Service set 054 758

Instructions for use

Transformation set male part Dalbo® with 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.

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.

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Indication
The retention cylinder according to Gerber on the cap of a root canal post in the mouth is to be converted to a Dalbo® ball anchor. This measure may be indicated after tooth loss and a single remaining rigid prosthetic anchor.

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
A root cap with rigid Gerber RZ unit cemented into the mouth is to be converted to a resilient Dalbo® spherical anchor.

Instructions

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.

Removing the old attachment
Unscrew the Gerber retention core in the mouth with a screwdriver (070 262) (Figure 1). Then use a heating rod (070 151) to remove the housing of the Gerber RZ from the removable denture.

Fitting the conversion male
Use the inserting device (070 547) to screw the conversion male part (052 089) onto the solder on the Gerber RZ (Figure 2).

Ensuring that the threaded joint is tight
To prevent the conversion male part loosening inadvertently, unscrew it from the Gerber RZ retention core and clean the threads on the retention core and in the conversion male. Place a drop of nut locking liquid in the clean hole to secure the threaded joint and screw the conversion male part in again.

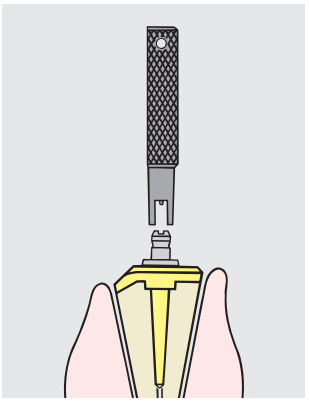
Fig. 1

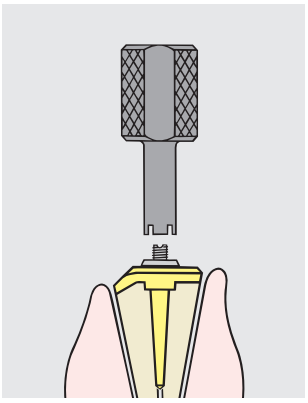
Fig. 2

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Fitting the female part
The Dalbo® female part (051 511) should be placed on the conversion male part (Figure 3).
If the new attachment is to be resilient, the tin disc must be pressed over the male part to act as a spacer and adapted to the surface of the root cap before the female part is fitted.
Relieve the removable denture to create adequate space for the new female part. Then try the denture in and check for correct seating.
The Dalbo® female part can be polymerized into place in the patient's mouth with a small amount of cold-curing resin. Use a small amount of soft wax to block out the space between the female part and male part (when fitting resilient attachments, place the wax between the female part and tin disc) prior to polymerizing the female part into place. This prevents the cold-curing resin creeping between the female part 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 (Figure 4).
Once the resin has cured, remove the denture from the patient's mouth and trim off any excess resin.
The tin disc must also be removed completely from resilient attachments after the resin has cured.

The set comprises:

1 conversion male part	052 089
1 Dalbo® female part	051 511
1 inserting device	070 547
1 tin disc	

Please note
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.

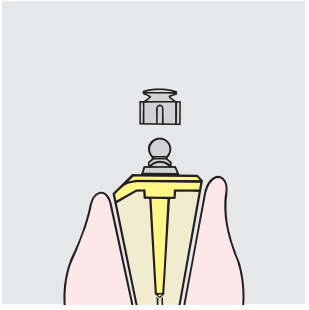
Fig. 3

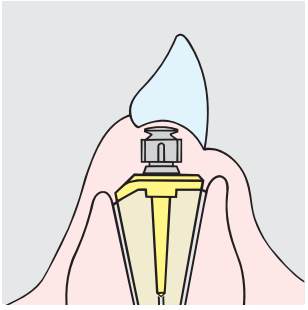
Fig. 4

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 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)