

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

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06.2015
US Version

1 Product name

Pekkton® ivory

2 Product description

Technique: Milling Banks

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 Disposal

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

4 Instructions for use

4.1 Intended use

Pekkton® ivory is intended to be used for long-term, temporary dental crowns and bridge frameworks.

4.2 Indications

(Pekkton® ivory)

- Long-term, temporary veneered single crowns and 3-unit bridges in the frontal and side region for a maximum wearing time of 12 months.
- Long-term, temporary unveneered crowns in the side region for a maximum wearing period of 12 months
- Unveneered parts e.g. crown margins and backings.

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

4.3 Contraindications

(Pekkton® ivory)

- Bridge reconstructions with more than one intermediate element.
- Patients with parafunctions e.g. bruxism.
- Unveneered crowns in the lateral mouth area for use of more than 12 months.
- Veneered single crown and 3-unit bridge in the frontal and side mouth area for a use exceeding 12 months.

- 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 10 mm²
 - Connector dimensions of side (posterior) bridges less than 12 mm²
- When patients have a known allergy to one or more components of the material.

4.4 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.

⚠ A professional dentist and dental technician know-how is required. The instructions for use must be available and understood before the first application. The manufacturing process must be only carried out by qualified specialists.

4.5 Preventive measures

When grinding the Pekkton® framework, wear protective goggles with a dust mask and use a suction unit.

4.6 Side effects

No known side effects if used as intended.

5 Instructions

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. 1 mm 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

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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.

We recommend the following parameters are important for a good fit:

	3shape Scanner and CAD-Software	Imetric Scanner (with Exocad CAD-Software)	
		Posterior teeth	Anterior teeth
Crown edge: Recommended minimum width	0.15 mm	0.15 mm	0.15 mm
Cement GAP	0.010 mm	0.03 – 0.06 mm	0.03 – 0.06 mm
Extra Cement GAP	0.035 mm	–	–
Start Cement GAP	–	1.0 mm	1.0 mm
Occlusal Cement GAP	–	0.02–0.05 mm	0.02 mm
XY (Vertical) Cement GAP	–	0.02–0.075 mm	0.02 mm
Edge / Border thickness	0.15 mm	0.15 – 0.2 mm	0.15 – 0.2 mm
Thickness	0.6 mm	0.6 mm	0.6 mm
Drill radius	0.6 mm	1.1 mm	1.1 mm
Drill compensation	yes / 1.1	yes	yes
Distance to margin line	1.5 mm	–	–
Smooth	0.2 mm	–	–
Remove undercuts	yes	yes	yes
Offset Angle	72°	–	–

5.3 Milling (CAM)

Pekkton® ivory is processed dry.

The millings must be easily suctioned away during the 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 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. After milling is complete, sandblast the framework with aluminum oxide 110µm under 2 bar pressure, and clean well using steam.

5.5 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.

5.6 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 visio.link (Bredent) 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 visio.link (Order No. 08000570) to increase the bond.

📖 Please follow the manufacturer's instructions for the visio.link.

⚠ 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.

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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	
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
08000570	visio.link / PMMA & Composite Primer

* 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

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