

prosthetic.line

Root canal posts and anchors

EN

Summary of Safety and Clinical Performance

English

2

Doc. ID: 249262-000-03

Issue date: 11.2024

Based on: FO 7.255 / V02

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 root canal posts and anchors.

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

	Preface	2
1	Device identification and general information	4
1.1	Device trade name	4
1.2	Manufacturer name and address	4
1.3	Medical device description, basic UDI-DI, classification	4
1.4	Authorised representative	7
1.5	Certificate, single registration number and notified body	7
PART A		
Information for user and medical experts		
2	Device description	7
2.1	Description of the device group (key functions, design characteristics, materials with body contact)	7
2.2	Intended purpose, medical condition, anatomic locality of application	7
2.3	Indications	8
2.4	Contraindications	8
2.5	Affected articles	8
2.6	Reference and description of variants and previous generations	8
2.7	Description of any accessories	9
2.8	Combination products	9
3	Residual risks, side effects, warnings, and preventive measures	10
3.1	Residual risks	10
3.2	Side effects	10
3.3	Warnings	10
3.4	Preventive measures	10
3.5	Other relevant aspect of safety, including a summary of any field safety corrective action	10
4	Summary of clinical evaluation and post-market clinical follow-up	10
4.1	Summary of clinical data related to equivalent device	10
4.2	Summary of clinical data from conducted investigations of the device before the CE-marking	10
4.3	Summary of clinical data from other sources	10
4.4	An overall summary of the safety and clinical performance	11
4.5	Ongoing or planned post-market clinical follow-up	12
5	Possible diagnostic or therapeutic alternatives	12
6	Suggested profile and training for users	12
7	Reference to any standards and common specifications (CS) applied	12

PART B

Relevant information for the patient

PART C

Revision history

PART D

List of articles

1 Device identification and general information

1.1 Device trade name

Root canal posts:

1. root canal post Mooser
2. CM root canal post
3. MP-Post

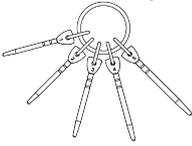
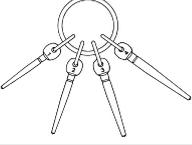
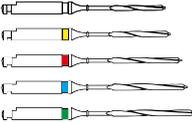
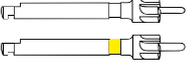
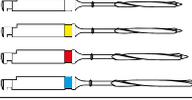
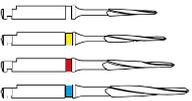
Root canal anchors:

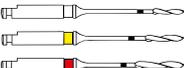
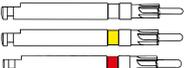
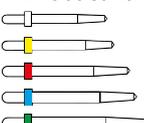
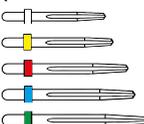
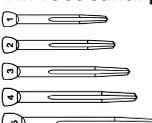
1. Dalbo®-Rotex according to Dr. Dalla Bona
2. Dalbo®-Rotex according to Prof. Brunner
3. Rotex
4. Rotex-RD

1.2 Manufacturer name and address

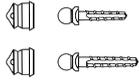
Cendres+Métaux SA
Rue de Boujean 122
CH-2501 Biel/Bienne

1.3 Medical device description, basic UDI-DI, classification

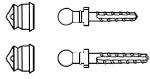
Medical device	Basic UDI-DI	Class of device according to Annex VIII of the Medical Device Regulation 2017/745
CM root canal posts Post gauge Post size 1-5 	764016651000061E3	Ila
Root canal posts Mooser Post gauge Post size 1-4 	764016651000061E3	Ila
CM root canal posts Root canal drill (White) Post size 1 CM root canal posts Root canal drill (Yellow) Post size 2 CM root canal posts Root canal drill (Red) Post size 3 CM root canal posts Root canal drill (Blue) Post size 4 CM root canal posts Root canal drill (Green) Post size 5 	764016651000060DZ	Ila
Dalbo®-Rotex by Dr. Dalla Bona Face cutting drill (White) Anchor size 1 Dalbo®-Rotex by Prof. Brunner Face cutting drill (Yellow) Anchor size 2 Dalbo®-Rotex by Dr. Dalla Bona Face cutting drill (Yellow) Anchor size 2 	764016651000060DZ	Ila
Root canal posts Mooser Root canal drill (White) Post size 1 Root canal posts Mooser Root canal drill (Yellow) Post size 2 Root canal posts Mooser Root canal drill (Red) Post size 3 Root canal posts Mooser Root canal drill (Blue) Post size 4 	764016651000060DZ	Ila
Root canal posts Mooser Pilot reamer (White) Post size 1 Root canal posts Mooser Pilot reamer (Yellow) Post size 2 Root canal posts Mooser Pilot reamer (Red) Post size 3 Root canal posts Mooser Pilot reamer (Blue) Post size 4 	764016651000060DZ	Ila
MP-Post MP root canal drill 	764016651000060DZ	Ila

MP-Post MP auxiliary drill 	764016651000060DZ	Ila
MP-Post root canal drill yellow Size 1 MP-Post root canal drill red Size 2 MP-Post root canal drill blue Size 3 MP-Post root canal drill green Size 4 	764016651000060DZ	Ila
Rotex / Dalbo®-Rotex Face cutting drill (White) Anchor size 1 	764016651000060DZ	Ila
Rotex Face cutting drill (Yellow) Anchor size 2 	764016651000060DZ	Ila
Rotex Face cutting drill (Red) Anchor size 3 	764016651000060DZ	Ila
Rotex / Rotex-RD / Dalbo®-Rotex Root canal drill (White) Anchor size 1 Rotex / Rotex-RD / Dalbo®-Rotex Root canal drill (Yellow) Anchor size 2 Rotex / Rotex-RD Root canal drill (Red) Anchor size 3 	764016651000060DZ	Ila
Rotex-RD Face cutting drill (White) Anchor size 1 Rotex-RD Face cutting drill (Yellow) Anchor size 2 Rotex-RD Face cutting drill (Red) Anchor size 3 	764016651000060DZ	Ila
CM root canal post Adhesive head C (Size 1) CM root canal post Adhesive head C (Size 2) CM root canal post Adhesive head C (Size 3) CM root canal post Adhesive head C (Size 4) CM root canal post Adhesive head C (Size 5) 	764016651000048EB	Ila
CM root canal post Adhesive head C (Size 1) (with cement flow-off groove) CM root canal post Adhesive head C (Size 2) (with cement flow-off groove) CM root canal post Adhesive head C (Size 3) (with cement flow-off groove) CM root canal post Adhesive head C (Size 4) (with cement flow-off groove) CM root canal post Adhesive head C (Size 5) (with cement flow-off groove) 	764016651000048EB	Ila
CM root canal post Flat head T (Size 1) (with cement flow-off groove) CM root canal post Flat head T (Size 2) (with cement flow-off groove) CM root canal post Flat head T (Size 3) (with cement flow-off groove) CM root canal post Flat head T (Size 4) (with cement flow-off groove) CM root canal post Flat head T (Size 5) (with cement flow-off groove) 	764016651000048EB	Ila

Dalbo®-Rotex GT (Size 1) by Dr. Dalla Bona 764016651000049ED Ila
Dalbo®-Rotex GT (Size 2) by Dr. Dalla Bona



Dalbo®-Rotex GT (Size 1) by Prof. Brunner 764016651000049ED Ila
Dalbo®-Rotex GT (Size 2) by Prof. Brunner



Dalbo®-Rotex by Dr. Dalla Bona Male part T (Size 1) 764016651000049ED Ila
Dalbo®-Rotex by Dr. Dalla Bona Male part T (Size 2)



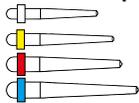
Dalbo®-Rotex by Prof. Brunner Male part T (Size 1) 764016651000049ED Ila
Dalbo®-Rotex by Prof. Brunner Male part T (Size 2)



Dalbo®-Rotex Introduction set (Brunner/Dalla Bona) 764016651000059EG Ila



Root canal post Mooser Adhesive head C (Size 1) 764016651000048EB Ila
Root canal post Mooser Adhesive head C (Size 2)
Root canal post Mooser Adhesive head C (Size 3)
Root canal post Mooser Adhesive head C (Size 4)



Root canal post Mooser Flat head T (Size 1) 764016651000048EB Ila
Root canal post Mooser Flat head T (Size 2)
Root canal post Mooser Flat head T (Size 3)
Root canal post Mooser Flat head T (Size 4)



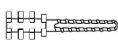
Rotex T Size 1 764016651000049ED Ila



Rotex T Size 2 764016651000049ED Ila



Rotex T Size 3 764016651000049ED Ila



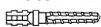
Rotex Introduction set 764016651000059EG Ila



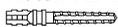
Rotex-RD T Size 1 764016651000049ED Ila



Rotex-RD T Size 2 764016651000049ED Ila



Rotex-RD T Size 3 764016651000049ED Ila



Rotex-RD Introduction set

764016651000059EG

IIa

**Dalbo®-Rotex Female part G**

764016651000063E7

IIa

**MP-Post X yellow Size 1**

764016651000066ED

IIa

MP-Post X red Size 2**MP-Post X blue Size 3****MP-Post X green Size 4**

Material legend:

C=Ceramicor® (precious gold alloy)

T=titanium

X=stainless steel

G=Galak (Grilamid L 20 G: a polyamide polymer)

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:	1998
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)**

Root canal posts are available in different materials. With high-quality in precious metal casted post copings (root canal caps) are manufactured to accommodate retentive elements, posts for composite resin build-ups, or cast post build-ups, post crowns and bridges. Burn-out root canal posts allow for cost-effective solutions. Root canal anchors with self-tapping thread are used for the reconstruction of endodontically treated teeth. Once a tooth with severely reduced coronal tooth substance, e.g. destroyed by caries, is subjected to root canal treatment, only little of the original tooth structure usually remains. To compensate for the lost substance, the post-endodontic coronal build-up is anchored in the interradicular post-space by a post construction. While root canal posts are usually only cemented in the prepared post space of the remaining teeth, root canal anchors are screwed and cemented. The root canal post or anchor elements serve as attachments such as posts for composite resin build-ups, cast post build-ups, post crowns, casted post copings with retentive elements or direct retentive elements to retain removable dental prostheses. The root canal anchor combined with the Dalbo® ball anchorage enables the fixation of removable dental prostheses (hybrid and partial dentures). Such dental prostheses contain female elements (matrices) embedded in the polymer of the denture to firmly attach the prostheses to the root canal posts or anchors with a ball anchorage associated to the remaining teeth.

The advantages of the root canal posts and anchors:

- Decades of clinical experience.
- Manufactured from the high-quality materials precious metal Ceramicor® and pure titanium.
- Optimally matched, standardized preparation instruments for a high level of occupational safety and durability of the reconstruction.
- Draining grooves for cement allow stress-free cementing.

2.2 Intended purpose, medical condition, anatomic locality of application

The components are intended for use for prosthetic restoration on natural teeth and to support procedures in the dental clinic or laboratory.

2.3 Indications**Rotex / Rotex-RD**

- Direct abutments.
- Larger fillings with amalgam or composite resin materials.

Dalbo®-Rotex

- Retention of removable partial dentures (hybrid or partial dentures).

Root canal posts

- These products are inserted into the tooth root if the dental crown is largely destroyed. They are intended for providing retention for posts for composite resin build-ups, or cast post build-ups, in the context of endodontic treatment.
- Post crowns.
- Casted post copings with retentive elements to retain removable dental prostheses.
- Direct retentive elements to retain removable dental prostheses.

2.4 Contraindications**Root canal posts and anchors**

- If a snug fit root canal preparation is not possible in the case of a very large root canal.
- In the case of very thin-walled and/or brittle roots.
- Periodontitis, severe gum disease, poor oral hygiene, caries and marginal inter-occlusal space.
- 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.

Root canal posts

- The titanium and steel root canal posts are not suitable for final restoration due to the geometry of the post head (flat head).

2.5 Affected articles

N/A

2.6 Reference and description of variants and previous generations**Variants**

N/A

Previous generations (inclusive justification of change)

Article No	Description of change
072326	CM root canal posts Root canal drill (White) Post size 1
072321	CM root canal posts Root canal drill (Yellow) Post size 2
072327	CM root canal posts Root canal drill (Red) Post size 3
072328	CM root canal posts Root canal drill (Blue) Post size 4
072329	CM root canal posts Root canal drill (Green) Post size 5
072314	Root canal posts Mooser Pilot reamer (White) Post size 1
072315	Root canal posts Mooser Pilot reamer (Yellow) Post size 2
072316	Root canal posts Mooser Pilot reamer (Red) Post size 3
072317	Root canal posts Mooser Pilot reamer (Blue) Post size 4
070499	Dalbo®-Rotex by Dr. DALLA BONA Face cutting drill (White) Anchor size 1
072474	Dalbo®-Rotex by Dr. DALLA BONA Face cutting drill (Yellow) Anchor size 2
070295	Rotex / Dalbo®-Rotex Face cutting drill (White) Anchor size 1
072473	Dalbo®-Rotex by Prof. BRUNNER Face cutting drill (Yellow) Anchor size 2
070380	Rotex / Rotex-RD / Dalbo®-Rotex Root canal drill (White) Anchor size 1
070381	Rotex / Rotex-RD / Dalbo®-Rotex Root canal drill (Yellow) Anchor size 2
070382	Rotex / Rotex-RD Root canal drill (Red) Anchor size 3
070296	Rotex Face cutting drill (Yellow) Anchor size 2
070297	Rotex Face cutting drill (Red) Anchor size 3
072470	Rotex-RD Face cutting drill (White) Anchor size 1
072471	Rotex-RD Face cutting drill (Yellow) Anchor size 2
072472	Rotex-RD Face cutting drill (Red) Anchor size 3
MD.200004441	MP-Post root canal drill yellow Size 1
MD.200004447	MP-Post root canal drill red Size 2
MD.200004451	MP-Post root canal drill blue Size 3
MD.200004455	MP-Post root canal drill green Size 4
MD.200004436	MP-Post MP root canal drill
MD.200004442	MP-Post MP auxiliary drill

Change from single use instruments to multiple use instruments

Previous generations (inclusive justification of change)	
Article No	Description of change
MD.200004301	MP-Post X yellow Size 1
MD.200004310	MP-Post X red Size 2
MD.200004319	MP-Post X blue Size 3
MD.200004328	MP-Post X green Size 4
MD.200004441	MP-Post root canal drill yellow Size 1
MD.200004447	MP-Post root canal drill red Size 2
MD.200004451	MP-Post root canal drill blue Size 3
MD.200004455	MP-Post root canal drill green Size 4
MD.200004436	MP-Post MP root canal drill
MD.200004442	MP-Post MP auxiliary drill

Material change: from Sandvik 4C27 A stainless steel to the almost identical 1.4197 stainless steel

2.7 Description of any accessories

Available components	
051511	Dalbo®-B female part E

Auxiliary parts	
08000003	Root canal posts Mooser Endobox
070440	Spacer G
070511	Transfer Jig
070512	
08000002	Endobox Rotex / Rotex-RD / Dalbo®-Rotex

Auxiliary instruments	
070221	Thomas spanner key
072414	Coupling piece
070498	Spanner key for spherical head
070500	
070205	Instrument for mounting of elastomeric ring
070197	Activator
070199	Deactivator
070301	Spanner key (White) Anchor size 1
070302	Spanner key (Yellow) Anchor size 2
070303	Spanner key (Red) Anchor size 3

2.8 Combination products

The following combination products are usually used together with the root canal post and anchor products on remaining, prepared teeth:

Products	Root canal post	Root canal anchor	Root canal anchor with prosthetic retainer
cements for the fixation of the root canal posts and anchors	X	X	X
composite for the modelling of direct cores and larger fillings		X	
amalgam for the modelling of direct cores and larger fillings (rather seldom)		X	
composite for the modelling of additions			X
wax or modeling resin for the modelling of cast cores, post crowns, crowns, or bridges	X		
investment material for the cast-on technique	X		
dental alloys for cast cores, post crowns, crowns, or bridges	X		
impression materials for the impression in the mouth	X		
model material , plaster or resin (e.g. Polyurock)	X		
Dalbo® female parts (Dalbo® G, Dalbo®-B, Dalbo®-Classic and Dalbo®-PLUS for the connection with the prosthesis.)			X

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 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

- Only original tools and parts may be used for this work.
- The product components are supplied non-sterile.
- 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.
- Do not clean any cutting instruments in the ultrasonic cleaner as this could blunt the instruments.
- Avoid high pressures, tilting or leverage to prevent the risk of instrument fracture.
- The root canal instruments should be used a maximum of 10 times only.
- Products made of titanium are not suitable for casting.

Root canal anchors

- Dalbo®-Rotex; as a preventive measure to protect against secondary caries, the root surface must receive a fluoride treatment at regular intervals.

Root canal posts

- The root canal posts must not be exchanged (even with identical shapes and sizes). Changes of position may be the result.
- The colour-coded plastic rings on the root canal posts must be removed before impression-taking.
- Ceramicor® is a non-oxidizing gold-platinum alloy and is suitable for casting with all precious metal alloys.
- Ceramicor® is not suitable for casting with non-precious alloys.
- The castable root canal post in Ceramicor® precious metal alloys are not suitable for firing ceramic.
- Products made of steel are not suitable for casting.

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

Once a tooth with severely reduced coronal tooth substance, e.g. destroyed by caries, is subjected to root canal treatment, only little of the original tooth structure usually remains. To compensate for the lost substance, the post-endodontic coronal build-up is anchored in the interradicular post-space by a post construction. The inserted post with the coronal build-up provides sufficient retention for a fixed dental prosthesis (i.e. crowns and bridges). While root canal posts are usually only cemented in the prepared post space of the remaining teeth, root canal anchors are screwed and cemented. The root canal post or anchor elements serve as attachments such as posts for composite resin build-ups, cast post build-ups, post crowns, casted post copings with retentive elements or direct retentive elements to retain removable dental prostheses. The root canal anchor combined with the Dalbo® ball anchorage enables the fixation of removable dental prostheses (hybrid and partial dentures). Such dental prostheses contain female elements (matrices) embedded in the polymer of the denture to firmly attach the prostheses to the root canal posts or anchors with a ball anchorage associated to the remaining teeth.

The advantages of the root canal posts and anchors:

- Decades of clinical experience.
- Manufactured from the high-quality materials precious metal Ceramcor® and pure titanium.
- Optimally matched, standardized preparation instruments for a high level of occupational safety and durability of the reconstruction.
- Draining grooves for cement allow stress-free cementing.

Identification and justification of potential equivalent device(s)

Several similar root canal post and anchor devices could be identified. Analogous to the corresponding Cendres+Métaux SA (CM) root canal post and anchor medical devices, the similar devices of the competitors were also marketed successfully since decades. For one similar device, the radix system, clinical trial data were available demonstrating sufficiently the safety and clinical performance of this device. Since the similarity between different root canal posts and anchors is very close, it can be assumed that the results evaluated for the radix root canal posts are also applicable to the other individual root canal post and anchor devices.

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 root canal posts and anchors manufactured by CM and the information provided in the evaluated scientific textbooks and further documents, it can be concluded that the root canal posts and anchors (and included instruments) represent "state of the art" technologies and materials when used as retainers for anchoring a definitive prosthetic restoration (single crown, partial denture, overdenture). Root pins are usually made from metallic such as gold-alloy, titanium, stainless steel, and non-metallic materials such as (glass-)fiber reinforced composites or ceramics (zirconium dioxide = zirconia). Although it is agreed in scientific textbooks that absolute biocompatibility does not exist and there is a potential risk of systemic toxicity, allergic reaction, local reaction (e.g. inflammation) and other reactions (e.g. genotoxicity) for any dental material, it can be 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

Although no clinical data were available for all types of root canal posts and anchors, it can be assumed that similar successful clinical data as were sufficiently obtained for the Dalbo®-Rotex root canal anchor can be expected for the non-investigated root canal posts and anchors. Based upon the appraisal of the clinical data obtained through a systematic literature review in scientific journals, it can be concluded that the results support compliance of the root canal posts and anchors with the General Safety and Performance Requirements (GSPR) of the Medical Device Regulation (MDR). Furthermore, the identified pertinent clinical data support a positive benefits-versus-risks profile of the investigated medical devices.

Results from post-market surveillance (PMS)

In the 5-year report period the complaint statistic provides a low number of complaints when compared with the number of sales resulting in an overall complaint rate of 0.0155%. A similar low overall complaint rate could also be observed for the last year report period (0.0275%). Both statistical results demonstrate an acceptable overall complaint rate for the root canal post and anchor devices, which is consistent with a positive benefits-versus-risks profile and represent their clinically safe use and performance. Based upon the evaluation of these PMS data it can be concluded that these results support compliance of the root canal posts and anchors with the GSPR as especially set out in sections 1 and 8 of annex I of the MDR.

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

Results from publicly available safety databases

The root canal post and anchor medical devices manufactured by CM have been safely used since their introduction and perform as intended with no relevant 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 these medical 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 PMCF 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 root canal post and anchor devices, no clinical study is required in this case. However, 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 summarized that the information given in the various documents, the Instruction for Use (IFU), the Risk Management documents, and the product catalogue are comprehensive and conform to the clinical data and scientific information identified in the CER. The wording of the IFU was improved.

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 root canal posts and anchors, 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 root canal posts and anchors 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 and answered in the current CER. Therefore, the root canal posts and anchors 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 root canal posts and anchors 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 root canal posts and anchors 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

In contrast to alternative treatment options of partially edentulous or fully edentulous patients with dental clasps, partial or full dentures, prostheses attached by the root canal post and anchor devices are mechanically more stable anchored and can restore to a significant degree chewing function.

6 Suggested profile and training for users

The expertise of a professional dentist or dental technician is required. The current IFU 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 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
 - ASTM B348: Standard Specification for Titanium and Titanium Alloy Bars and Billets
 - ASTM F899-19: Standard Specification for Wrought Stainless Steels for Surgical Instruments
 - SN EN ISO 7153-1: Surgical instruments – Materials – Part 1: Metals
 - SN EN ISO 1797: Dentistry – Shanks for rotary and oscillating instruments
 - ISO 10271: Dentistry – Corrosion test methods for metallic materials
 - ISO 7405: Dentistry – Evaluation of biocompatibility of medical devices used in dentistry
 - ISO 10993-1: Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
 - 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.

The materials selected for the production of the different root canal post and anchor devices were carefully selected and intensely tested for biocompatibility according to harmonized standards. Biocompatibility is a general term describing the compatibility with living tissue. Such materials do not produce a toxic or immunological response (inflammation, allergy) when exposed to the human body or body fluids. The biocompatible materials used for the root canal posts and anchors were Ceramicor[®], which is a precious gold alloy, pure titanium, stainless steel and the plastic Grilamid, which is a polyamide polymer. The gold alloy Cermaicor[®] consists of the chemical element gold or aurum (Au=60%), palladium (Pd=20%), platinum (Pt=19%), and iridium (Ir=1%). In the context of the Ceramicor[®] gold alloy, these individual chemical components are highly corrosion resistant and hence do not release toxic substances in contact with liquids such as human blood. The same is also true for the metal stainless steel and especially for pure titanium. The plastic Grilamid is part of the removable dental prosthesis and is embedded in the polymer of the denture.

PART C

Revision history

Edition	Issue date	Change description	Edition validated by notified body
01	11.2022	First version of SSCP for root canal posts and anchors	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> 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 report	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> 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.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No Language used: english

PART D

List of articles

EMDN codes:

Female parts: Q010299 – Prosthetic dentistry devices - other

Root canal gauges: Q010199 – Conservative dentistry and endodontic devices – other

Root canal mechanic instruments: L159004 – Endodontic rasps and files, reusable

Root canal posts and anchors: Q01010203 – Dental cones

Device number	Product name	Class
070481	CM root canal posts Post gauge Post size 1-5	Ila
070483	Root canal posts Mooser Post gauge Post size 1-4	Ila
072326	CM root canal posts Root canal drill (White) Post size 1	Ila
072321	CM root canal posts Root canal drill (Yellow) Post size 2	Ila
072327	CM root canal posts Root canal drill (Red) Post size 3	Ila
072328	CM root canal posts Root canal drill (Blue) Post size 4	Ila
072329	CM root canal posts Root canal drill (Green) Post size 5	Ila
070499	Dalbo [®] -Rotex by Dr. Dalla Bona Face cutting drill (White) Anchor size 1	Ila
072473	Dalbo [®] -Rotex by Prof. Brunner Face cutting drill (Yellow) Anchor size 2	Ila
072474	Dalbo [®] -Rotex by Dr. Dalla Bona Face cutting drill (Yellow) Anchor size 2	Ila
072310	Root canal posts Mooser Root canal drill (White) Post size 1	Ila
072311	Root canal posts Mooser Root canal drill (Yellow) Post size 2	Ila
072312	Root canal posts Mooser Root canal drill (Red) Post size 3	Ila
072313	Root canal posts Mooser Root canal drill (Blue) Post size 4	Ila
072314	Root canal posts Mooser Pilot reamer (White) Post size 1	Ila
072315	Root canal posts Mooser Pilot reamer (Yellow) Post size 2	Ila
072316	Root canal posts Mooser Pilot reamer (Red) Post size 3	Ila
072317	Root canal posts Mooser Pilot reamer (Blue) Post size 4	Ila
MD.200004436	MP-Post MP root canal drill	Ila
MD.200004442	MP-Post MP auxiliary drill	Ila

MD.200004441	MP-Post root canal drill yellow Size 1	Ila
MD.200004447	MP-Post root canal drill red Size 2	Ila
MD.200004451	MP-Post root canal drill blue Size 3	Ila
MD.200004455	MP-Post root canal drill green Size 4	Ila
070295	Rotex / Dalbo®-Rotex Face cutting drill (White) Anchor size 1	Ila
070296	Rotex Face cutting drill (Yellow) Anchor size 2	Ila
070297	Rotex Face cutting drill (Red) Anchor size 3	Ila
070380	Rotex / Rotex-RD / Dalbo®-Rotex Root canal drill (White) Anchor size 1	Ila
070381	Rotex / Rotex-RD / Dalbo®-Rotex Root canal drill (Yellow) Anchor size 2	Ila
070382	Rotex / Rotex-RD Root canal drill (Red) Anchor size 3	Ila
072470	Rotex-RD Face cutting drill (White) Anchor size 1	Ila
072471	Rotex-RD Face cutting drill (Yellow) Anchor size 2	Ila
072472	Rotex-RD Face cutting drill (Red) Anchor size 3	Ila
05003194	CM root canal post Adhesive head C (Size 1)	Ila
05003195	CM root canal post Adhesive head C (Size 2)	Ila
05003202	CM root canal post Adhesive head C (Size 3)	Ila
05003210	CM root canal post Adhesive head C (Size 4)	Ila
05003211	CM root canal post Adhesive head C (Size 5)	Ila
05003219	CM root canal post Adhesive head C (Size 1) (with cement flow-off groove)	Ila
05003226	CM root canal post Adhesive head C (Size 2) (with cement flow-off groove)	Ila
05003234	CM root canal post Adhesive head C (Size 3) (with cement flow-off groove)	Ila
05003242	CM root canal post Adhesive head C (Size 4) (with cement flow-off groove)	Ila
05003250	CM root canal post Adhesive head C (Size 5) (with cement flow-off groove)	Ila
05003584	CM root canal post Flat head T (Size 1) (with cement flow-off groove)	Ila
05003585	CM root canal post Flat head T (Size 2) (with cement flow-off groove)	Ila
05003586	CM root canal post Flat head T (Size 3) (with cement flow-off groove)	Ila
05003587	CM root canal post Flat head T (Size 4) (with cement flow-off groove)	Ila
05003588	CM root canal post Flat head T (Size 5) (with cement flow-off groove)	Ila
051864	Dalbo®-Rotex GT (Size 1) by Dr. Dalla Bona	Ila
051865	Dalbo®-Rotex GT (Size 2) by Dr. Dalla Bona	Ila
051866	Dalbo®-Rotex GT (Size 1) by Prof. Brunner	Ila
051867	Dalbo®-Rotex GT (Size 2) by Prof. Brunner	Ila
051869	Dalbo®-Rotex by Dr. Dalla Bona Male part T (Size 1)	Ila
051870	Dalbo®-Rotex by Dr. Dalla Bona Male part T (Size 2)	Ila
051871	Dalbo®-Rotex by Prof. Brunner Male part T (Size 1)	Ila
051872	Dalbo®-Rotex by Prof. Brunner Male part T (Size 2)	Ila
051904	Dalbo®-Rotex Introduction set (Brunner/Dalla Bona)	Ila
05003505	Root canal post Mooser Adhesive head C (Size 1)	Ila
05003506	Root canal post Mooser Adhesive head C (Size 2)	Ila
05003507	Root canal post Mooser Adhesive head C (Size 3)	Ila
05003509	Root canal post Mooser Adhesive head C (Size 4)	Ila
05003589	Root canal post Mooser Flat head T (Size 1)	Ila
05003590	Root canal post Mooser Flat head T (Size 2)	Ila
05003591	Root canal post Mooser Flat head T (Size 3)	Ila
05003592	Root canal post Mooser Flat head T (Size 4)	Ila
051289	Rotex T Size 1	Ila
051290	Rotex T Size 2	Ila
051291	Rotex T Size 3	Ila
051497	Rotex Introduction set	Ila
055195	Rotex-RD T Size 1	Ila
055196	Rotex-RD T Size 2	Ila
055197	Rotex-RD T Size 3	Ila
055236	Rotex-RD Introduction set	Ila
051868	Dalbo®-Rotex Female part G	Ila
MD.200004301	MP-Post X yellow Size 1	Ila
MD.200004310	MP-Post X red Size 2	Ila
MD.200004319	MP-Post X blue Size 3	Ila
MD.200004328	MP-Post X green Size 4	Ila