CENDRES+ MÉTAUX

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Bars

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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 bars.

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.

Table of content

1 Device identification and general information

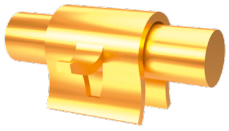
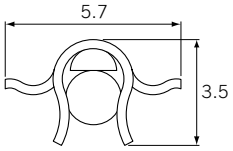
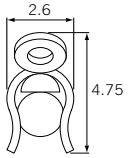
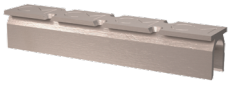
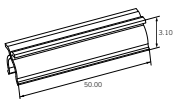
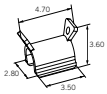
1.1 Device trade name

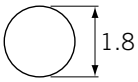
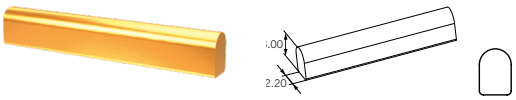
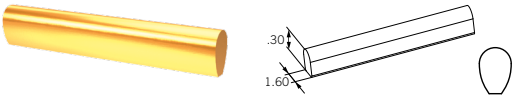
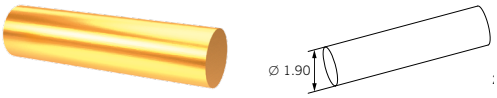
1. Ackermann-Bar
2. Dolder® bar system
3. Round bar with rider

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	Basic UDI-DI	Class of device according to Annex VIII of the Medical Device Regulation 2017/745
Female parts		
Ackermann-Bar A, female part E  Male with female part  Cross-section of male with female part and micro spacer	764016651000055E8	IIa
Ackermann-Bar B, female part E  Male with female part  Cross-section of male with female part and micro spacer	764016651000055E8	IIa
Dolder® System Female part E micro L50 **Dolder® System Female part E macro L50** **Dolder® System Female part E micro L25** **Dolder® System Female part E macro L25** 	764016651000055E8	IIa
Dolder® System Female part T micro L47.5 **Dolder® System Female part T macro L47.5** 	764016651000055E8	IIa
Dolder® System Female part D macro L50 **Dolder® System Female part D micro L50** 	764016651000055E8	IIa
Round bar with rider Female part E **Round bar with rider Female part E**  	764016651000055E8	IIa
Round bar with rider Female part E L50   	764016651000055E8	IIa

Medical device	Basic UDI-DI	Class of device according to Annex VIII of the Medical Device Regulation 2017/745
Male parts		
Ackermann-Bar Male part P3 L60 	764016651000052E2	IIb
Dolder® System Male part E macro L50 (Bar attachment) **Dolder® System Male part E micro L50 (Bar attachment)** 	764016651000052E2	IIb
Dolder® System Male part E macro L50 (Resilient bar) **Dolder® System Male part E micro L50 (Resilient bar)** 	764016651000052E2	IIb
Round bar with rider Male part P3 L200 **Round bar with rider Male part P3 L50** 	764016651000052E2	IIb

Material legend:
E=Elitor®, T=Titanium, D=Doral, P3=Protor 3

1.4 Authorised representative

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

Single registration number: NL-AR-000000537

1.5 Certificate, single registration number and notified body

Year when the first certificate was issued:	1997
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)

A bar is a prosthetic retaining element consisting of a female (outer) part and a male (inner) part. The male part is fixed on at least two anchor elements, tooth abutments and/or implants. The female part is polymerized into the removable dental prosthesis. One can distinguish between round, oval and parallel-walled bar male parts according to their cross-sectional shape. Round, and to a lesser extent oval bars, allow their bar riders to rotate around the bar axis, so that good stability is ensured and the masticatory pressure is transferred to the alveolar ridge by the rotation, thus reducing the load on the anchor elements. Parallel-walled bars, on the other hand, do not allow rotation and are selected, if at least three anchor elements are available or if purely tooth/implant-supported borne superstructures are desired.

The advantages of the bar systems:

- Primary splinting stabilizes abutment teeth.
- Primary splinting of implants increases stability and enables immediate restoration with a denture.
- Vertical forces are distributed more evenly over the abutment teeth and the implants, which protects the anchor elements and increases the service life.
- Primary splinting increases the position and stability of the denture.
- Bar splints as retentive system of implants facilitates retention on cantilevers and subsequently support in the molar region.
- Bar splints of implants allows compensation of divergent implant angulations.

2.2 Intended purpose, medical condition, anatomic locality of application

The products are intended for prosthetic restorations and to support procedures in the dental clinic or laboratory. Remaining teeth and/or inserted implants of partially or fully edentulous patients are used to attach the retaining elements. Patient population is predominantly represented by adult individuals.

2.3 Indications

Dolder® bar system, round bar with rider, and Ackermann-Bar
- Removable dental prostheses (definitely)
- Tooth and combined tooth-mucosa supported dentures.
- Implant and implant-mucosa supported dentures.

Dolder® bar attachments, and round bars
- Removable partial denture.
- Free-end removable partial denture.
- Hybrid denture.

Dolder® bar joint
- Hybrid denture.

2.4 Contraindications

- Partial denture without transversal support.
- Hybrid denture supported on a single anchor element (crown, root canal cap or implant).
- Patients who are unable to keep the regularly required check-up appointments for health reasons.
- Patients with bruxism or other para-functional habits.
- Patients with allergies to materials used in the product.
- 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)	
Article No	**Description of change**
05001125	Dolder® female parts macro first only in Elitor®, later also in Doral available
05001201	Dolder® female parts micro first only in Elitor®, later also in Doral available
054747 054746 052046 052043 05001125 05001201	Dolder® Elitor® and Dolder® Doral female parts with optimized surface treatment to improve manufacturing process
05001125	Dolder® female parts macro with optimized laser welding process to improve mechanical strength
05001201	Dolder® female parts micro with optimized laser welding process to improve mechanical strength

2.7 Description of any accessories

Available components	
N/A	N/A

Auxiliary parts	
052081	Spacer macro
052081	Spacer micro
05000559	Male parts K L75 macro (bar attachment)
05000266	Male parts K L75 micro (bar attachment)
05000563	Male parts K L75 macro (resilient bar)
05000561	Male parts K L75 micro (resilient bar)
052082	Spacer (tin) 50 x 0.60 mm
052085	Spacer (tin) 200 x 0.60 mm
055881	Male part K L75 (burn out plastic)
052080	Spacer micro (brass)

Auxiliary instruments	
070198	Activator set
070201	Deactivator macro
070200	Deactivator micro
070173	Transfer jig macro
070171	Transfer jig micro
070144	Parallelometer insert macro (bar attachment)
070143	Parallelometer insert micro (bar attachment)
072517	Parallelometer insert macro (resilient bar)
072515	Parallelometer insert micro (resilient bar)
072293	Transfer jig (for fabricating the master model)

2.8 Combination products

Fixing elements for the bar systems are diverse copings such as gold alloy abutments for soldering, plastic devices made of POM for example for casting, and gold alloy or plastic root canal posts either for attaching directly to the prefabricated cap of the posts or for casting.

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

3.1 Residual risks

- Allergic reactions to materials.
- Loosening of components / of denture.
- Fracture of denture.
- Aspiration of fractured fragments of denture.
- Inflammation of soft tissue.
- Plaque accumulation.

3.2 Side effects

- This product must not be used in patients with allergies to materials used in the product, or only after prior allergological clarification.
- Auxiliary instruments may contain nickel.
- If applied as intended, side effects can be excluded.

3.3 Warnings

Magnetic resonance (MR) environment

- The device has not been evaluated for safety and compatibility in the MR environment.
- The product has not been tested for heating or migration in the MR environment.

3.4 Preventive measures

- The product components are supplied non-sterile. For more information see Section “Reprocessing”.
- Only original tools and parts may be used for this work. For information and additional details, please contact your Cendres+Métaux SA representative.
- Before any procedure, ensure that all required product components are available in sufficient quantity.
- For your own safety, always wear suitable protective clothing. In particular when your 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 safety and clinical performance

Description of the device
Chapter 2.1

Identification and justification of potential equivalent device(s)
Several similar bar devices could be identified. In analogy to the corresponding CM bar medical devices, the similar devices of the competitors were also marketed successfully since decades. However, no clinical trial data for similar devices could be identified through the literature search in the clinical database pubmed.

Results from medical textbooks: Current knowledge and state of the art in the medical field concerned
Considering the main technical, clinical, and material characteristics of the bars manufactured by CM and the information provided in the scientific textbooks, it can be concluded that the different bars represent “state of the art” technology and materials when used as retainers for (root canal treated) abutment tooth- or implant-supported dental prostheses. Bar attachments can be used for removable dental prosthesis replacing missing teeth in edentulous spaces, free-end dentures or a combination of both, and for hybrid dentures.

Results from scientific publications in journals
The presented clinical data approve the information received from the analysis of the scientific textbooks: The prosthetic concept of a bar attachment is most widely used for removable dental prostheses supported on two or more dental implants or abutment teeth located in the interforaminal region of the mandible (although bars are also used in further indications). Additionally, the evaluated clinical data of the literature search in the clinical database pubmed confirm that all three bar systems, Dolder® bar attachment, round bar with rider, Ackermann-Bar, perform safely when used for the treatment of patients with removable dental prostheses and with no serious adverse effects and/or complications.

Results from post-market surveillance
In the 5-year report period the complaint statistic provides a low number of complaints when compared with the number of sales, respectively resulting in an overall complaint rate of 0.0356%. A similar low overall complaint rate could also be observed for the last year report period (0.0067%). This statistical result demonstrates an acceptable overall complaint rate for the bars, which is consistent with a positive zu risk-versus-benefit profile for the bars representing their clinically safe use and performance. Based upon the evaluation of these post-market surveillance data it can be concluded that these results support compliance of the bars with the General Safety and Performance requirements (GSPR), as especially set out in sections 1 and 8 of annex I of the Medical Device Regulation (MDR).

Results from updated PMS data are included in Chapter 4.5. of this document.

Results from publicly available safety databases
The bar medical devices manufactured by CM have been safely used since their introduction and perform as intended with no product recalls / adverse event reports / incidences registered in the databases of Regulatory Authorities. Based upon the evaluation of the safety data received from the databases of Regulatory Authorities (FDA, BfArM, and Swissmedic) it can be concluded that the results support compliance of the bar attachment devices with the GSPR, in particular Sections 1 and 8 according to Annex I of the MDR.

Results from post-market clinical follow-up (PMCF)
Due to sufficient clinical data / evidence a post-market clinical follow-up was previously not deemed necessary. Based on the sufficient clinical evidence and since the residual risks appears to be acceptable and not any new emerging risks are detectable, a PMCF study is still not required. Furthermore, if Paragraph 6 of Article 61 of the MDR is fulfilled for implantable devices, such as the male parts of the bars are, no clinical study is required in this case. Nevertheless, results from PMCF are collected according to the PMCF plan for the annual update of the PMCF report.

Accuracy of product information documents
It can be stated that the information given in the various documents, Instruction for Use (IFU), Risk Management documents, product catalogue are comprehensive and conform to the clinical data and scientific information identified in the CER.

Overall conclusion
If the evaluated clinical evidence, the scientific information and the reported potential risks are considered, a positive overall benefit-versus-risk profile can be expected for the bars, 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 bars fulfill the 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. Therefore, the bars 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 according to the PMCF plan were followed: Literature searches including the here described medical devices bars and their similar devices were performed, feedback from users (complaint data) were analyzed, and publicly available safety data of Regulatory Authorities were systematically screened. As documented in the PMCF report the bars are still safe and perform clinically as intended when applied according to the Instruction for Use. No new substantial information or risks regarding safety and clinical performance had emerged that require to initiate a clinical PMCF study. PMCF will be continued according to the current PMCF plan.

5 Possible diagnostic or therapeutic alternatives

Classical dentures with clasp fixations. Restorations produced with alternative attachment elements such as anchors or slide attachments.

6 Suggested profile and training for users

Patients are treated with the bars by trained health care professionals such as dentists in the dental surgery. Associated work on the prostheses is done by dental technicians in the dental laboratory.

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

- SN EN ISO 9001: Quality management systems – Requirements
- SN EN ISO 14001: Environmental Management System – Requirements with guidance for use
- 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 ISO 20417: Medical devices – Information to be supplied by the manufacturer
- SN EN ISO/IEC 17050-1: Conformity assessment - Supplier's declaration of conformity – Part 1: General requirements
- SN EN ISO/IEC 17050-2: 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
- SN EN 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
- ISO 22674: Dentistry – Metallic materials for fixed and removable restorations and appliances
- ASTM F67: Standard Specification for Unalloyed Titanium, for Surgical Implant Applications
- ISO 5832-2: Implants for surgery – Metallic materials - Part 2: Unalloyed titanium
- ISO 10271: Dentistry – Corrosion test methods for metallic materials
- ISO 7405: Dentistry – Evaluation of biocompatibility of medical devices used in dentistry
- 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 10993-10: Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization
- 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

- Common specification (CS): not yet available

PART B
Relevant information for the patient

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

Material specifications
E=Elitor®, T=Titanium, D=Doral, P3=Protor 3

Biocompatibility is a general term describing the property of a particular material being compatible with living tissue. Such biocompatible materials do not produce a toxic or immunological response when exposed to the body or its body fluids enabling a safe application as medical devices in humans. The terms E and P3 are used by Cendres+Métaux SA as abbreviations for two biocompatible gold alloys, Elitor® and Protor 3, D for the biocompatible silver alloy Doral. T is the abbreviation for titanium, which is a pure material composed of this particular chemical element. Analogous to the other 3 mentioned biocompatible alloys, titanium comprises of the same biological features. These 4 materials comply with the Standard ISO 10993-1, which regulates the biological evaluation of medical devices.

PART C
Revision history

Edition	Issue date	Change description	Edition validated by notified body
01	11.2022	First version of SSCP for bars	☐ Yes ☒ No Language used: english
02	11.2023	Regular annually update with strictly editorial modifications: authorized representative, adaption of title 3, adaption of chapter 4.5 ongoing or planned PMCF according to the PMCF plan, nomenclature description of bars and EMDN codes added	☒ Yes ☐ No Language used: english
03	11.2024	Regular annually update according to MDR with strictly editorial modifications: adaption of Chapter 4.5 ongoing or planned PMCF according to the PMCF plan.	☐ Yes ☒ No Language used: engllish

PART D
List of articles

EMDN codes of bar devices

- Female parts: Q010299; Prosthetic dentistry devices - other
- Male parts: Q010299; Prosthetic dentistry devices - other

Device number	Product name	Class
05050010	Ackermann-Bar A Female part E	IIa
05050011	Ackermann-Bar B Female part E	IIa
052043	Dolder® System Female part E micro L50	IIa
052046	Dolder® System Female part E macro L50	IIa
054746	Dolder® System Female part E micro L25	IIa
054747	Dolder® System Female part E macro L25	IIa
05000680	Dolder® System Female part T micro L47.5	IIa
05000681	Dolder® System Female part T macro L47.5	IIa
05001125	Dolder® System Female part D macro L50	IIa
05001201	Dolder® System Female part D micro L50	IIa
050527	Round bar with rider Female part E	IIa
055801	Round bar with rider Female part E	IIa
05000679	Round bar with rider Female part E L50	IIa
05050014	Ackermann-Bar Male part P3 L60	IIb
052053	Dolder® System Male part E macro L50 (Bar attachment)	IIb
052057	Dolder® System Male part E micro L50 (Resilient bar)	IIb
052061	Dolder® System Male part E macro L50 (Resilient bar)	IIb
05000289	Dolder® System Male part E micro L50 (Bar attachment)	IIb
052028	Round bar with rider Male part P3 L200	IIb
052030	Round bar with rider Male part P3 L50	IIb

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