CENDRES+ MÉTAUX

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Polymers: Pekkton® ivory

Preface

This short report based on the current Medical Device Coordination Group document (MDCG 2019-9) is a summary of information regarding safety and clinical performance of the Pekkton® ivory.

This report is not meant to be used as a practical guide for the application of our products. The current technical data for the correct handling of the products are described in the instructions for use available on www.cmsa.ch/docs, at the sales representatives or customer service of Cendres+Métaux (CM). More detailed information on products, the materials used as well as their compositions can be found in the product-specific material data sheets, the product information as well as the instructions for use. These documents as well as numerous clinical cases and scientific publications can be found on the website www.cmsa.ch/docs by entering the relevant product name.

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1 Device identification and general information

1.1 Device trade name

Pekkton® ivory

1.2 Manufacturer name and address

Cendres+Métaux SA
Rue de Boujean 122
CH-2501 Biel/Bienne

1.3 Medical device description, basic UDI-DI, classification

Medical device	Medical device	Class of device according to Annex VIII of the Medical Device Regulation 2017/745
Pekkton® ivory press-blanks 	764016651000036E4	IIa
Pekkton® ivory milling-blanks 	764016651000036E4	IIa

1.4 Authorised representative

QualRep Services B.V.
Utrechtseweg 310 – Bldg B42
NL-6812 AR Arnhem
The Netherlands

Single registration number: NL-AR-000000537

1.5 Certificate, single registration number and notified body

Year when the first certificate was issued:	2012
Manufacturer's single registration number:	CH-MF-000030696
Notified body:	mdc medical device certification GmbH
Single identification number:	0483

PART A
Information for user and medical experts

This Section contains information regarding safety and clinical performance, especially relevant for user and medical experts.

2 Device description

2.1 Description of the device group (key functions, design characteristics, materials with body contact)

The following main characteristics of Pekkton® ivory can be summarized:
– Pekkton® ivory is a high performance compounded thermoplastic material composed of 90%wt of Oxpekk® Implantable Grade (highest purity) and titanium dioxide (10%wt) as whitener and mechanical enhancer[1].
– The device is currently delivered in two forms, press-blanks and milling-blanks.

[1]OPM, Oxford Performance Materials, USA

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. Based on the application dental restorations made from Pekkton® ivory may potentially contact mouth tissue (mucosal membrane, dentin, bone).

2.2 Intended purpose, medical condition, anatomic locality of application

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

2.3 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.

2.4 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 mm^2.
  - Connector cross-section lateral (posterior) bridge 14 mm^2.
- 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.

2.5 Affected articles

N/A

2.6 Reference and description of variants and previous generations

Variants	
N/A	N/A

Previous generations (inclusive justification of change)	
N/A	N/A

2.7 Description of any accessories

Available components	
N/A	N/A

Auxiliary parts	
N/A	N/A

Auxiliary instruments	
N/A	N/A

2.8 Combination products

The following combination products are usually used together with Pekkton® ivory frameworks, crowns and bridges:

a) on remaining teeth or surgically placed implants
- cements and bonds for the fixation to natural teeth
- cements and bonds for the fixation to titanium implant abutments that are subsequently screwed on the implants
- cements and bonds for the fixation to non-precious alloy implant abutments that are subsequently screwed on the implants
- cements and bonds for the fixation to zirconium oxide implant abutments that are subsequently screwed on the implants
- cements and bonds for the fixation to metal alloy implant abutments that are subsequently screwed on the implants

b) for veneering (white and pink aesthetics)
- composites to individually layer
- affixing custom-made pressable ceramic crowns made of lithium disilicate
- prefabricated acrylic teeth or shells

The different individual preparation procedures of such crowns and bridges are described in detail in the corresponding Instructions for use for Pekkton® ivory.

3 Residual risks, side effects, warnings, and preventive measures

3.1 Residual risks

- Allergic reactions to materials.
- Loosening of components / of denture.
- Fracture of bridge / of denture.
- Swallowing or aspiration of fractured fragments of bridge or of denture.
- Inflammation of soft tissue.
- Plaque accumulation.

3.2 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.

3.3 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.

3.4 Preventive measures

- The product components are supplied non-sterile.
- 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

3.5 Other relevant aspect of safety, including a summary of any field safety corrective action

N/A

4 Summary of clinical evaluation and post-market clinical follow-up

4.1 Summary of clinical data related to equivalent device

See Chapter 4.4 Identification and justification of equivalent devices

4.2 Summary of clinical data from conducted investigations of the device before the CE-marking

N/A

4.3 Summary of clinical data from other sources

N/A

4.4 An overall summary of the clinical performance and safety

Description of the device

Fixed dental prostheses (FDP) are restorations securely fixed to a natural tooth or teeth, or to one or more dental implants/implant abutments, and cannot be removed by the patient. FDP comprise crowns and bridges, in which the abutment tooth or implant abutment are completely capped or encircled. FDP are mostly designed with a framework, which acts as an inner structural frame and span an edentulous area by connecting adjacent teeth or dental implants. Crown and bridges frameworks are typically bonded to the teeth and dental implant abutments using dental cements, or screwed to the dental implants. The final restoration can also be cemented extraorally on implants abutments and is then screwed on implants. The final white tooth-like appearance of the crown or bridge is given by veneering the frameworks. The polymer Pekkton® ivory where Cendres+Métaux SA (CM) is the legal manufacturer, includes the following main characteristics: the device is currently delivered in so called press-blanks or milling blanks. Pressing or milling the blank gives a crown or bridge framework, from which the dental technician manufactures the final veneered crown and/or temporary bridge with composite.

Crown and bridge frameworks and more generally FDP on natural tooth abutments or on implants are classified as class IIa medical devices according to the rules of annex VIII of the Medical Device Regulation (MDR). The polymer Pekkton® ivory does bear the CE mark since 2012. As the clinical evaluation is an ongoing process conducted throughout the life cycle of a medical device, the intention for this clinical evaluation was to gather and to update safety and performance information for the already marketed Pekkton® ivory and to adapt the clinical evaluation process resulting in the CER at hand that is in accordance with the MDR.

Identification and justification of potential equivalent device(s)

Several chemically comparable similar/equivalent devices to be used in comparable clinical indications were selected from numerous similar/equivalent devices identified. These devices confirmed that the chemical and clinical concept of the medical device under consideration is well established in the market and represents current medical practice and state of the art technologies in the manufacture of crown and bridge frameworks.

Results from medical textbooks: Current knowledge and state of the art in the medical field concerned

Considering general information on polyetherketoneketone (PEKK) provided in scientific textbooks and derived from previous clinical evaluations, it can be concluded that the main technical, clinical and material characteristics of the Pekkton® ivory represent “state of the art” technology and materials, when used as blanks for the processing of dental prostheses. Pekkton® ivory marketed by CM complies with recognized standards (e.g. ASTM F2820: Standard Specification for Polyetherketoneketone (PEKK) Polymers for Surgical Implant Applications). Although it is agreed in scientific textbooks that absolute biocompatibility is not possible and that there is a potential risk of systemic toxicity, allergic reaction, local reaction (e.g. inflammation) and other reactions (e.g. genotoxicity) for all dental materials, it is concluded that the benefits of the standard dental or medical device materials are higher than any risks resulting from the particles that may dissolve from the material.

Results from scientific publications in journals

The results obtained from clinical trial data demonstrated that Pekkton® ivory have been safely and effectively used for the treatment of patients with removable partial dentures with no serious adverse effects. The following complication was mentioned in one scientific article: fracture of cantilever bridges, which is an indication the material has not been recommended for. Based upon the appraisal of the clinical data obtained through the systematic literature review in scientific journals, it can be concluded that the clinical results support compliance of the Pekkton® ivory with the General Safety and Performance Requirements (GSPR) as set out in annex I of the MDR. Furthermore, the identified pertinent clinical data support a positive benefits-versus-risks profile of the Pekkton® ivory.

Results from post-market surveillance

It is concluded from clinical experience data (medical device vigilance) that the Pekkton® ivory have been safely used since years with a current, overall complaint rate of 0.192% in the current report period and they perform as intended with no product recalls or adverse event reports/incidences registered in the databases of Regulatory Authorities. The identified complaint data support a positive benefits-versus-risks profile for the Pekkton® ivory. The Pekkton® ivory have been safely used and performed as intended. Based upon the evaluation of these PMS data it can be concluded that these results support compliance of the Pekkton® ivory with the GSPR as especially set out in sections 1 and 8 of annex I of the MDR.

Updated complaint data are referred in Chapter 4.5

Results from publicly available safety databases

No safety issues could be identified for the Pekkton® ivory and its similar devices in the databases of Regulatory Authorities. The Pekkton® ivory have been safely used since their introduction and perform as intended with no product recalls and/or adverse event reports/incidences/recalls registered in the databases of Regulatory Authorities. Based upon the evaluation of the safety data it can be concluded that these results support compliance of the Pekkton® ivory with the GSPR as especially set out in sections 1 and 8 of annex I of the MDR.

Results from post-market clinical follow-up (PMCF)

Due to sufficient clinical data/evidence a PMCF was previously not deemed necessary. A PMCF study is still not required based on the sufficient clinical evidence and since the residual risks appears to be acceptable and not any new emerging risks are detectable. However, results from PMCF are collected annually and are integrated in the corresponding updated report.

Accuracy of product information documents

The following documents
- Instruction for Use (IFU)
- Risk management documents

were checked regarding their completeness and appropriateness in view of the scientific information and clinical data identified in this CER. In summary except for some minor adjustments in the wording relating to the indications of the IFU, all information given in the aforementioned documents are comprehensive and conform with the clinical experience data and scientific information identified in this CER.

Overall conclusion

If the evaluated clinical evidence, the scientific information and the reported potential risks are considered, a positive overall benefits-versus-risks profile can be expected for the Pekkton® ivory, provided that they are applied in accordance with their intended use, as outlined in the current IFUs. Based upon the clinical (experience) data and scientific information investigated in the course of this clinical evaluation, it is concluded that the Pekkton® ivory is conform to the General Safety and Performance Requirements (GSPR), in particular sections 1 and 8 according to annex I of the MDR, saying that:

- any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety, taking into account the generally acknowledged state of the art.
- devices shall achieve the performance intended by their manufacturer and shall be designed and manufactured in such a way that, during normal conditions of use, they are suitable for their intended purpose.
- all known and foreseeable risks, and any undesirable side-effects, shall be minimised and be acceptable when weighed against the evaluated benefits to the patient and/or user arising from the achieved performance of the device during normal conditions of use.

This conclusion is supported by the answers given to the concluding analysis questions raised prospectively in the clinical evaluation plan respectively in the clinical evaluation report. Therefore, the Pekkton® ivory can be expected to exhibit the claimed technical and medical performance, and potential undesirable clinical effects and risks are well controlled and acceptable, when weighed against their benefits in prosthodontics.

4.5 Ongoing or planned post-market clinical follow-up

Several PMCF activities were carried out: The scientific literature (PubMed) was systematically searched using search terms covering the here described Pekkton® ivory and its similar devices, feedback from users (complaint data) were collected and analyzed, and several publicly available safety databases of Regulatory Authorities (FDA MAUDE, BfArM, Swissmedic) were systematically screened. As documented in the current PMCF report, the polymer is still safe and is performing clinically as intended when applied according to the Instruction for Use. No new substantial information or risks regarding safety and clinical performance were emerged that require to initiate a clinical PMCF study. PMCF will be continued according to MDR following the current PMCF plan.

5 Possible diagnostic or therapeutic alternatives

Classical dentures with clasp fixations. Restorations produced with other materials than PEKK such as Cobalt Chrome or suitable metal alloys.

6 Suggested profile and training for users

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.

7 Reference to any standards and common specifications (CS) applied

– SN EN ISO 13485: Medical devices, Quality management systems, Requirements for Regulatory purposes
– SN EN ISO 14971: Medical devices – Application of risk management to medical devices
– SN EN ISO 15223-1: Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements
– SN EN 1041+A1: Information supplied by the manufacturer of medical devices
– SN EN ISO/IEC 17050-1: Conformity assessment – Supplier's declaration of conformity – Part 1: General requirements
– SN EN ISO/IEC 17050-1: Conformity assessment – Supplier's declaration of conformity – Part 2: Supporting documentation
– IEC 62366-1: Medical devices – Part 1: Application of usability engineering to medical devices
– IEC 62366+A1: Medical devices – Part 1: Application of usability engineering to medical devices
– SN EN ISO 17664: Processing of health care products – Information to be provided by the medical device manufacturer for the processing of medical devices
– SN EN ISO 10477: Dentistry – Polymer-based crown and veneering materials
– ASTM F2820: Standard Specification for Polyetherketoneketone (PEKK) Polymers for Surgical Implant Applications
– ASTM D638: Standard Test Method for Tensile Properties of Plastics
– ASTM D790-17: Standard Test Methods for Flexural Properties of Unreinforced and Reinforced Plastics and Electrical Insulating Materials
– ISO 7405: Dentistry – Evaluation of biocompatibility of medical devices used in dentistry
– ISO 7491: Dental materials – Determination of colour stability
– SN EN ISO 10993-1: Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
– SN EN ISO 10993-3: Biological evaluation of medical devices – Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity
– SN EN ISO 10993-5: Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity
– SN EN ISO 10993-6: Biological evaluation of medical devices. Tests for local effects after implantation
– SN EN ISO 10993-10: Biological evaluation of medical devices – Part 10: Tests for skin sensitization
– SN EN ISO 10993-11: Biological evaluation of medical devices – Part 11: Tests for systemic toxicity
– SN EN ISO 10993-12: Biological evaluation of medical devices – Part 12: Sample preparation and reference materials
– SN EN ISO 10993-18: Biological evaluation of medical devices – Part 18: Chemical characterization of medical device materials within a risk management process
– ISO 14801: Dentistry – Implants – Dynamic loading test for endosseous dental implants
– SN EN ISO 20795-1: Dentistry – Base polymers – Part 1: Denture base polymers
– SN EN ISO 20795-2: Dentistry – Base polymers – Part 2: Orthodontic base polymers
– CS: not yet available

PART B
Relevant information for the patient

This Section contains information regarding safety and clinical performance, especially relevant for patients.

N/A

PART C
Revision history

Edition	Issue date	Change description	Edition validated by notified body
1.0	06.2021	First version of SSCP for polymers	☒ Yes ☐ No Language used: english
1.0	09.2021	Inclusion of Chapter 2.8 combination products	☒ Yes ☐ No Language used: english
2.0	09.2022	Chapter 4.5 Ongoing or planned clinical post-market follow-up	☐ Yes ☒ No Language used: english
3.0	08.2023	Regular annually update with strictly editorial modifications: applied MDCG document mentioned; new authorized representative; single registration number; formulation of indications, contraindications, side effects, warnings, and preventive measures was improved without changing the meaning; completion of standard list	☐ Yes ☒ No Language used: english
4.0	08.2024	Regular annually update according to MDR with strictly editorial modifications: Ongoing, planned PMCF updated with new complaint data and with results of the various database searches including a literature search in PubMed and evaluation of the identified data.	☐ Yes ☒ No Language used: english

PART D
List of articles

EMDN code: Q010699

Device number	Product name	Class
01060003	Pekkton® ivory Press blank	IIa
01060152	Pekkton® ivory Milling blank 98.5/t12mm	IIa
01060011	Pekkton® ivory Milling blank 98.5/t16mm	IIa
01060020	Pekkton® ivory Milling blank 98.5/t20mm	IIa
01060022	Pekkton® ivory Milling blank 98.5/t24mm	IIa
01060089	Pekkton® ivory Milling blank 98.5/t28mm	IIa
01060110	Pekkton® ivory Milling blank 95/t12mm	IIa
01060028	Pekkton® ivory Milling blank 95/t16mm	IIa
01060030	Pekkton® ivory Milling blank 95/t20mm	IIa
01060131	Pekkton® ivory Milling blank 95/t25mm	IIa
01060132	Pekkton® ivory Milling blank 95/t30mm	IIa

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