prosthetic.line

Pekkton® ivory Milling blank

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 Section 29. 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 Section 29.

3 Intended use

The products are intended for prosthetic restorations and to support procedures in the dental clinic or laboratory.

4 Expected clinical benefit

Restoration of chewing function and improved aesthetics.

The Summary of Safety and Clinical Performance, SSCP for the implantable devices covered by these Instructions for Use, is available on our website and accessible at this address: www.cmsa.ch/docs.

5 Product description

Pekkton® ivory is a material based on PEKK composed of OXPEKK® IG[1] (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 Indications

– Definitively restored, veneered and screw-retained fixed dental prostheses (single crowns and bridges) on implants with a maximum of two adjacent pontics, which can be veneered with bonded pressed crowns, composites and prefabricated acrylic teeth and shells.
– Definitively restored, veneered fixed dental prostheses (single crowns and 3-unit bridges) with a maximum of one pontic cemented on natural teeth.
– Unveneered parts e.g. crown margins and backings.
– Unveneered fixed dental prostheses (single crowns and bridges) in the posterior region for a maximum wearing period of 12 months.
– Removable dental prostheses 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 (clearance from abutment tooth) < 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 mm^2.
  – Connector cross-section lateral (posterior) bridge 14 mm^2.
– Bridges on implants with more than two pontics.
– Bridges on natural abutment teeth with more than one pontic.
– Extensions / Cantilever fixed dental prostheses.
– Unveneered crowns and bridges with a wearing period > 12 months.
– Patients who are unable to keep the regularly required check-up appointments for health reasons.
– Patients with bruxism or other para-functional habits.
– Patients with allergies to materials used in the product, see Section 19.
– Existing clinical picture in the patient's mouth does not permit the correct application of the products.

8 Compatible products

To fabricate the finished denture, a number of general laboratory supplies are required in addition to the products listed under Section 29. The following gives a selection of materials that Cendres+Métaux SA offers in its portfolio.

08052138	Polyurock Kit
08052135	Polyurock Catalyst
08052137	Polyurock Mixer
08052307	Legabril Diamond (50 g)

9 Qualification of the specialist

Expertise in professional dentistry and dental technology is assumed. The current Instructions for Use must be available at all times and be completely read and understood before the first application. The fabrication of dentures and their maintenance may only be performed by qualified specialists.

Important information for the specialist

Warning symbol for increased caution

10 Prescription

Federal laws in the USA prohibit the use by or sale to unlicensed dentists.

11 Side effects

⚠ This product must not be used in patients with allergies or suspected allergies to materials used in the product (see Section 19), or only after prior allergological clarification.
Auxiliary instruments may contain nickel.
If applied as intended, side effects can be excluded.

12 Warnings

⚠ **Magnetic resonance (MR) 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

N/A

14 Preventive measures

📖 – The product components are supplied non-sterile. For more information see Section 16 "Reprocessing".
– Only original tools and parts may be used for this work. For information and additional details, please contact your Cendres+Métaux SA representative.
– Before any procedure, ensure that all required product components are available in sufficient quantity.
– For your own safety, always wear suitable protective clothing. In particular when grinding, we recommend wearing protective goggles and a dust mask as well as the use of a suction unit.
– Secure parts against aspiration.
– The mechanical cleaning by patients with a toothbrush and toothpaste may lead to premature wear.

15 Single use

Products that are intended for single use and are labelled "single-use" accordingly are subject to a certain amount of stress, increased wear, and even loss of functionality during their use.

⚠ Multiple application of products labelled «single use» was not tested. This can impair the safety, function and performance of the products as well as increase the risk of transmitting infections.

16 Reprocessing

📖 The prosthetic work, including all system components, must be cleaned, disinfected and, if appropriate, sterilised prior to each work step.
Materials made of metal alloys, high-performance polymers (Pekkton®) and ceramics are suitable for steam sterilisation. With the exception of Pekkton®, components made of plastics are not suitable for steam sterilisation.
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).

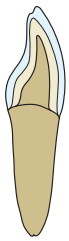
17 Scope of application

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.

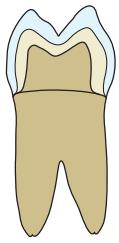
18 Procedure

18.1 Crowns and bridges

1. Preparation



a)



b)

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

a)

b)

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.

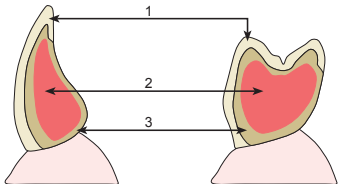
a) Anterior tooth
b) Posterior tooth

⚠ 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 mm²	> 14 mm²

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

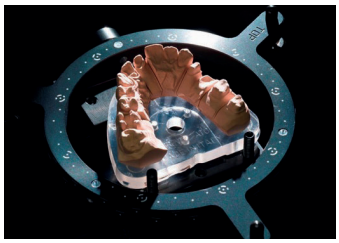
The stability of the connector surface is increased when the ratio of vertical to horizontal is significantly greater (ratio of approx. 60% to 40%).

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.

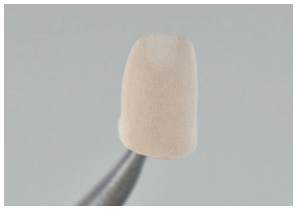
18.7 Finishing

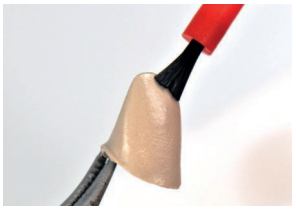

Cross-toothed milling is used to finish the framework. Finishing is performed at 5›000 - 10›000 rpm. Do not operate with too high a pressure on the object. Roughen the surface using a diamond milling cutter before sandblasting. Clean with alcohol.

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.

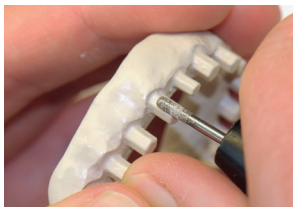


First apply the opaquer with a brush. This can be applied in several layers. The opaquer must cover the framework, but nonetheless be as thin as possible. The ultimate shape is achieved with suitable burs, rubber polishers and various aids.

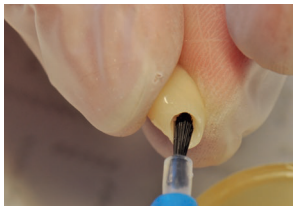
Bridge work: to avoid cracks (also as a late consequence) in the veneer due to different E-modulus values of Pekkton® ivory and the veneering material, a separation should be made between the teeth down to the opaquer.

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.



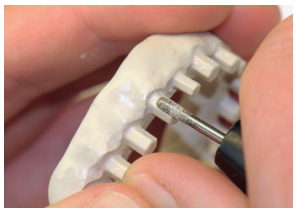

Clean the surfaces to be bonded with alcohol.


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 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.

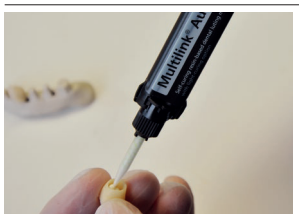

Clean the surfaces to be bonded with alcohol.


Sandblast the plastic teeth with unrecycled aluminium oxide (Al_2O_3) with a grain size of 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 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.

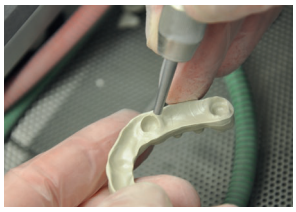

Apply ceramic primer to the inside of the ceramic crown and allow to react for 30 seconds.

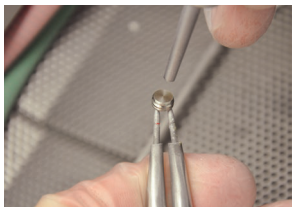


Inject luting composite into the crown and then place on the framework. Allow the cement to cure according the manufacturer›s instructions. (self-curing)

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	Length of stump >4mm	short stump, < 4mm
	Preparation angle: 4-8°	Preparation angle: 4-8°	Preparation angle: > 8°

19 Materials

Pekkton® ivory

Compression strength	246	MPa	Density	1.4	g/cm³
Bending strength	200	MPa	Water absorption	8.7	µg/mm³
Flexural modulus	5.1	GPa	Solubility	0.2	µg/mm³
Yield strength	115	MPa	Hardness HV	33	MPa
Melting point	363	°C	Hardness (DIN EN ISO 2039-1)	252	MPa

More detailed information on the materials as well as their compositions can be found in the product-specific material data sheets, the product information as well as the product list compiled in Section 29. All relevant documents can be found on the website www.cmsa.ch/docs by entering the relevant product name.

20 Notes on storage

Insofar as no specific information on storage is given on the packaging of the product, we recommend storing the product in its original packaging, in a dry place, at room temperature and without direct sunlight. 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 the patients are motivated and instructed with regard to caring for their teeth as well as dentures.

Permanent and removable dentures are subject to considerable stress. Signs of wear are normal 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

It should be ensured that the dentures do not tilt, as any tilting can lead to damage. The denture should never be inserted by clenching the teeth, as this can damage or even break the connecting element.

Insertion

The denture can be placed on the anchor elements in the mouth using the thumb and index finger. Then it is correctly positioned on the anchoring elements applying gentle, even pressure. By carefully closing the jaws, it is possible to check whether the denture is in its correct final position.

Removal

For removal, the denture can be grasped with the thumb and index finger and carefully pulled from the anchor elements and taken out of the mouth.

21.3 Cleaning and care

We recommend cleaning teeth and dentures after every meal. Cleaning of dentures includes cleaning of the connecting element. Gentlest cleaning can be achieved by cleaning the restoration under running water with a soft toothbrush and the connecting element in the mouth with an interdental brush. The most intensive cleaning of the restoration is achieved with the aid of an ultrasonic device and a cleaning additive suitable for dentures.
Never clean the high precision connecting elements with toothpaste as this could lead to damage. Caution should also be exercised in the case of aggressive cleaning agents or tablets as this could damage the high-quality connecting element or impair its function.

Regular cleaning of the anchorage can prevent inflammation of the soft tissue.

22 Ordering information

The information relevant to your order can be found in the product list in Section 29 of this document. The product information is also helpful. This and other relevant documents can be found on the website www.cmsa.ch/docs by entering the relevant product name.

23 Availability

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

24 Traceability of the lot number

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

25 Complaint

Cendres+Métaux SA must be notified immediately of any incident that has occurred with regard to the product. To do this, please contact your customer advisor or send us your message by e-mail to the address complaints-cmbrand@cmsa.ch. In serious cases, also send a report to the competent authority where you are domiciled.

26 Safe disposal

The products 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. Cendres+Métaux SA products are parts 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 lot number.

The use of third party products not distributed by Cendres+Métaux SA in connection with the products mentioned in the product list in Section 29 will void any warranty or other express or implied obligation of Cendres+Métaux SA.

Responsibility regarding the suitability of a product for the specific patient case is at the discretion of the specialist.

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 of Cendres+Métaux SA products.

The specialist is obliged to regularly study the latest developments of the products mentioned in the product list in Section 29 and their applications.

It should be noted that the descriptions contained in this document are not sufficient for the immediate application of Cendres+Métaux SA products. Expertise in dentistry, dental technology and instructions by an experienced specialist in the use of the products mentioned in the product list under Section 29 is always necessary.

In case of inconsistencies in translations, the English language version shall prevail.

29 Product list

Cat. No.	Product name	Contents	Labelling	UDI-DI
01060152	**Pekkton® ivory Milling blank 98.5/t12mm**	1 pc.	CE 0483	07640173099383
01060011	**Pekkton® ivory Milling blank 98.5/t16mm**	1 pc.	CE 0483	07640166511458
01060020	**Pekkton® ivory Milling blank 98.5/t20mm**	1 pc.	CE 0483	07640166511472
01060022	**Pekkton® ivory Milling blank 98.5/t24mm**	1 pc.	CE 0483	07640166511489
01060089	**Pekkton® ivory Milling blank 98.5/t28mm**	1 pc.	CE 0483	07640173099390
01060110	**Pekkton® ivory Milling blank 95/t12mm**	1 pc.	CE 0483	07640173099406
01060028	**Pekkton® ivory Milling blank 95/t16mm**	1 pc.	CE 0483	07640166511496
01060030	**Pekkton® ivory Milling blank 95/t20mm**	1 pc.	CE 0483	07640166511502
01060131	**Pekkton® ivory Milling blank 95/t25mm**	1 pc.	CE 0483	07640173099413
01060132	**Pekkton® ivory Milling blank 95/t30mm**	1 pc.	CE 0483	07640173099420

30 Labelling on packaging / symbols

	Date of manufacture
	Manufacturer
REF	Catalogue number
LOT	Lot number
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
	Protect from sunlight
	Attention, observe accompanying documents
UDI 	Clear product identification
EC REP	European Authorised Representative
	Importer
MD	Medical device

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