

Instructions for Use Pekkton® ivory Milling blank

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.

5 Product description

Pekkton® ivory is a material based on PEKK composed of OXPEKK® IG¹ (Implant Grade) and titanium dioxide for the definition of the colour tone and the mechanical properties. Colour: whitish.

¹ OPM, Oxford Performance Materials, USA

6 Indication

- Definitively restored, veneered and screw-retained crowns and bridges on implants with a maximum of two pontics, which can be veneered with bonded pressed crowns, composites and prefabricated acrylic teeth and shells.
- Definitively restored, veneered single crowns and bridges with a maximum of one pontic on natural teeth.
- Unveneered parts e.g. crown margins and backings.
- Unveneered crowns and bridges in the posterior region for a maximum wearing period of 12 months.
- Removable dentures, such as, for example, secondary structures on bars and telescopes, transversal connections, occlusal splints and prosthetic bases.



The responsibility for the use of custom-made products beyond the described indications lies with the clinician.

7 Contraindications

- Occlusal space conditions < 1.3 mm.
- - When the following minimum dimensions of the framework cannot be maintained:
- Circular wall thickness < 0.6 mm.
- Occlusal wall thickness < 0.8 mm.
- Connector cross section of front (anterior) bridge < 12 mm².
- Connector cross-section lateral (posterior) bridge < 14 mm².
- Bridges on implants with more than two pontics.
- Bridges on natural teeth with more than one pontic.
- Extensions.
- Unveneered crowns and bridges with a wearing period > 12 months.
- Lacking compliance of the patient with respect to follow-up / recall instructions.
- Patients with bruxism or other para-functional habits.
- In patients with allergies to one or more elements of the materials used in the product.
- Existing clinical picture in the patient's mouth does not permit the correct application of the products.

8 Compatible products

Not applicable.

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.



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 and products made of steel 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.


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


14 Preventive measures

-  – The mechanical cleaning with a toothbrush and toothpaste may lead to premature wear.
- When grinding, wear protective goggles and a dust mask and use a suction unit.
- Only original tools and parts may be used for this work. For information and additional details, please contact your Cendres+Métaux SA representative.
- 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

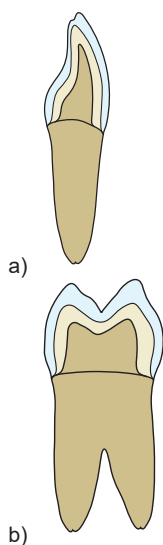
- Unless labelled otherwise, the product components are only intended for single use. Products that are marked for single-use are subject to a certain load during use, which can lead to wear, loss of function and/or malfunctions.
-  Reuse of products marked as single-use products may compromise safety, 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 "Reprocessing of surgical and prosthetic products" (www.cmsa.ch/docs).


17 Scope of application

Pekkton® ivory was developed as an alternative, metal-free framework material. The material can be used to fabricate classical crowns and bridges on natural teeth. Due to the masticatory force-absorbing properties of Pekkton® ivory, the material is also frequently used for implant-supported prostheses. For example, crowns, bridges or individual abutments bonded to titanium bases can be covered with Pekkton® ivory. The high performance polymer can also be used for removable dentures. Examples for this are prosthesis bases on construction elements or prosthesis reinforcements.

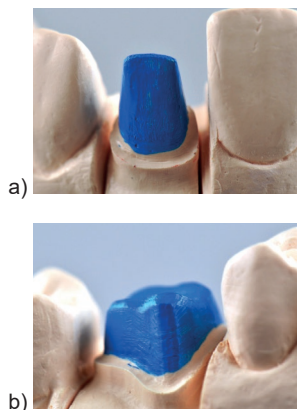
18 Procedure**18.1 Crowns and bridges****1. Preparation**

Principally, the preparation technology corresponds to that of full ceramic reconstructions. Preparation is based on the concept of the reduced, anatomical shape. A circular chamfer preparation at an angle of approx. 10 - 30° or a shoulder preparation with rounded inner edges is ideal. The width of the circular chamfer and the shoulder is approx. 0.8 mm each.

- a) Preparation design of an anterior tooth
- b) Preparation design of a posterior tooth


-  A reduction in framework thickness always means a reduction in strength. This aspect must be considered in the preparation, in particular within the occlusal area. The height of the crown stump preparation should be at least 4mm and the angle of convergence should be 4-6°. Eliminate undercuts.

-  Be careful with insulating varnish when digitising the model. This can lead to errors during scanning.

2. Model and stump preparation

Careful preparation of the work models is required to obtain a well fitting crown or bridge. The stumps must fit reproducibly and be removable. It is advisable to apply a sealer to harden the surface and to protect the stump. Two layers of insulating varnish are applied to max. 1mm from the preparation margin.

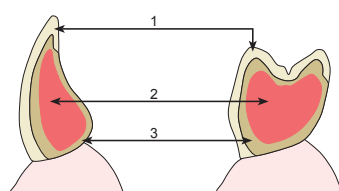
- a) Anterior tooth
- b) Posterior tooth

-  Be careful with insulating varnish when digitising the model. This can lead to errors during scanning.

18.2 Material thickness of the frameworks

Pekkton® ivory	Crown anterior tooth	Crown posterior tooth	Bridge anterior tooth	Bridge posterior tooth
Design type	Tooth shape supporting	Cusp supporting	Tooth shape supporting	Cusp supporting
Minimum wall thickness circular	> 0.6 mm	> 0.6 mm	> 0.6 mm	> 0.6 mm
Minimum wall thickness occlusal	> 0.8 mm	> 0.8 mm	> 0.8 mm	> 0.8 mm
Connector dimensions	–	–	> 12 mm ²	> 14 mm ²

The key for clinical success and a durable restoration in the patient's mouth is compliance with the guidelines for the design of a reconstruction in Pekkton®. The change from framework to veneering material may not occur in the functional contact area. If there is insufficient space, do not rely on the layer thickness of the veneer, but keep to the maximum possible framework thickness.



- 1) Veneering
- 2) Connecting parts
- 3) Framework

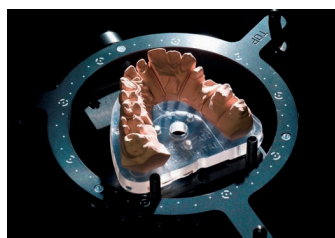
The stability of the connector surface is increased when the ratio of vertical to horizontal is significantly greater (ratio of approx. 60% to 40%).

The maximum possible framework thickness should be the aim by maximising the connector dimensions and a full anatomy designed if necessary in the lingual area that is not critical aesthetically to achieve the maximum possible connector dimensions.

18.3 Removable restoration

Long-term stability depends on the dimensions and design of the restoration. Ideally, the cross-section of a Pekkton® ivory framework should be increased minimally by a factor of 1.5 compared to work with metal alloys.

18.4 Data acquisition (scanning)



Narrow incisal edges (< 0.6 mm) on tooth stumps must be blocked out with wax before scanning.

18.5 Design (CAD)

Parameters	Anterior teeth	Posterior teeth
Crown edge: recommended minimum width	0.3 mm	0.3 mm
Cement gap	0.03 – 0.06 mm	0.2 mm
Additional cement gap	–	–
Edge thickness	0.15 – 0.2 mm	0.15 – 0.2 mm
Minimum thickness	0.6 mm	0.6 mm
Drill radius compensation	YES	YES
Remove undercuts	YES	YES

Details are to be considered as guide values and must be adjusted depending on the machine type used.

18.6 Milling (CAM)

Milling tool PMMA	Speed	Feed rate
Ø 2 mm	13'000 – 18'000 rpm	30 mm/s
Ø 1 mm	17'000 rpm	25 mm/s
Ø 0.6 mm	34'000 rpm	15 mm/s

Pekkton® ivory can be processed dry and wet. The milling chips must be easy to suction away during dry machining. To avoid the framework from warping (from a material temperature of approx. 160°C), the sharpest possible milling tools must be used for processing, and good air or water cooling of Pekkton® ivory must be ensured during the milling process. Milling is performed with ball-end cutters in the basic PMMA setting.

Details are to be considered as guide values and must be adjusted depending on the machine type used.

18.7 Finishing



Cross-toothed milling is used to finish the framework. Finishing is performed at 5'000 - 10'000 rpm. Do not operate with too high a pressure on the object. Roughen the surface using a diamond milling cutter before sandblasting. Clean with alcohol.

18.8 Veneering

After preparation of the framework, Pekkton® ivory can be aesthetically enhanced in various ways. For example, it can be enhanced by veneering with composites, affixing custom-made pressable ceramic crowns or using prefabricated acrylic teeth and shells.

18.9 Veneering with composites



After completion with the milling cutters, the framework is blasted with abrasive 110 µm blasting medium at a pressure of 2 bar. Clean with alcohol. Prior to veneering, it is imperative to treat the Pekkton® ivory framework with MMA-based composite primer.



First apply the opaquer with a brush. This can be applied in several layers. The opaquer must cover the framework, but nonetheless be as thin as possible. The ultimate shape is achieved with suitable burs, rubber polishers and various aids.

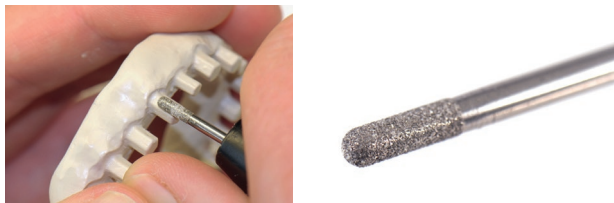


Bridge work: to avoid cracks (also as a late consequence) in the veneer due to different E-modulus values of Pekkton® ivory and the veneering material, a separation should be made between the teeth down to the opaquer.



As veneering is outside the area of responsibility of Cendres+Métaux SA, it is not further described in these Instructions for Use. Please follow the manufacturer's instructions for the veneering concept selected.

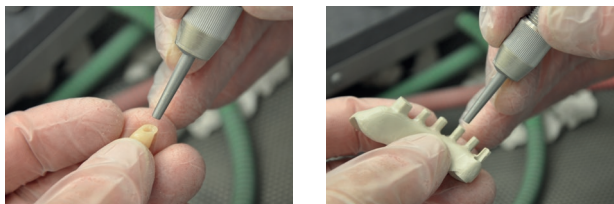
18.10 Bonding with composite / acrylic / PMMA



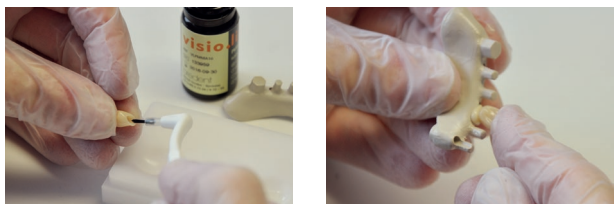
Roughen the surface with a diamond. At low speed and with little force. The recommended speed is between 5'000–10'000 rpm.



Clean the surfaces to be bonded with alcohol.



Sandblast the plastic teeth with unrecycled aluminium oxide (Al_2O_3) with a grain size of 110µm and a pressure of 2 - 3 bar. Sandblast the Pekkton® ivory framework with unrecycled aluminium oxide (Al_2O_3) with a grain size of 110µm and a pressure of 2 bar. Then clean with oil-free compressed air or with alcohol. Not with a steam cleaner!



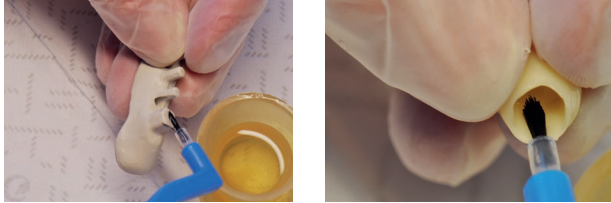
Apply a thin coat of composite primer to the connecting areas of the teeth and the Pekkton® ivory framework with a disposable brush. Then cure with a suitable light-curing device according to the manufacturer's instructions.

Apply the composite into the cavities of the plastic teeth and then press the tooth onto the assigned retention on the framework by hand. Curing is performed using a suitable light-curing device according to the Instructions for Use.

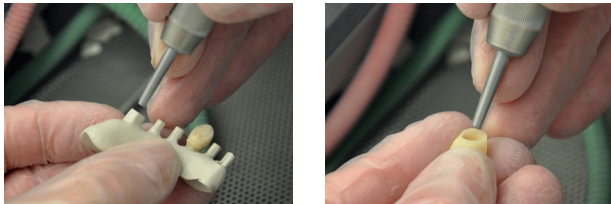
18.11 Bonding with ceramic/ Livento® press / zirconium oxide



Roughen the surface with a diamond. At low speed and with little force. The recommended speed is between 5'000 – 10'000 rpm.



Clean the surfaces to be bonded with alcohol.



Sandblast the plastic teeth with unrecycled aluminium oxide (Al_2O_3) with a grain size of $110\mu\text{m}$ and a pressure of 2 - 3 bar. Sandblast the Pekkton® ivory framework with unrecycled aluminium oxide (Al_2O_3) with a grain size of $110\mu\text{m}$ and a pressure of 2 bar. Then clean with oil-free compressed air or with alcohol. Not with a steam cleaner!



Apply ceramic etch gel to the inside of the ceramic crown with a non-metallic instrument. Allow to react for 60 seconds.



Remove etching gel under running water. Apply composite primer to the surface of the Pekkton® ivory framework and light cure according to the manufacturer's instructions.

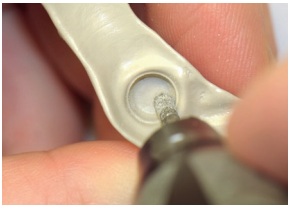


Apply ceramic primer to the inside of the ceramic crown and allow to react for 30 seconds.

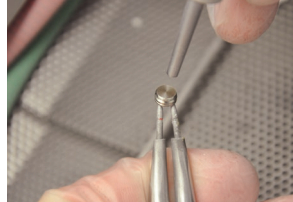
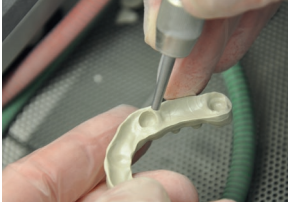


Inject luting composite into the crown and then place on the framework. Allow the cement to cure according the manufacturer's instructions. (self-curing)

18.12 Bonding with titanium



Roughen the Pekkton® ivory surface with a diamond. At low speed and with little force. The recommended speed is between 5'000–10'000 rpm. Clean with alcohol.



Sandblast the Pekkton® ivory framework with unrecycled aluminium oxide (Al_2O_3) with a grain size of 110 μm and a pressure of 2 bar. Then clean with oil-free compressed air or with alcohol. Not with a steam cleaner!

The titanium abutment is sandblasted with unrecycled aluminium oxide (Al_2O_3) with a grain size of 110 μm and a pressure of 3 bar. Then clean with a steam device or oil-free compressed air.



Block any undercuts with wax. Insulate the model.

Apply composite primer to the surface of the Pekkton® ivory framework and light cure according to the manufacturer's instructions.




Apply silane to the titanium surface and allow to react for 60 seconds. Apply cement or bonding composite to the Pekkton® ivory framework and allow to cure according to the manufacturer's instructions.



Remove excess bond professionally.

18.13 Cementing crowns and bridges


 Please follow the manufacturer's instructions.

Preparation

Sandblast the inner surface of the reconstruction with abrasive 110 μm blasting medium at a pressure of 2 bar.

Prior to cementation:

- 1) Check reconstruction for fit and correct by grinding, if necessary.
- 2) Occlusal precision corrections can be performed after cementation because composite veneering is very easy to polish in the patient's mouth.
- 3) Pretreat inner surface with MMA-based composite primer to increase the bond.

 To increase the bond to Pekkton® ivory, the inner surface can be silicatised before application of the composite primer and subsequently silanised.

Cementation

Method of cementation:	Conventional (glass ionomer cements)	Cementation: Self-adhesive	Cementation: Adhesive
Stump	Length of stump >4mm Preparation angle: 4-8°	Length of stump >4mm Preparation angle: 4-8°	short stump, < 4mm Preparation angle: > 8°


19 Materials

Pekkton® ivory

Compression strength	246	MPa	Density	1.4	g/cm ³
Bending strength	200	MPa	Water absorption	8.7	µg/mm ³
Flexural modulus	5.1	GPa	Solubility	0.2	µg/mm ³
Yield strength	115	MPa	Hardness HV	33	MPa
Melting point	363	°C	Hardness (DIN EN ISO 2039-1)	252	MPa

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 batch 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:

Pekkton® ivory

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



















All Pekkton® ivory products have the basic UDI-DI: 764016651000036E4

Cat. No.	Product name	Contents	UDI-DI
01060152	Pekkton® ivory Milling blank 98.5/t12mm	1 pc.	07640173099383
01060011	Pekkton® ivory Milling blank 98.5/t16mm	1 pc.	07640166511458
01060020	Pekkton® ivory Milling blank 98.5/t20mm	1 pc.	07640166511472
01060022	Pekkton® ivory Milling blank 98.5/t24mm	1 pc.	07640166511489
01060089	Pekkton® ivory Milling blank 98.5/t28mm	1 pc.	07640173099390
01060110	Pekkton® ivory Milling blank 95/t12mm	1 pc.	07640173099406
01060028	Pekkton® ivory Milling blank 95/t16mm	1 pc.	07640166511496
01060030	Pekkton® ivory Milling blank 95/t20mm	1 pc.	07640166511502
01060131	Pekkton® ivory Milling blank 95/t25mm	1 pc.	07640173099413
01060132	Pekkton® ivory Milling blank 95/t30mm	1 pc.	07640173099420

30 Symbols

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

Labelling on packaging/symbols

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