Cendres+Métaux hexagonal screw system

Instructions for use

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.

Intended use
The screw and retention elements manufactured by Cendres+Métaux SA serve as connectors (connecting elements) for tooth or implant supported, removable dental prostheses. The screws and retaining elements support/anchoring devices, connect the prostheses to teeth or implants.

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.

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.

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.

Accuracy of fit: the secondary component must have a defined position in relation to the primary component.

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 screw and retention elements. Dental or laboratory knowledge is required, as well as an introduction to handling the Cendres+Métaux screw and retention elements 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 chapter on «Disinfection».
– For intraoral use, all products must be generally secured against aspiration.
– No cutting work may be carried out in the patient's mouth.
– Additional bonding of the screw in the thread to secure the screw may increase the loosening torque considerably, such that the internal hexagon may be destroyed during loosening.

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.

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Cendres+Métaux hexagonal screw system

Materials
Screws O = OSV
High-strength precious metal alloy
Countersunk collar and sleeve C = Ceramicor®
Non-oxidising, cast-on precious metal alloy
Fixation screw X = Steel

Assembly and application
Sleeve:
Can be resin-bonded, cast-on, laser-welded or soldered.
Countersunk collar:
Casting-on recommended. Can also be laser-welded or soldered.
Mounting screw:
Fixes the sleeve during casting.
Fixation screw:
Used for retaining the sleeve when casting-on or soldering, protects the thread from inflow of alloy.

Indications
Cap screw: Vertical screw-retention of crowns and bridges in implantology and in the conventional technique, e.g. bridge sections or operator-removable restorations.
Pin screw: Transversal screw-retention of crowns and bridges in implantology and in the conventional technique, e.g. bridge sections or operator-removable restorations.

Contraindication
– No angled load on the screw.
– No vertical screw retention (stud screw).
– Restoration of severely periodontally damaged abutment teeth.
– 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.

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).

Instructions for use

Note
– Always use the largest screw possible, both in length and diameter, for the space available.
– Only the screw heads can be shortened by max. 1 mm (to ensure the screwdriver fits properly).
– Refer to the detailed information on Cendres+Métaux resin-bonding technique, soldering, casting on and laser-welding technique with alloys contained in interesting facts about precision attachments. This information can be obtained at any time **on our website** www.cmsa.ch/dental.
– **Cast-on alloys:** Non-precious alloys should not be used for casting on. Some precious metal alloys for low-fusing porcelains are less suited for casting-on due to their high CTE (risk of cracks forming during porcelain application).
– The fixation screw can be destroyed at temperatures above 1400 °C and by excessive overheating of the casting alloy.
– If the fixation screw breaks after casting, despite taking all precautionary measures, it will dissolve after approx. 1 hour in a heated 30 % hydrochloric acid solution (HCL).

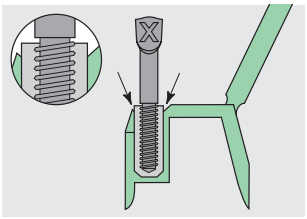
Fig. 1

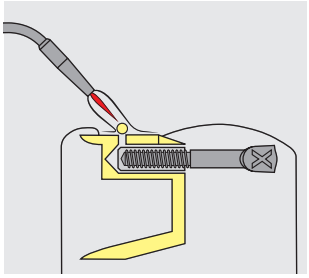
Fig. 2

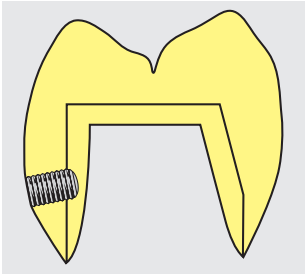
Fig. 3

O = OSV
Au 60 %, Pt 10.5 %, Pd 6.5 %, Ag 7 %, Cu 14 %, Zn 2.0 %

C = Ceramicor®
Au 60 %, Pt 19 %, Pd 20 %, Ir 1 %
T_S – T_L 1400–1490 °C

X = Steel

Cap screw

Primary unit: Inserting the sleeve
After waxing up the primary crown or bridge unit, position the sleeve according to anatomical, functional and aesthetic principles. The sleeve should be completely surrounded by wax. A small groove can be cut around the junction between the wax and sleeve to prevent an inflow of alloy when casting (Fig. 1).
Note: Check the occlusion with the countersunk collar and screw inserted. The head of the screw should not come into contact with the opposing bite. If required, the screw head can be shortened by max. 1 mm.

Casting on and soldering
For investing, insert the fixation screw to retain the sleeve in the investment and to protect the thread. Oxidise the fixation screw (400 °C/10 min.) before use, then coat the thread with colloidal graphite (Order no. 080 241), insert the screw into the sleeve, invest and cast. After casting, carefully unscrew the fixation screw from the sleeve without bending it.
Soldering: The fixation screw is also used for fabricating the solder model. We recommend venting the pocket hole to ensure the solder surrounds the sleeve completely and to prevent the solder flowing into the thread. This can be done by drilling a small hole or making a slit (Fig. 2).

Resin bonding & laser welding
When waxing up the primary crown or bridge unit, ensure that there is adequate material at the screw area for drilling the hole. After drilling a centring point (standard round bur ∅ 1 mm), the final dimensions of the hole can be drilled directly with the spiral drill that corresponds with the screw diameter (oil well and lift alternately!). After sandblasting and cleaning the bonding areas, resin bond the sleeve with a suitable adhesive. The sleeve can also be laser welded instead of resin bonded. Filler material of the same alloy as the crown material should be used to ensure a reliable weld. The laser seam should be completely sealed to prevent corrosion due to pitting.

Secondary unit:
Integration of the countersunk collar by casting on
The secondary unit is fabricated after trimming and polishing the primary unit. This involves inserting the countersunk collar with the screw, which has already been shortened as required. The countersunk collar is integrated in the wax pattern. A small groove should be cut around the junction between the wax and countersunk collar to prevent molten alloy flowing into the ring when casting. Invest, cast and polish the unit.
Note: If the countersunk collar has been properly invested without bubbles, it should be adequately retained in the investment.

Pin screw
First fabricate the crown units that are to be transversely screw-retained. Allow a minimum wall thickness of 2 mm in the area of the secondary screw for fabricating a thread.
Fabricating the thread:
To attain a press fit of the secondary unit, the screw should be positioned facing upwards and slightly inclined (Fig. 3).
Separating the primary and secondary units. After drilling a centring point on the secondary unit (standard round bur ∅ 1 mm), the final dimensions of the hole can be drilled directly with the spiral drill that corresponds with the screw diameter (oil well and lift alternately!). Then both units are fitted together and retention fabricated in the primary anchor using the standard round bur ∅ 1 mm with the same diameter as the screw. After separating the crown units again, cut the thread manually (in the thread tap holder) using the thread tap with the same diameter as the screw. The thread is tapped in a clockwise direction until resistance is felt with the fingertips (after approx. two turns). Then turn the thread tap back once to remove the chips and continue this procedure until the whole length of the thread is cut.

Intraoral safety of the screw
The hex key (Order No. 0700 0008) is designed to ensure proper retention of the screws and safe handling intraorally. Note, retention of the screw on the hex key can be reduced while unscrewing. When the screw is almost completely undone, increase pressure to make sure it remains on the hex key. The hex key should also be secured with a cord in the drill hole provided. We also recommend covering the working area with a rubber dam to safeguard against aspiration.

Correct method for tightening and removing screws
Always use the original hexagonal screwdriver (Order no. 0700 0008) to tighten the screws fully without using excessive force. The maximum insertion and removal torque is limited due to the geometry of the screwdriver shank. The screwdriver is designed so that the screw is not damaged during insertion or removal, though sufficient force can be applied to ensure reliable retention. Additional blocking of the screw in the thread with resin to safeguard against the screw loosening can increase the removal torque to the extent that the inner hex can be destroyed when loosening the screw.

Removing screws with a defective inner hex
The following options are available for removing the screw without damaging the restoration rather than drilling it out:
1. Shorten the tip (about 1 mm) of the square mandrel of the SERVICE-SET Regulex (Order No. 072 332). Then insert the square mandrel into the hex profile with a light hammering.
Turn the screw counter clockwise to remove it.
2. More complex but possible solution: using a small drill (round bur), cut out a slit allowing unscrewing with a conventional screwdriver.
3. Use a «screw extraction kit», available from several implant manufacturers.

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.

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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.

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 CE labelling meet the requirements of the relevant European requirements.
	Do not re-use
	Non-sterile
	Keep away from sunlight
	Caution, consult accompanying documents