+ CM LOC®.

Instructions for use.

CENDRES + MÉTAUX
Medtech

CM LOC®.
Instructions for use.

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® Abutment components are designed to fixate overdentures (total dentures) or partial dentures completely or partially through endosseous implants (see web list) in the maxilla or mandible.
The CM LOC® CAD CAM Retention element is used as an additional retention element on CAD CAM milled dental bars.

Device Description
The CM LOC® is used for the following clinical situations:
– CM LOC® Abutment:
  Implant anchorage of hybrid-supported removable dental prostheses on implants.
– CM LOC® CAD CAM Retention element:
  As an additional retaining element on CAD CAM milled dental bars.

Materials
S = Syntax
  – Abutment (male part)
  – Housing (female part)
  – Case Guide
P = Pekkton®
  – Retention inserts Pekkton®
  – Housing (female part)
  – Processing insert
  – Impression part
  – Spacer
Auxiliary instruments S, Pekkton®, Santoprene, POM, X
  – 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
CM LOC® Abutment:
Implant anchorage of hybrid-supported
removable dental prostheses on implants, in combination with the specific CM LOC® system for female parts.

Mandible
CM LOC® Abutment:
Anchorage of mandibular (MD) prosthesis on 2 or more implants.

Maxilla
– CM LOC® Abutment:
  Anchorage of maxillary (MX) prosthesis on 4 or more implants.
– CM LOC® CAD CAM Retention element:
  As an additional retaining element on CAD CAM milled dental bars, in combination with the specific CM LOC® system for female parts.

Contraindication
– Implant divergences > 20°.
– The CM LOC® Abutments are to be used exclusively with the specific implant systems listed in the web list www.cmloc.ch.
– 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 followup/recall instructions.
– Patients with bruxism or other parafunctional habits.
– Unilateral free-end prosthesis without transversal support.
– Use on root caps.
– If not indicated for implant immediate loading.
– Implant system is not approved for use. www.cmsa.ch/docs
– For additional contraindications, please refer to the instructions for use from the implant manufacturer.

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

CM LOC® Spacer
The CM LOC® Spacer is slightly oversized versus the original components. This ensures optimal space conditions for later polymerization in the mouth. The spacer must not be used as a temporary replacement in place of the female part.

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

Precautions
– 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.
– 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
– The CM LOC® Block-out spacer can be shortened when using different abutment heights for better assembly of the female part.
– When handling the CM LOC® Abutments for retention of overdentures, direct or indirect handling may be used.
– 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.

Direct method
The treating dentist may integrate the CM LOC® Housing of the female part and retention inserts in an existing or new prosthesis during the treatment session directly.

Indirect method
The dentist must take an impression of the CM LOC® Abutments with the CM LOC® Impression part and send the impression to the laboratory to fabricate the subsequent model. The laboratory then inserts the CM LOC® Analog in the CM LOC® Impression part to carefully transfer the position of the CM LOC® Abutment in the mouth and fabricates the master model.

Symbols

	Important information for the specialist
⚠	Warning symbol for increased caution

Labeling on packaging/symbols

	Date of manufacture
	Manufacturer
REF	Catalogue number
LOT	Batch code
QTY	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.
CE 1250 CE	Cendres+Métaux products with CE labeling meet the requirements of the Medical Device Directive 93/42/EEC.
	Do not re-use
NON STERILE	Non-sterile
	Keep away from sunlight
	Attention, observe accompanying documents
	Unique Device Identification – UDI

Recommendation
When fabricating new dentures and in palate-free design, we recommend fabricating an individual reinforcement framework.

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), 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.

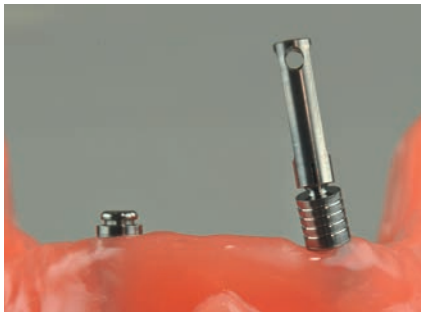
Sterilization method
The original packaging shall not be used for the sterilization process. Steam sterilization for sterilization of system components was validated with the following parameters:
– Temperature of saturated steam: 132°C (270°F)
– Flash-gravity (gravity displacement according to ANSI/AAMI 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.

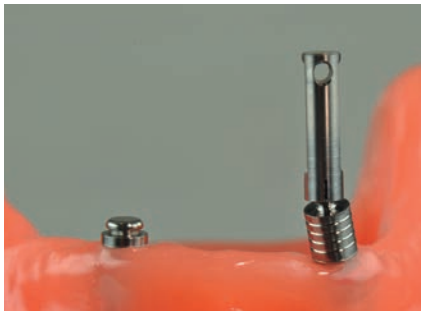
Processing
Prior placement of the implants is a precondition. It is essential to follow the manufacturer's instructions.

Fabrication of a new Prosthesis CM LOC® Abutment.
Patient Situation, Initial Position.

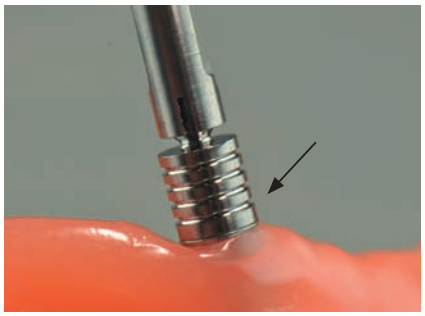


Determining the implant axis
Use the CM LOC® Case Guide to determine the divergence of the implant axes between the implants. Place the CM LOC® Case Guide on the implant.

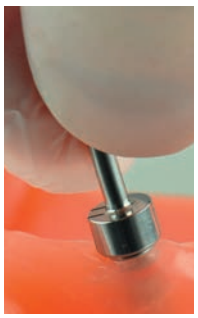
Note: A corresponding CM LOC® Case Guide is available for each implant system.
www.cmsa.ch/docs



By cyclically tipping, use the CM LOC® Case Guide to determine the implant axis, so that the individual implant axes to each other can be determined.
Attention: View from sagittal and front.
Should it not be possible to align the Case Guides parallel, a divergence of 20° between the implants is exceeded.
If the divergence is greater than 20°, the CM LOC® Abutment may not be used, instead the CM LOC® FLEX is used.



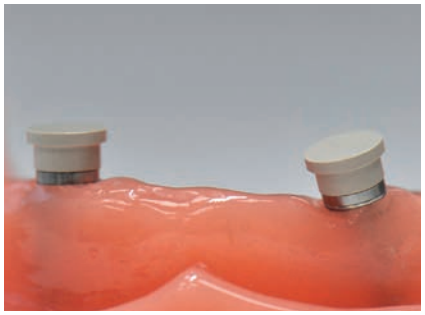
Determining the abutment height
Choose the abutment height based on the gingival height and read based on the graduation marks on the CM LOC® Case Guide. Determine the correct height of the CM LOC® Abutment in that the lower edge of the CM LOC® Abutment is at least 1 mm above the gingiva. The lowest height starts at graduation marking 1.



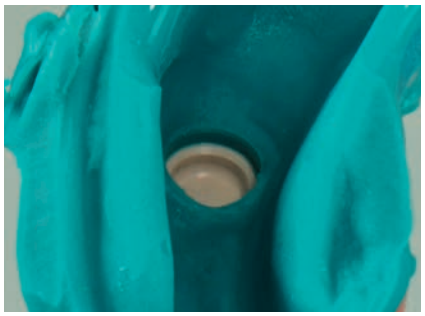
Insert the CM LOC® Abutment
First, place the CM LOC® Abutment on the CM LOC® Screwdriver and screw it into the implant by hand.

Use the torque wrench to tighten to the required torque. Make sure that the screwdriver is correctly seated on the abutment. Secure all parts against aspiration.

The screwdriver features an ISO connection and fits onto the coupling inserts for the corresponding torque wrenches.

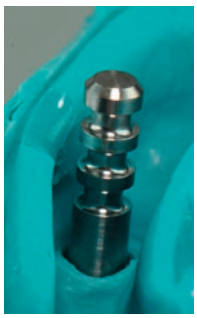


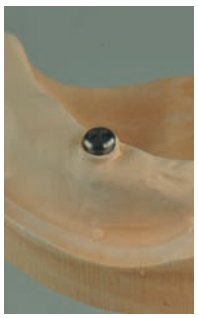
Indirect method – Mucodynamic impression of the oral situation for further use
Place the CM LOC® Impression part for impression taking of the oral situation for further processing for indirect method on the CM LOC® Abutment and create a functional impression. Please ensure that the CM LOC® Impression part is correctly seated. Use a solid impression material (e.g., Impregum™).



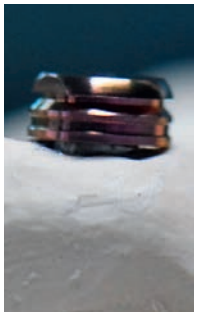
⚠ Check that the material is fully distributed around the CM LOC® Impression part and that no impression material has spilled into the CM LOC® Impression part.

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





Then pass to dental laboratory for fabrication of the model. To fabricate the model in the laboratory, place the CM LOC® Analog in the CM LOC® Impression part and fabricate the master model.



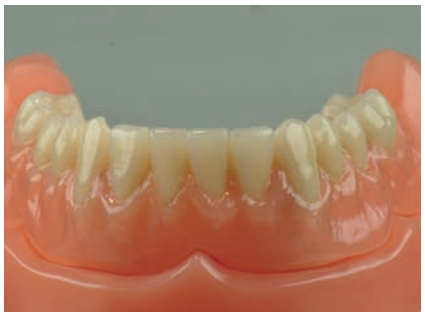
Then insert the CM LOC® Housing of the female part with mounted CM LOC® Processing insert or place the CM LOC® Spacer on the CM LOC® Analog. The user can decide to use the CM LOC® Spacer or the original CM LOC® Housing of the female part.

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.

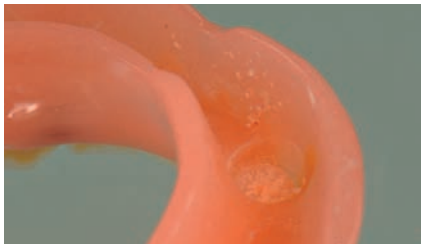


The prosthesis can now be fabricated using conventional technology.
Then replace the processing insert in the CM LOC® Housing of the female part with a Pekkton® Retention insert in the desired force level.

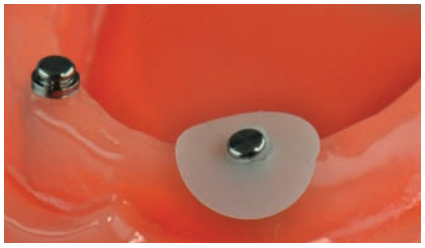
📖 See description in Selection of retention inserts.

📖 To provide the patient with comfortable and easy insertion of the prosthesis as well as familiarization with retention in the mouth, it is recommended to fit the prosthesis with an CM LOC® Retention insert, extra-low first. 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 instructions: Assembly and disassembly of retention inserts.

Direct method: processing the CM LOC® Housing of the female part during the treatment session.

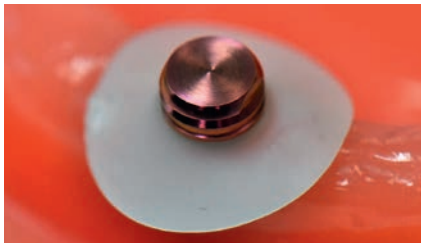


It is essential to create sufficient space in the prosthesis prior to inclusion in the prosthetic body. Use a standard round bur. There must be no contact between the prosthesis and the CM LOC® Housing of the female part.



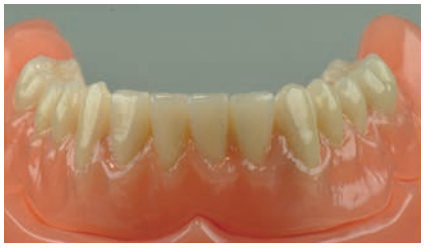
Mount the CM LOC® Block-out spacer on the male part. Make sure that it is seated correctly.

Make sure that the CM LOC® Block-out spacer has a good fit.

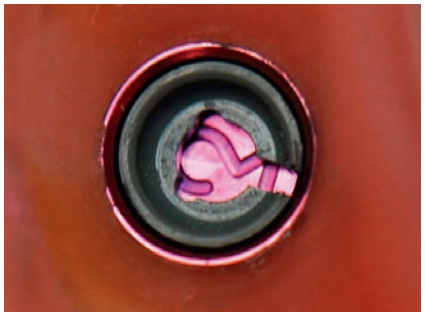


Then mount the CM LOC® Housing of the female part with mounted retention insert on the male part.

Make sure that all undercuts are blocked out prior to inclusion of the female part. Use a cold-curing polymer (e.g., GC Reline™, GC Advanced Technologies® Inc.) to anchor the CM LOC® Housing of the female part in the prosthesis. Apply the cold-curing polymer in the exposed area in the prosthesis and around the CM LOC® Housing of the female part.



Place the prosthesis on the CM LOC® Abutment. Make sure that the prosthesis is entirely in occlusion with the opposing jaw. Ensure that the prosthesis is retained passively without compression on the soft tissue while the cold-curing polymer cures. Excessive occlusal pressure during curing can cause the soft tissue to be compressed and then decompressed again. This can cause the retention inserts to then click out of position.

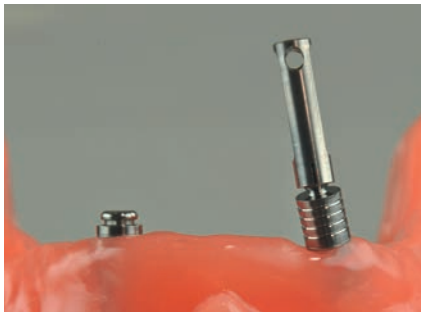


After processing, take the CM LOC® Block-out spacer out of the mouth. Then use a round bur to remove any excess polymer around the CM LOC® Housing of the female part. Then finish and polish the prosthesis.
Then replace the processing insert in the CM LOC® Housing of the female part with a Pekkton® Retention insert in the desired force level.

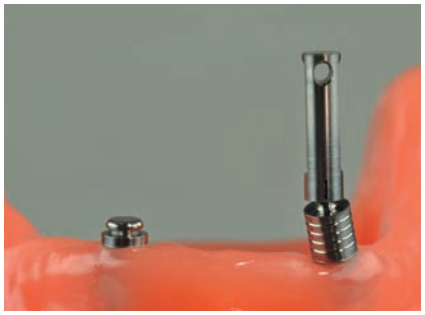
See description in Selection of retention inserts.

To provide the patient with comfortable and easy insertion of the prosthesis as well as familiarization with retention in the mouth, it is recommended to fit the prosthesis with an CM LOC® Retention insert, extra-low first. 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 instructions: Assembly and disassembly of retention inserts.

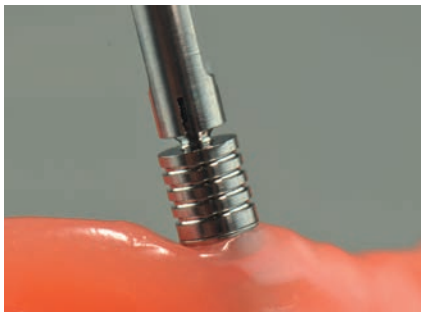
Modifying an existing prosthesis using CM LOC® components with simultaneous relining.



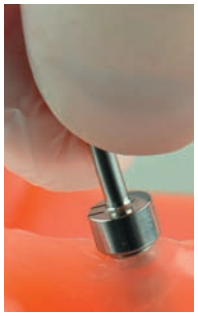
Remove existing anchorage from the patient's mouth. Use the CM LOC® Case Guide to determine the divergence of the implant axes between the implants. Place the CM LOC® Case Guide on the implant.



By cyclically tipping until it stops, use the CM LOC® Case Guide to determine the implant axis, so that the individual implant axes to each other can be determined. Attention: View from side and front. If the divergence is greater than 20°, the CM LOC® Abutment may not be used.



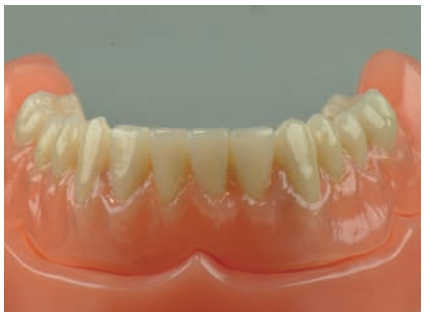
Determining the abutment height
Choose the abutment height based on the gingival height and read based on the graduation marks on the CM LOC® Case Guide. Determine the correct height of the CM LOC® Abutment in that the lower edge of the CM LOC® Abutment is at least 1 mm above the gingiva. The lowest height starts at graduation marking 1.



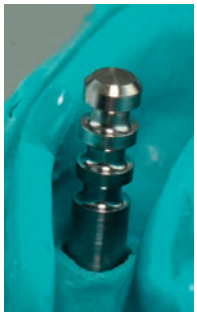
Insert the CM LOC® Abutment
First, place the CM LOC® Abutment on the CM LOC® Screwdriver and screw it into the implant by hand.

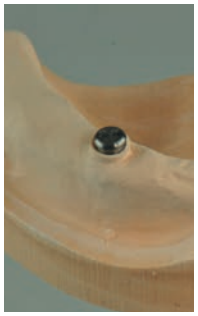
Use the torque wrench to tighten to the required torque. Make sure that the screwdriver is correctly seated on the abutment.
Secure all parts against aspiration. Followed by the same procedure up to and with polymerization of the CM LOC® Housing of the female part as already described in section Fabrication of a new prosthesis.

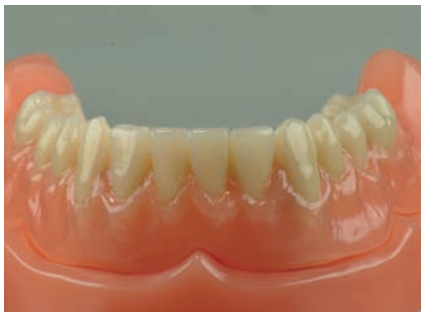
Relining
The already mounted CM LOC® Housing of the female part with mounted retention insert fixates the prosthesis during impression-taking.



An impression of the relining with the existing prosthesis is then taken in the usual manner.
Do not apply impression material in the CM LOC® Housing of the female part and make sure that the prosthesis is properly seated on the CM LOC® Abutment. Otherwise, clean the CM LOC® Housing of the female part immediately.







The impression is then passed to the dental laboratory for fabrication of the model for the relining using conventional technology and for subsequent finishing and polishing of the prosthesis.
After processing, remove the CM LOC® Block-out spacer from the mouth. Use a round bur to remove any excess plastic around the CM LOC® Housing of the female part.
Then replace the processing insert in the CM LOC® Housing of the female part with a Pekkton® Retention Insert in the desired force level.

See description in Selection of retention inserts.

To provide the patient with comfortable and easy insertion of the prosthesis as well as familiarization with retention in the mouth, it is recommended to fit the prosthesis with an CM LOC® Retention insert, extra-low first. 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 instructions: Assembly and disassembly of retention inserts.

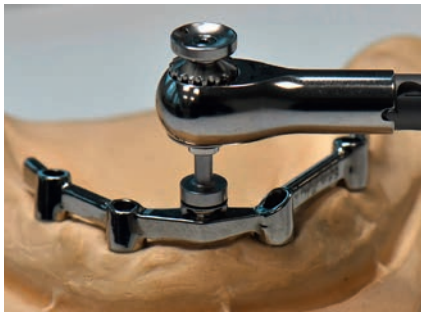
In case of a new prosthesis, use a CM LOC® CAD/CAM Retention element as an additional retention element on a milled bar.

Impression of the clinical situation in the mouth and fabrication of the master model as specified by the implant manufacturer.

Then fabricate the prosthesis using a conventional wax setup. The bar is then fabricated using CAD CAM technology. Please follow the manufacturer's instructions of the respective system. When modeling the bar in the CAD software, allow for the position of the CM LOC® CAD/CAM Retention element.

A standard thread M2 is required for bar-side fixation.

After fabricating the CAD CAM dental bar, the CM LOC® CAD/CAM Retention element can be mounted to the milled bar using the CM LOC® Screwdriver.



Torque for the CM LOC® CAD CAM Retention element 35 Ncm.

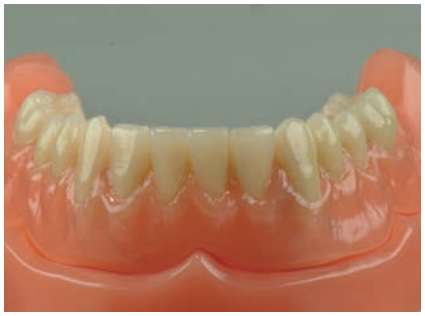
After assembly of the milled bar with mounted CM LOC® CAD CAM Retention element and fixed housing of the female part on the master model, the prosthesis can be fabricated.

Take an impression of the relining with impression posts from the respective implant manufacturer and prosthesis. Then pass to dental laboratory for fabrication of the model. Fabrication of milled bar with mounted female part according to description; use of CM LOC® CAD/CAM Retention element as an additional retention element on a milled bar for a new prosthesis.

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.

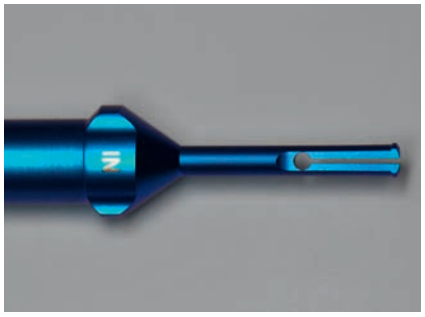


The prosthesis can now be fabricated using conventional technology.
Then replace the processing insert in the CM LOC® Housing of the female part with a Pekkton® Retention insert in the desired force level.

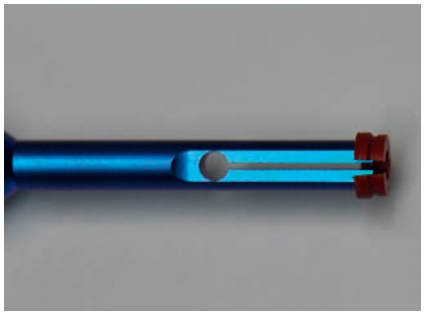
📖 See description in Selection of retention inserts.

📖 To provide the patient with comfortable and easy insertion of the prosthesis as well as familiarization with retention in the mouth, it is recommended to fit the prosthesis with an CM LOC® Retention insert, extra-low first. 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 instructions: Assembly and disassembly of retention inserts.

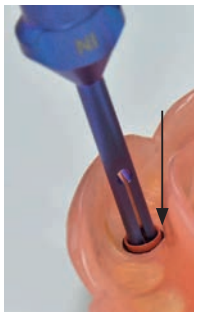
Assembly and disassembly of the retention inserts.

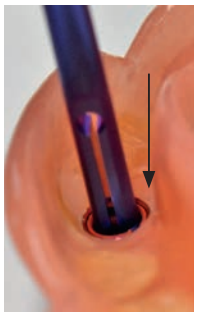


Assembly
The retention inserts are placed in the housing of the female par using the provided tool. Take up the CM LOC® Retention insert with the side IN.

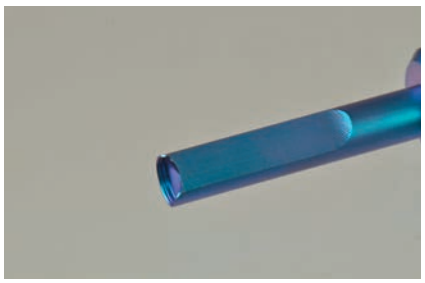


The CM LOC® Retention insert locks into place on the punch tangibly and audibly.

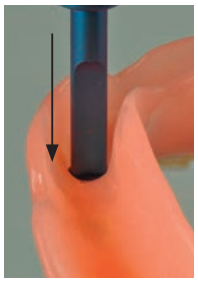


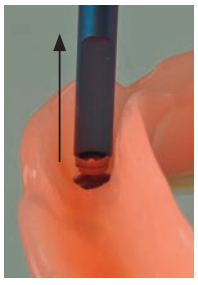


Press the CM LOC® Retention insert into the CM LOC® Housing of the female part straight and parallel until it clicks tangibly and audibly.



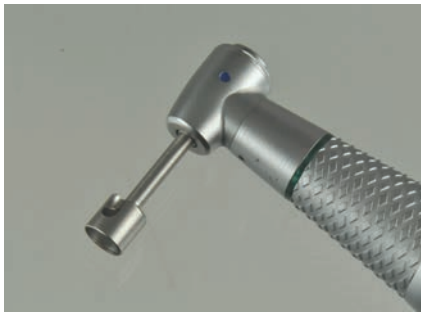
Disassembly
With the OUT side.



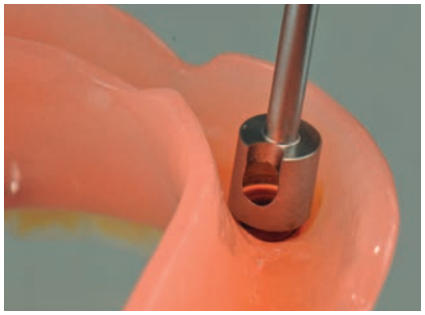


Place in straight and parallel fashion over the CM LOC® Retention insert between the CM LOC® Housing of the female part, and gently press into the CM LOC® Housing of the female part. The CM LOC® Retention insert disengages in this way and can be withdrawn from the CM LOC® Housing of the female part while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

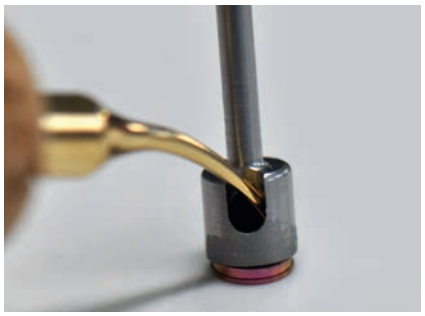
Disassembling the CM LOC® Housing of the female part.



For this purpose, use the CM LOC® Housing of the female part Extractor.



Use the CM LOC® Housing of the female part Extractor to mill out the complete CM LOC® Housing of the female part



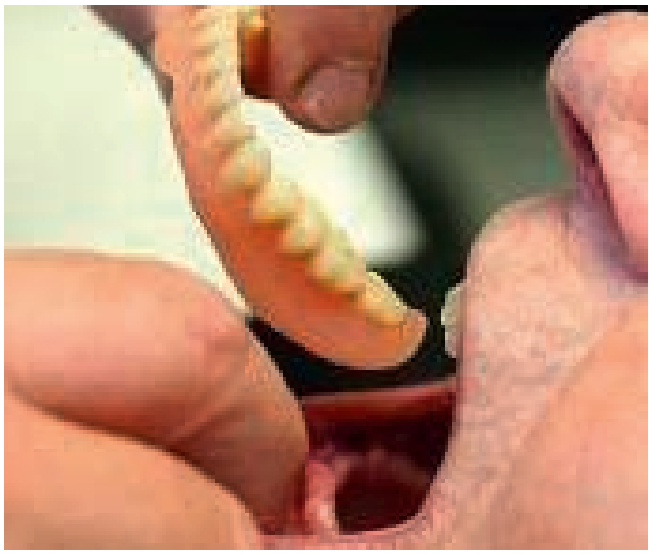
Then use an instrument to remove the CM LOC® Housing of the female part from the CM LOC® Housing of the female part Extractor through the side opening. For better removal, it is recommended to briefly warm the CM LOC® Housing of the female part Extractor over a flame.

Daily use.

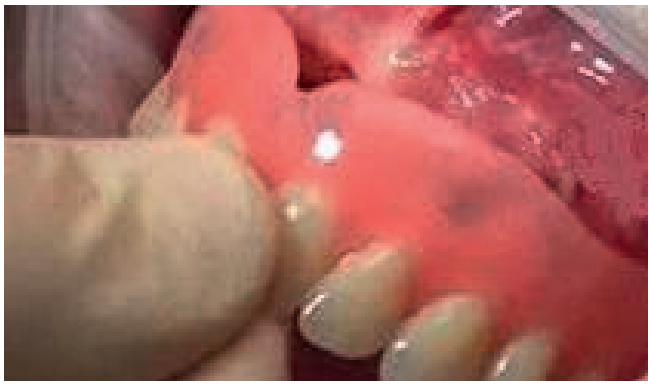
Handling/follow-up
Retaining elements in prosthetic work are subject to considerable stress in the mouth in a constantly changing environment, and thus are subject to wear over time. Wear is routine and cannot be avoided, only reduced. The amount of wear depends on the overall system. Our endeavors are 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 issue. 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.

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