

+ **CM LOC®.**

Instructions for use root canal caps.

CM LOC®.

Instructions for use for solutions on root canal caps.

Dear Customer,

Thank you and congratulations on choosing a premium, Swiss-quality product as well as a reliable partner. Cendres+Métaux products are manufactured in Switzerland with the highest precision and using selected materials. A superior standard of quality is ensured thanks to the latest technology as well as qualified experts. It's what we stand for!

Best regards,
Chief Executive Officer

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. Compliance with the following instructions for use is a prerequisite for proper system function. 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.

Device (trade) Name

CM LOC®

Intended use

The CM LOC® male parts are designed to fixate overdentures (total dentures) or partial dentures completely or partially through root canal caps in the maxilla and/or mandible.

Device Description

The CM LOC® male part C and CM LOC® male part E can be used for the following clinical situations:

- Removable hybrid-supported dental prostheses on root canal caps in combination with the specific CM LOC® female part system.

Materials

C = Ceramicor®

- male part

E = Elitor®

- male part

S = Syntax

- female part

Pekkton®

- Retention inserts Pekkton®
- female part
- Processing insert
- Impression part
- Spacer

Auxiliary instruments S, Pekkton®, X, Santoprene

- S = Syntax: TiAl6 V4 ELI (Grade 5),
Ti > 89.478 %, Al 6.0 %, V 4.0 %
- Santoprene
- Pekkton®
- X = steel

Detailed information on the materials and their classification is given in the specific material data sheets and the catalog. See website www.cmsa.ch/docs or the Cendres+Métaux Dental Documentation (available free of charge from all Cendres+Métaux subsidiaries, branches and dealers).

Indication

Removable hybrid-supported dental prostheses on root canal caps in the maxilla and/or mandible in combination with the specific CM LOC® female part system.

Mandible

CM LOC® male part C and CM LOC® male part E Anchorage of mandible (MD) prosthesis on 2 or more root canal caps.

Maxilla

CM LOC® male part C and CM LOC® male part E Anchorage of maxillary (MX) prosthesis on 4 or more root canal caps.

Contraindication

- Restoration of severely periodontally damaged abutment teeth.
- In patients with allergies to one or more elements of the attachment materials.
- Use on a single root canal cap.
- Not suitable if fixed connections are required.
- Existing clinical picture in the patient's mouth does not permit the correct use of the CM LOC®.
- Lacking cooperation of the patient with respect to follow-up/recall instructions.
- Patients with bruxism or other parafunctional habits.
- Unilateral free-end prosthesis without transversal support.

Warnings:**Allergies**

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. Auxiliary instruments may contain nickel.

MR environment

The CM LOC® male part C and CM LOC® male part E have not been evaluated for safety and compatibility in the MR environment.

The CM LOC® male part C and CM LOC® male part E have not been tested for heating or migration in the MR environment.

Prescription

Federal laws (USA) prohibit use or sale by unlicensed dentists.

Note

These instructions for use are not sufficient for immediate use of the anchors. Dental or laboratory knowledge is required, as well as an introduction to handling the CM LOC® by an experienced person. Information: www.cmsa.ch/docs

Précautions

- The male parts must be placed parallel to the direction of insertion.
- The processing, activation, deactivation, repair and periodic maintenance of attachment elements of the CM LOC® must be carried out exclusively by skilled persons. Only original tools and parts may be used for this work.
- The mechanical cleaning of the CM LOC® using a toothbrush and toothpaste may lead to premature wear of the functional parts.
- The CM LOC® components are supplied non-sterile. For further information, please see workflow/handling, sterilization/disinfection.
- Secure parts against aspiration.
- No cutting work may be carried out in the patient's mouth.
- It is essential to block out undercuts prior to polymerizing the female part.
- Do not use the CM LOC® Spacer as a temporary female part.
- Unless labelled otherwise, CM LOC® components are only for single use.
- Before any procedure, ensure that all required CM LOC® components are available in sufficient quantity.
- For your safety, always wear suitable protective clothing.

Side effects

No known side effects if used as intended.



Workflow/handling

The procedure is valid for use in the dental practice and the laboratory.














General information

- Wax-up of the root canal cap with root canal post: If there are multiple root canal caps, prepare the soldering/laser surface at right angles to the direction of insertion. Use prefabricated, cast-on precious metal pins.
- After soldering/casting, slowly cool to room temperature. The optimal mechanical properties are achieved allowing it to bench-cool to room temperature. Fit the CM LOC® spacer to protect the male part while sandblasting and processing.
- We recommend to design the clinical case in such a way 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.
- The correct seating of the prosthesis on the mucous membrane must be checked at least once a year, if necessary it must be relined to prevent swinging movements (overloads). We recommend checking the prosthesis at regular intervals of approximately three months and replacing the retention inserts if necessary.
- In patients with suspected titanium allergy or hypersensitivity, we alternatively recommend the use of the Pekkton® female part.
⚠ One must allow for increased aftercare effort and, if necessary, replacement of the female part system, as Pekkton® is somewhat softer than titanium as material for the female part.

Symbols

-  Important information for the specialist
 Warning symbol for increased caution

Abbreviations labeling on packaging/symbols

-  Date of manufacture
 Manufacturer
 Catalogue number
 Batch code
 Quantity
 Consult instructions for use
URL: cmsa.ch/docs
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 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
 Unique Device Identification – UDI

Sterilization/Disinfection

After any fabrication or modification and prior to use, the prosthetic work, including the female part components, must be cleaned, disinfected and, if appropriate, sterilized. Metal and Pekkton® components are suitable for steam sterilization (see below), while components made of plastic other than Pekkton® are not. Consider published national guidelines when selecting a disinfection and sterilization process. For re-usable surgical and prosthetic instruments, consult the dedicated documentation Care and Maintenance Surgical and Prosthetic Instruments (available for download on www.cmsa.ch/docs/Download-Center), which provides detailed instructions and recommendations (partly instrument-specific) regarding, maintenance, cleaning, disinfection and sterilization.

Recommendation: Disinfection

All the parts must be disinfected before use with a high-level disinfectant. Follow the instructions of the manufacturer regarding dosage and exposure time.

When choosing the disinfectant, ensure that:

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

We recommend using an ortho-phthaldehyde (OPA) solution like the Cidex® OPA Solution. Strictly follow the manufacturer's instructions.

Sterilization

After cleaning and disinfection, and prior to use, all metal and Pekkton® components must be sterilized. Plastic parts, except those made of Pekkton®, are not suitable for steam sterilization and are processed as indicated in the section Sterilization/Disinfection above.

Sterilization method

The original packaging shall not be used for the sterilization process. Steam sterilization for sterilization of system components was validated with the following parameters:

- Temperature of saturated steam: 132°C (270°F)
- Flash-gravity (gravity displacement according to ANSI/AAMI ST79: 2010)
- Sterilization time 10 min (components unwrapped in an unclosed container)
- Drying time: 1 min

According to material properties, metal and Pekkton® components are also compatible with prevacuum steam sterilization at 134°C (273°F) for 18 minutes. Do not exceed 140°C (284°F).

Allow system components to cool before use. Only use approved sterilizers, sterilization containers, sterilization pouches, biological indicators, chemical indicators and other sterilization accessories appropriately identified and recommended for sterilization and the sterilization cycle.

Processing.

Inserting the male part in Elitor[®] by laser welding.



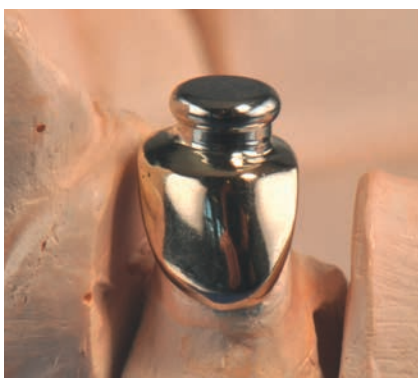
In a first step, face mill the root canal cap using a milling machine at right angles parallel to the direction of insertion.



With the parallelometer insert, set the male part E as centrally as possible and wax it cleanly to the root canal cap.



Then fill all undercuts with laser wire.



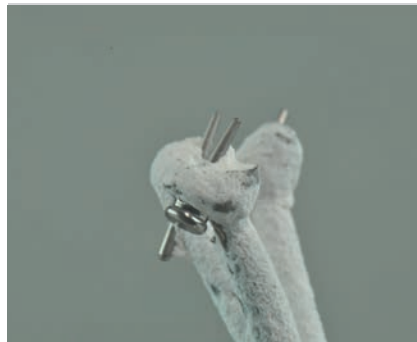
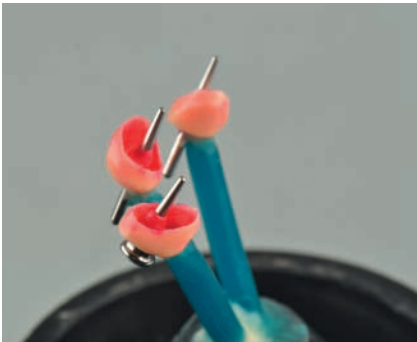
Then, using a standard rubber wheel, smooth down the laser welds and polish using a polishing brush.

To simplify working with and protecting the CM LOC[®] male part E, put the CM LOC[®] spacer on the CM LOC[®] male part E. Make sure that no more material is removed than to the outer bottom edge of the CM LOC[®] male part E.

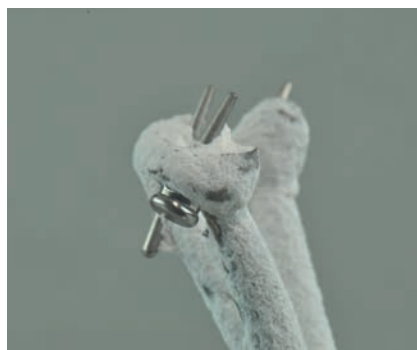
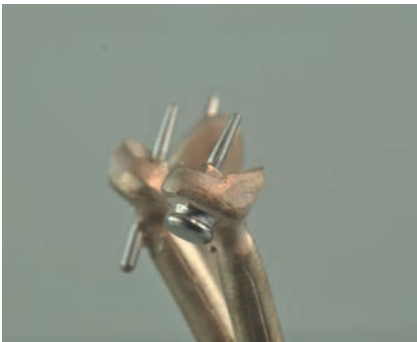
Inserting the male part in Ceramicor®. Casting.



With the parallelometer insert, set the male part C as centrally as possible and wax it cleanly to the root canal cap.

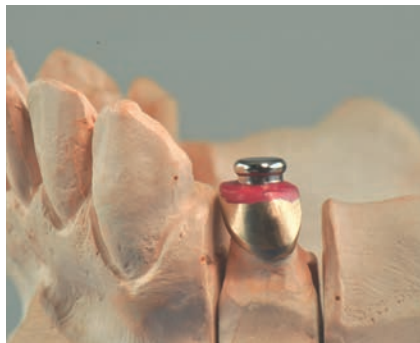


Then embed and cast. Please observe the instructions for use for the dental casting alloys.
www.cmsa.ch/docs



Fit the CM LOC® spacer to protect the male part while sandblasting and processing.

Inserting the male part in Ceramicor®. Soldering.

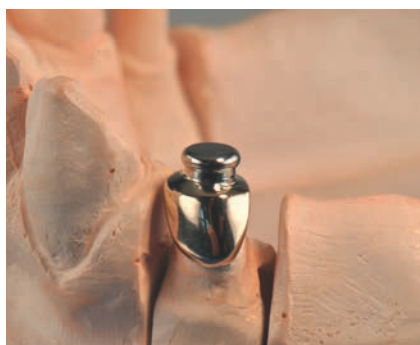


With the parallelometer insert, set the male part as centrally as possible on the already cast, face-milled root canal cap and fix it with wax.



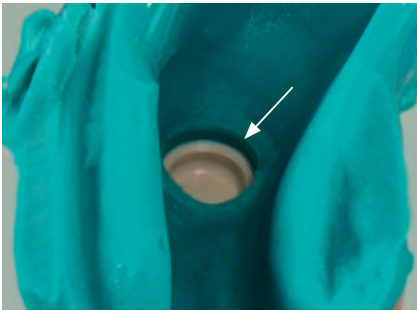
The solder gap should be continuous and between 0.05 – 0.20 mm wide. Then design the soldering block, so that the male part is securely held and good flame access is ensured (observe corresponding solidus).

After soldering, slowly cool to room temperature. The optimal mechanical properties are achieved allowing it to bench-cool to room temperature. As described in Inserting the male part in Elitor® by laser welding, finish the work.



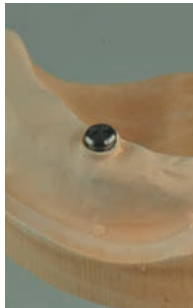
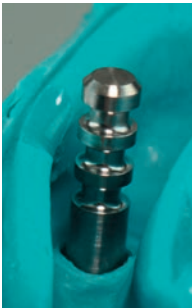
Impression taking of the oral situation for further processing using the indirect method.

Place the CM LOC® Impression part on the CM LOC® male part C or CM LOC® male part E and create a functional impression. Ensure that the CM LOC® Impression part is correctly seated. Use a solid impression material (e.g., Impregum™).

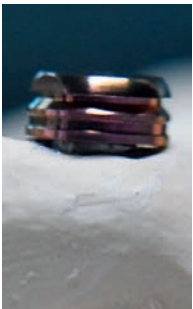


⚠ Check that the material is fully distributed around the CM LOC® Impression part and that no impression material has flowed into the CM LOC® Impression part.

ℹ Otherwise, clean the abutment and repeat the impression-taking process.



This is followed by transfer to the dental laboratory for fabrication of the model. For fabrication of the model in the laboratory, then place the CM LOC® Analogs in the CM LOC® Impression part, followed by fabrication of the master model.



Then place either the CM LOC® Housing with a mounted CM LOC® Processing insert or the CM LOC® Spacer onto the CM LOC® Analogs. Use of the CM LOC® Spacer or the CM LOC® Housing is a decision that is at the discretion of the user.



The prosthesis can now be fabricated using conventional technology. Then replace the processing insert in the CM LOC® Housing with a Pekkton® Retention insert in the desired force level.

ℹ See description in Selection of retention inserts.

ℹ To allow the patient comfortable and easy insertion of the prosthesis as well as facilitate familiarization with retention in the mouth, it is recommended to first fit the prosthesis with an extra-low CM LOC® Retention insert. If the patient demands stronger retention, CM LOC® Retention insert offering greater retention force can be used. For assembly and disassembly of the retention inserts, see description: Assembly and disassembly of retention inserts.

Assembly and disassembly of the retention inserts.

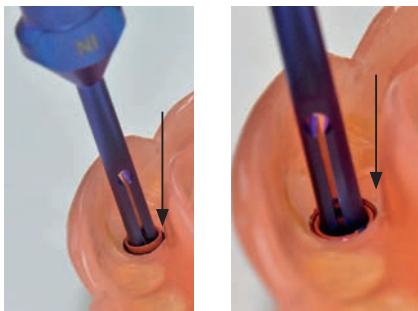


Assembly

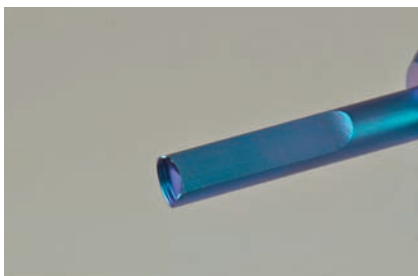
The retention inserts are placed in the housing using the tool provided for this purpose. Pick up the CM LOC® Retention insert with IN side.



You can feel and hear the CM LOC® Retention insert lock into place.

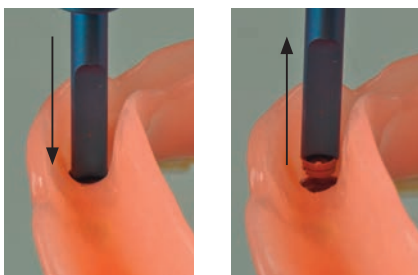


Press the CM LOC® Retention insert into the CM LOC® Housing in straight and parallel fashion until you can feel and hear it click into place.



Disassembly

With the OUT side.



Place in straight and parallel fashion over the CM LOC® Retention insert between the CM LOC® Housing, and gently press into the CM LOC® Housing. The CM LOC® Retention insert disengages in this way and can be withdrawn from the CM LOC® Housing while held straight. Then withdraw the retention insert from the CM LOC® Housing without applying force and remove.



Selection of retention inserts

Four different CM LOC® Retention inserts made of Pekkton® are available for retention. The retention inserts are color-coded and divided into four different levels of retention force.

yellow: extra-low red: low
green: medium blue: strong

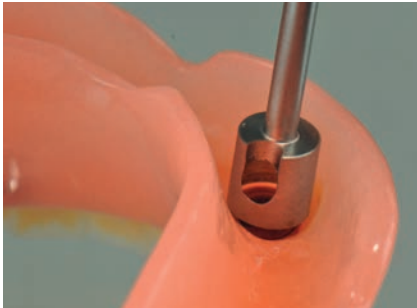
⚠ Ensure that the selection of pull-off forces is adapted to the clinical situation. Only use the extra-low insert for immediate loading from the start.

📖 To allow the patient comfortable and easy insertion of the prosthesis as well as facilitate familiarization with retention in the mouth, it is recommended to first fit the prosthesis with an extra-low CM LOC® Retention insert. If the patient demands stronger retention, CM LOC® Retention inserts offering greater retention force can be used. For assembly and disassembly of the retention inserts, see description: Assembly and disassembly of retention inserts.

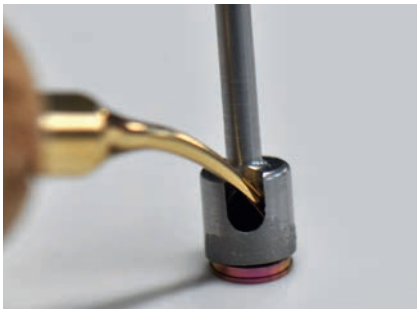
Disassembling the CM LOC[®] Housing.



For this purpose, use the CM LOC[®] Housing Extractor.



Use the CM LOC[®] Housing Extractor to mill out the complete CM LOC[®] Housing.



Then use an instrument to remove the CM LOC[®] Housing from the CM LOC[®] Housing Extractor through the side opening. For better withdrawal, it is recommended to briefly warm the CM LOC[®] Housing Extractor over a flame.

Daily use.

Handling/follow-up

Retaining elements in prosthetic work are subject to considerable stress in the mouth in a constantly changing environment, and thus are subject to wear over time. Wear is 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).

We recommend checking hybrid prostheses at three-monthly intervals initially and to replace the retention inserts if necessary.

Insertion and removal of the dentures

Ensure that the dentures do not cant, as any canting can lead to damage. Never place dentures by biting the teeth together. This can lead to damage or even to breaking of the attachment elements. Further information on handling/aftercare of dentures is available in the patient information brochure. www.cmsa.ch/docs.

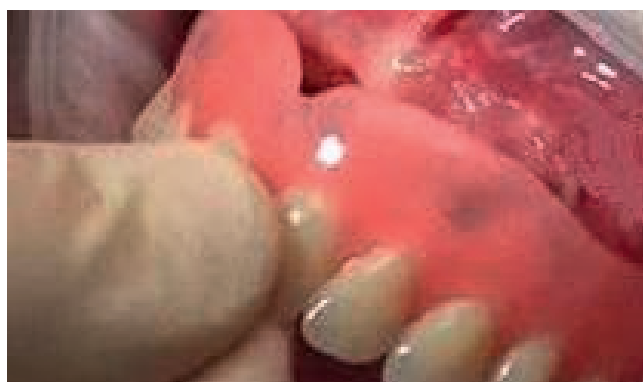
Insertion

Hold the dentures between the thumb and forefinger, and place them back into the mouth on the anchors. Search or feel for the correct insertion position and push the dentures onto the anchors with gentle, steady pressure. Carefully close your jaws and check whether the dentures are in the correct final position.



Removal

Hold the dentures between the thumb and forefinger, and slowly, carefully and steadily pull them off the anchors and remove them from the mouth.



Cleaning and care

It is best to clean your teeth and your dentures after every meal. Cleaning of dentures includes cleaning of the connecting element. The most gentle cleaning is achieved by cleaning the connecting element under running water with a soft toothbrush. Most intensive cleaning is achieved when cleaning the dentures in a small ultrasonic device and adding a suitable cleansing agent. Never clean the high precision connecting elements with toothpaste as this could lead to damage. Caution should also be exercised in the case of unsuitable cleansing agents or tablets. This could also damage the high quality connecting element or impair its function. Only clean the connecting parts on the other teeth or implants with water and a soft toothbrush as well as an interdental brush. Do not use toothpaste to avoid damage. Pay attention to regular cleaning of the anchorage to prevent any inflammation of the soft tissue. For information and additional tips on caring for the instruments see www.cmsa.ch/docs.

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

Traceability of the batch numbers

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

Disclaimer of liability

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. 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.

Copyrights and Trademarks

CM LOC[®], Pekkton^{®*} and Elitor[®] are registered trademarks of Cendres+Métaux Holding SA, Biel/Bienne, Switzerland.

* Pekkton[®] is based on OXPEKK[®] from OPM, Oxford Performance Materials, Inc., USA

GC RELINE[™] is a registered trademark of GC Advanced Technologies[®] Inc.

Impregum[™] is a registered trademark of 3M ESPE.

