Pekkton[®] ivory – Instructions for use CAD/CAM Technology.

1 Product name

Pekkton® ivory milling blanks

2 Product description

 $\mathsf{Pekkton}^{\circledast}$ ivory is a material based on PEKK composed of $\mathsf{OXPEKK}^{\circledast}$ IG¹ (Implantable Grade with pur material) and Titanium Dioxide for the determination of tint and mechanical properties. Color: whitish.

3 General information

For the exact specifications of Pekkton[®] ivory, please refer to the material data sheet and the safety data sheet. You will find the data sheets mentioned free of charge at www.pekkton.com.

 \triangle Warning symbol for increased caution.

3.1 Intended use

 $\mathsf{Pekkton}^{\circledast}$ ivory is intended for use with fixed (crowns and bridges) and removable dental prostheses.

3.2 Disposal

Pekkton® ivory waste can be disposed of along with normal household garbage.

4 Instructions for use

4.1 Indications

(Pekkton® ivory)

- Definitive supported and veneered crowns and bridges with maximum two pontics. Can be veneered with bonded press crowns, with composites or prefabricated acrylic teeth and veneers.
- Definitive supported, veneered single crowns and bridges with maximum one pontic on natural teeth.
- Removable restorations such as secondary constructions on bars and telescopic crowns, transversal connectors, occlusal splints and denture bases.
- \triangle The responsibility for the use of custom-made products beyond the described indications lies with the dentist.

4.2 Contraindications

(Pekkton[®] ivory)

- When patients have a known allergy to one or more components of the material.
- Patients with parafunctions e.g. bruxism.
- Crowns and bridges with less than 1.3 mm of occlusal space.
- When the minimum dimensions of the framework cannot be maintained:
 - Minimum circular wall thickness less than 0.6 mm.
 - Minimum occlusal wall thickness less than 0.8 mm.
 Connector dimensions of front (anterior) bridges less than 12 mm².
 - Connector dimensions of side (posterior) bridges less than 14 mm².
- Bridges on implants with more than two intermediate elements or extensions.
- Bridges on natural teeth with more than one intermediate element or extension.
- Unveneered crowns and bridges with a wearing period of more than 12 months.

4.3 Warnings

If patients are allergic to one or more elements of the material, the latter should not be used. 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.

Pekkton[®] ivory has not been evaluated for safety and compatibility in the MR environment. Pekkton[®] ivory has not been tested for heating or migration in the MR environment.

For further information, please contact your Cendres+Métaux representative.

4.4 Preventive measures

When grinding the Pekkton $^{\mbox{\tiny (B)}}$ framework, wear protective goggles with a dust mask and use a suction unit.

4.5 Side effects

No known side effects if used as intended.

5 Processing instructions

5.1 Technical parameters Please refer to Data Sheet «Pekkton[®] ivory – Material Data Sheet» following URL: www.cmsa.ch/docs Document Type: Factsheet, Product category: Pekkton[®]

¹ OPM, Oxford Performance Materials, USA.

Our current list of distributors is available on our website at www.cmsa.ch/dental

Medical devices of Cendres+Métaux SA correspond to the Medical Device Directive 93/42/EEC and carry the CE mark. See packaging for details.



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Rx only

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5.2 Model and stump preparation

Careful preparation of the work models is required to obtain a well fitting crown or bridge.

The dies must fit reproducibly and be removable. It is advisable to apply a sealer to harden the surface and to protect the die.

Two layers of spacer are applied to max. 1mm from the preparation margin.

Narrow incisal edges (< less than 0.6 mm) of tooth stumps must be blocked with wax prior to scanning.

5.3 Design (CAD)

The minimum wall thickness should be at least 0.6 mm circular and 0.8 mm occlusal.

The connector dimensions of anterior bridges is at least $12\,mm^2,$ of side bridges $14\,mm^2.$

The change from framework to veneering material may not occur in the functional contact area.

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

For optimal color reproduction, a veneering thickness of 0.5 mm is recommended.

Removable restorations

The long-term stability depends on the dimensioning of design of the prosthesis.

The cross section of a Pekkton[®] ivory framework stand against works in metal should be by a factor of 1.5 increased.

5.4 Milling (CAM)

Pekkton® ivory can be processed dry and wet.

The millings must be easily suctioned away during the dry milling process. To prevent the framework (from a material temperature of approx. 160 °C) from warping, the milling tools must be as sharp as possible and Pekkton[®] ivory efficiently air/water cooled during the milling process. A ball nose mill is used in the basic PMMA setting.

Milling tool PMMA	Speed	Feed rate
Ø2mm	13'000-18'000 rpm	30 mm/s
Ø1mm	17'000 rpm	25 mm/s
Ø 0.6 mm	34'000 rpm	15 mm/s

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

5.5 Conditioning

Cross-toothed milling is used to finish the framework. Speed limit max. 15,000 rotations/min. Do not work on the object if the pressure is too high. Roughen the surface using a diamond milling cutter before sandblasting the framework.

5.6 Preparation for veneering

After milling is complete, sandblast the framework with aluminum oxide 110μ m under 2 bar pressure, and clean well using steam. After finishing by milling, the framework is sandblasted with a 110μ m blasting agent at a pressure of 2 bar, and then well cleaned with steam. Prior to veneering, it is essential to treat the Pekkton[®] ivory framework with an MMA-based composite primer.

- \triangle Caution: Sandblast only the framework and not the interface connection.
- Dease observe the manufacturer's instructions.

5.7 Veneering

After preparation of the framework Pekkton[®] ivory can be refined esthetically in different ways. For example, it can be refined by veneering with composites, affixing custom-made pressable ceramic crowns or using prefabricated acrylic teeth and trays.

▲ 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.

Information about the veneering concepts is available from our clinical case documentation on our website www.pekkton.com.

▲ Bridge work: To avoid cracks (and late effects) in the veneering as a result of different modulus of elasticity values for Pekkton[®] ivory and the veneering material, a separation should be made between the teeth down to the opaque.

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Before cementation:

- 1) Check reconstruction for fit and correct by grinding, if necessary.
- Occlusal precision corrections can be performed after cementation because composite veneering is very easy to polish in the patient's mouth.

Preparation:

- 1) Sandblast the inner surface of the reconstruction with abrasive $110 \mu m$ grit at a pressure of 2 bar.
- 2) To increase the bond of the temporary cement with $\mathsf{Pekkton}^\circledast$
- ivory, silicatize and silanize the inner surface of the restoration.3) Pretreat inner surface with composite primer based on MMA to increase the bond.
- \triangle To increase the bond to Pekkton® ivory, the inner surface can be silicatized before application of the composite primer and subsequently silanized.

Cementation:

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

Dease follow the manufacturer's instructions.

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Please remove remaining processing debris and then air dry the denture.

8 Traceability of the batch numbers

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

9 Ordering information*

	Order No.	Description
	Milling blanks	with a diameter of 98.5 mm, incl. groove
	01060014	Pekkton [®] ivory Milling Blank 98.5/t12 mm
	01060011	Pekkton [®] ivory Milling Blank 98.5/t16mm
	01060020	Pekkton [®] ivory Milling Blank 98.5/t20mm
	01060022	Pekkton [®] ivory Milling Blank 98.5/t24 mm
Milling blanks with a diameter of 95 mm		
	01060028	Pekkton [®] ivory Milling Blank 95/t16 mm
	01060030	Pekkton [®] ivory Milling Blank 95/t20mm
	01060032	Pekkton [®] ivory Milling Blank 95/t24mm

* Available shapes and thicknesses of blanks can be found on our homepage www.pekkton.com

10 Symbols

10 091115015	
Гм	Date of manufacture
	Manufacturer
# #	Patient No.
REF	Catalogue number
LOT	Batch code
QTY	Quantity
[]i]	Consult instructions for use
Rx only	Attention: According to US federal law, this product may only be sold by or on behalf of a physician.
	Cendres+Métaux SA products with CE labeling meet the requirements of the Medical Device Directive 93/42/EEC.
\otimes	Do not re-use
NON	Non-sterile
_ 茶	Keep away from sunlight
\triangle	Attention (observe accompanying documents)

11 Disclaimer / Validity

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.

In case of complaints, please always include the batch number.

The latest instructions are available on the Cendres+Métaux homepage. www.cmsa.ch/dental

The product must be used exclusively by skilled persons.

12 Availability

Country-specific differences in product range are possible.

13 Copyright and trademarks

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