prosthetic.line





+ CM LOC[®] FLEX.

Instructions for use.



CM LOC® FLEX. 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® FLEX

Intended use

The CM LOC[®] FLEX Abutment components are designed for complete or partial fixation of overdentures (total dentures) or partial dentures using endosseous implants (see web list) in the maxilla or mandible.

Product description

The CM LOC $^{\ensuremath{\circledast}}$ FLEX Abutment can be used for the following clinical situations:

Implant anchorage of hybrid-supported removable dental prostheses on implants, in combination with the specific CM LOC[®] system for female parts.

Materials

- S = Syntax
 - Abutment (male part)
 - Female part
 - Case Guide
- $P = Pekkton^{\mathbb{R}}$
 - Pekkton® Retention inserts
 - Female part
 - Processing insert
 - Impression part
 - Spacer

Auxiliary instruments S, Pekkton®, Santoprene, POM, X

- S = Syntax: TiAl6 V4 ELI (Grade 5),
- Ti > 89.478%, AI 6.0%, V 4.0%
- Santoprene
- Pekkton[®]
- POM
- -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

Implant anchorage of hybrid-supported removable dental prostheses on implants, in combination with the specific CM LOC[®] system for female parts.

Mandible

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

Maxilla

CM LOC[®] FLEX Abutment: Anchorage of maxillary (MX) prosthesis on 4 or more implants.

Further information on CM LOC[®] FLEX at www.cmsa.ch/docs.

Contraindication

- Implant divergences >30°
- The CM LOC[®] FLEX Abutments are to be used exclusively with the implant systems listed explicitly for this purpose in the web list www.cmsa.ch/docs.
- Alignment of the CM LOC[®] FLEX Abutment outside of the mouth.
- In patients with a pre-existing allergy to one or more elements of the attachment element materials.
- Use on a single implant.
- Not suitable if a fixed connection is required.
- The patient's existing oral situation does not permit correct application of CM LOC[®] FLEX.
- Lack of patient cooperation with respect to correct compliance with follow-up / recall instructions.
- Patients with bruxism or other para-functional habits.
- Unilateral free-end prosthesis without transversal support.
- Use on root caps.
- If immediate loading is not indicated for the implant.
- Implant system is not approved for the application.
- For additional contraindications and information, 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

CM LOC[®] FLEX has not been evaluated with regard to safety and compatibility in the MR environment. CM LOC[®] FLEX has not been tested with regard to 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 with regard to the original components. This ensures optimal spacing for subsequent inclusion of the female part. The spacer must not be used as a temporary replacement instead of the female part.

Note

These instructions for use are not sufficient for immediate use of the anchors. Knowledge of dental medicine or dental technology is required, as well as training by an experienced person on how to handle CM LOC® FLEX. Information: www.cmsa.ch/docs

Precautions

- The processing, activation, deactivation, repair and periodic maintenance of attachment elements of the CM LOC[®] FLEX 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[®] FLEX using a toothbrush and toothpaste may lead to premature wear of the functional parts.
- The CM LOC[®] FLEX 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.
- As far as possible, align the male parts parallel to each other and to the direction of insertion. Alignment only in the mouth.
- It is essential to block out undercuts prior to inclusion of the female part.
- Coat male part undercuts with petroleum jelly for better cleaning during cementation. (Better removal of excess composite bonding cement)
- Screw in the CM LOC[®] FLEX Abutment only once using the torque specified for this purpose.
- 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.
 Recommendation: 5 Ncm less than the implant tightening torque.
- Ensure that the position of the abutment is not rotated when working with the CM LOC[®] FLEX Aligner.
- It is essential to remove excess composite bonding cement.
- Do not use the CM LOC[®] Spacer as a temporary female part.
- Unless labeled otherwise, CM LOC[®] FLEX components are only for single use.
- Clean and dry the abutment surface with oil-free air prior to cementation with RelyX[™] Unicem or RelyX[™] Unicem 2.

- RelyX[™] Unicem 2 is an Automix product and a dualcuring material, and is therefore also sensitive to daylight or artificial lighting. The processing time is significantly shorter in the case of application under surgical lighting. For this reason, avoid intense lighting while processing.
- No pre-treatment required, such as sandblasting or silanization.
- The processing and setting times depend on the ambient temperature or the temperature in the mouth. The specified times are adapted for conditions relevant to use in practice. As is the case with any composite cement, setting slows down considerably at room temperature.
- In the event of excessive contact between the mucosa and RelyX[™] Unicem or RelyX[™] Unicem 2, clean thoroughly with water.

Start of curing after mixing has begun: 02:30 min. End of curing after mixing has begun: 06:00 min.

- For additional contraindications with regard to RelyX[™] Unicem and RelyX[™] Unicem 2, please refer to the instructions for use provided by the manufacturer, 3M ESPE.
- Before any procedure, ensure that all required CM LOC[®] and CM LOC[®] FLEX components are available in sufficient quantities.
- For your safety, always wear suitable protective clothing.

Side effects

There are no known side effects when used as intended.

Workflow / handling

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

General information

The difference between CM LOC[®] FLEX and CM LOC[®] is that the CM LOC[®] FLEX Abutment also supports alignment. The following CM LOC[®] components are also suitable for use with CM LOC[®] FLEX.

- System for female parts
- All auxiliary tools and auxiliary instruments
- Except screwdriver: CM LOC[®] FLEX has a specific screwdriver.
- 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.
- The CM LOC[®] FLEX Aligner can be shortened to the existing notch (end of cylindrical diameter) if required. This simplifies application in the posterior region. When using the CM LOC[®] FLEX Aligner, it is essential to ensure correct seating on the abutment and to ensure that the aligner is no longer rotated around its own axis after placement. When working with the CM LOC[®] FLEX Abutment for retention of overdentures, the direct or indirect approach may be used.
- 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.
- Further information on CM LOC[®] is available at www.cmsa.ch/docs.

Direct method

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

Indirect method

The dentist must take an impression of the CM LOC[®] FLEX Abutments with the CM LOC[®] Impression part and send the impression to the laboratory for subsequent fabrication of the model. The laboratory then inserts the CM LOC[®] Analog in the CM LOC[®] Impression part in order to facilitate reliable transfer of the position of the CM LOC[®] FLEX Abutment in the mouth, and fabricates the master model.

Symbols

	Important information for the specialist
\wedge	Warning symbol for increased caution

Labeling on packaging / symbols

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

Recommendation

When fabricating new dentures and when using a palate-free design, we recommend fabricating an individual reinforcement framework. The use of the standard commercial, mouth-compatible and self-adhesive composite bonding cement RelyX[™] Unicem and RelyX[™] Unicem 2 by 3M ESPE is recommended for CM LOC[®] FLEX. It is essential to observe the manufacturer's instructions in this regard. When using other mouth-compatible composite bonding cements, ensure that these are chemically curing.

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 guide-lines 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 observe the manufacturer's instructions in this regard.

Fabrication of a new prosthesis.

Patient situation, initial clinical picture.



Determining the implant axis

Use the CM LOC[®] FLEX Case Guide to determine the divergence of the implant axes between the implants. Place the CM LOC[®] FLEX Case Guide on the implant for this purpose.

Www.cmsa.ch/docs Case Guide is available for each implant system.



By axially tipping until it stops (30°), use the CM LOC[®] FLEX Case Guide to then determine the implant axis, so that the individual implant axes can be determined relative to each other.

Warning: Take the sagittal and the anterior plane into consideration. Should it not be possible to align the Case Guides parallel, a divergence of 30°

between the implants is exceeded. If the divergence is greater than 30°, the CM LOC® FLEX Abutment may not be used.



Determining the abutment height

Select the abutment height in accordance with the gingival height and read based on the graduation marks on the CM LOC[®] FLEX Case Guide. Determine the correct height of the CM LOC[®] FLEX Abutment with the lower edge of the CM LOC[®] FLEX Abutment positioned at least 1 mm above the gingiva. The lowest height starts at graduation marking 1.



Inserting the CM LOC[®] FLEX Abutment First, place the CM LOC[®] FLEX Abutment on the CM LOC[®] Screwdriver and screw it into the implant by hand.



Then tighten with a standard commercial torque wrench or contra-angle handpiece using the corresponding torque. Make sure that the CM LOC[®] 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.



Injecting composite bonding cement

Coat male part undercuts with some petroleum jelly to facilitate the removal of bonding cement residue.



Then mount the CM LOC FLEX[®] Aligner. Press the aligner correctly and firmly onto the abutment. You can hear the aligner click into its final position. Note: The injection funnel of the CM LOC[®] Aligner creates a seal in conjunction with the abutment filler opening and prevents the cement from escaping inadvertently and flowing into the undercuts. The CM LOC[®] Aligner is co-linear with the implant axis when mounted (ready for injection). Tilting and alignment take place after the bonding cement is injected.











Then inject the bonding cement into the CM LOC[®] FLEX Abutment until the composite bonding cement visibly escapes again from the two vent holes.

This provides a self-check that filling is fully complete. Please ensure correct vertical and horizontal seating of the CM LOC® FLEX Aligner on the abutment. An incorrectly mounted aligner is immediately obvious as the cement escapes from the filler opening and flows outside of the aligner. In this case, remove the aligner and dispose of it. Then clean the abutment and gingiva using water, correctly remount a new aligner and repeat the injection process. Ensure that the working time is not exceeded.



Alignment of the CM LOC® FLEX Abutment

Tip the placed CM LOC[®] FLEX Aligner in the alignment axis (do not rotate) until the second position is reached and then align the CM LOC[®] FLEX Abutment parallel to the occlusal plane and allow the bonding cement to cure for approx. 6-8 minutes.

Observe the manufacturer's instructions.

UTU I

- □ Start of curing after mixing has begun: 02:30 min. End of curing after mixing has begun: 06:00 min.
- ⚠ After injecting the bonding cement and aligning the abutment, take special care not to adjust the position of the abutment until the bonding cement has fully cured. Remove any excess immediately.

Note: An optimal alignment result is achieved by aligning the CM LOC® FLEX Abutments simultaneously parallel to each other and to the occlusal plane using the CM LOC® FLEX Aligner. After curing of the bonding cement, remove the CM LOC® FLEX Aligner, clean the male part and remove excess bonding cement.

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



Place the CM LOC[®] Impression part on the CM LOC[®] FLEX Abutment 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 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 CM LOC[®] Spacer is used for fabrication of the prosthesis. It is essential that it be replaced subsequently by a CM LOC[®] Housing of the female part. Use of the CM LOC[®] Spacer or the CM LOC[®] Housing of the female part is a decision that is at the discretion of the user.



The prosthesis can now be fabricated using conventional techniques. 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.

Direct method: Processing of 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 for this purpose. There must not be any 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 the CM LOC[®] Block-out spacer has a good fit.



Then mount the CM ${\rm LOC}^{\scriptscriptstyle (\! 8\!)}$ Housing of the female part with mounted processing 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 in the oral cavity. 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, 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 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.

I See description in Selection of retention inserts.

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

A 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 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 a 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[®] FLEX and CM LOC[®] components with simultaneous relining.



Remove existing anchorage from the patient's mouth. Then place the corresponding CM LOC[®] FLEX Case Guide onto the implant and check that the implant axis does not show a divergence greater than 30°. Otherwise, CM LOC[®] FLEX cannot be used.



This is followed by determination of the abutment height, insertion of the abutment, injection of the bonding cement and alignment of the abutment as described in the section on fabrication of a new prosthesis. This is then followed by inclusion of the housing of the female part as described in the section "Direct method: Processing the CM LOC[®] Housing of the female part during the treatment session".

Note: Alternatively, the housing of the female part can also be integrated in the laboratory. See the section on "Impression taking of the oral situation for further processing using the indirect method".



Relining

The previously mounted CM LOC[®] Housing of the female part with a mounted processing insert secures 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 securely seated on the CM LOC[®] FLEX Abutment. Otherwise, clean the CM LOC[®] Housing of the female part immediately. The impression is then sent to the dental laboratory for fabrication of the model for relining using the conventional technique, as well as subsequent finishing and polishing of the prosthesis.

Assembly and disassembly of the retention inserts.



Assembly

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



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





Press the CM LOC[®] Retention insert into the CM LOC[®] Housing of the female part 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 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.



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



Use the CM LOC $^{\rm \tiny (B)}$ Housing of the female part Extractor to mill out the complete CM LOC $^{\rm \tiny (B)}$ 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 withdrawal, 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.

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

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

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

Traceability of the batch numbers

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



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