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Pekkton[®] ivory Press blanks

Pressing technique with PEKKtherm
and PEKKpress

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Instructions for Use Pekkton® ivory Press blanks

Pressing technique with PEKKtherm and PEKKpress

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® ivory is a material based on PEKK composed of OXPEKK® IG¹ (Implant Grade) and titanium dioxide for the definition of the colour tone and the mechanical properties. Colour: whitish.

¹ 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 mm².
 - Connector cross-section lateral (posterior) bridge 14 mm².
- 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.

08052138	Polyurock Kit	08055014	Livento® invest Powder (50 x 100 g)
08052135	Polyurock Catalyst	083739	Livento® invest Liquid (1000 ml)
08052136	Polyurock Release Spray	08052307	Legabril Diamond (50 g)
08052137	Polyurock Mixer	08000626	Disposable press-stamp 12 mm (50 pcs.)
08052566	Polyurock Colour yellow	08000627	Disposable press-stamp 26 mm (20 pcs.)
08052149	ABF Wax Universal	08000628	PEKKpress mould set 200 g
08052150	ABF Wax Creativ light	08000629	PEKKpress mould set 600 g
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



Warning 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

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

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 surgical and prosthetic products" (www.cmsa.ch/docs).

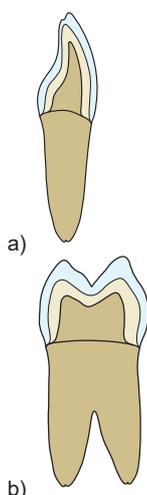
17 Scope of application

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

18 Procedure

18.1 Crowns and bridges

1. Preparation



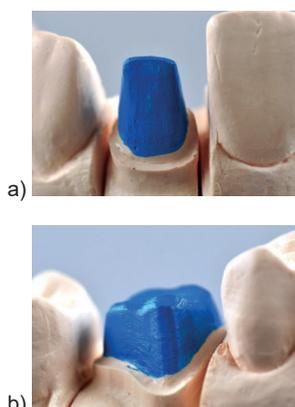
Principally, the preparation technology corresponds to that of full ceramic reconstructions. Preparation is based on the concept of the reduced, anatomical shape. A circular chamfer preparation at an angle of approx. 10 - 30° or a shoulder preparation with rounded inner edges is ideal. The width of the circular chamfer and the shoulder is approx. 0.8 mm each.

- a) Preparation design of an anterior tooth
- b) Preparation design of a posterior tooth

 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 stump preparation should be at least 4mm and the angle of convergence should be 4-6°. Eliminate undercuts.

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

2. Model and stump preparation



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

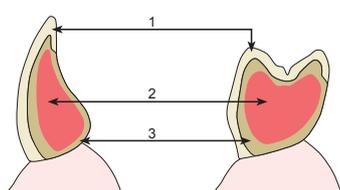
- a) Anterior tooth
- b) Posterior tooth

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

18.2 Material thickness of the frameworks

Pekkton® 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 ²	> 14 mm ²

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®. 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.



- 1) Veneering
- 2) Connecting parts
- 3) 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® 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



PEKKtherm

The device makes it easy and safe to stabilise 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.



PEKKpress

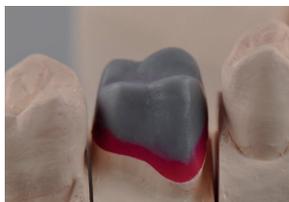
Pekkton® ivory is pressed efficiently and material-friendly in this unit after the material and the investment ring have been prepared in the PEKKtherm device.

 The devices are distributed exclusively by Cendres+Métaux SA. The manufacturer is Effegi Brega srl, IT-29010 Sarmato. Please follow the included operating instructions from the manufacturer when operating the device.

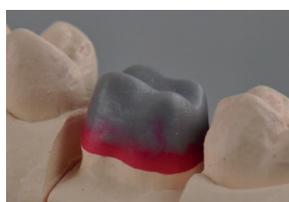
18.5 Waxing

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

Posterior tooth (molar)



Buccal

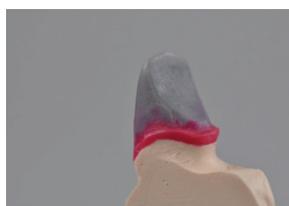


Palatal/lingual

Anterior tooth



Labial circular tapered edge design



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.



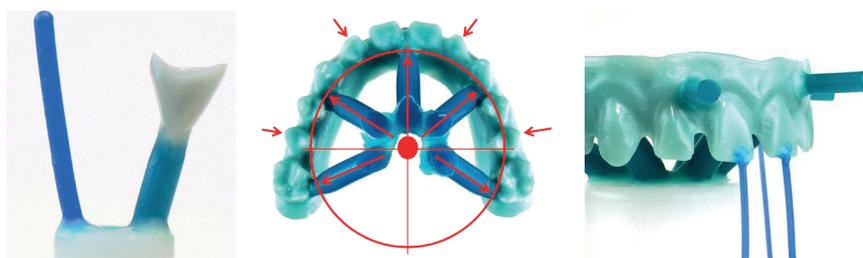
Buccal/labial



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® 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.

	Single crowns and smaller bridges	Large bridges and removable dentures
Recommendation mould systems	PEKKpress investment ring set 200g Catalogue number 08000628 Press stamp, diameter 12mm Catalogue number 08000626 Manufacturer: Cendres+Métaux SA	PEKKpress investment ring set 600g Catalogue number 08000629 Press stamp, diameter 26mm Catalogue number 08000627 Manufacturer: Cendres+Métaux SA
Diameter of the wax wire	Feed to the object: 3–3.5 mm	Feed to the object: 5.0 mm Ventilation: 3.0 mm Support*: 5.0 mm * e.g. burn-out plastic tube
Sprue point at the object	Single crown: Aligned with the stump. 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 shaped, without sharp edges and angles	Trumpet shaped, without sharp edges and angles
Distance to margin of investment ring	5– 10 mm	5– 10 mm
Distance to top edge	Min. 10 mm	Min. 10 mm
Distance between several objects	3–5 mm	–
Max. weight compressible	Max. 2 press blanks (2 grammes)	Max. 12 press blanks (12 grammes)
Distance to margin of investment ring	10 mm	10 mm
Air outlets	Not necessary	For larger bridge elements, install air extraction channels (∅ 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).

Definition of wax weight:

- 0.7g wax corresponds to one press blank (1 g)
- Place the base of the investment ring without wax objects on the balance and calibrate to 0.
- Fix the wax objects on the base of the investment ring.
- Place the base of investment ring with the wax objects on the balance.
- 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	12 ml	50 ml

 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.

Quic Quick press technique k press technique

Stand-by temperature of the preheating furnace	850° C
Holding times in the preheating furnace at 850°C:	
– Cylinder (100 g)	45 min.
– Cylinder (200 g)	60 min.
– Cylinder (300 g)	75 min.
– Cylinder (400–600 g)	90 min.
Positioning of the investment ring in the furnace	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 – When using the 600g investment ring, also place the 26mm press stamp in the preheating furnace, as there is no room for it in the PEKKtherm. Allow to cool to temperature outside the burn-out furnace approx. 10 minutes before pressing.

Start PEKKtherm

Press Heat (blue button)

PEKKtherm is blocked for 15 minutes.

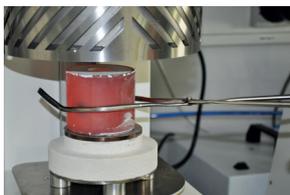


When the Go LED lights up green (audible beep), the device is ready for operation (at 390°C) and ready for programme selection.

Use the Stop button to select the programme
(Keep the key pressed until the desired programme is displayed)

- 5 programmes are available:
- 1 = 100 g LED ● ○ ○
 - 2 = 200 g LED ● ● ○
 - 3 = 300 g LED ● ● ●
 - 4 = 400–600 g LED ● ○ ○

Press the GO button



The furnace opens, programme starts.
Put the investment ring and press stamp next to each other in the PEKKtherm.

- Depending on the programme selected, PEKKtherm remains open as follows:
- 1 = 5 minutes
 - 2 = 10 minutes
 - 3 = 15 minutes
 - 4 = 20 minutes

PEKKtherm then closes automatically and remains closed for 20 minutes to allow the temperature to stabilise.
An alarm sounds when the programme is finished.

Melting Pekkton® ivory



Press the Go button, furnace opens.
Cylinder can now be loaded with the Pekkton® ivory press blanks.

 Wear gloves for heat protection.

Press the Go button



PEKKtherm remains closed for 20 minutes followed by an alarm. Press the Go button, furnace opens.

The melted Pekkton® ivory has an even cream colour and has no brown discolourations. The material is ready for the pressing process.

Insert the preheated single-use press stamp, press lightly and place in the PEKKpress

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

18.9 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 programme selection.

Set pressure

Pressure regulator is freely adjustable from 0 – 6 bar.

- Cylinder (100 g) 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.

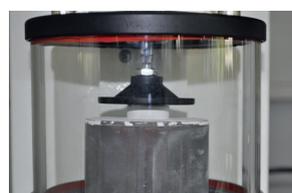
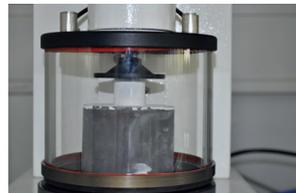
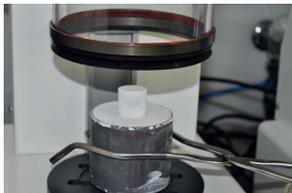
Large pieces are pressed under vacuum.

LED red → vacuum off
LED green → vacuum on

Use the red button to select the programme

4 programmes are available:

- 1 = 100 g
- 2 = 200 g
- 3 = 300 g
- 4 = 400–600 g



Cooling cycle after pressing

- 1 = 10 minutes
 - 2 = 20 minutes
 - 3 = 30 minutes
 - 4 = 40 minutes
- PEKKpress then opens automatically.

Switch off PEKKpress main switch

Device closes automatically.

Allow the investment ring to cool to room temperature



18.10 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.

18.11 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.

18.12 Veneering

After preparation of the framework, Pekkton® 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.

18.13 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.

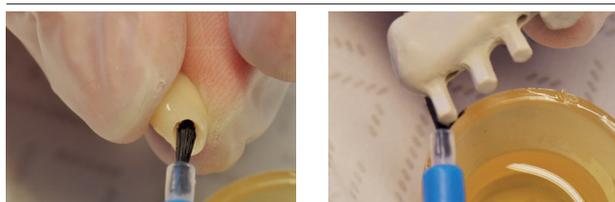
 Bridge work: to avoid cracks (also as a late consequence) in the veneer due to different E-modulus values of Pekkton® ivory and the veneering material, a separation should be made between the teeth down to the opaquer.

 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 manufacturer's instructions for the veneering concept selected.

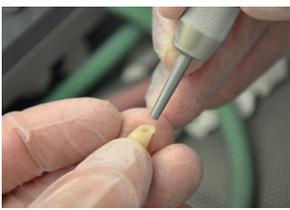
18.4 Bonding with composite / acrylic / PMMA



Roughen the surface with a diamond. At low speed and with little force. The recommended speed is between 5'000–10'000 rpm.



Clean the surfaces to be bonded with alcohol.



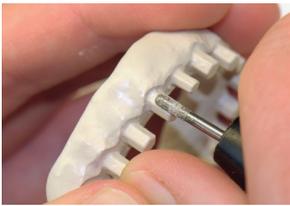
Sandblast the plastic teeth with unrecycled aluminium oxide (Al_2O_3) with a grain size of $110\mu m$ and a pressure of 2 - 3 bar. Sandblast the Pekkton® ivory framework with unrecycled aluminium oxide (Al_2O_3) with a grain size of $110\mu m$ and a pressure of 2 bar. Then clean with oil-free compressed air or with alcohol. Not with a steam cleaner!



Apply a thin coat of composite primer to the connecting areas of the teeth and the Pekkton® ivory framework with a disposable brush. Then cure with a suitable light-curing device according the manufacturer's instructions.

Apply the composite into the cavities of the plastic teeth and then press the tooth onto the assigned retention on the framework by hand. Curing is performed using a suitable light-curing device according to the Instructions for Use.

18.15 Bonding with ceramic/ Livento® press / zirconium oxide



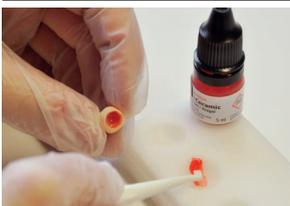
Roughen the surface with a diamond. At low speed and with little force. The recommended speed is between 5,000–10,000 rpm.



Clean the surfaces to be bonded with alcohol.



Sandblast the plastic teeth with unrecycled aluminium oxide (Al_2O_3) with a grain size of $110\mu m$ and a pressure of 2 - 3 bar. Sandblast the Pekkton® ivory framework with unrecycled aluminium oxide (Al_2O_3) with a grain size of $110\mu m$ and a pressure of 2 bar. Then clean with oil-free compressed air or with alcohol. Not with a steam cleaner!



Apply ceramic etch gel to the inside of the ceramic crown with a non-metallic instrument. Allow to react for 60 seconds.



Remove etching gel under running water. Apply composite primer to the surface of the Pekkton® ivory framework and light cure according to the manufacturer's instructions.



Apply ceramic primer to the inside of the ceramic crown and allow to react for 30 seconds.

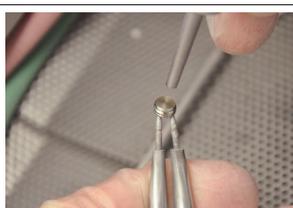


Inject luting composite into the crown and then place on the framework. Allow the cement to cure according to the manufacturer's instructions. (self-curing)

18.16 Bonding with titanium



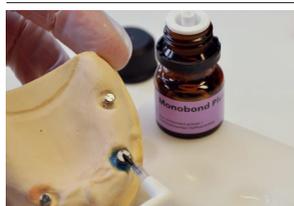
Roughen the Pekkton® ivory surface with a diamond. At low speed and with little force. The recommended speed is between 5'000 – 10'000 rpm. Clean with alcohol.



Sandblast the Pekkton® ivory framework with unrecycled aluminium oxide (Al₂O₃) 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 (Al₂O₃) with a grain size of 110 µm and a pressure of 3 bar. Then clean with a steam device or oil-free compressed air.



Block any undercuts with wax. Insulate the model. Apply composite primer to the surface of the Pekkton® ivory framework and light cure according to the manufacturer's instructions.



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 manufacturer's instructions.



Remove excess bond professionally.

18.17 Cementing crowns and bridges

Please follow the manufacturer's 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® 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 Preparation angle: 4-8°	Length of stump >4mm Preparation angle: 4-8°	short stump, < 4mm Preparation angle: > 8°

19 Materials

Pekkton® ivory

Compression strength	246	MPa	Density	1.4	g/cm ³
Bending strength	200	MPa	Water absorption	8.7	µg/mm ³
Flexural modulus	5.1	GPa	Solubility	0.2	µg/mm ³
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® ivory

Unless explained specifically, all products marked with "®" 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.

29 Product list

Cat. No.	Product name	Contents	Labelling	UDI-DI
01060003	Pekkton® ivory Press blanks	10 pca.	CE 0483	07640166511793
70202393	PEKKpress (220 V), pressing device	N/A	CE*	N/A
70202394	PEKKtherm (220 V), temperature stabilisation and melting furnace	N/A	CE*	N/A

*EFEGE BREGA srl, Via Ferdinando Magellano, 7, IT-29010 Sarmato

30 Labelling on packaging/symbols

Date of manufacture



Manufacturer



Catalogue number



Lot number



Quantity



www.cmsa.ch/docs

Observe the Instructions for Use, which are available 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.



Cendres+Métaux products with CE labelling meet the requirements of the relevant European requirements.



Do not re-use



Non-sterile



Protect from sunlight



Attention, observe accompanying documents



Clear product identification



European Authorised Representative



Importer



Medical device



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Rx only

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