

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

1 / 4
04.2016
Version Canada

1 Product name

Pekkton® ivory milling blanks

2 Product description

Pekkton® ivory is a high performance material (based on PEKK) composed of OXPEKK® IG¹ (Implantable Grade with highest purity) and Titanium Dioxide for optimization 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.

⚠ Warning symbol for increased caution.

3.1 Intended use

Pekkton® 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, veneered and screw-retained crowns and bridges on dental implants, with maximum two pontics and a maximum of four units per bridge. 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.
- 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 restorations such as secondary constructions on bars and telescopic crowns, transversal connectors, occlusal splints and denture bases.

⚠ 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® 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 Instructions for use

5.1 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.

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.

Rx only

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

5.2 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 mm², of side bridges 14 mm².

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.

5.3 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
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


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

5.4 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.


5.5 Preparation for veneering

After milling is complete, sandblast the framework with aluminum oxide 110µm under 2 bar pressure, and clean well using steam. After finishing by milling, the framework is sandblasted with a 110µm 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.


 Please observe the manufacturer's instructions.

5.6 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.

5.7 Bond to titanium bases (laboratory)

The following procedure describes the cementation of Ti bases and frameworks of Pekkton® ivory.

In choosing cement, Multilink® Hybrid Abutment (Ivoclar Vivadent) is recommended.

1. The Ti base is screwed onto the analog. Seal the screw channel of the Ti base and the Pekkton® ivory framework with wax.
2. Carefully sandblast the surface of the Ti base with 110µm aluminum oxide and 3 bar pressure.
3. Also carefully sandblast the contact surface on the inside of the framework. 110µm aluminum oxide and 2 bar pressure.
4. Monobond plus is applied to the sandblasted surfaces to silanize them. Application time approx. 60 seconds.
5. Apply composite primer based on MMA to the Pekkton® ivory surface with a single-use brush and light cure for 90 seconds (Dentacolor XS, Kulzer).
6. Apply the cement to the inner surface of the framework and place on the Ti base.
7. Then follow the manufacturer's instructions.


6 Cementation

Before 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.


Preparation:

- 1) Sandblast the inner surface of the reconstruction with abrasive 110µm grit at a pressure of 2 bar.
- 2) To increase the bond of the temporary cement with Pekkton® ivory, silicize and silanize the inner surface of the restoration.
- 3) Pretreat inner surface with composite primer based on MMA to increase the bond.

 To increase the bond to Pekkton® ivory, the inner surface can be silicized 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 Preparation angle: 4–8°	Length of stump > 4 mm Preparation angle: 4–8°	short stump, < 4 mm Preparation angle: > 8°

 Please follow the manufacturer's instructions.

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

7 Disinfection

After any fabrication or modification the prosthetic work must be cleaned and disinfected according to national guidelines. When choosing the disinfectant, ensure that:

- it is suitable for the cleaning and disinfection of dental prosthetic components,
- it is compatible with the materials of the products to be cleaned and disinfected, and
- it has proven efficacy in disinfection.

The prosthetic work must be disinfected with a high EPA-registered disinfectant prior to use.
Recommended: Cidex® OPA Solution. Strictly follow the manufacturer's instructions.

8 Cleaning and care

It is best to clean your teeth and your dentures after every meal. Be careful when using tooth pastes. Do not use agents that are too abrasive.
For further information, please contact your Cendres+Métaux representative.

9 Traceability of the batch numbers

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

10 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/t16 mm
01060020	Pekkton® ivory Milling Blank 98.5/t20 mm
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/t20 mm
01060032	Pekkton® ivory Milling Blank 95/t24 mm

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

11 Symbols



Date of manufacture



Manufacturer



Patient No.



Catalogue number



Batch code



Quantity



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.



Do not re-use



Non-sterile



Keep away from sunlight



Attention (observe accompanying documents)

12 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.

13 Availability

Country-specific differences in product range are possible.

14 Copyright and trademarks

Pekkton® ivory is a registered trademark of Cendres+Métaux Holding SA, Biel/Bienne, Switzerland.

Reprints or publication – even excerpts – require the written permission of the publisher.