Pekkton® ivory – Instructions for use.

Pressing technique with PEKKtherm and PEKKpress.

Pekkton®

CENDRES+ MÉTAUX

esthetic.line

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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.

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1 Product name
Pekkton® ivory (pressing blanks)

2 Product description
Pekkton® ivory is a material based on PEKK composed of OXPEKK® IG1 (Implantable Grade with pur material) and Titanium Dioxide for the determination of tint and mechanical properties. Color: whitish.

The material is available to users 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.

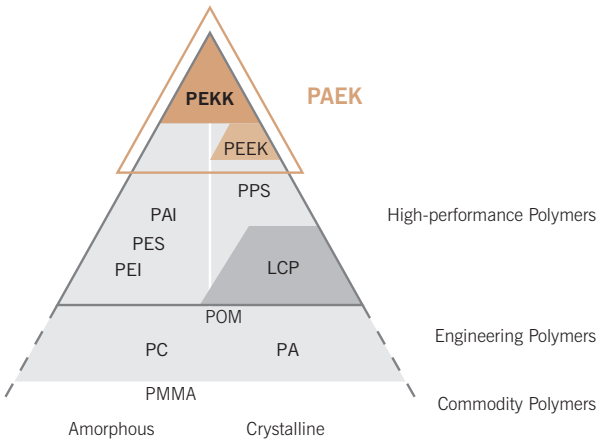
3 General information
For the exact specifications of Pekkton® ivory, please refer to the material data sheet and the safety data sheet. You will find the data sheets mentioned free of charge at www.pekkton.com.

📖 Important information for the specialist / note instructions for use.

⚠ 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 and veneered crowns and bridges 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.
- 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 mm^2
  - Connector dimensions of side (posterior) bridges less than 14 mm^2
- 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.
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 work must be carried on by qualified specialists.

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.

[1] Pekkton® based on OXPEKK® from OPM, Oxford Performance Materials, USA.

5 Processing instructions

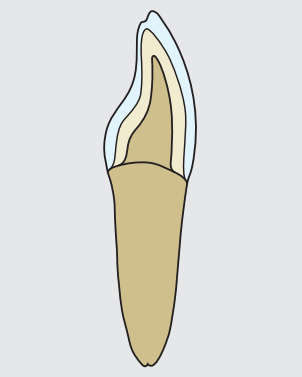
5.1 Technical parameters

Please refer to Data Sheet «Pekkton® ivory – Material Data Sheet» following URL: www.cmsa.ch/docs
Document Type: Factsheet, Product category: Pekkton®

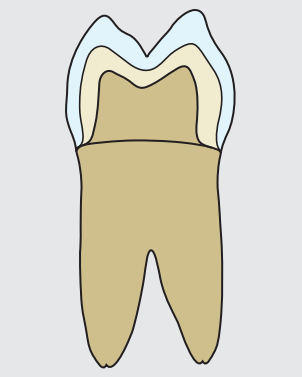
5.2 Preparation

Any 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°.
Eliminate undercuts.

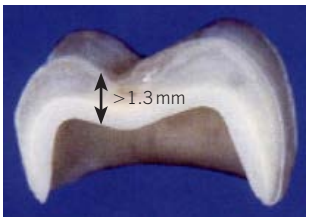
Principally, the preparation technology corresponds to the one of full ceramic reconstructions.
The preparation is based on the concept of reduced, anatomical form. A chamfer preparation in the angle of approx. 10–30° or a shoulder preparation with rounded inside edges is ideal. The width of the chamfer/shoulder is approx. 0.8 mm.



Preparation design of a anterior tooth



Preparation design of a molar



Minimal occlusal thickness

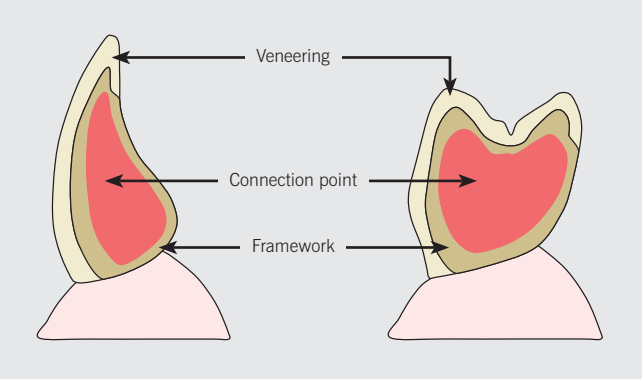
5.3 Framework criteria

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

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	–	–	> 12 mm²	> 14 mm²

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



5.4 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 1 mm from the preparation margin.

Anterior tooth

Posterior tooth

5.5 Manufacturing by pressing

5.5.1 Equipment

PEKKtherm

The device makes it easy and safe to stabilize the muffle temperature (out of the preheating furnace) to the pressing temperature, which is 385°–395° C depending on the size of the cylinder. Pekkton® ivory is then melted before the pressing process.

The device is distributed exclusively by Cendres+Metaux SA.
The manufacturer is Effegi Brega srl, IT-29010 Sarmato.

Please follow the included operating instructions from the manufacturer when operating the device.

PEKKpress

This device is used to efficiently and gently inject Pekkton® ivory after the material and muffle have been prepared in the PEKKtherm device.

The device is distributed exclusively by Cendres+Metaux SA.
The manufacturer is Effegi Brega srl, IT-29010 Sarmato.

Please follow the included operating instructions from the manufacturer when operating the device.

PEKKtherm

PEKKpress

5.5.2 Waxing

🕮 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.

Posterior tooth (molar)

Buccal

Palatinal/lingual

Anterior tooth

Labial circular tapered edge design

Palatinal/lingual mini edge (garland)

Buccal/labial

Palatinal/lingual

After pressing. Conditioned on the model.

Finished and polished Pekkton® ivory bridge.

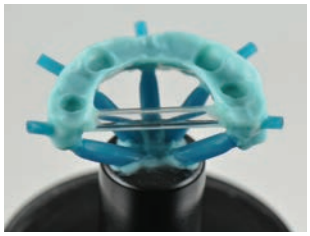
Removable restoration

⚠ Long-term stability depends on the dimensions and design of the restoration.
Ideally, the cross-section of a Pekkton® ivory framework should be minimally increased by a factor of 1.5 in contrast to working with metal alloys.

5.5.3 Sprueing

The sprues should be attached in an angle of 5–10°, 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 crowns and smaller bridges	Large bridges and removable restoration
Ring system recommendation	PEKKpress mould set 200g Order No. 08000628 Pressplunger, Diameter 12 mm Order No. 08000626 Manufacturer: Cendres+Métaux SA	PEKKpress mould set 600g Order No. 08000629 Pressplunger, Diameter 26 mm Order No. 08000627 Manufacturer: Cendres+Métaux SA
Diameter of the wax wire	Supply to the object: 3–3.5 mm Ventilation: For bridge elements Air outlets (0.8–1 mm) to prevent bubbles.	Supply to the object: 5.0 mm Ventilation: 3.0 mm Support*: 5.0 mm *e.g. burnout plastic tube
Sprue point at the object	Single crown: Aligned with the die. Bridge: Attach to the thickest connection point.	Attach to the thickest connection point.
Sprue angle to investment ring base	In a small angle of approx. 5–10°	–
Press channel	Position centrally in the cylinder	Position as centrally as possible in the cylinder
Design of sprueing points	trumpet shape, without sharp edges and angles	trumpet shape, without sharp edges and angles
Distance to margin of investment ring	5–10 mm	5–10 mm
Distance to margin of investment ring	Min. 10 mm	Min. 10 mm
Distance between various objects	3–5 mm	–
Max. weight compressible	Up to 2 press blanks (2 gramm)	Up to 18 press blanks (18 grams) Pro melt phase max. 9 blanks (9 grams)

5.5.4 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).

Please follow the manufacturer's instructions for use for correct processing of the investment material!

Definition of wax weight:
1. Put the base of investment ring without wax objects on the balance and calibrate to 0.
2. Fix the wax objects on the base of the investment ring.
3. Put the base of investment ring with the wax objects on the balance.
4. The indicated value corresponds to the wax weight.

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.

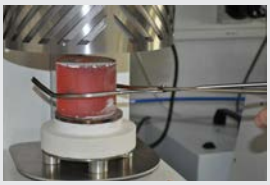
– Allow the investment ring to set without vibration.
– No investing before a weekend
(Danger of drying out or too much humidity through Hygrophor)

5.5.5 Preheating

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.
2. Carefully turn and remove the investment ring base, too.
3. Remove rough spots with a plaster knife or a belt grinder.
4. Please make sure that no investment material enters the press channel.

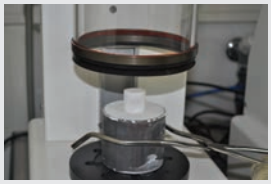
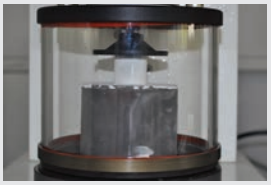
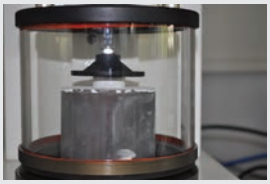
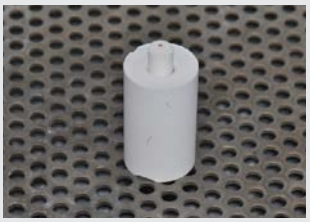
The investment ring base should have a 90° angle and be situated flat on the investment ring holder in the pressing furnace.

Quick press technology	
Recommended investment material	CM20. Manufacturer Cendres+Metaux SA anaxvest PM Manufacturer anaxdent
Standby temperature of the preheating furnace	850° C
Holding times in the preheating furnace at 850° C: – Cylinder (100 g) – Cylinder (200 g) – Cylinder (300 g) – Cylinder (400–600 g)	 45 min. 60 min. 75 min. 90 min.
Position der Muffel im Ofen	Opening downwards. 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 – Preheat the self-produced, not yet burned out press stamp, or that for the 400–600 g cylinder, in the furnace heated to 850° C with the ring.
Start PEKKtherm	
Press Heat (blue button) 	PEKKtherm is blocked for 15 minutes. When the Go LED lights up green (audible beep), the device is ready to operate (at 390° C) and ready for program selection.
Use the Stop button to select the program (Keep the key pressed until the desired program is displayed)	5 programs are available: 1 = 100 g LED ● ○ ○ 2 = 200 g LED ● ● ○ 3 = 300 g LED ● ● ● 4 = 400–600 g LED ● ○ ○ 5 = 400–600 g LED ● ● ○
Press the Go button 	The furnace opens, program starts. Put the ring and press stamp 12 mm next to each other in the PEKKtherm immediately. Depending on the program selected, PEKKtherm remains open as follows: 1 = 5 minutes 2 = 10 minutes 3 = 15 minutes 4 = 20 minutes 5 = 20 minutes PEKKtherm then closes automatically and **remains closed for 20 minutes** to allow the temperature to stabilize. An alarm sounds when the program is done. ⚠ Take the press stamp (26 mm) for the 400–600 g ring out of the preheating furnace 10 min. prior to pressing and let it cool on the PEKKtherm device.
Melting Pekkton® ivory 	Press the Go button, furnace opens. Cylinder can now be loaded with the PekktonR ivory press blanks. ⚠ Max. 9 pcs. (9 grams) at one time! (400–600 g investment ring)

Press the Go button 	PEKKtherm remains closed for 20 minutes followed by an alarm (beep). Press the Go button, furnace opens. The melted PekktonR ivory normally has a cream color and has no brown discoloration. The material is ready for the pressing process. Insert the preheated single-use press stamp, press lightly and put in the PEKKpress press (pressing process, see 5.4.6).
Option (for program 5) (if more than 10 g are needed)	1) Audible beep. 2) Press the Go button (furnace opens). 3) Fill material. 4) Press the Go button (furnace closes). 5) Wait 15 minutes (no alarm) 6) Press the Go button (furnace opens) 7) Insert the preheated single-use press stamp, press lightly and put in the PEKKpress press (pressing process, see 5.4.6).

⚠ If PEKKtherm is not operated for one hour and the green Go button is illuminated, PEKKtherm is in Standby mode and automatically switches off.

5.5.6 Pressing

Start PEKKpress	The red LED lamp is illuminated above the green and blue button.
Press the green button	LED lamp turns green. Furnace opens. PEKKpress is ready for program selection.
Set pressure	Pressure regulator is adjustable from 0–6 bar. – Cylinder 1.5 Bar – Cylinder (200 g) 2.5 Bar – Cylinder (300 g) 3.5 Bar – Cylinder (400–600 g) 5.8 Bar
The vacuum is deactivated by pressing the blue button.	Large pieces are pressed under vacuum. LED red –> vacuum off LED green –> vacuum on
Use the red button to select the program	4 programs are available: 1 = 100 g ●○○ 2 = 200 g ●●○ 3 = 300 g ●●● 4 = 400–600 g ●●●
  	
Cooling phase after pressing	1 = 10 minutes 2 = 20 minutes 3 = 30 minutes 4 = 40 minutes PEKKpress then opens automatically.
Switch off PEKKpress (green illuminated button)	Device closes automatically.
Cool the investment ring to room temperature	

5.5.7 Divestment and cleaning

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

🕮 Divest as soon is the investment ring is room temperature.

⚠ Do not use tongs to divest larger pieces.

Fine divestment is carried out with abrasive 110μm aluminum oxide under pressure of 2 bars.

⚠ Caution: Sandblast for a short period only to prevent damage. Sandblast only the framework and not the interface connection.

Crown framework after fine divestment.

🕮 The material can be pressed only one time.

5.6 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.

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 before sandblasting the framework.

After milling is complete, sandblast the framework with aluminum oxide 110μm under 2 bar pressure and clean well using oil-free compressed air.

⚠ Caution: Sandblast only the framework and not the interface connection.

After sandblasting the surface, do not touch the surface with your bare fingers. Never clean the framework with steam or water.

5.7 Veneering

5.7.1 Preparation

Before veneering, it is imperative that the Pekkton® framework is treated with composite primer.
We recommend the primer visio.link, Cendres+Métaux SA, Order No. 0800 0570.

🕮 Please follow the manufacturer's instructions.

5.7.2 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.

5.8 Cementation

Preparation: (in the laboratory):

1) Sandblast the inner surface of the reconstruction with abrasive 110μm grit 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 the 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 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 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.

5.9 Handling after integration

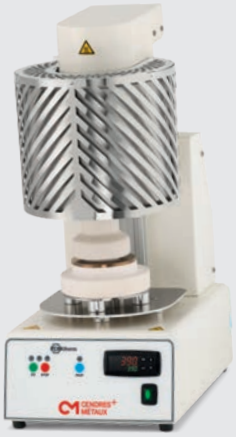
5.9.1 Cleaning and follow-up

Please remove remaining processing debris and then air dry the denture.

5.9.2 Traceability

The batch numbers must be documented to ensure traceability.

6 Ordering information

Material	Description	Order No.	Manufacturer
	PEKKtherm	7020 2394	Effegi-Brega
	PEKKpress	7020 2393	Effegi-Brega
	Pekkton® ivory Pressrohling (Core material)	0106 0003 (Packaging of 10 pieces)	Cendres+Métaux SA
	visio.link (PMMA & Composite Primer)	0800 0570	Bredent
	Disposable Pressplunger (Diameter 12 mm)	0800 0626 (Boîte de 50 unités)	Cendres+Métaux SA
	Disposable Pressplunger (Diameter 26 mm)	0800 0627 (Boîte de 20 unités)	Cendres+Métaux SA
	PEKKpress mould set 200g	08000628	Cendres+Métaux SA
	PEKKpress mould set 600g	08000629	Cendres+Métaux SA

7 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)

8 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.

Illustrated step-by-step instructions are available on the Cendres+Métaux homepage. www.cmsa.ch/dental

The product must be used exclusively by skilled persons.

9 Availability

Country-specific differences in product range are possible.

10 Copyright and trademarks

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

11 Further information

11.1 Troubleshooting

Problem	Cause	Solution
Workpiece not pressed out	– Investment ring has not been preheated to recommended temperature. – Duration of transport from the preheating furnace to the pressing furnace is too long. – Insufficient material used.	– Check program and final temperature. – Perform furnace change as quickly as possible. – Weigh press items before pressing.
Framework broke during divestment	– The divestment pliers got too close to the item, the margin.	– Only divest roughly with the pliers, sandblast the rest.
Framework no longer fits 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 110μm.
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.

11.2 FAQ

The information can be founded on our Website www.pekkton.com

11.3 Acknowledgments

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