

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 Point 29 in Table 1. 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 Point 29, Table 1.

3 Intended use

The products are intended for use for prosthetic restorations and to support procedures in the dental clinic or laboratory.

4 Expected clinical benefit

Restoration of chewing function and improved aesthetics.

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.
- Lacking compliance of the patient with respect to follow-up / recall instructions.
- Patients with bruxism or other para-functional habits.
- In patients with allergies to one or more elements of the materials used in the product.
- Existing clinical picture in the patient's mouth does not permit the correct application of the products.

8 Compatible products

Not applicable.

9 User qualification

The expertise of a professional dentist or dental technician is required. The current Instructions for Use must be available at all times and be completely read and understood before the first application. The manufacturing work and its maintenance must be carried out by qualified specialists.

 Important information for the specialist

 Warning symbol for increased caution

10 Prescription

Federal laws (USA) prohibit the use or sale by unlicensed dentists.

11 Side effects

 This product may not be used in patients with allergies to one or more elements of the product materials. 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.

Auxiliary instruments and products made of steel may contain nickel.

No known side effects if applied as intended.

12 Warnings

Magnetic resonance 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

These Instructions for Use are sufficient for immediate application for the products described in this application area of the Instructions for Use. Dental or laboratory knowledge is required. Information: www.cmsa.ch/docs

14 Preventive measures

-  – The mechanical cleaning with a toothbrush and toothpaste may lead to premature wear.
- When grinding, wear protective goggles and a dust mask and use a suction unit.
- Only original tools and parts may be used for this work. For information and additional details, please contact your Cendres+Métaux SA representative.
- The product components are supplied non-sterile. For more information see Point 16 Preparation.
- Secure parts against aspiration.
- Before any procedure, ensure that all required product components are available in sufficient quantity.
- For your safety, always wear suitable protective clothing.

15 Single use

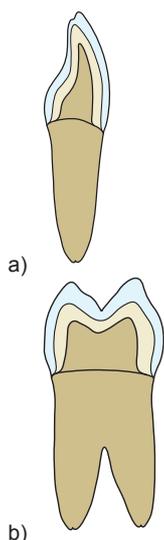
- Unless labelled otherwise, the product components are only intended for single use. Products that are marked for single-use are subject to a certain load during use, which can lead to wear, loss of function and/or malfunctions.
-  Reuse of products marked as single-use products may compromise safety, function and performance. Products for single-use have not been tested for reuse/reprocessing, which increases the risk of infection transmission.

16 Preparation

-  After any fabrication or modification and prior to use, the prosthetic work, including all system components, must be cleaned, disinfected and, if appropriate, sterilised. Materials made of metal alloys, high-performance polymers (Pekkton®) and ceramics are suitable for steam sterilisation, whereas components made of plastic other than Pekkton® are not suitable. 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

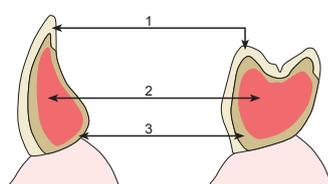


-  Be careful with insulating varnish when digitising the model. This can lead to errors during scanning.

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.

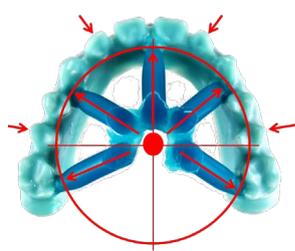


Buccal/labial



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 Spruing**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	PEKKpress investment ring set 600g Catalogue number 08000629
	Press stamp, diameter 12mm Catalogue number 08000626	Press stamp, diameter 26mm Catalogue number 08000627
	Manufacturer: Cendres+Métaux SA	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 spruing 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)

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:

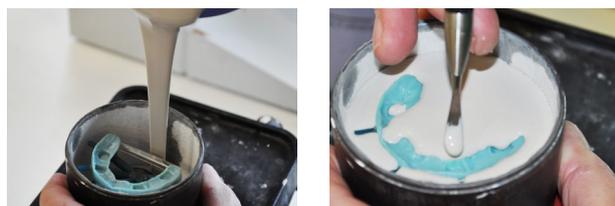
1. 0.7g wax corresponds to one press blank (1 g)
2. Place the base of the investment ring without wax objects on the balance and calibrate to 0.
3. Fix the wax objects on the base of the investment ring.
4. Place the base of investment ring with the wax objects on the balance.
5. The indicated value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

Recommended investment material

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

Mixing ratio	CM-20 Liquid	Dist. water	Total
100g	19 ml	6 ml	25 ml
200g	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 remove the investment ring from the base.
2. Remove rough spots dry with a plaster knife or a belt grinder.
3. 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.

Quick 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.



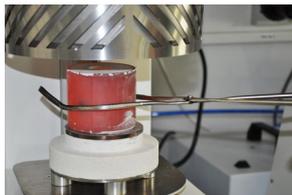
When the Go LED lights up green (audible beep), the device is ready for operation (at 390°C) and ready for programme selection.

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



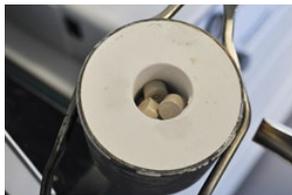
The furnace opens, programme starts.
Put the investment ring and press stamp next to each other in the PEKKtherm.

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 press

 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

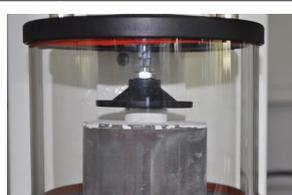
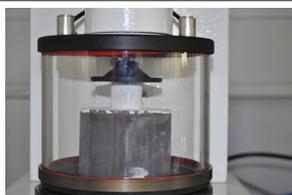
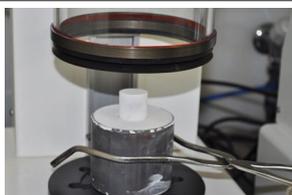
The vacuum is deactivated by pressing the blue button.

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.

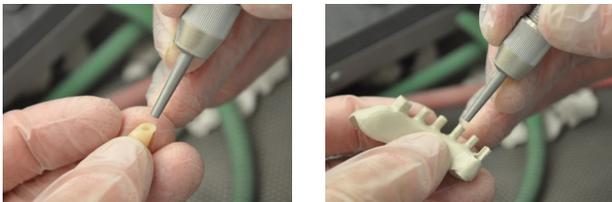
18.14 Bonding with composite / acrylic / PMMA



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!



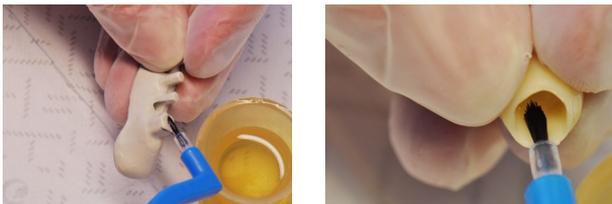
Apply a thin coat of composite primer to the connecting areas of the teeth and the Pekkton® ivory framework with a disposable brush. Then cure with a suitable light-curing device according to the manufacturer's instructions.

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.

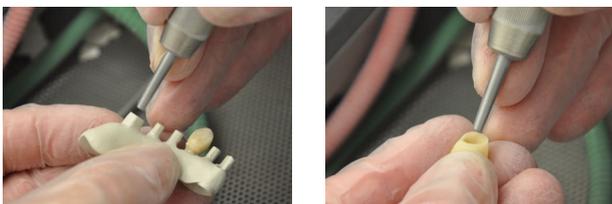
18.15 Bonding with ceramic/ Livento® press / zirconium oxide



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 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 (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 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

Detailed information on the materials and their classification is given in the specific material data sheets, the catalogue as well as the product list given in Table 1 in Point 29. See website www.cmsa.ch/docs or the Cendres+Métaux SA Dental Documentation (available free of charge from all Cendres+Métaux SA subsidiaries, branches and dealers).

20 Notes on storage

The product must be stored in a dry place in its original packaging, at room temperature and without direct sunlight, unless otherwise stated on the packaging. 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 patients are motivated and instructed according to their own abilities such as manual dexterity and vision with regard to the handling and care of their teeth and dentures.

Permanent and removable dentures are subject to considerable stress in the mouth in a constantly changing environment, and thus more or less subjected to signs of wear. Wear is omnipresent in daily routine 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

Ensure that the dentures do not tilt, as any tilting can lead to damage. Never insert dentures by biting the teeth together. This can lead to damage or even breakage of the connecting element. Further information on handling and aftercare of dentures is available in the patient information brochure at www.cmsa.ch/docs.

Insertion

Hold the dentures between the thumb and forefinger, and place them back into the mouth on the anchors. Search or feel for the correct insertion position and push the dentures onto the anchors with gentle, steady pressure. Carefully close your jaws and check whether the dentures are in the correct final position.

Removal

Hold the dentures between the thumb and forefinger, and slowly, carefully and steadily pull them off the anchors and remove them from the mouth.

21.3 Cleaning and care

We recommend cleaning your teeth and your dentures after every meal. Cleaning of dentures includes cleaning of the connecting element.

The gentlest cleaning is achieved by cleaning the connecting element under running water with a soft toothbrush. The most intensive cleaning is achieved when cleaning the dentures in a small ultrasonic device and adding a suitable cleaning agent. Never clean the high precision connecting elements with toothpaste. This could lead to damage. Caution should also be exercised in the case of unsuitable cleaning agents or tablets. This could also damage the high quality connecting element or impair its function. Only clean the connecting parts on the other teeth or implants with water and a soft toothbrush as well as an interdental brush. Do not use toothpaste to avoid damage.

Pay attention to regular cleaning of the anchorage to prevent any inflammation of the soft tissue.
For information and additional tips on caring for the instruments see the website (www.cmsa.ch/docs).
For information and additional details, please contact your Cendres+Métaux SA representative.

22 Ordering information

More detailed information on the catalogue numbers, the number of products and their classification can be found in the product list under Point 29 in Table 1, the specific product catalogue, the packaging and, in the case of individual products, also directly on the product itself. You can find further information on the website www.cmsa.ch/docs or the Cendres+Métaux SA Dental Documentation (available free of charge from all Cendres+Métaux SA subsidiaries, branches and dealers).
For information and additional details, please contact your Cendres+Métaux SA representative.

23 Availability

Some of the products described in this document may possibly not be available in all countries.

24 Traceability batch number

The batch numbers of all parts used must be documented to ensure traceability. If different batch numbers are used for the products described in this application area of the Instructions for Use for the fabrication of dentures, all the batch numbers concerned must be recorded to ensure traceability.

25 Complaint

Cendres+Métaux SA must be notified immediately of any incident that has occurred with regard to the product to all branches, offices and dealers of Cendres+Métaux SA and, in case of serious cases, to the competent authority where the user is registered.

26 Safe disposal

The product 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. This product is part of an overall concept and may only be used or combined with the corresponding original components and instruments. Otherwise, the manufacturer rejects any responsibility and liability. In case of complaints, please always include the batch number.

The use of third party products not distributed by Cendres+Métaux SA in connection with the products listed in Table 1 will void any warranty or other express or implied obligations of Cendres+Métaux SA.

The user of Cendres+Métaux SA products is responsible for determining whether or not a product is suitable for a specific patient and a specific situation.

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 or installation of Cendres+Métaux SA products.

The user is also obliged to regularly study the latest developments of the Cendres+Métaux SA products listed in Table 1 and their applications.

Please note: the descriptions contained in this document are not sufficient for the immediate application of Cendres+Métaux SA products.

Specialist knowledge of dentistry, dental technology and instructions in handling the products listed in Table 1 by an operator with appropriate experience is always required.

29 Product list

All Pekkton® ivory products have the basic UDI-DI: 764016651000036E4

Cat. No.	Product name	Contents	UDI-DI
0106 0003	Pekkton® ivory Press blanks	10 pcs.	07640166511793

Accessories (NO MED products)

Cat. No.	Product name	Contents
0800 0626	Disposable press stamp Ø 12 mm	50 pcs.
0800 0627	Disposable press stamp Ø 26 mm	20 pcs.
0800 0628	PEKKpress investment ring former set, filling quantity: 200 g	1 pc.
0800 0629	PEKKpress investment ring former set, filling quantity: 600 g	1 pc.
083 872	Investment material CM-20, powder.	50 x 160 g
083 739	Investment material CM-20, liquid.	1000 ml

Equipment

Cat. No.	Product name
7020 2393	PEKKpress (220 V), pressing device
7020 2394	PEKKtherm (220 V), temperature stabilisation and melting furnace

30 Symbols

-  Important information for the specialist
-  Warning symbol for increased caution

Labelling on packaging/symbols

-  Date of manufacture
-  Manufacturer
-  Catalogue number
-  Batch code
-  Quantity
-  Observe the Instructions for Use, which are available in electronic form at the address specified.
www.cmsa.ch/docs
- 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
-  Keep away from sunlight
-  Attention, observe accompanying documents
-   Unique Device Identification – UDI
-  European Authorised Representative
-  Importer in EU
-  Medical device