

## prosthetic.line

# **Pekkton<sup>®</sup> ivory Press blanks**

## Pressing technique with Dekema

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## Instructions for Use Pekkton<sup>®</sup> ivory Press blanks Pressing technique with Dekema

## 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<sup>®</sup> ivory is a material based on PEKK composed of OXPEKK<sup>®</sup> IG<sup>1</sup> (Implant Grade) and titanium dioxide for the definition of the colour tone and the mechanical properties. Colour: whitish.

<sup>1</sup> 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<sup>2</sup>.
  - Connector cross-section lateral (posterior) bridge 14 mm<sup>2</sup>.
- 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.

08055014

08052307

08000626

083739

Livento<sup>®</sup> invest Powder (50 x 100 g)

Disposable press-stamp 12 mm (50 pcs.)

Disposable press-stamp 26 mm (20 pcs.)

Livento<sup>®</sup> invest Liquid (1000 ml) Legabril Diamond (50 g)

08052138	Polyurock Kit
08052135	Polyurock Catalyst
08052136	Polyurock Release Spray
08052137	Polyurock Mixer
08052566	Polyurock Colour yellow
08052149	ABF Wax Universal
08052150	ABF Wax Creativ light
08052151	ABF Wax Creativ dark
08052154	ABF Wax Special
08052148	ABF Wax Margin
08052153	ABF Wax Position
08052152	ABF Wax Tecno

#### 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** 

Marning 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

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#### 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

 Image: The prosthetic work, including all system components, must be cleaned, disinfected and, if appropriate, sterilised prior to each work step.

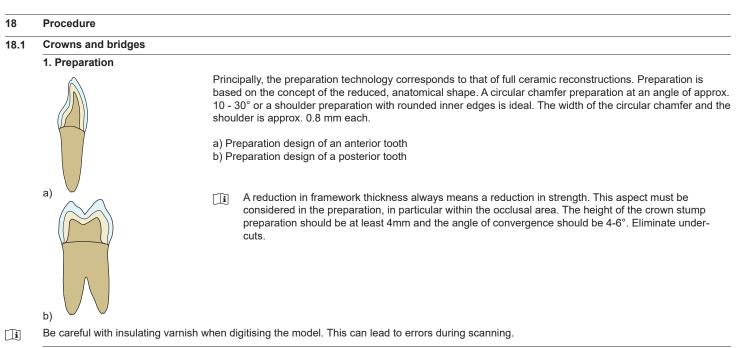
 Materials made of metal alloys, high-performance polymers (Pekkton®) and ceramics are suitable for steam sterilisation. With the exception of Pekkton®, components made of plastics are not suitable for steam sterilisation.

 Consider published national guidelines when selecting a disinfection and sterilisation process and the Instructions for Use "Reprocessing of surgi

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<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> ivory. The high performance polymer can also be used for removable dentures. Examples for this are prosthesis bases on construction elements or prosthesis reinforcements.



#### 2. Model and stump preparation



a) Anterior tooth b) Posterior tooth

margin.

A Be careful with insulating varnish when digitising the model. This can lead to errors during scanning.

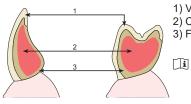
The stumps must fit reproducibly and be removable. It is advisable to apply a sealer to harden the surface and to protect the stump. Two layers of insulating varnish are applied to max. 1mm from the preparation

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

## 18.2 Material thickness of the frameworks

Pekkton <sup>®</sup> 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 mm <sup>2</sup>	> 14 mm <sup>2</sup>

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<sup>®</sup>. 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.



Veneering
 Connecting parts
 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<sup>®</sup> ivory framework should be increased minimally by a factor of 1.5 compared to work with metal alloys.

## 18.4 Production in the pressing process



Pressing device To make sure the material is homogeneous, it must be possible to cool Pekkton® ivory under pressure after the pressing operation. The following devices meet this requirement: AUSTROMAT 354 press-i-dent AUSTROMAT 654 press-i-dent AUSTROMAT 3001 press-i-dent

Manufacturer: DEKEMA Dental-Keramiköfen GmbH, D-83395 Freilassing (This product is marketed by the DEKEMA company and DEKEMA applies the CE mark.)

#### 18.5 Waxing

Only use wax that can be burned out without leaving a residue.

## Posterior tooth (molar)



Buccal

Anterior tooth



Labial circular tapered edge design



Palatal/lingual



Palatal/lingual mini edge (garland)

Design the caps and bridge elements in accordance with the basic principle of the maximum possible framework thickness, as well as the cusp-supported reduced tooth form. Avoid dirt-collecting recesses on the gingival design when modelling the pontics. A thin garland can be designed circularly or partially on the posterior tooth. In case of insufficient space, a direct stop can also be prepared.



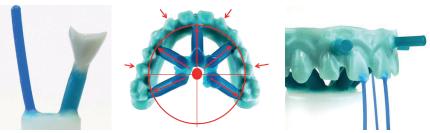
Buccal/labial



Palatal/lingual

For larger bridge work, form the palatal/lingual part in the framework material Pekkton® ivory in favour of a maximum possible framework thickness and do not veneer.

## 18.6 Sprueing



## Single tooth crown / small pressing objects

The object to be pressed is placed on the investment ring former at an angle of approx. 5 - 10°, similar to the specifications from the press ceramic. It is essential to avoid sharp edges as investment material can be entrained when pressing viscous Pekkton<sup>®</sup> ivory. This can prevent inclusions, especially in the marginal zone. To avoid pressure losses due to too long a flow path of the material, the length of the pressing channel must be strictly adhered to. In addition, it is recommended to place a 2mm wax wire as a compensation channel, which slightly exceeds the object in length.

#### Bridges / large pressed objects

For the pressing of larger objects such as bridges, several press channels (diameter 5mm) are placed on the object. If possible, the press channels should be of the same length and located centrally to allow the material to be pressed in evenly. To avoid air inclusions, so-called ventilation reservoirs (diameter 3mm) and air extraction channels (diameter 0.8 - 1mm) are placed where the material meets.

		B 11
	Single tooth crown	Bridge
Press channel	Diameter 12 mm	Diameter 12 mm
Recommendation mould systems	<ul> <li>Trixpress (Dekema)</li> <li>Empress mould system (Ivoclar Viva- dent, FL-Schaan)</li> </ul>	– Trixpress (Dekema) – Empress mould system (Ivoclar Vivadent, FL-Schaan)
Size of the investment ring	100g (suitable for 1 or a maximum of 2 equal-sized objects) 200g (suitable for 4 objects max.)	200g (suitable for 4 objects max.) 380g (suitable for up to full bridges)
Diameter of the wax wire	3–3.5mm	3–3.5mm Full bridge up to 5mm
Length of press channel (wax wire)	3−5mm (max. height incl. object 18mm)	3–5mm (max. height incl. object 18mm) Full bridge: customized length. Ensure that the material can be pressed evenly.
Sprue point at the object	Aligned with the stump (prevents it from breaking off)	Fit the press channel to the connection point.
Sprue angle to the object	axial	axial
Sprue angle to investment ring base	In a small angle of approx. 5-10°	In a small angle of approx. 5-10°
Design of sprueing points	trumpet shaped, without sharp edges and angles	trumpet shaped, without sharp edges and angles
Distance between several objects	3–5mm	3–5mm
Distance to margin of investment ring	10 mm	10mm
Air outlets	Not necessary	For larger bridge elements, install air extraction channels ( $\emptyset$ 0.8–1mm) to reduce the pressure and to avoid bubbles.

## 18.7 Investing

Please weigh the wax object including the press channel to avoid pressing with too little material. Do not use a debubbliser spray on the wax objects (danger of micro bubbling on the surface).

	Weight	Indication
Investment ring	100 g	Wax weight max. 1.4 g Maximum 2 units of small to medium size.
Investment ring	200 g	Wax weight of 1.4 g max. per press channel From 1 to a max. 4 units of each size per press channel*.
Investment ring	380 g	Wax weight of 1.4 g max. per press channel From 1 to a maximum of 4 units of any size per press channel (for large objects use a maximum of 5 press channels)*.

\* With the investment ring former set from DEKEMA, it is possible to use more than one press channel. Please follow the manufacturer's work instructions.

## Definition of wax weight:

- 1. 0.7g wax corresponds to one press blank (1 g)
- 2. Place the base of the investment ring without wax objects on the balance and calibrate to 0.
- 3. Fix the wax objects on the base of the investment ring.
- 4. Place the base of investment ring with the wax objects on the balance.
- 5. The indicated value corresponds to the wax weight.

#### **Recommended investment material**

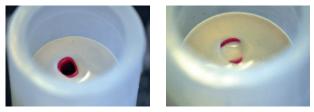
CM 20 (Cendres+Métaux SA, CH-Biel/Bienne)

Mixing ratio	CM-20 Liquid	Dist. water	Total	
100 g	19 ml	6 ml	25 ml	
200 g	38 ml	12ml	50 ml	

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Observe the manufacturer's Instructions for Use for the correct processing of the investment material!

Other investment materials are not recommended because the bond between Pekkton® and the quartz particles in the investment material is often too strong.



Slowly and carefully fill in the investment material up to the wax margin. Use a moist brush for the fine investment of the cavity (so that humidity is not extracted from the investment material). A fine probe can also be used for this purpose. Please make sure that the usually delicate wax margins are not damaged.





Carefully fill the investment ring up to the margin and position the ring gauge with a combined hinged and rotating movement. - Allow the investment ring to set without vibration.

- No hardening under pressure (e.g. in a pressure pot)
- Do not invest before a weekend (danger of drying out or too much humidity through the hygrophor).

#### 18.8 Preheating

Check the temperature precision of the burnout furnace regularly. Please follow the manufacturer's work instructions.

After setting of the investment material according to manufacturer' indications, the investment ring is prepared for preheating.

- 1. Carefully turn and remove the investment gauge.
- 2. Carefully turn and remove the investment ring base as well.
- 3. Remove rough spots dry with a plaster knife or a belt grinder.

4. Please make sure that no investment material enters the press channel.

The investment ring base should have a 90° angle and be situated flat on the investment ring holder in the press furnace.

	Conventional	Speed		
Programme	Stand-by temperature: room temperature	Stand-by temperature: 650°C		
(preheating furnace)	Rate of increase: 5°C/min	Burn-out and preheating:		
(pronoaling famado)	Phase 1: 250°C for 60 min.	60 min_at 650°C		
	Phase 2: 800°C for 60 min.			
	Phase 3: Cool to 390°C in the furnace			
Programme		Place investment ring directly into the press fur-		
(Dekema)		nace from the preheating furnace (650/850°C).		
Press furnace dwell time		L9 C650 T300		
Programme for cooling investment		L9 C650 V.C385 VO T600		
ring				
Positioning of the investment ring	Opening downwards.			
in the furnace	Please make sure that the wax burn-out occurs outside of the investment ring, e.g.:			
	- Tip out the investment ring in the direction of the rear wall			
	<ul> <li>Support, e.g. with 3 small cones of investment material</li> </ul>			
Preheating	No	No		
Press stamp				
Preheating press blank	No	No		
Important	No rapid cooling, as cracks may appear in the investment material.	-		
	Changing furnaces (e.g. from a hot 650 °C furnace to a			
	warm 390 °C furnace) can also lead to cracks or bursting			
	of the investment ring.			
Recommendation	As the preheating process is time consuming, preheating overnight is recommended.	-		

## 18.9 Pressing



The internal temperature of the investment ring must be 390°C. This will be the case after a holding time of approximately 1 hour after reaching the final temperature. (depending on the number of investment rings in the furnace).

DEKEMA press-i-dent: the press furnace must be sufficiently preheated in order to avoid incomplete pressing due to the cooled investment ring. Comment: the exterior of the combustion chamber is lukewarm.

Prepare the press stamp and the quantity of press blanks required for pressing. Then carefully remove the investment ring from the preheating furnace using pliers and set it on a refractory support.

Wear gloves for heat protection.

Carefully place press blanks into investment ring. A maximum of 2 press blanks can be used per press channel. With the Trixpress system from DEKEMA, it is possible to provide the investment ring with more than one press channel.

- In case of 2 press blanks, place sides with logos on top of each other!
- Insert press stamp into the investment ring.
- Keep the loading time to 1 minute max. to keep the escaping heat loss as low as possible.

#### 18.10 Programme overview (Pekkton® ivory)

-			
Manufacturer	Furnace		Programme
DEKEMA	Austromat 654 press-i-dent	100 g	L9 T20.C380 VO T570 L92 T40 V.C250 L8 V.C200 C0 L0 T5
		200 g	L9 T20.C385 VO T780 L92 T40 V.C250 L8 V.C200 C0 L0 T5
		380 g (Trixpress)	L9 T20.C395 V0 T1200 L92 T40 V.C250 L8 V.C200 C0 L0 T5
	Austromat 3001 press-i-dent	100 g	L9 T20.C390 V0 T600 L92 T40 V.C250 L8 V.C200 C0 L0 T5
		200 g	L9 T20.C395 V0 T1200 L92 T40 V.C250 L8 V.C200 C0 L0 T5
		380 g (Trixpress)	L9 T20.C395 V0 T1200 L92 T40 V.C250 L8 V.C200 C0 L0 T5

## 18.11 Pressing technique in cold press furnace

- Heat at 800° C in the investment furnace
- Cool to 380-390°C in investment furnace
- Place ingots and stamps
- Continue to preheat at 380-390°C for 20min
- Transfer to press-i-dent. Both at room temperature.
- Cycle in press-i-dent: L9 V9 L98 T120 V.C120 T900 L9 C0 L0 T5
- Total cycle time 1981s (33min)
- Remove and divest.

#### 18.12 Cooling cycle



After the end of press cycle, the combustion chamber is flooded with fresh air by vacuum until the temperature reaches 200° C. Then remove the investment ring from the press furnace using pliers. Cool the investment ring outside of the furnace to room temperature.

## Wear gloves for heat protection.

#### 18.13 Divesting and cleaning



Rough divestment is performed with divesting pliers and with care. Divest as soon as the investment ring is at room temperature. Do not use divesting pliers to divest larger pieces. Fine divestment is performed with abrasive 110 µm aluminium oxide under pressure of 2 bars. Once pressed, the material must not be reused.

Caution: sandblast margins for a short period only to prevent damage.

## 18.14 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.

Ceramic stones or old burs can smudge, which makes finishing more difficult and may lead to overlaps.

## 18.15 Veneering

After preparation of the framework, Pekkton<sup>®</sup> 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.

#### 18.16 Veneering with composites



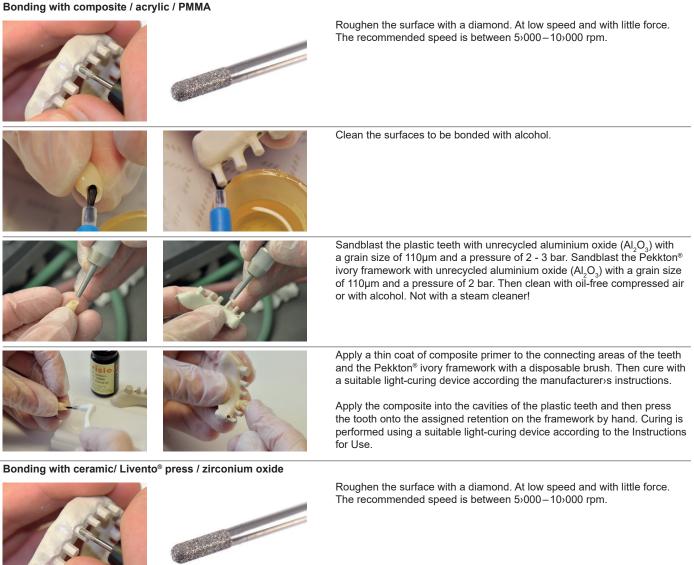
After completion with the milling cutters, the framework is blasted with abrasive 110 µm blasting medium at a pressure of 2 bar. Clean with alcohol. Prior to veneering, it is imperative to treat the Pekkton® ivory framework with MMA-based composite primer.



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 i 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 li manufacturer's instructions for the veneering concept selected.

#### 18.17



18.18



Image: Clean the surfaces to be bonded with alcohd.         Image: Clean the surfaces to be bonded with alcohd.         Image: Clean the surfaces to be bonded with alcohd.         Image: Clean the surfaces to be bonded with alcohd.         Image: Clean the surfaces to be bonded with alcohd.         Image: Clean the surfaces to be bonded with alcohd.         Image: Clean the surfaces to be bonded with alcohd.         Image: Clean the surfaces to be bonded with alcohd.         Image: Clean the surfaces to be bonded with alcohd.         Image: Clean the surfaces to be bonded with alcohd.         Image: Clean the surface to the surface to the plate teeth with uncerpleted aluministic cover with a non-me- face techning gel under trunking water.         Apply certaint tech gel to the inside of the certaint crown with a non-me- face techning gel under trunking water.         Apply certaint perimet to the surface of the Pekkton* hory framework and light care according to the manufactures restructions.         Image: Clean the surface of the plate of the plate on the framework.         Image: Clean the surface of the plate on the framework.         Image: Clean the plate on the framework.         Image: Clean the surface of the certaint crown and ben place on the framework.         Image: Clean the plate on the framework.         Image: Clean the sufface of the certaint crown and then place on the framework.         Image: Clean the sufface of the certaint crown and then place on the framework. </th <th></th> <th>Clean the surfaces to be bonded with alcohol.</th>		Clean the surfaces to be bonded with alcohol.
argan size of 110µm and a pressure 0/2 bar. Then deam with a Fekkton <sup>4</sup> locy framework with unrecycled aluminium oxide (AQ, 0) with a grain size of 110µm and a pressure 0/2 bar. Then deam with oll-free compressed air or with alcohol. Not with a setam cleaner!         argan size of 110µm and a pressure 0/2 bar. Then deam with oll-free compressed air or with alcohol. Not with a setam cleaner!       Apply ceramic etch get to the inside of the ceramic crown with a non-me-tail in instrument. Allow to react for 60 seconds.         argan size of 120µm and a pressure 0/2 bar. Then deam with oll-free compressed air or with alcohol. Not with a setam cleaner!       Apply ceramic etch get to the inside of the ceramic crown with a non-me-tail in instrument. Allow to react for 60 seconds.         argan size of 120µm and a pressure 0/2 bar. Then deam with oll-free compressed air or with alcohol. Not with a setam cleaner!       Apply ceramic etch get to the inside of the ceramic crown with a non-me-tail in instrument. Allow to react for 60 seconds.         argan size of 110µm and a pressure 0/2 bar. Then deam with allow to react for 30 seconds.       Apply ceramic primer to the inside of the ceramic crown and allow to react for 30 seconds.         argan size of 110µm and a pressure 0/2 bar. Then deam with allow to react for 30 seconds.       Apply ceramic primer to the inside of the ceramic crown and allow to react for 30 seconds.         argan size of 110µm and a pressure 0/2 bar. Then deam with allow to react for 30 seconds.       Apply ceramic primer to the inside of the ceramic crown and allow to react for 30 seconds.         argan size of 110µm and a pressure 0/2 bar. Then deam with ittle force. The recommended speed is between 50000 - 10.0000 pm. Cera with ac		
Image: Second		a grain size of 110µm and a pressure of 2 - 3 bar. Sandblast the Pekkton <sup>®</sup> ivory framework with unrecycled aluminium oxide (Al <sub>2</sub> O <sub>3</sub> ) with a grain size of 110µm and a pressure of 2 bar. Then clean with oil-free compressed air
Apply composite primer to the surface of the Pekkton <sup>®</sup> ivory framework and light cure according to the manufacturens instructions.         Apply ceramic primer to the inside of the ceramic crown and allow to react for 30 seconds.         Apply ceramic primer to the inside of the ceramic crown and allow to react for 30 seconds.         Image: Apply ceramic primer to the inside of the ceramic crown and allow to react for 30 seconds.         Image: Apply ceramic primer to the inside of the ceramic crown and allow to react for 30 seconds.         Image: Apply ceramic primer to the inside of the ceramic crown and allow to react for 30 seconds.         Image: Apply ceramic primer to the inside of the ceramic crown and allow to react for 30 seconds.         Image: Apply ceramic primer to the inside of the ceramic crown and allow to react for 30 seconds.         Image: Apply ceramic primer to the inside of the ceramic crown and allow to react for 30 seconds.         Image: Apply ceramic primer to the inside of the ceramic crown and allow to react for 30 seconds.         Image: Apply ceramic primer to the inside of the ceramic crown and then place on the framework. Allow the ceremit to cure according the manufacturens instructions.         Image: Apply ceramic primer to the inside of the ceramic primer to the inside of the ceramic crown and then place on the framework. Allow the ceremit to cure according the manufacturens instructions.         Image: Apply ceramic primer to the inside of the ceramic primer to the instructions.         Image: Apply ceramic primer to the inside of the ceramic primer to the instructions.         Image		tallic instrument.
image: seconds.       for 30 seconds.         image: seconds.       image: seconds.		Apply composite primer to the surface of the Pekkton® ivory framework
Allow the cement to cure according the manufacturers instructions. (self-curing)         Allow the cement to cure according the manufacturers instructions. (self-curing)         Bonding with titanium         Bonding with titanium         Image: State of the second s		
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.         Standblast the Pekkton® ivory framework with unrecycled aluminium oxide (Al <sub>2</sub> O <sub>3</sub> ) 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 <sub>2</sub> O <sub>3</sub> ) with a grain size of 110 µm and a pressure of 3 bar. Then clean		Allow the cement to cure according the manufacturers instructions.
with little force. The recommended speed is between 5:000 – 10:000 rpm. Clean with alcohol.         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 <sub>2</sub> O <sub>3</sub> ) 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 <sub>2</sub> O <sub>3</sub> ) with a grain size of 110 µm and a pressure of 3 bar. Then clean	8.19 Bonding with titanium	
$(Al_2O_3)$ 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 little force. The recommended speed is between 5>000-10>000 rpm.
		$(Al_2O_3)$ 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

ΕN



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 manufacturers instructions.



#### Remove excess bond professionally.

Block any undercuts with wax. Insulate the model.

#### 18.20 Cementing crowns and bridges

Please follow the manufacturers 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<sup>®</sup> 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<sup>®</sup> ivory

Compression strength	246	MPa	Density	1.4	g/cm <sup>3</sup>
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<sup>®</sup> ivory

Unless explained specifically, all products marked with "<sup>®</sup>" 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.

Product li	st			
Cat. No.	Product name	Contents	Labelling	UDI-DI
01060003	Pekkton <sup>®</sup> ivory Press blanks	10 pcs.	CE 0483	07640166511793
Labelling	on packaging/symbols			
~~	Date of manufacture			
	Manufacturer			
REF	Catalogue number			
LOT	Lot number			
QTY	Quantity			
www.cmsa.ch	Observe the Instructions for Use, which are avail- able 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.			
<b>CE C</b>	Cendres+Métaux products with CE labelling meet the requirements of the relevant European requirements.			
(2)	Do not re-use			
NON	Non-sterile			
×	Protect from sunlight			
$\triangle$	Attention, observe accompanying documents			
UDI	Clear product identification			
EC REP	European Authorised Representative			
	Importer			
MD	Medical device			





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