

+ CM LOC®.

Instructions for use root canal caps.

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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 work instructions is a prerequisite for proper function of the system.

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

- Abutment (male part)
- CAD CAM Retention Element (male part)
- Housing (female part)

Pekkton®, E = Elitor®

- Retention inserts Pekkton®
- Retention inserts Elitor®
- Housing (female part)

Instruments auxiliaires 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/dental or the Cendres+Métaux Dental Documentation (available free of charge from all Cendres+Métaux subsidiaries, branches and dealers). Further information on CM LOC® at www.cmsa.ch/dental

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 implant.
- 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.

The CM LOC® has not been evaluated for safety and compatibility in the MR environment. The CM LOC® has not been tested for heating or migration in the MR environment. 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/dental

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 nonsterile. 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.
- Screw in the CM LOC® Abutment and CAD CAM Retention Element with the specified torque only once.
- In case of immediate loading (observe implant manufacturer's indication), ensure that the tightening torque of the abutment does not exceed the torque of the implant 5 Ncm below implant tightening torque is recommended.
- 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.

Symbols

| | |
|---|--|
|  | Important information for the specialist |
|  | Warning symbol for increased caution |

Abbreviations labeling on packaging/symbols

| | |
|---|---|
|  | Date of manufacture |
|  | Manufacturer |
|  | Item 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/Dental/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:

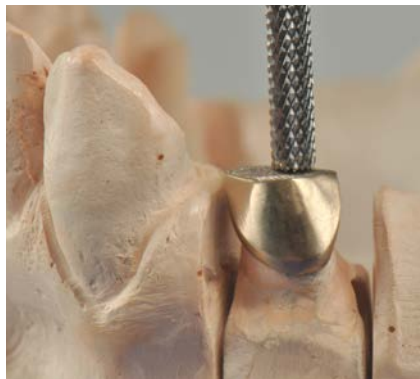
- Temperature of saturated steam: 132°C (270°F)
- Flash-gravity (gravity displacement according to ANSI/AAMI ST79: 2010)
- Sterilization time 10 min (components unwrapped in an unclosed container)
- Drying time: 1 min

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.



Then place the CM LOC[®] male part E and laser weld around circumference.



Then fill all undercuts with laser wire.



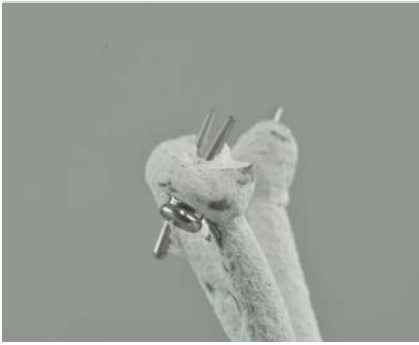
Then, using a standard rubber wheel, smooth down the laser welds and polish using a polishing brush.

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.

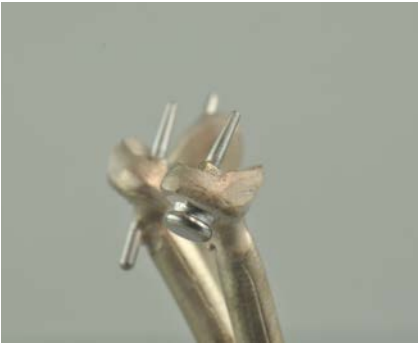
Inserting the male part in Ceramicor®. Casting.



With the parallelometer insert, set the male part 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/dental



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.



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/dental

Insertion: Hold the denture at both ends, ideally between thumb and forefinger, and place it back in the mouth on the anchors. Search or feel for the correct insertion position and push the denture onto the anchors with gentle, even pressure. Carefully close your jaws and check whether the denture is in its correct final position.

Removal: Hold the denture at both ends, ideally between thumb and forefinger, and slowly, carefully and steadily pull it off the anchors and remove it out of 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/dental

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/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.

Illustrated step-by-step instructions are available on the Cendres+Métaux homepage. www.cmsa.ch/dental

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