

Retention elements

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.

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.

Description

The Ipsoclip® 102.01.1 (SE) (Fig. 1) is a screw-retained retentive element.

The Ipsoclip® 102.02.1 (RE) (Fig. 2) is an operator removable retentive element.

These attachments allow, due to identical housings, the transformation from an operator removable to a removable or vice-versa. Shortening of both versions is possible on the posterior side by max. 0.50mm. Care has to be taken to keep the screw slot of the cap screw or that of the bolt screw operative.

The Ipsoclip® 102.02.2 (Fig. 3) is a retention element with access for dismantling of the mechanism on the posterior side (opposite the snap bolt).

The Ipsoclip® 102.03.2 (Fig. 4) is a retention element with access for dismantling of the mechanism on the anterior side (the side of the snap bolt).

Both versions have a retentive mechanism, which is fixed by a bayonet lock in the housing. The housing of these two versions must not be shortened. The function of the bayonet lock of the version 102.03.2 can be improved by inserting a plastic disc between housing base and spiral spring.

Rx only

The housing of all Ipsoclip® versions is made of the alloy Ceramicor allowing casting-on as well as soldering of precious metal alloys.

The mechanisms of the three removable Ipsoclip® versions are similar. They consist of a retention bolt made of precious metal alloy and a steel spiral spring. Both parts are exchangeable, the spiral springs can be activated by extension. Dentures having Ipsoclip® systems need periodical function control. For this the components are dismantled, **cleaned of plaque and tartar in a ultrasonic apparatus** in order to recondition the perfect function of the mechanism. This service must be carried out in the dental practice or the dental laboratory by a specialist.

Desinfection

The product is delivered non-sterile.

Every prosthetic reconstruction must be cleaned and disinfected before each try-in or definite placement.

Further information

On processing precious metal alloys, soldering and casting-on are included in the Dental documentation of Cendres+Métaux.

Allergies

With patients having an existing allergy to one or several elements of the materials contained in any one attachment, this particular product must not be used. With patients suspected of having an allergy to one or several of these elements contained in any one attachment, this product can only be used after preliminary allergological testing and proof of a non-existing allergy.

Ipsoclip® SE 102.01.1C

Screw-retained element

Housing

C = Ceramicor®

Part to be dismantled:

Screw bolt

O = OSV

Ipsoclip® RE 102.02.1C

Retentive element

Housing

C = Ceramicor®

Parts to be dismantled:

Retention bolt

A = Alpa

Spiral spring

Inox 1.4310

Cap screw

O = OSV

Ipsoclip® 102.02.2C

Retentive element Posterior

Housing

C = Ceramicor®

Parts to be dismantled:

Retention bolt

A = Alpa

Spiral spring

Inox 1.4435

Bayonet lock

O = OSV

Ipsoclip® 102.03.2C

Retentive element Anterior

Housing

C = Ceramicor®

Parts to be dismantled:

Retention bolt

A = Alpa

Spiral spring

Inox 1.4435

Bayonet lock

O = OSV

Buffer disc

Silicone

C = Ceramicor®

Au 60.0 %, Pt 19.0 %, Pd 20.0 %, Ir 1.0 %

T_s – T_L 1400–1490°C

O = OSV

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

A = Alpa

Au 35.0 %, Pt 1.0 %, Pd 10.5 %, Ag 41.0 %, Cu 12.0 %, In 0 < 1.0 %

Inox 1.4310

C ≤ 0.14 %, Si ≤ 1.5 %, Mn ≤ 2.0 %, P ≤ 0.045 %, S ≤ 0.030 %, Cr ≤ 17.0 %, Mo ≤ 0.8 %, Ni 14.0 %

Inox 1.4435

C ≤ 0.030 %, Si ≤ 1.0 %, Mn ≤ 2.0 %, P ≤ 0.045 %, S ≤ 0.025 %, Cr ≤ 17.75 %, Mo ≤ 2.75 %, Ni 14.0 %

Indications

Retentive or screw retained element for mounting into secondary parts of milled work. For example:

- Telescope crowns
- Individually milled bar sleeves
- Individual slide attachments
- Implant-supported restorations

Contraindication

- For wall thicknesses of primary components thinner than 0.8 mm.
- For conically milled primary components.
- 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).

Equipment necessary for correct processing

Auxiliary instruments, see Dental documentation of Cendres+Métaux).

Instructions for use

Before placement in the wax model and before investing the Ipsoclip® must be dismantled.

Mounting into the wax model

Place the anterior part of the housing against the wall of the milled primary part and complete modelling of the secondary part. The housings of the versions 102.01.1C (SE) and the 102.02.1C (RE) can be precisely set and held with the auxiliary modelling screw (102.02.13) Remove this screw before investing. Notches serving for the retention in the wax may only be made on the four rounded edges of the housing and only have a depth of max. 0.2 mm. If a housing is to be soldered to the secondary part, it has to be isolated on the exterior before modelling and is to be removed before investing.

Investing

The interior and the two extremities of the housing must be absolutely free of wax residues. Care has to be taken, that the investment completely fills the the space of the housing and wets the free surfaces of the ends. Carefully handle the cylinder during preheating and casting. Avoid shocks.

Devesting

Do not use any metal instruments in order to prevent damage to the thread or the bayonet lock. If necessary use the thread tap (Auxiliary instrument 70507) for the versions 102.01.1 SE and 102.02.1 RE.



Fig. 1



Fig. 2



Fig. 3



Fig. 4

Assembly / function check

After fitting the cast secondary part onto the primary part assemble them. With the versions 102.01 et 102.02 drill a 0.5mm deep hole into the wall of the primary part through the hollow space of the housing with the centering drill Ø 1 mm (Auxiliary instrument 80798). This hole will take up the retention bolt. Grind a guiding groove into the occlusal side of the primary part serving as guide for the retention bolt when inserting the denture. Then dismantle all parts and check the function.

For the **version 102.03.2** mount the mechanism using the key (102.03.20), then colour the retention bolt with a contact colour, place the secondary part onto the primary part and mark the position of the occlusal notch and the hollow space on the primary part. Then remove the secondary part and drill a hole with a max. depth of 0.5mm for the retention bolt with the centering drill (auxiliary instrument 80798). Carry out a function check.

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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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) |