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

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. 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.

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1 OPM, Oxford Performance Materials, USA.

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

Rx only

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

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

<table>
<thead>
<tr>
<th>3shape Scanner and CAD-Software</th>
<th>Imetric Scanner (with Exocad CAD-Software)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Posterior teeth</td>
</tr>
<tr>
<td>Crown edge: Recommended minimum width</td>
<td>0.15 mm</td>
</tr>
<tr>
<td>Cement GAP</td>
<td>0.010 mm</td>
</tr>
<tr>
<td>Extra Cement GAP</td>
<td>0.035 mm</td>
</tr>
<tr>
<td>Start Cement GAP</td>
<td>–</td>
</tr>
<tr>
<td>Occlusal Cement GAP</td>
<td>–</td>
</tr>
<tr>
<td>XY (Vertical) Cement GAP</td>
<td>–</td>
</tr>
<tr>
<td>Edge / Border thickness</td>
<td>0.15 mm</td>
</tr>
<tr>
<td>Thickness</td>
<td>0.6 mm</td>
</tr>
<tr>
<td>Drill radius</td>
<td>0.6 mm</td>
</tr>
<tr>
<td>Drill compensation</td>
<td>yes / 1.1</td>
</tr>
<tr>
<td>Distance to margin line</td>
<td>1.5 mm</td>
</tr>
<tr>
<td>Smooth</td>
<td>0.2 mm</td>
</tr>
<tr>
<td>Remove undercuts</td>
<td>yes</td>
</tr>
<tr>
<td>Offset Angle</td>
<td>72°</td>
</tr>
</tbody>
</table>

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.

<table>
<thead>
<tr>
<th>Milling tool PMMA</th>
<th>Speed</th>
<th>Feed rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ø 2 mm</td>
<td>13’000–18’000 rpm</td>
<td>30 mm/s</td>
</tr>
<tr>
<td>Ø 1 mm</td>
<td>17’000 rpm</td>
<td>25 mm/s</td>
</tr>
<tr>
<td>Ø 0.6 mm</td>
<td>34’000 rpm</td>
<td>15 mm/s</td>
</tr>
</tbody>
</table>

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, silicatize and silanize the inner surface of the restoration.
3) Pretreat inner surface with composite primer visio.link (Order No. 0800 0570) 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 silicatized before application of the composite primer and subsequently silanized.

Cementation:

<table>
<thead>
<tr>
<th>Method of cementation:</th>
<th>Conventional (glass ionomer cements)</th>
<th>Self-adhesive</th>
<th>Adhesive</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stump</td>
<td>Length of stump &gt; 4 mm Preparation angle: 4 – 8°</td>
<td>Length of stump &gt; 4 mm Preparation angle: 4 – 8° short stump, &lt; 4 mm Preparation angle: &gt; 8°</td>
<td></td>
</tr>
</tbody>
</table>

⚠️ Please follow the manufacturer’s instructions.
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 before use with a low or intermediate EPA-registered hospital disinfectant. 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 no 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*

<table>
<thead>
<tr>
<th>Order No.</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>01060011</td>
<td>Pekkton® ivory Milling Blank 98.5/116 mm</td>
</tr>
<tr>
<td>01060020</td>
<td>Pekkton® ivory Milling Blank 98.5/120 mm</td>
</tr>
<tr>
<td>01060022</td>
<td>Pekkton® ivory Milling Blank 98.5/124 mm</td>
</tr>
<tr>
<td>01060028</td>
<td>Pekkton® ivory Milling Blank 95/116 mm</td>
</tr>
<tr>
<td>01060030</td>
<td>Pekkton® ivory Milling Blank 95/120 mm</td>
</tr>
<tr>
<td>01060032</td>
<td>Pekkton® ivory Milling Blank 95/124 mm</td>
</tr>
<tr>
<td>08000570</td>
<td>visio.link / PMMA &amp; Composite Primer</td>
</tr>
</tbody>
</table>

*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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