+ Pekkton[®] ivory – Instructions for use. Pressing technique with Dekema.





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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.

1 Product name

Pekkton[®] ivory (pressing blanks)

2 Product description

Pekkton[®] ivory is a high performance material (based on PEKK) composed of OXPEKK[®] IG¹ (Implantable Grade with highest purity) and Oxide for optimization of tint and mechanical properties. Color: whitish.

The material is available to users, among other things, as a pressing blank. The dental technician fabricates crown and bridge frameworks from the pressing blank. The frameworks are then esthetically veneered in the laboratory with bonded pressable crowns, veneering composites, prefabricated acrylic teeth or trays.

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.

(II) Important information for the specialist / note instructions for use.

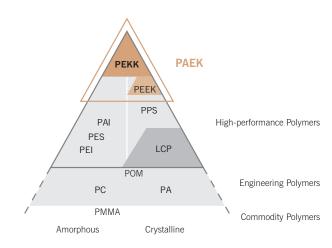
 \triangle Warning symbol for increased caution.

3.1 Intended use

Pekkton[®] ivory is intended for use with fixed (crowns and bridges) and removable dental prostheses.

3.2 Disposal

Pekkton[®] 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 side 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 1.3mm 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 (assertation) bridges less than 14 mm²
- Connector dimensions of side (posterior) bridges less than 14 mm²
 Bridge structures with more than two pontics or extensions.
- Bridges on natural teeth with more than one pontic or extension.
- Unveneered crowns in the lateral mouth area for use of more
- than 12 months.
- 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.

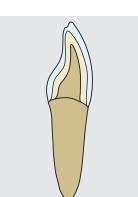
5 Instructions for use

5.1 Preparation

- \Box A reduction in framework thickness always means a reduction in strength.
 - This aspect must be considered in the preparation, in particular within the occlusal area.
 - The height of the crown die preparation should be at least 4 mm and the angle of convergence should be $4-6^{\circ}$.
 - Eliminate undercuts.

Principally, the preparation technology corresponds to the one of full ceramic reconstructions.

The preparation is based on the concept of reduced, anatomical form. A chamfer preparation in the angle of approx. $10-30^{\circ}$ or a shoulder preparation with rounded inside edges is ideal. The width of the chamfer/shoulder is approx. 0.8 mm.



Preparation design of a anterior tooth

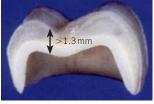


Preparation design of a molar

5.2 Framework criteria

The key for clinical success and a durable restoration in the patient's mouth is compliance with the guidelines for the design of a crown or bridge in Pekkton[®]. The change from framework to veneering material may not occur in the functional contact area. In there is a lack of space, please respect the maximal possible framework thickness. For an optimal color reproduction, a veneering thickness of 0.5 mm is recommended. The occlusal minimum thickness of a crown should be < 1.3 mm.

Material thickness of the frameworks



Minimal occlusal thickness

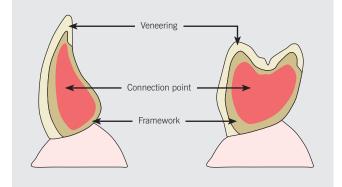
Pekkton [®] ivory	Crown		Bridge	
	Anterior tooth	Posterior tooth	Anterior tooth	Posterior tooth
Design type	Tooth shape-supporting	Cusp supporting	Tooth shape-supporting	Cusp supporting
Minimum wall thickness circular	> 0.6 mm	> 0.6 mm	> 0.6 mm	> 0.6 mm
Minimum wall thickness occlusal	> 0.8 mm	> 0.8 mm	> 0.8 mm	> 0.8 mm
Connector dimensions	-	-	$> 12mm^2$	$> 14mm^2$

⚠ The stability of the connector surface is increased when the ratio of vertical to horizontal is significantly greater (ratio of approx. 60% to 40%).

Removable restorations

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

The cross section of a Pekkton $^{\oplus}$ ivory framework stand against works in metal should be by a factor of 1.5 increased.



5.3 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 maximum 1mm from the preparation margin.

5.4 Production in the pressing process 5.4.1 Pressing device

4 Recommended pressing devices for processing Pekkton[®] ivory. 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.)

5.4.2 Waxing

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

Design the caps and bridge elements in accordance with the basic principle of the maximum possible framework thickness, as well as the cusps-supported reduced tooth form.

Avoid dirt-collecting recesses on the gingival design when modeling 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.

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



Anterior tooth



Posterior tooth (molar)



Buccal



Labial circular tapered edge design



Buccal/labial



After pressing. Conditioned on the model.



Posterior tooth



Palatinal/lingual



Palatinal/lingual mini edge (garland)



Palatinal/lingual

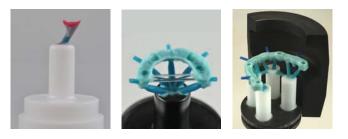


Finished and polished $\ensuremath{\mathsf{Pekkton}}\xspace^{\ensuremath{\mathbb{B}}}$ ivory bridge.

5.4.3 Sprueing

The sprues should be attached in an angle of $5-10^{\circ}$, similar to the indications for press ceramic systems.

It is essential to avoid sharp edges because when pressing viscous Pekkton[®] investment material can be entrained. This can prevent inclusions, especially in the marginal zone. Respect the length of the press channel to avoid loss of pressure.



	Single tooth crown	Bridge
Press channel	Diameter 12 mm	Diameter 12 mm
Ring system recommendation	 Trixpress (Dekema) Investment ring system Empress (Ivoclar Vivadent, FL-Schaan) 	 Trixpress (Dekema) Investment ring system Empress (Ivoclar Vivadent, FL-Schaan)
Size of the investment ring	100g (suitable for 1 or a maxi- mum of 2 equal-sized items) 200g (suitable for 4 items max.)	200g (suitable for 4 items max.) 380g (suitable for up to complete bridges)
Diameter of the wax wire	3 to 3.5 mm	3 to 3.5mm Total bridge until 5mm
Length of press channel (wax wire)	3 to 5 mm (max. height incl. object 18 mm)	3 to 5 mm (max. height incl. object 18 mm) Total bridge: individual length. Ensure that the material can be pressed in evenly.
Sprue point at the object	Aligned with the die (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. $5-10^{\circ}$
Design of sprueing points	trumpet shape, without sharp edges and angles	trumpet shape, without sharp edges and angles
Distance between various objects	> 3-5mm	> 3-5mm
Distance to margin of investment ring	10mm	10mm
Air outlets	Not necessary	For larger bridge elements, fit air outlets ($\not 00.8-1mm$) to reduce pressure and to avoid bubbles.

5.4.4 Investing

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

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

Definition of wax weight:

- 1. 0.7g wax \cong 1st press blank (1g)
- 2. Put the base of 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. Put the base of investment ring with the wax objects on the balance.
- 5. The indicated value corresponds to the wax weight.

Recommended investment volumes		Manufacturer			
Standard process:			Cendres+Métaux SA, CH-Biel/Bienne		
Speed process: ⚠️ Not suitable for 380 g investment ring			Anaxdent, DE-Stuttgart		
	Mixing ratio	CM-20 L	iquid	Dist. water	Total
CM-20	100g	19 ml		6 ml	25 ml
	200 g	38 ml		12 ml	50 ml
	Mixing ratio	Liquid		Dist. water	Total
AnaxVest pm	100g	18ml		6 ml	24 ml

Please follow the manufacturer's instructions for use for 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 suitable instrument for the fine investment of the cavity (e.g. small brush), so that the humidity will not be withdrawn from the investment material.

A fine probe can also be used. Please make sure that the 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)
- No investing before a weekend
- (Danger of drying out or too much humidity through Hygrophor)







5.4.5 Preheating

Li Check 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.
- Carefully turn and remove the investment ring base, too.
 Remove rough spots with a plaster knife or a belt grinder.
- Please make sure that no investment material enters the press channel.
- **I** The investment ring base should have a 90° angle and be situated flat on the investment ring holder in the pressing furnace.

	Standard	Speed
	CM-20	AnaxVest pm
Setting time	30 minutes	30-35 minutes
Program (preheating furnace)	Stand-by temperature: room temperature Rate of rise: 5 °C/min. Phase 1: 250 °C for 60 min. Phase 2: 800 °C for 60 min. Phase 3: Cooling in the furnace at 390 °C	Stand-by temperature: 650 °C Burn out and preheating: 60 min. at 650 °C
Program (Dekema)		Place investment ring directly into the pressing furnace from the preheating furnace (650/850°C).
Pressing furnace dwell time		L9 C650 T300
Program for cooling investment ring		L9 C650 V.C385 VO T600
Positioning of the investment ring in the furnace	Opening downwards. Please make sure that the wax bur investment ring, e.g.: – Tip out the investment ring in the – Support, e.g. with 3 small invest	e direction of the rear wall
Preheating plunger	No	No
Preheating press blank	No	No
Important	No rapid cooling, as cracks may appear in the investment material. A change of preheating furnace (e.g. 650°C to 390°C) can also cause cracks.	-
Recommendation	As the preheating process is time consuming, preheating overnight is recommended.	-

5.4.6 Pressing

☐ The internal temperature of the investment ring must be 390 °C. This will be the case after a one hour setting time after

reaching the final temperature (depending upon the quantity of investment rings in the furnace).

△ DEKEMA press-i-dent: The press furnace must be sufficiently preheated to avoid incomplete pressing due to the cooled investment ring. Suggestion: The outside of the combustion chamber is lukewarm.

Prepare plunger and correct quantity of press blanks.

Carefully remove the investment ring from the preheating furnace using pliers and set it on a refractory support.

 \triangle Wear gloves for heat protection.

Program overview (Pekkton® ivory)

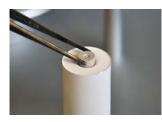
Carefully place press blanks into investment ring.

- Up to 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.
- ${\rm \ensuremath{\Delta}}$ In case of 2 pressing blanks, place sides with logos on top of each other!

Place plunger in the investment ring with the rubber seal face down.

 \triangle Keep the loading time to 1 minute maximum to keep the escaping heat loss as low as possible.







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

Pressing technology in cold press furnace

- Heating at 800 $^\circ$ C in the investment ring furnace Cooling to 380-390 $^\circ$ C in the investment ring
- Placing the ingots and the plungers
- 20 min. further preheating at 380-390 ° C
- Handing over the press-i-dent. Both at room temperature.
- Transfer into the press-i-dent: L9 V9 L98 T120 T900 V.C120 L9 L0 C0 T5
- Cycle time 1'981s (33 min.)
- Removing and divesting.

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.

 \triangle Wear gloves for heat protection.

Cool the investment ring outside of the furnace to room temperature.





5.4.7 Divestment and cleaning

Using pliers, carefully remove the investment material without damaging the frames.

Divest as soon is the investment ring is room temperature.

 \triangle Do not use tongs to divest larger pieces.

Fine divestment is carried out with abrasive $110 \mu m$ aluminum oxide under pressure of 2 bars.

 \triangle Caution: Sandblast for a short period only to prevent damage.

Crown framework after fine divestment.

III The material can be pressed only one time.







5.5 Conditioning

Cleaning with oil-free compressed air only. Ceramic stones and old burs can cause clogging, which makes conditioning difficult and may lead to overlaps.

Check the fit and adjust, if necessary.



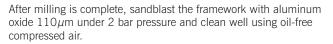
Cut the sprue by using a cutting wheel.

(II) When grinding the Pekkton[®] framework, wear protective goggles with a dust mask and use a suction unit. The cutting wheels available from Cendres+Métaux SA are ideal for removing surplus material.

Cross-toothed milling is used to finish the framework.

Speed limit maximum 15,000 rotations/min. Do not work on the object if the pressure is too high.

Roughen the surface using a diamond milling cutter and clean with alcohol before sandblasting the framework.



After sandblasting the surface, do not touch the surface with your bare fingers.

Never clean the framework with steam or water.







5.6 Veneering

5.6.1 Preparation

Before veneering, it is imperative that the Pekkton[®] framework is treated with composite primer based on MMA.

Dease follow the manufacturer's instructions.



5.6.2 Veneering concepts

After preparation of the framework as described in Section 5.6.1, 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 titanium bases and frameworks of Pekkton[®] ivory.

In choosing cement, ${\sf Multilink}^{\circledast}$ Hybrid Abutment (Ivoclar Vivadent) is recommended.

- The abutment is screwed onto the analog. Seal the screw channel of the titanium abutment and the Pekkton[®] ivory framework with wax.
- 2. Carefully sandblast the surface of the titanium abutment with 110μ m aluminum oxide and 3 bar pressure.
- 3. Also carefully sandblast the contact surface on the inside of the framework. $110 \mu m$ aluminum oxide and 2 bar pressure.
- Monobond plus is applied to the sandblasted surfaces (abutment + inner surface of the framework) to silanize them. Application time approx. 60 seconds.
- 5. Apply (abutment + inner surface of the framework) to the Pekkton[®] ivory surface with a single-use brush and light cure according to manufacturers'instructions.
- 6. Apply the cement to the inner surface of the framework and place on the abutment.
- 7. Then follow the manufacturers instructions.

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5.8 Try-in and cementation

5.8.1 Disinfection

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

- It is suitable for cleaning and disinfection of dental prosthetic components.
- It is compatible with the materials of the products to be cleaned and disinfected.
- It has tested 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 manufacturer's instructions.

5.8.2 Cementation

Preparation: (in the laboratory):

1) Sandblast the inner surface of the reconstruction with abrasive $110 \mu m$ grit at a pressure of 2 bar.

Prior to 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.
- 3) Pretreat the inner surface with composite based on MMA to increase the bond.
- [i] 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:

Method of cementation:	Conventional (glass ionomer cements)	Self-adhesive	Adhesive
Stump	Length of stump $> 4 \text{ mm}$	Length of stump $> 4 \text{ mm}$	short stump, $< 4 \text{ mm}$
	Preparation angle: $4-8^{\circ}$	Preparation angle: $4-8^{\circ}$	Preparation angle: $> 8^{\circ}$

Delease follow the manufacturer's instructions.

5.9 Handling after integration

5.9.1 Cleaning and follow-up

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.

5.9.2 Traceability

The batch numbers must be documented to ensure traceability.

6 Ordering information Material

er en	Pekkton [®] iv (Core mater
EIEEEEEE	Disposable seal (Diameter 1



Description	Order No.	Manufacturer
Pekkton [®] ivory press blank (Core material)	0106 0003 (Packaging of 10 pieces)	Cendres+Métaux SA
Disposable Pressplunger with seal (Diameter 12 mm)	0800 0141 (Packaging of 50 pieces)	Cendres+Métaux SA
	0800 0517 (Packaging of 3 pieces)	

7 Symbols		8 Disclaimer / Validity
M	Date of manufacture	The issuing of these instructions for use renders all previous versions invalid.
	Manufacturer	The manufacturer rejects any liability for damages resulting from
 n #	Patient No.	non-compliance with these instructions for use.
II REF	Catalogue number	In case of complaints, please always include the batch number.
LOT	Batch code	Illustrated step-by-step instructions are available on the Cendres+Métaux homepage. www.cmsa.ch/dental
QTY	Quantity	The product must be used exclusively by skilled persons.
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.	9 Availability Country-specific differences in product range are possible.
	Cendres+Métaux SA products with CE labeling meet the requirements of the Medical Device Directive 93/42/EEC.	10 Copyright and trademarks Pekkton [®] ivory is a registered trademark of Cendres+Métaux
(Do not re-use	Holding SA, Biel/Bienne, Switzerland.
NON	Non-sterile	Reprints or publication – even excerpts – require the written
*	Keep away from sunlight	permission of the publisher.
\triangle	Attention (observe accompanying documents)	

11 Further information

11.1 Troubleshooting

Problem	Cause	Solution
Workpiece not pressed out	 Investment ring has not been preheated to recommended temperature. Investment ring too cold. Duration of transport from the preheating furnace to the pressing furnace is too long. Pressing furnace is too cold. Insufficient material used. 	 Check program and final temperature. Check calibration of the furnace. Perform furnace change as quickly as possible. Silver test. Weigh press items before pressing.
Investment ring burst/broken	 Investment ring too cold. Plunger is not properly inserted. Dissimilar press items. Minimum distance from the investment ring wall not maintained or too many items in too small an investment ring mold. 	 Check program and final temperature. Make sure the plunger is not positioned at an angle in the investment ring channel. Invest roughly same-size items (especially in the 100 g ring). Take sufficient investment ring wall thickness into account. Comply with the values stated.
Framework broke during divestment	 The divestment pliers got too close to the item, the margin. 	 Only divest roughly with the pliers, sandblast the rest.
Margins no longer fit properly after divestment	 Sandblasting pressure is too high. Microbubbles. Investment material residues on the inner surfaces. 	– Set max. pressure to 2 bar. – Fit carefully with a precision bur, then sandblast at 2 bar and 110μ m.
Veneer becomes detached from the framework (insufficient adhesion)	 Surface not properly prepared for bonding. Primer not used. Grease on the surface. Moisture between the framework and the veneering material. 	 Prepare surface according to instructions. Always use primer. After sandblasting, never touch the surface with your fingers. Do not clean the framework with water or steam.
Error message from the pressing furnace		

