

Instructions for use

Set with spherical anchor Dalbo® with threaded bush and auxiliary instruments

The use, activation, deactivation, repair and periodic maintenance of attachment elements must be carried out exclusively by skilled persons. Only original tools and parts may be used for this work. The mechanical cleaning of attachment elements using a toothbrush and toothpaste may lead to premature wear of the functional parts.

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.

For hygienic reasons we cannot take back used service sets.

Intended use

The service sets manufactured by Cendres+Métaux SA are intended for the modification / reconstruction / repair / adaptation of (prosthetic) restorations with root canal posts or root canal anchors.

General information

Traceability of the batch numbers

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

Maintenance

All components are supplied non-sterile. Therefore the parts and instruments must be cleaned and disinfected prior to use.

Sterilization

The root canal posts, cutting drills and auxiliary instruments are supplied non-sterile.

All metal components must be sterilized prior to use. Sterilization is performed as steam sterilization at 134 °C, duration: 18 min. (see Care and maintenance surgical and prosthetic instruments / www.cmsa.ch/dental)

Disinfection

After any fabrication or modification, the prosthetic work, including the matrix components, must be cleaned and disinfected according to national guidelines. When choosing the disinfectant, ensure that:

- It is suitable for cleaning and disinfection of dental prosthetic components.
- It is compatible with the materials of the products to be cleaned and disinfected.
- It has tested efficacy in disinfection.

All parts made of plastic must be disinfected with a high EPA-registered disinfectant prior to use.

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

Important information

The repaired anchors are not as strong as the original versions, they are only a temporary solution. The prosthetic status needs to be re-assessed. Excessive para-functional loading should be avoided. Guide the drill at low speed –4000 revolutions per minute. Remove the chippings.

Warnings

This product may not be used in patients with allergies to one or more elements of the attachment materials. In patients with suspected allergy to one or more elements of the materials, this product may only be used following allergological clarification and proof of non-existence of an allergy.

For further information, please contact your Cendres+Métaux representative.

Auxiliary instruments may contain nickel (see Labeling on packaging).

The product was not tested/evaluated in an MRT environment with regard to overheating and movement.

These instructions for use are not sufficient for immediate use of the service set. Dental or laboratory knowledge is required, as well as an introduction to handling the Cendres+Métaux root canal posts by an experienced person. Courses and training are regularly offered by Cendres+Métaux. Only original tools and parts may be used for this work.

Preventive measures

- The components are supplied non-sterile. Proper preparation of the components prior to use in the patient is described in the «Sterilization» and «Disinfection» chapters.
- For intraoral use, all products must be generally secured against aspiration.
- No cutting work may be carried out in the patient's mouth.

Safety measures

- To prevent swallowing or aspiration, several precautions must be taken, e.g. rubber dam, instruments secured by dental floss.
- Protect your eyes by wearing protective glasses.
- It is essential to always cool the area when drilling (cutting).
- As the drills (milling cutters) have to cut efficiently, each drill (cutter) may only be used once for repairs to root caps.

Rx only

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

Indication

The Dalbo® ball anchor (054 744) included in the service set can be used for:

- defective male anchor components
- defective magnet anchors (primary magnets)

Contraindication

- Unilateral prostheses without transversal support.
- Restoration of severely periodontally damaged abutment teeth.
- Hybrid prostheses, which are restored with a single root canal post cap.
- In patients with allergies to one or more elements of the attachment materials.
- Lacking cooperation of the patient with respect to follow-up/ recall instructions.
- Patients with bruxism or other para-functional habits.
- Planning without an X-ray.

Auxiliary instruments

The supporting instruments to be used are listed in the main Cendres+Métaux catalog under the sections of the relevant attachments. See website www.cmsa.ch/dental or the Cendres+Métaux Dental Documentation (available free of charge from all Cendres+Métaux subsidiaries, branches and dealers).

Initial condition

1. Patient with root cap – the retentive male part no longer functions due to severe wear, or is fractured.
2. The service set can only be used with magnet anchors (part on the root cap) which can be removed by grinding from the root cap. The root cap must be made of a precious metal alloy.

Instructions for use for a used or broken male part

Safety precautions

To prevent the components being swallowed or aspirated, various safety precautions must be taken, e.g. place a rubber dam, attach the auxiliary instruments with dental floss. Wear safety glasses for eye protection.

Preparing the root cap

Trim the occlusal aspect of the worn male part on the root cap down to the solder. The solder must not be trimmed off – this ensures adequate thickness for a hole to be drilled (Fig. 1). Use a right angle hand piece and 1.0 ws Ø centre drill (080 798) to **mark** the centre of the solder (Fig. 2). Use the right angle hand piece and 1.15 ws Ø drill (072 429) to drill a 4.5mm deep hole perpendicular to the solder and in the centre of the root cap (Fig. 3).



Fig. 1

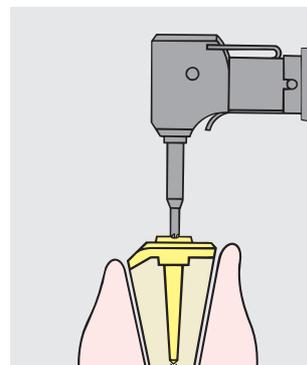


Fig. 2

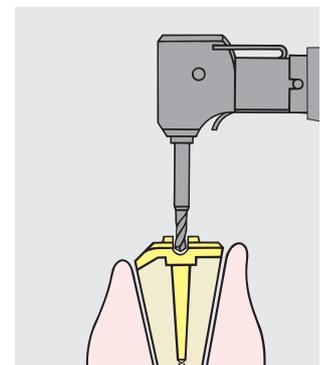


Fig. 3

Instructions for use for a no longer functioning magnet anchor

Remove the magnet on the root cap completely by grinding (Fig. 1). Take care to obtain a flat surface. Note: In order to have sufficient stability the occlusal height of the root cap must be at least 0.5 mm after grinding.

Vertically centre the root cap base using the right angle hand piece and the centre drill \varnothing 1.00 mm (080798). Then vertically drill a 4.5 mm deep hole into the root cap using the drill \varnothing 1.15 mm (072429). Important! Use a low speed of 4000 rpm, cool well and continuously remove the turnings. Only use the drill once. The working steps thread cutting, placing the repair male part, securing the screw connection and mounting of the female part are done as described above.

Important

Run the drill at low speed (4000 r.p.m.) (green marking on right angle hand piece), cool it and remove the turnings frequently. Always use a new drill. Use a right angle hand piece and face-cutting drill (070499) to trim the solder flat and countersink it slightly (Fig. 4). Manually check the depth of the hole with the drill \varnothing 1.15 mm (072429).

Tapping the thread

An M 1.40 (070211) thread tap and surgery wrench (070213) are used for tapping the thread in the hole for the replacement male part (052091). This is carried out by hand (Fig. 6).

Fitting the replacement male part

This should be screwed into the hole with the wrench (070498), exerting moderate pressure along its axis. Check that it fits properly.

Ensuring that the threaded joint is tight

To prevent the replacement male part loosening inadvertently, unscrew it from the root cap and clean the threaded rod on the male and the hole. Place a drop of nut locking liquid in the clean hole to secure the threaded joint and screw the replacement male in again. For securing the screw a lacquer, e.g. Ceka Bond, is recommended.

O = OSV

Au 60.0 %, Pt 10.5 %, Ag 7.0 %, Pd 6.5 %, Cu 14.0 %, Zn 2.0 %

E = Elitor

Au 68.60 %, Pt 2.45 %, Pd 3.95 %, Ag 11.85 %, Cu 10.60 %, Ir 0.05 %, Zn 2.50 %

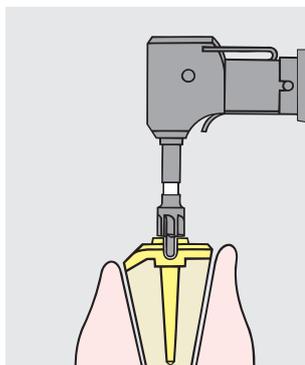


Fig. 4

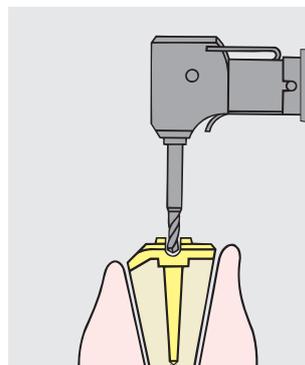


Fig. 5

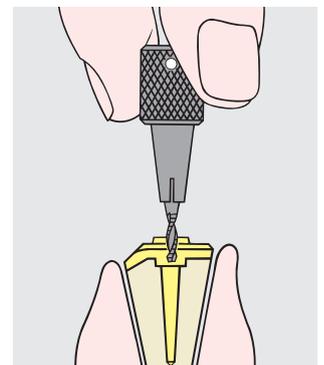


Fig. 6

Fitting the female part

The easiest method is to polymerize the Dalbo® female part into the removable denture directly in the patient's mouth. Trim a large enough recess in the denture for the female part to fit into, place the female part on the male part and try the denture into the patient's mouth to eliminate any high spots.

Remove the denture and blow out the recess for the female part. Use a small amount of soft wax to block out the space between the female part and the soldering base of the male part before polymerizing it into place. This prevents the cold-curing resin creeping between the female and male part. Ensure that the PVC ring covers the grooves in the female part so that once the female part has been fixed in place, the lamellae on its housing still have adequate clearance for inserting and removing the denture.

The set comprises:

1 center drill, Ø 1.00 ws	080 798
2 drills, Ø 1.15 ws	072 429
1 face cutting drill	070 499
1 thread tap	070 211
1 surgery wrench	070 213
1 wrench	070 498
1 male part with threaded post	052 091
1 Dalbo®-Classic elliptic female part	055 887

Please note

Milling and thread cutting are facilitated by using a little oil, e.g. salad oil. The strength of the attachments in the service set is lower than that of the original attachments. As this is a temporary situation, the conditions in the mouth have to be evaluated again. The service set attachments must not be exposed to heavy loads.

Maintenance

All parts are delivered non-sterile. Therefore, the parts and the instruments must be disinfected before use.

Materials

052 091

Male part with threaded post O = OSV

055 887

Dalbo-Classic® elliptic female part E = Elitor

Fitting: Polymerized

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 optimally matched materials as far as possible to reduce wear to an absolute minimum. The good fit of dentures on the mucosa is to be checked at least once per year, and relined if required to prevent tilting movement (overload), especially in the case of free-end prostheses.

Patients can obtain information and recommendations about the use, removal and care of prostheses on the patient website at www.cmsa.ch/dental/infos.

Disclaimer

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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 appropriate original components and instruments. Otherwise, the manufacturer rejects any responsibility and liability. In case of complaints, please always include the batch number.

Labeling on packaging / symbols

	Date of manufacture
	Manufacturer
	Catalogue number
	Batch code
	Quantity
	Consult instructions for use
Rx only	Attention: According to US federal law, this product may only be sold by or on behalf of a physician.
	Cendres+Métaux SA products with CE labeling meet the requirements of the Medical Device Directive 93/42/EEC.
	
	Do not re-use
	Non-sterile
	Keep away from sunlight
	Attention (observe accompanying documents)