Instructions for Use CM LOC® Root canal caps

1 Scope of application of instructions for use

These instructions for use apply to the products listed under Point 29 in Table 1. 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.

2 Trade name

See Point 29, Table 1.

3 Intended use

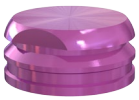
The components are intended for use for prosthetic restoration on natural teeth and to support procedures in the dental clinic or laboratory.

4 Expected clinical benefit

Restoration of chewing function and improved aesthetics.

For implantable products, link to "Summary of safety and clinical performance".
The summaries of safety and clinical performance (SSCP) for the implantable devices covered by these instructions for use, are available in the European database on medical devices EUDAMED, accessible at this address: https://ec.europa.eu/tools/eudamed

5 Product description

Product	Description
	**CM LOC® Male parts** Castable, solderable or laserable male parts for hybrid-supported, removable dental prostheses on root canal caps.
	**CM LOC® Female part** Retaining element as connecting part between denture and abutment.
 extra-low ca. 400g low ca. 1200g medium ca. 1800g strong ca. 2400g	**CM LOC® Retention inserts** Exchangeable retention inserts in four defined force levels. yellow: extra-low red: low green: medium blue: strong

6 Indication

CM LOC® male part C and CM LOC® male part E
Implant anchorage for hybrid-supported removable dental prostheses on root canal caps, in combination with the specific CM LOC® system for female parts.

Mandible
Anchorage of mandible (MD) prosthesis on two or more root canal caps.

Maxilla
Anchorage of maxillary (MX) prosthesis on four or more root canal caps.

7 Contraindications

– Divergences > 20° (per anchoring element).
– Use on a single root canal cap.
– Restoration of severely periodontally damaged abutment teeth.

– Not suitable if a fixed connection is required.
– Unilateral free-end prosthesis without transversal support.

– Lacking compliance of the patient with respect to follow-up / recall instructions.
– Patients with bruxism or other para-functional habits.
– In patients with a pre-existing allergy to one or more elements of the attachment element materials.
– Existing clinical picture in the patient's mouth does not permit the correct application of the products.

8 Compatible products

The CM LOC® system for female parts is also compatible with the following Locator®-like male parts:
Please contact us for further information regarding other compatibilities.
– CM LOC®
– CM LOC® FLEX
– Locator®
– MedentiLOC®
– Novaloc™

The retention force on these abutments may vary due to the different manufacturing tolerances and surfaces of the various male parts.

9 User qualification

The expertise of a professional dentist or dental technician is required. The current instructions for use must be available at all times and be completely read and understood before the first application. The manufacturing work and its maintenance must be carried out by qualified specialists.

Only original tools and parts may be used for this work. For information and additional details, please contact your Cendres+Métaux SA representative.

Important information for the specialist

Warning symbol for increased caution

10 Prescription

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

11 Side effects

This product may not be used in patients with allergies to one or more elements of the product 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. No known side effects if applied as intended.

12 Warnings

Magnetic resonance environment
The device has not been evaluated for safety and compatibility in the MR environment. The product has not been tested for heating or migration in the MR environment.

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

13 General information

These instructions for use are sufficient for immediate application for the products described in this application area of the instructions for use. Dental or laboratory knowledge is required. Information: www.cmsa.ch/docs

– Wax-up of the root canal cap with root canal post: If there are multiple root canal caps, prepare the solder/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.

– The height of the CM LOC® Block-out spacer can be shortened to achieve better mounting of the female part.
– When working with the CM LOC® male part for retention of overdentures, the direct or indirect approach may be used.
– We recommend that the clinical case be designed such that the largest possible support polygon is achieved. Small distances between consecutive implants and long free-end saddles can cause undesirable effects such as increased wear of the system components.
– Proper seating of the dentures on the mucosa must be checked at least once each year, and relining carried out if required to prevent rocking movement (overload). We recommend checking the prosthesis at regular intervals of approx. 3 months and to replace the retention inserts if necessary.
– In patients with suspected titanium allergy or hypersensitivity, we alternatively recommend the use of the Pekkton® female part.
– When fabricating new dentures and when using a palate-free design, we recommend fabricating an individual reinforcement framework.

– In patients with suspected titanium allergy or hypersensitivity, we alternatively recommend the use of the Pekkton® female part. One must allow for an increased aftercare effort and, if necessary, changing/replacing the system for female parts, as Pekkton® is somewhat softer than titanium as the material for the female part.

Integration of the housing of the female part

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® male part 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 to facilitate reliable transfer of the position of the CM LOC® Male part in the mouth, and fabricates the master model.

14 Preventive measures

– The processing, activation, deactivation, repair and periodic maintenance of the product must be carried out exclusively by trained persons.
– The mechanical cleaning of the product using a toothbrush and toothpaste may lead to premature wear of the functional parts.
– No cutting work may be carried out in the patient's mouth.
– It is essential to block out undercuts prior to polymerising the female part.
– No pre-treatment, such as sandblasting or silanisation of the housing of the female part, is required.

– Only original tools and parts may be used for this work.
– The product components are supplied non-sterile. For more information see Point 16 Preparation.
– Secure parts against aspiration.
– Before any procedure, ensure that all required product components are available in sufficient quantity.
– For your safety, always wear suitable protective clothing.

15 Single use

– Unless labelled otherwise, the product components are only intended for single use. Products that are marked for single-use are subject to a certain load during use, which can lead to wear, loss of function and/or malfunctions.

⚠ Reuse of products marked as single-use products may compromise safety, function and performance. Products for single-use have not been tested for reuse/reprocessing, which increases the risk of infection transmission.

16 Preparation

After any fabrication or modification and prior to use, the prosthetic work, including all system components, must be cleaned, disinfected and, if appropriate, sterilised. Materials made of metal alloys, high-performance polymers (Pekkton®) and ceramics are suitable for steam sterilisation, whereas components made of plastic other than Pekkton® are not suitable. Consider published national guidelines when selecting a disinfection and sterilisation process and the Instructions for Use “Preparation of surgical and prosthetic products” (www.cmsa.ch/docs).

17 Scope of application

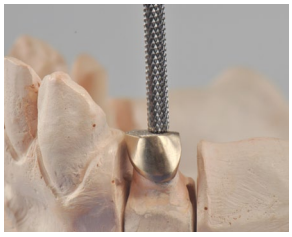
After fabricating the root post cap, the CM LOC® male part can be inserted or processed according to the indication.

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 using the specific CM LOC® System for female parts.
The CM LOC® Anchoring system consists of a root canal cap consisting of two standardised male parts for casting, soldering or lasering with which implant divergences of up to 20° are compensated and a system for female parts with four exchangeable retention inserts in four defined force levels.

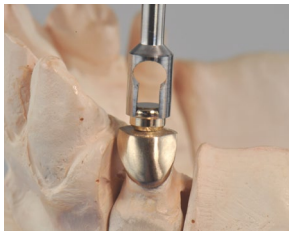
18 Procedure

Inserting the CM LOC® male part E in Elitor® by laser welding.

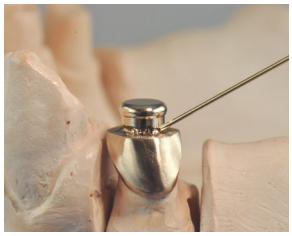
Initial situation.



Preparation for laser welding
In a first step, face mill the root canal cap already fabricated using a milling machine at right angles parallel to the direction of insertion.



With the CM LOC® Parallelometer insert, set the CM LOC® male part as centrally as possible on the already cast, face-milled root canal cap and securely fix it with wax using the root canal cap.



Laser welding
Then fill all undercuts circularly around the entire CM LOC® male part in the laser unit with laser wire.

Please observe the manufacturer's instructions on the laser procedure.

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

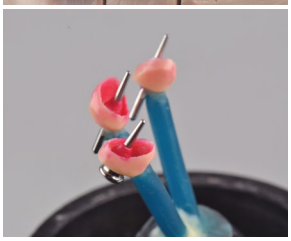
To simplify working with and protecting the CM LOC® male part, put the CM LOC® Spacer on the CM LOC® male part.

Make sure that no more material is removed than to the outer bottom edge of the CM LOC® male part.

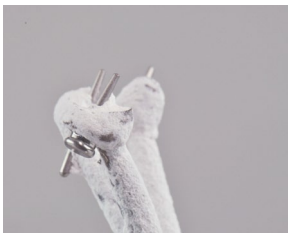
Inserting the CM LOC® male part in Ceramicor® by casting-on.

Initial situation.

Preparation for casting-on
With the CM LOC® Parallelometer insert, set the CM LOC® male part as centrally as possible on the already modelled root canal cap and securely fix it with wax using the root canal cap.



Casting / Finishing
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 CM LOC® male part while sandblasting and processing.
Then, using a standard rubber wheel, smooth down the cast and polish using a polishing brush.

To simplify working with and protecting the CM LOC® male part, put the CM LOC® Spacer on the CM LOC® male part.

Make sure that no more material is removed than to the outer bottom edge of the CM LOC® male part.

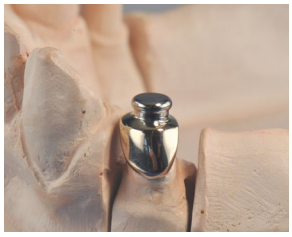
Inserting the CM LOC® male part in Ceramicor® by soldering-on.

Initial situation.

Preparation for soldering-on
With the CM LOC® Parallelometer insert, set the CM LOC® male part as centrally as possible on the already cast, face-milled root canal cap and securely fix it circularly with wax using the root canal cap.

Soldering
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.



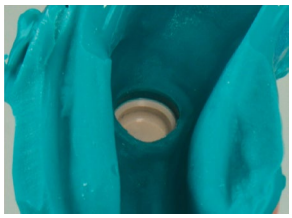
Finishing
Then, using a standard rubber wheel, smooth down the solder joint and polish using a polishing brush.

To simplify working with and protecting the CM LOC® male part, put the CM LOC® Spacer on the CM LOC® male part.

Make sure that no more material is removed than to the outer bottom edge of the CM LOC® male part.

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 and create a functional impression. Ensure that the CM LOC® Impression part is correctly seated.
Use a solid impression material (e.g. Impregum™).



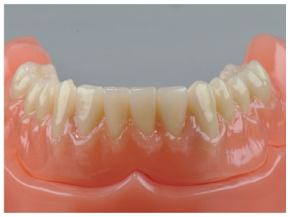
Check that the material is fully distributed around the CM LOC® Impression part and that no impression material has spilled into the CM LOC® Impression part.

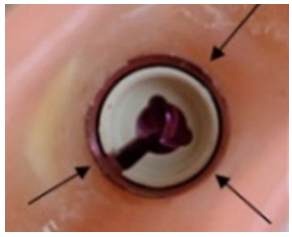
Otherwise, clean the abutment and repeat the impression-taking process.

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 place either the CM LOC® Housing of the female part with a mounted CM LOC® Processing insert or the CM LOC® Spacer onto the CM LOC® Analog. Use of the CM LOC® Spacer or the original CM LOC® Housing of the female part is at the discretion of the user.

Spacer = place holder for polymerisation in mouth.
Direct polymerisation with CM LOC® Housing of the female part in the laboratory.
Block out all undercuts during further processing and fabrication of the denture.





Finalisation
The prosthesis can now be fabricated using conventional technology. After processing, remove excess resin around the CM LOC® Housing of the female part with a round bur.
Then finish and polish the prosthesis. Afterwards 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.

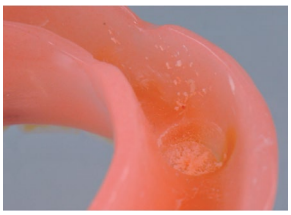
Make sure that no polymer has flowed into the housing of the female part. If necessary, remove the processing insert and carefully remove excess polymer from the inside of the housing of the female part with a probe.

Selection of retention inserts
Four different CM LOC® Retention inserts made of Pekkton® are available for retention. The retention inserts are colour-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 at the start.

To provide the patient with comfortable and easy integration of the prosthesis as well as familiarisation with the 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 description: assembly and disassembly of retention inserts.

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



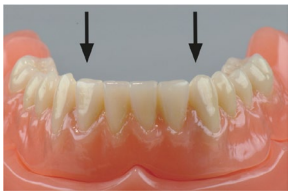
It is essential to create sufficient space in the prosthesis prior to inclusion in the prosthetic body. Use a standard round bur for this purpose. There must not be any contact between the prosthesis and the CM LOC® Housing of the female part.

Mount the CM LOC® Block-out spacer on the male part.

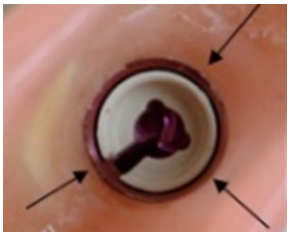
Make sure that the CM LOC® Block-out spacer fits well. The height of the CM LOC® Block-out spacer can be shortened to achieve better mounting of the female part.

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

Make sure that all undercuts are blocked out before polymerisation.
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.



Finalisation
Place the prosthesis on the CM LOC® Male part 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 processing inserts to then click out of position.



After processing, take the CM LOC® Block-out spacer out of the mouth.
After processing, remove excess resin around the CM LOC® Housing of the female part with a round bur. Then finish and polish the prosthesis.
Afterwards 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.

Make sure that no polymer has flowed into the housing of the female part. If necessary, remove the processing insert and carefully remove excess polymer from the inside of the housing of the female part with a probe.

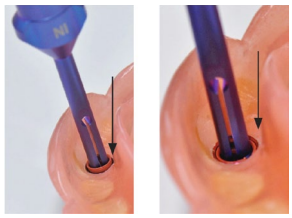
Selection of retention inserts
Four different CM LOC® Retention inserts made of Pekkton® are available for retention. The retention inserts are colour-coded and divided into four different levels of retention force.
yellow: extra-low red: low
green: medium blue: strong

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

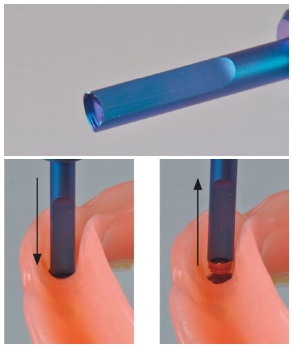
To provide the patient with comfortable and easy integration of the prosthesis as well as familiarisation with the retention in the mouth, it is recommended to fit the prosthesis with a CM LOC® Retention insert, extra-low, first. If the patient demands stronger retention, CM LOC® Retention inserts offering greater retention force can be used. For assembly and disassembly of the retention inserts, see description: 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 part using the CM LOC® Multi-tool provided. Pick up the CM LOC® Retention insert with the IN side.

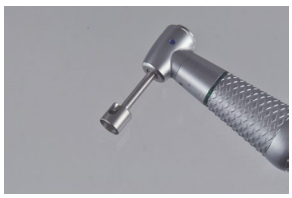


You can feel and hear the CM LOC® Retention insert lock into place.
Press the CM LOC® Retention insert into the CM LOC® Housing of the female part in straight and parallel fashion until you can feel and hear it click into place.

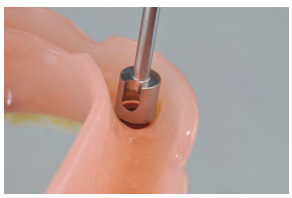


Disassembly
Position the CM LOC® Multi-tool with the OUT side straight and parallel in the space between the CM LOC® Housing of the female part and the retention insert and press lightly into the CM LOC® Housing of the female part.
The CM LOC® Retention insert thus unlocks and can be removed in a straight manner from the CM LOC® Housing of the female part.

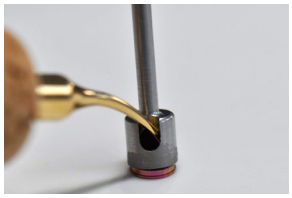
Disassembly CM LOC® Housing of the female part.



To disassemble the CM LOC® Housing of the female part, use the CM LOC® Extractor for the housing of the female part.



Mill the complete CM LOC® Housing of the female part with the CM LOC® Extractor for the housing of the female part.



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

19 Materials

Detailed information on the materials and their classification is given in the specific material data sheets, the catalogue as well as the product list given in Table 1 in Point 29. See website www.cmsa.ch/docs or the Cendres+Métaux SA Dental Documentation (available free of charge from all Cendres+Métaux SA subsidiaries, branches and dealers).

20 Notes on storage

The product must be stored in a dry place in its original packaging, at room temperature and without direct sunlight, unless otherwise stated on the packaging. Improper storage can influence the product properties and lead to failure of the restoration.

21 Patient information

21.1 Handling / follow-up

On the day of insertion of the dentures at the latest, the patient must be informed that regular follow-up care is necessary to maintain the health of the entire masticatory system and the functionality of the denture. Ensure that patients are motivated and instructed according to their own abilities such as manual dexterity and vision with regard to the handling and care of their teeth and dentures.

Permanent and removable dentures are subject to considerable stress in the mouth in a constantly changing environment, and thus more or less subjected to signs of wear. Wear is omnipresent in daily routine and cannot be avoided, only reduced. The amount of wear depends on the overall system.

Our endeavours are aimed at using materials that are as optimally matched as possible in order to reduce wear to an absolute minimum. Proper seating of the dentures on the mucosa must be checked at least once each year, and relining must be performed if required to prevent rocking movement (overload). We recommend checking the dentures at intervals of approx. 3 months initially and to replace the auxiliary parts such as retention inserts if necessary.

21.2 Insertion and removal of the dentures

Ensure that the dentures do not tilt, as any tilting can lead to damage. Never insert dentures by biting the teeth together. This can lead to damage or even breakage of the connecting element. Further information on handling and aftercare of dentures is available in the patient information brochure at 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.

21.3 Cleaning and care

We recommend cleaning your teeth and your dentures after every meal. Cleaning of dentures includes cleaning of the connecting element. The gentlest cleaning is achieved by cleaning the connecting element under running water with a soft toothbrush. The most intensive cleaning is achieved when cleaning the dentures in a small ultrasonic device and adding a suitable cleaning agent. Never clean the high precision connecting elements with toothpaste. This could lead to damage. Caution should also be exercised in the case of unsuitable cleaning 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 the website (www.cmsa.ch/docs).

For information and additional details, please contact your Cendres+Métaux SA representative.

22 Ordering information

More detailed information on the catalogue numbers, the number of products and their classification can be found in the product list under Point 29 in Table 1, the specific product catalogue, the packaging and, in the case of individual products, also directly on the product itself. You can find further information on the website www.cmsa.ch/docs or the Cendres+Métaux SA Dental Documentation (available free of charge from all Cendres+Métaux SA subsidiaries, branches and dealers).
For information and additional details, please contact your Cendres+Métaux SA representative.

23 Availability

Some of the products described in this document may possibly not be available in all countries.

24 Traceability Lot number

The batch numbers of all parts used must be documented to ensure traceability. If different batch numbers are used for the products described in this application area of the instructions for use for the fabrication of dentures, all the batch numbers concerned must be recorded to ensure traceability.

25 Complaint

Cendres+Métaux SA must be notified immediately of any incident that has occurred with regard to the product to all branches, offices and dealers of Cendres+Métaux SA and, in case of serious cases, to the competent authority where the user is registered.

26 Safe disposal

The product must be disposed of in accordance with local laws and environmental regulations, taking into account the level of contamination. Cendres+Métaux LUX SA would be very pleased to accept precious metal waste. For information and additional details, please contact your Cendres+Métaux SA representative.

27 Trademarks

Registered trademarks of Cendres+Métaux Holding SA, Biel/Bienne, Switzerland include:

CM LOC® / Pekkton® / Elitor® / Ceramicor®

Unless explained specifically, all products marked with "®" are not registered trademarks of Cendres+Métaux Holding SA, but registered trademarks of the respective manufacturer.

28 Disclaimer

The manufacturer rejects any liability for damages resulting from non-compliance with these instructions for use. This product is part of an overall concept and may only be used or combined with the corresponding original components and instruments. Otherwise, the manufacturer rejects any responsibility and liability. In case of complaints, please always include the batch number.

The use of third party products not distributed by Cendres+Métaux SA in connection with the products listed in Table 1 will void any warranty or other express or implied obligations of Cendres+Métaux SA.

The user of Cendres+Métaux SA products is responsible for determining whether or not a product is suitable for a specific patient and a specific situation.

Cendres+Métaux SA disclaims any express or implied liability and shall not be responsible for any direct, indirect, punitive or other damages arising from or in connection with errors in professional judgement or practice in the use or installation of Cendres+Métaux SA products.

The user is also obliged to regularly study the latest developments of the Cendres+Métaux SA products listed in Table 1 and their applications.

Please note: the descriptions contained in this document are not sufficient for the immediate application of Cendres+Métaux SA products. Specialist knowledge of dentistry, dental technology and instructions in handling the products listed in Table 1 by an operator with appropriate experience is always required.

29 Product list

Table 1

Cat. No.	Product name	Material	Single use	Multiple use	Basic UDI-DI
05001605	CM LOC® male part C Cast-on / soldering technique	Ceramicor®	Yes	No	764016651000050DW
05001606	CM LOC® male part E Laser welding technique	Elitor®	Yes	No	764016651000050DW
05003001	CM LOC® Basic Set Titanium	TiAl6 V4 ELI, (Grade5)	Yes	No	764016651000057EC
05001995	CM LOC® Housing of the female part titanium for Pekkton® inserts	Pekkton®	Yes	No	764016651000053E4
05001314	CM LOC® Retention insert, extra-low	TiAl6 V4 ELI, (Grade5)	Yes	No	764016651000053E4
05001315	CM LOC® Retention insert, low	Pekkton®	Yes	No	764016651000053E4
05001316	CM LOC® Retention insert, medium	Pekkton®	Yes	No	764016651000053E4
05001317	CM LOC® Retention insert, strong	Pekkton®	Yes	No	764016651000053E4
05001328	CM LOC® Processing insert	Pekkton®	Yes	No	764016651000007DV
05001306	CM LOC® Housing of the female part Pekkton® for Pekkton® inserts	Pekkton®	Yes	No	764016651000053E4
07000201	CM LOC® Spacer	Pekkton®	Yes	No	764016651000026DZ
07000202	CM LOC® Block-out spacer	Santoprene	Yes	No	764016651000027E3
07000204	CM LOC® Analog	TiAl6 V4 ELI, (Grade5)	Yes	No	764016651000034DY
07000205	CM LOC® Multi-tool for Pekkton® Retention insert	TiAl6 V4 ELI, (Grade5)	No	Yes	764016651000001DH
07000206	CM LOC® Screwdriver	TiAl6 V4 ELI, (Grade5)	No	Yes	764016651000022DR
07000213	CM LOC® Impression part	Pekkton®	Yes	No	764016651000017DY
07000217	CM LOC® Extractor for housing of the female part	Steel	No	Yes	764016651000009DZ
07000200	CM LOC® Instrument Set		No	Yes	764016651000025DX

30 Symbols

	Important information for the specialist
	Warning symbol for increased caution

Labelling on packaging / symbols

	Date of manufacture
	Manufacturer
REF	Catalogue number
LOT	Batch code
QTY	Quantity
 www.cmsa.ch/docs	Observe the instructions for use, which are available in electronic form at the address specified.
Rx only	Attention: According to US federal law, this product may only be sold by or on behalf of a physician.
CE 0483 CE	Cendres+Métaux products with CE labelling meet the requirements of the relevant European requirements.
	Do not re-use
	Non-sterile
	Keep away from sunlight
	Attention, observe accompanying documents
UDI 	Unique Device Identification – UDI
EC REP	European Authorised Representative
	Importer in EU
MD	Medical device

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