	Dalbo® Abutment	Straumann® RC 4.1/4.8, GH4	Torque 35Ncm	07640166516996
	05002458	Dalbo® Abutment	Straumann® RC 4.1/4.8, GH5	Torque 35Ncm	07640166517009
	05002476	Dalbo® Abutment	Straumann® NC 3.3, GH3	Torque 35Ncm	07640166517016
	05002477	Dalbo® Abutment	Straumann® NC 3.3, GH4	Torque 35Ncm	07640166517023
	05002478	Dalbo® Abutment	Straumann® NC 3.3, GH5	Torque 35Ncm	07640166517030
Astra Tech	05002706	Dalbo® Abutment	Astra Tech OsseoSpeed® EV 3.6, GH3	Torque 25Ncm	07640166517047
	05002707	Dalbo® Abutment	Astra Tech OsseoSpeed® EV 3.6, GH4	Torque 25Ncm	07640166517054
	05002708	Dalbo® Abutment	Astra Tech OsseoSpeed® EV 3.6, GH5	Torque 25Ncm	07640166517061
	05002716	Dalbo® Abutment	Astra Tech OsseoSpeed® EV 4.2, GH3	Torque 25Ncm	07640166517078
	05002717	Dalbo® Abutment	Astra Tech OsseoSpeed® EV 4.2, GH4	Torque 25Ncm	07640166517085
	05002718	Dalbo® Abutment	Astra Tech OsseoSpeed® EV 4.2, GH5	Torque 25Ncm	07640166517092
	05002726	Dalbo® Abutment	Astra Tech OsseoSpeed® EV 4.8, GH3	Torque 25Ncm	07640166517108
	05002727	Dalbo® Abutment	Astra Tech OsseoSpeed® EV 4.8, GH4	Torque 25Ncm	07640166517115
	05002728	Dalbo® Abutment	Astra Tech OsseoSpeed® EV 4.8, GH5	Torque 25Ncm	07640166517122
	05002736	Dalbo® Abutment	Astra Tech OsseoSpeed® 3.5/4.0, GH3	Torque 25Ncm	07640166517139
	05002737	Dalbo® Abutment	Astra Tech OsseoSpeed® 3.5/4.0, GH4	Torque 25Ncm	07640166517146
	05002738	Dalbo® Abutment	Astra Tech OsseoSpeed® 3.5/4.0, GH5	Torque 25Ncm	07640166517153
	05002746	Dalbo® Abutment	Astra Tech OsseoSpeed® 4.5/5.0, GH3	Torque 25Ncm	07640166517160
	05002747	Dalbo® Abutment	Astra Tech OsseoSpeed® 4.5/5.0, GH4	Torque 25Ncm	07640166517177
	05002748	Dalbo® Abutment	Astra Tech OsseoSpeed® 4.5/5.0, GH5	Torque 25Ncm	07640166517184
Dentsply	05002756	Dalbo® Abutment	DENTSPLY Ankylos® C 3.5,4.5,5.5,7.0, GH3	Torque 25Ncm	07640166517191
	05002757	Dalbo® Abutment	DENTSPLY Ankylos® C 3.5,4.5,5.5,7.0, GH4	Torque 25Ncm	07640166517207
	05002758	Dalbo® Abutment	DENTSPLY Ankylos® C 3.5,4.5,5.5,7.0, GH5	Torque 25Ncm	07640166517214
Nobel Biocare	05002486	Dalbo® Abutment	Nobel Biocare Replace Select® RP 4.3, GH1	Torque 35Ncm	07640166517221
	05002487	Dalbo® Abutment	Nobel Biocare Replace Select® RP 4.3, GH2	Torque 35Ncm	07640166517238
	05002488	Dalbo® Abutment	Nobel Biocare Replace Select® RP 4.3, GH3	Torque 35Ncm	07640166517245
	05002496	Dalbo® Abutment	Nobel Biocare Replace Select® NP 3.5, GH1	Torque 35Ncm	07640166517252
	05002497	Dalbo® Abutment	Nobel Biocare Replace Select® NP 3.5, GH2	Torque 35Ncm	07640166517269
	05002498	Dalbo® Abutment	Nobel Biocare Replace Select® NP 3.5, GH3	Torque 35Ncm	07640166517276
	05002506	Dalbo® Abutment	Nobel Biocare Active® RP 4.3/5.0, GH3	Torque 35Ncm	07640166517283
	05002507	Dalbo® Abutment	Nobel Biocare Active® RP 4.3/5.0, GH4	Torque 35Ncm	07640166517290
	05002508	Dalbo® Abutment	Nobel Biocare Active® RP 4.3/5.0, GH5	Torque 35Ncm	07640166517306
	05002516	Dalbo® Abutment	Nobel Biocare Active® NP 3.5, GH3	Torque 35Ncm	07640166517313
	05002517	Dalbo® Abutment	Nobel Biocare Active® NP 3.5, GH4	Torque 35Ncm	07640166517320
	05002518	Dalbo® Abutment	Nobel Biocare Active® NP 3.5, GH5	Torque 35Ncm	07640166517337
	05002526	Dalbo® Abutment	Nobel Biocare Brånemark® RP 4.0, GH3	Torque 35Ncm	07640166517344
	05002527	Dalbo® Abutment	Nobel Biocare Brånemark® RP 4.0, GH4	Torque 35Ncm	07640166517351
	05002528	Dalbo® Abutment	Nobel Biocare Brånemark® RP 4.0, GH5	Torque 35Ncm	07640166517368
Osstem®	05002796	Dalbo® Abutment	Osstem® US Regular 4.1, GH3	Torque 30Ncm	07640166517375
	05002797	Dalbo® Abutment	Osstem® US Regular 4.1, GH4	Torque 30Ncm	07640166517382
	05002798	Dalbo® Abutment	Osstem® US Regular 4.1, GH5	Torque 30Ncm	07640166517399
	05002906	Dalbo® Abutment	Osstem® T _s Regular 4.0/4.5/5.0/6.0/7.0, GH3	Torque 30Ncm	07640166517405
	05002907	Dalbo® Abutment	Osstem® T _s Regular 4.0/4.5/5.0/6.0/7.0, GH4	Torque 30Ncm	07640166517412
	05002908	Dalbo® Abutment	Osstem® T _s Regular 4.0/4.5/5.0/6.0/7.0, GH5	Torque 30Ncm	07640166517429
	05002916	Dalbo® Abutment	Osstem® T _s Mini 3.5, GH3	Torque 30Ncm	07640166517436
	05002917	Dalbo® Abutment	Osstem® T _s Mini 3.5, GH4	Torque 30Ncm	07640166517443
	05002918	Dalbo® Abutment	Osstem® T _s Mini 3.5, GH5	Torque 30Ncm	07640166517450
	05002926	Dalbo® Abutment	Osstem® SS Regular 4.8, GH1	Torque 30Ncm	07640166517467
	05002927	Dalbo® Abutment	Osstem® SS Regular 4.8, GH2	Torque 30Ncm	07640166517474
	05002928	Dalbo® Abutment	Osstem® SS Regular 4.8, GH3	Torque 30Ncm	07640166517481

Implant system	Cat. No.	Product name	Platform	Torque (recommendation)	UDI-DI
Camlog®	05002766	Dalbo® Abutment	Camlog® 3.8, GH1	Torque 30Ncm	07640166517498
	05002767	Dalbo® Abutment	Camlog® 3.8, GH2	Torque 30Ncm	07640166517504
	05002768	Dalbo® Abutment	Camlog® 3.8, GH3	Torque 30Ncm	07640166517511
	05002776	Dalbo® Abutment	Camlog® 4.3, GH1	Torque 30Ncm	07640166517528
	05002777	Dalbo® Abutment	Camlog® 4.3, GH2	Torque 30Ncm	07640166517535
	05002778	Dalbo® Abutment	Camlog® 4.3, GH3	Torque 30Ncm	07640166517542
	05002786	Dalbo® Abutment	Conelog® 3.8/4.3, GH3	Torque 30Ncm	07640166517559
	05002787	Dalbo® Abutment	Conelog® 3.8/4.3, GH4	Torque 30Ncm	07640166517566
	05002788	Dalbo® Abutment	Conelog® 3.8/4.3, GH5	Torque 30Ncm	07640166517573
Zimmer	05002946	Dalbo® Abutment	Zimmer Tapered Screw-Vent® 3.5, GH3	Torque 30Ncm	07640166517887
	05002947	Dalbo® Abutment	Zimmer Tapered Screw-Vent® 3.5, GH4	Torque 30Ncm	07640166517856
	05002948	Dalbo® Abutment	Zimmer Tapered Screw-Vent® 3.5, GH5	Torque 30Ncm	07640166517849
	05002936	Dalbo® Abutment	Zimmer Tapered Screw-Vent® 4.5, GH3	Torque 30Ncm	07640166517757
	05002937	Dalbo® Abutment	Zimmer Tapered Screw-Vent® 4.5, GH4	Torque 30Ncm	07640166517764
	05002938	Dalbo® Abutment	Zimmer Tapered Screw-Vent® 4.5, GH5	Torque 30Ncm	07640166517771
MiS® (wide platform)	05002946	Dalbo® Abutment	MiS® Seven 3.5, GH3	Torque 30Ncm	07640166517887
	05002947	Dalbo® Abutment	MiS® Seven 3.5, GH4	Torque 30Ncm	07640166517856
	05002948	Dalbo® Abutment	MiS® Seven 3.5, GH5	Torque 30Ncm	07640166517849
	05002936	Dalbo® Abutment	MiS® Seven 4.5, GH3	Torque 30Ncm	07640166517757
	05002937	Dalbo® Abutment	MiS® Seven 4.5, GH4	Torque 30Ncm	07640166517764
	05002938	Dalbo® Abutment	MiS® Seven 4.5, GH5	Torque 30Ncm	07640166517771
BioHorizons®	05002946	Dalbo® Abutment	BioHorizons® Internal 3.5, GH3	Torque 30Ncm	07640166517887
	05002947	Dalbo® Abutment	BioHorizons® Internal 3.5, GH4	Torque 30Ncm	07640166517856
	05002948	Dalbo® Abutment	BioHorizons® Internal 3.5, GH5	Torque 30Ncm	07640166517849
	05002936	Dalbo® Abutment	BioHorizons® Internal 4.5, GH3	Torque 30Ncm	07640166517757
	05002937	Dalbo® Abutment	BioHorizons® Internal 4.5, GH4	Torque 30Ncm	07640166517764
	05002938	Dalbo® Abutment	BioHorizons® Internal 4.5, GH5	Torque 30Ncm	07640166517771
Sweden+Martina	05002956	Dalbo® Abutment	Sweden+Martina Premium Kohno 3.3, GH3	Torque 30Ncm	07640166517894
	05002957	Dalbo® Abutment	Sweden+Martina Premium Kohno 3.3, GH4	Torque 30Ncm	07640166517863
	05002958	Dalbo® Abutment	Sweden+Martina Premium Kohno 3.3, GH5	Torque 30Ncm	07640166517870
	05002966	Dalbo® Abutment	Sweden+Martina Premium Kohno 3.8, GH3	Torque 30Ncm	07640166517900
	05002967	Dalbo® Abutment	Sweden+Martina Premium Kohno 3.8, GH4	Torque 30Ncm	07640166517917
	05002968	Dalbo® Abutment	Sweden+Martina Premium Kohno 3.8, GH5	Torque 30Ncm	07640166517924
	05002976	Dalbo® Abutment	Sweden+Martina Premium Kohno 4.25, GH3	Torque 30Ncm	07640166517801
	05002977	Dalbo® Abutment	Sweden+Martina Premium Kohno 4.25, GH4	Torque 30Ncm	07640166517788
	05002978	Dalbo® Abutment	Sweden+Martina Premium Kohno 4.25, GH5	Torque 30Ncm	07640166517795
	05002986	Dalbo® Abutment	Sweden+Martina Premium Kohno 5.0/6.0, GH3	Torque 30Ncm	07640166517832
	05002987	Dalbo® Abutment	Sweden+Martina Premium Kohno 5.0/6.0, GH4	Torque 30Ncm	07640166517818
	05002988	Dalbo® Abutment	Sweden+Martina Premium Kohno 5.0/6.0, GH5	Torque 30Ncm	07640166517825

The products of the Dalbo® System are assigned the following basic UDI-DI:

Product	Basic UDI-DI
Abutments	764016651000046E7
	764016651000065EB
Male parts	764016651000050DW
Female parts	764016651000053E4
Activators and Desactivators	764016651000002DK
	764016651000003DM
Duplicating and Protection Aids	764016651000006DT
Extractors	764016651000010DJ
Gauges, non-Surgically Invasive	764016651000011DL
Handles	764016651000016DW
Parallelometer Inserts	764016651000018E2
Screwdrivers, invasive	764016651000022DR
Spacers	764016651000028E5
	764016651000026DZ
Transfer Jigs and Analogs	764016651000034DY
	764016651000032DU
Tweezers	764016651000035E2

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