Instructions for Use Pekkton® ivory Press blanks
Pressing technique with Dekema

1 Scope of application of Instructions for Use

These Instructions for Use apply to the products listed under 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 components are intended for use for prosthetic restoration on natural teeth 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® IG[1] (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 Indication

– Definitively restored, veneered and screw-retained crowns and bridges on implants with a maximum of two pontics, which can be veneered with bonded pressed crowns, composites and prefabricated acrylic teeth and shells.
– Definitively restored, veneered single crowns and bridges with a maximum of one pontic on natural teeth.
– Unveneered parts e.g. crown margins and backings.
– Unveneered crowns and bridges in the posterior region for a maximum wearing period of 12 months.
– Removable dentures, 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 < 1.3 mm.
– - When the following minimum dimensions of the framework cannot be maintained:
– Circular wall thickness < 0.6 mm.
– Occlusal wall thickness < 0.8 mm.
– Connector cross section of front (anterior) bridge < 12 mm^2.
– Connector cross-section lateral (posterior) bridge < 14 mm^2.
– Bridges on implants with more than two pontics.
– Bridges on natural teeth with more than one pontic.
– Extensions.
– 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

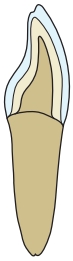
Pekkton® ivory was developed as an alternative, metal-free framework material. The material can be used to fabricate classical crowns and bridges on natural teeth. Due to the masticatory force-absorbing properties of Pekkton® ivory, the material is also frequently used for implant-supported prostheses. 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

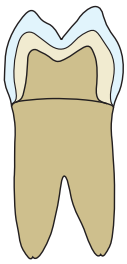
18.1 Crowns and bridges

1. Preparation

a)



b)



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

a)

b)

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.

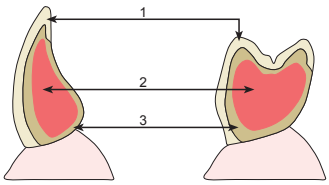
a) Anterior tooth
b) Posterior tooth

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 mm²	> 14 mm²

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

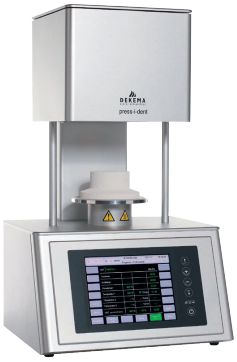
The stability of the connector surface is increased when the ratio of vertical to horizontal is significantly greater (ratio of approx. 60% to 40%).

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



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

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

18.5 Waxing

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

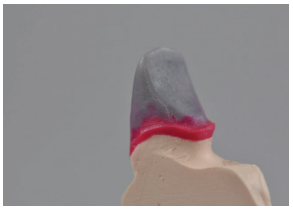
Posterior tooth (molar)

Buccal

Palatal/lingual

Anterior tooth

Labial circular tapered edge design



Palatal/lingual mini edge (garland)

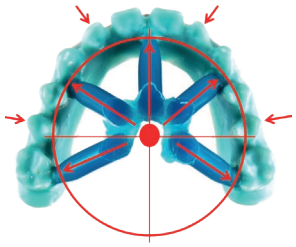
Design the caps and bridge elements in accordance with the basic principle of the maximum possible framework thickness, as well as the cusp-supported reduced tooth form. Avoid dirt-collecting recesses on the gingival design when modelling the pontics. A thin garland can be designed circularly or partially 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 tooth crown	Bridge
Press channel	Diameter 12 mm	Diameter 12 mm
Recommendation mould systems	– Trixpress (Dekema) – Empress mould system (Ivoclar Vivadent, FL-Schaan)	– Trixpress (Dekema) – Empress mould system (Ivoclar Vivadent, FL-Schaan)
Size of the investment ring	100g (suitable for 1 or a maximum of 2 equal-sized objects) 200g (suitable for 4 objects max.)	200g (suitable for 4 objects max.) 380 g (suitable for up to full bridges)
Diameter of the wax wire	3 – 3.5 mm	3 – 3.5 mm Full bridge up to 5mm
Length of press channel (wax wire)	3 – 5 mm (max. height incl. object 18mm)	3 – 5 mm (max. height incl. object 18mm) Full bridge: customized length. Ensure that the material can be pressed evenly.
Sprue point at the object	Aligned with the stump (prevents it from breaking off)	Fit the press channel to the connection point.
Sprue angle to the object	axial	axial
Sprue angle to investment ring base	In a small angle of approx. 5-10°	In a small angle of approx. 5-10°
Design of sprueing points	trumpet shaped, without sharp edges and angles	trumpet shaped, without sharp edges and angles
Distance between several objects	3 – 5 mm	3 – 5 mm
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).

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

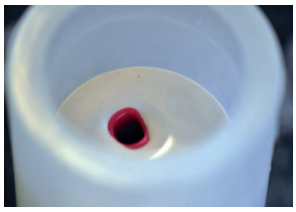
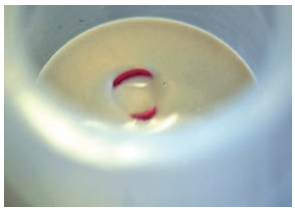
* With the investment ring former set from DEKEMA, it is possible to use more than one press channel. Please follow the manufacturer's work instructions.

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

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

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

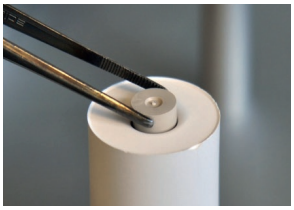
Check the temperature precision of the burnout furnace regularly. Please follow the manufacturer's work instructions.

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.

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

18.9 Pressing


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

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

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

Wear gloves for heat protection.

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

In case of 2 press blanks, place sides with logos on top of each other!

Insert press stamp into the investment ring.

Keep the loading time to 1 minute max. to keep the escaping heat loss as low as possible.

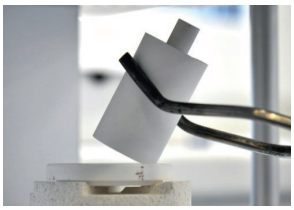
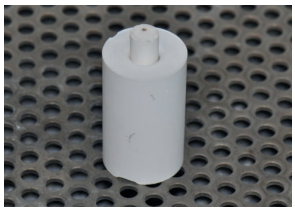
18.10 Programme overview (Pekkton® ivory)

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

18.11 Pressing technique in cold press furnace

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

18.12 Cooling cycle

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

Wear gloves for heat protection.

18.13 Divesting and cleaning



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

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

18.14 Finishing



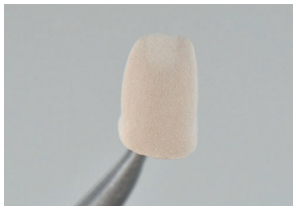
Cross-toothed milling is used to finish the framework. Finishing is performed at 5'000 - 10'000 rpm. Do not operate with too high a pressure on the object. Roughen the surface using a diamond milling cutter before sandblasting. Clean with alcohol.

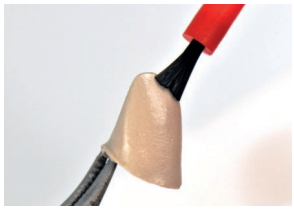
Ceramic stones or old burs can smudge, which makes finishing more difficult and may lead to overlaps.

18.15 Veneering

After preparation of the framework, Pekkton® ivory can be aesthetically enhanced in various ways. For example, it can be enhanced by veneering with composites, affixing custom-made pressable ceramic crowns or using prefabricated acrylic teeth and shells.

18.16 Veneering with composites





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

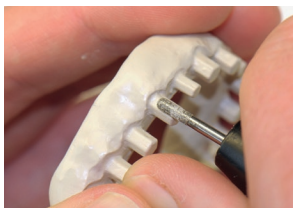


First apply the opaquer with a brush. This can be applied in several layers. The opaquer must cover the framework, but nonetheless be as thin as possible. The ultimate shape is achieved with suitable burs, rubber polishers and various aids.

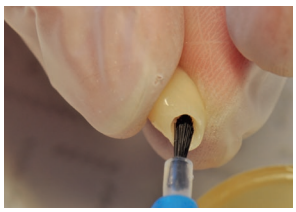
Bridge work: to avoid cracks (also as a late consequence) in the veneer due to different E-modulus values of Pekkton® ivory and the veneering material, a separation should be made between the teeth down to the opaquer.

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.

18.17 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.



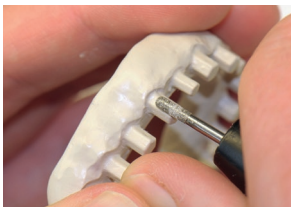

Clean the surfaces to be bonded with alcohol.


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

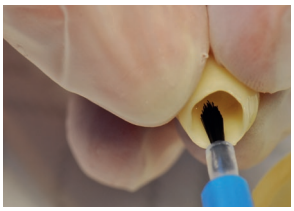

Apply a thin coat of composite primer to the connecting areas of the teeth and the Pekkton® ivory framework with a disposable brush. Then cure with a suitable light-curing device according the manufacturer's instructions.

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.

18.18 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 110µm and a pressure of 2 - 3 bar. Sandblast the Pekkton® ivory framework with unrecycled aluminium oxide (Al_2O_3) with a grain size of 110µm 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.

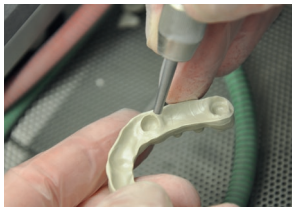
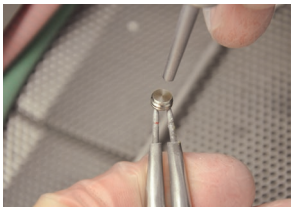

Remove etching gel under running water.
Apply composite primer to the surface of the Pekkton® ivory framework and light cure according to the manufacturer's instructions.


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

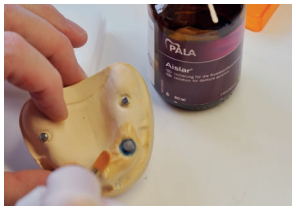
Inject luting composite into the crown and then place on the framework. Allow the cement to cure according the manufacturer's instructions. (self-curing)

18.19 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.

18.20 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	Length of stump >4mm	short stump, < 4mm
	Preparation angle: 4-8°	Preparation angle: 4-8°	Preparation angle: > 8°

19 Materials

Pekkton® ivory

Compression strength	246	MPa	Density	1.4	g/cm³
Bending strength	200	MPa	Water absorption	8.7	µg/mm³
Flexural modulus	5.1	GPa	Solubility	0.2	µg/mm³
Yield strength	115	MPa	Hardness HV	33	MPa
Melting point	363	°C	Hardness (DIN EN ISO 2039-1)	252	MPa

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.
083 872	**Investment material CM-20, powder.**	50 x 160 g
083 739	**Investment material CM-20, liquid.**	1000 ml

30 Symbols

	Important information for the specialist
	Warning symbol for increased caution

Labelling on packaging / symbols

	Date of manufacture
	Manufacturer
REF	Catalogue number
LOT	Batch code
QTY	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.
CE 0483 CE	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
UDI 	Unique Device Identification – UDI
EC REP	European Authorised Representative
	Importer in EU
MD	Medical device

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