

prosthetic.line

Slide attachments

EN

Summary of Safety and Clinical Performance

English

2

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 slide attachments.

This short report is a summary of information regarding safety and clinical performance of the slide attachments.

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

For product names of slide attachments see Chapter 1.3

1.2 Manufacturer name and address

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

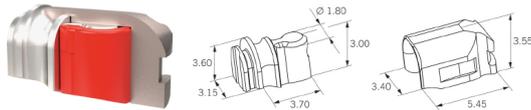
1.3 Medical device description, basic UDI-DI, classification

Medical device	Basic UDI-DI	Class of device according to Annex VIII of the Medical Device Regulation 2017/745
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M-SG® Star 1: Adjustable, extracoronary friction-retained slide attachment

Male part:
764016651000051DY

Ila



Female part:
764016651000067EF

Male parts:

- male part C for casting-on
- male part K (burn-out plastic)

Female parts:

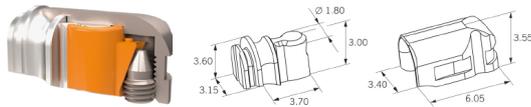
- female part T (for bonding or polymerization)
- female part M (for bonding, lasering, soldering or polymerization)

4 different friction inserts G

M-SG® Star 2: Screw-activated, extracoronary friction-retained slide attachment

Male part:
764016651000051DY

Ila



Female part:
764016651000067EF

Male parts:

- male part C for casting-on
- male part K (burn-out plastic)

Female parts:

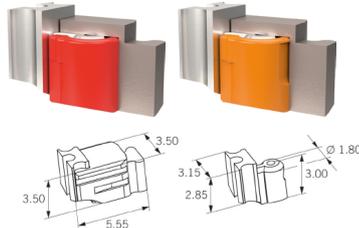
- female part T (for bonding or polymerization)

2 different friction inserts G

Mini-SG® F/R: Extracoronary friction-grip/retention-grip slide attachment, activatable

Male part:
764016651000051DY

Ila



Female part:
764016651000067EF

Male parts:

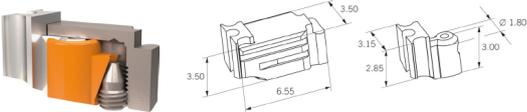
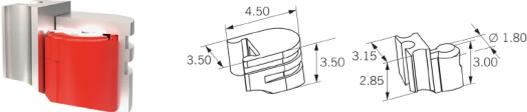
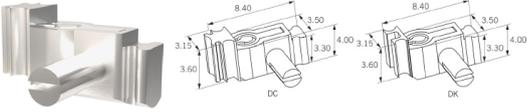
- male part V (cast-on)
- male part C (cast-on)
- male part K (burn-out plastic)

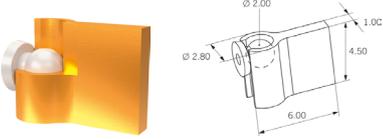
Female parts:

- female part T (for bonding or polymerization)
- female part C (for soldering or cast-on)
- tuning female part E (additional friction levels possible)

4 different friction inserts G

2 different retention inserts G

Medical device	Basic UDI-DI	Class of device according to Annex VIII of the Medical Device Regulation 2017/745
<p>Mini-SG® PLUS: Extracoronary screw-activated, slide attachment</p>  <p>Male parts:</p> <ul style="list-style-type: none"> - male part V (cast-on) - male part K (burn-out plastic) <p>Female parts:</p> <ul style="list-style-type: none"> - female part T <p>2 different friction inserts G</p> <p>1 Activating screw T</p>	<p>Male part: 764016651000051DY</p> <p>Female part: 764016651000067EF</p>	<p>Ila</p>
<p>Mini-SG®: Extracoronary adjustable friction-grip attachment</p>  <p>Male parts:</p> <ul style="list-style-type: none"> - male part C (cast-on) - male part K (burn-out plastic) <p>Female parts:</p> <ul style="list-style-type: none"> - female part D (for polymerization) - female part X and M (for soldering and polymerization) - tuning female part E (additional friction levels possible) <p>4 different friction inserts G</p>	<p>Male part: 764016651000051DY</p> <p>Female part: 764016651000067EF</p>	<p>Ila</p>
<p>SG® Slide attachment: Extracoronary adjustable friction-grip attachment</p>  <p>Male parts:</p> <ul style="list-style-type: none"> - male part C (cast-on) - male part K (burn-out plastic) <p>Female parts:</p> <ul style="list-style-type: none"> - female part D (for bonding or polymerization) <p>1 activating screw O</p> <p>1 Mounting screw X</p> <p>2 different friction inserts G</p>	<p>Male part: 764016651000051DY</p> <p>Female part: 764016651000067EF</p>	<p>Ila</p>
<p>Mini-Dalbo®: Extracoronary adjustable hinge attachment with rotation</p>  <p>Male parts:</p> <ul style="list-style-type: none"> - male part C (for soldering or cast-on with all precious metal alloys) - male part K (burn-out plastic) <p>Female parts:</p> <ul style="list-style-type: none"> - female part E (for polymerization) - female part D (for polymerization) 	<p>Male part: 764016651000051DY</p> <p>Female part: 764016651000067EF</p>	<p>Ila</p>

Medical device	Basic UDI-DI	Class of device according to Annex VIII of the Medical Device Regulation 2017/745
Tecnoroch: Extracoronar adjustable hinge attachment with rotation 	Female part: 764016651000067EF	Ila
Male parts: - male part K (burn-out plastic)		
Female parts: - female part E (for bonding, soldering or polymerization)		

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:	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)

A slide attachment is a prosthetic retaining element consisting of a female (outer part) and a male component (inner part). The male part is firmly connected to an abutment tooth, the female part is inserted into the removable denture. If implant prosthetics are out of the question, this type of prosthesis is suitable to provide retention of a removable dental prosthesis. The restoration with a slide attachment is successful for smaller and larger gaps between teeth or free-end situations, provided that there are still enough teeth with good prognosis available which can be crowned as abutment teeth or used for an adhesive attachment. As a rule, one abutment tooth on the left and right side is required to ensure stable retention and to protect the retaining teeth from leverage and pressure forces acting on the dentures when worn.

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.
The slide attachments come permanently in contact with tissue from the mouth.

2.3 Indications

Device name	Indications
M-SG® Star 1, M-SG® Star 2, Mini-SG®, Mini-SG® F/R, Mini-SG® PLUS, Mini-SG® Tuning female part and SG slide attachment	Tooth- and combined tooth-mucosal supported removable dental prostheses: - removable dental prostheses replacing missing teeth in edentulous spaces - rigidly anchored, uni- and bilateral free-end dentures - removable dental prostheses replacing missing teeth in edentulous spaces and free-end situations
Mini-SG® tuning female part	- Upgrading of removable dental prostheses which are no longer retained adequately on worn Mini-SG® male parts.
Mini-Dalbo® and Tecnoroch	Combined tooth-mucosal supported removable dental prostheses: - Free-end denture

2.4 Contraindications

Device name	Contraindications
M-SG® Star 1, M-SG® Star 2, Mini-SG®, Mini-SG® F/R, Mini-SG® PLUS, Mini-SG® Tuning female part and SG slide attachment	Unilateral, partial and free-end removable dental prostheses without transversal support (palatal or lingual major connector). Restoration of abutment teeth with severely reduced periodontal attachment.
Mini-Dalbo® and Tecnoroach	Unilateral free-end removable dental prostheses Unilateral free-end removable dental prostheses with or without hinged transversal support Combined partial denture with a saddle in the edentulous space and in the free-end section
Mini-SG® tuning female part	Use on non-worn Mini-SG® male parts.
M-SG® Star 1, M-SG® Star 2, Mini-SG®, Mini-SG® F/R, Mini-SG® PLUS, Mini-SG® Tuning female part and SG slide attachment, Mini-Dalbo®, and Tecnoroach	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)	
Several articles	Implementation of UDI code on label and replacing the gel capsule by a medical tube due to regulatory requirements, waiving of material with animal origin
05003033 05003036 05003037 05003049	Production outsourcing of Mini-SG® inserts at Mythentec AG
05000407 05000411 05000429 05000432 05000433 05000413 05000414	Blister packaging changed through tube bag in order to harmonize the packaging processes
055919 055487 055489	Change of material to improve corrosion resistance

2.7 Description of any accessories

Available components: M-SG® Star 1	
05000433	 Female part T
05000674	 Female part M
055691	 Friction inserts yellow (smooth friction)
055356	 Friction inserts red (normal friction)
055357	 Friction inserts green (strong friction)
055358	 Friction inserts blue (extra-strong friction)
05000407	 Male part C for casting-on
05000410	 Male part K

Auxiliary parts: M-SG® Star 1	
07000040	 Duplicating aid G
07000042	 Transfer Jig

Auxiliary instruments: M-SG® Star 1	
072627	 Special parallelometer insert
07000056	 Insert remover
070347	 Tweezers

Available components: M-SG® Star 2

05000414		Female part T
055774		Friction insert G orange (normal friction)
055811		Friction insert G violet (strong friction)
055775		Activating screw T
05000407		Male part C for casting-on
05000410		Male part K

Auxiliary parts: M-SG® Star 2

07000041		Duplicating aid G
07000042		Transfer Jig

Auxiliary instruments: M-SG® Star 2

072627		Special parallelometer insert
07000053		Screwdriver/activator
070347		Tweezers

Available components: Mini-SG® F/R

055531		Female part T
055677		Female part C
055925		Tuning female part E
055691		Friction insert G yellow (smooth friction)
055356		Friction insert G red (normal friction)
055357		Friction insert G green (strong friction)
055358		Friction insert G blue (extra-strong friction)
055718		Retention insert G orange (strong friction)
055766		Retention insert G violet (extra-strong friction)
055517		Male part V
055544		Male part C
055529		Male part K

Auxiliary parts: Mini-SG® F/R

072600		Duplicating aid G
072616		Transfer Jig

Auxiliary instruments: Mini-SG® F/R and Mini-SG®

072627		Special parallelometer insert
072483		Insert remover
070347		Tweezers

Available components: Mini-SG® PLUS

055807		Female part T
055774		Friction insert G orange (strong friction)
055811		Friction insert G violet (extra-strong friction)
055775		Activating screw T
05000407		Male part V
05000410		Male part K

Auxiliary parts: Mini-SG® PLUS

072649		Duplicating aid G
072616		Transfer Jig

Auxiliary instruments: Mini-SG® PLUS

072627		Special parallelometer insert
072653		Screwdriver/activator
070347		Tweezers

Available components: Mini-SG®

055371		Female part D
055489		Female part X
05003615		Female part M
055925		Tuning female part E
055691		Friction insert G yellow (smooth friction)
055356		Friction insert G red (normal friction)
055357		Friction insert G green (strong friction)
055358		Friction insert G blue (extra-strong friction)
055718		Retention insert G orange (strong friction)
055766		Retention insert G violet (extra-strong friction)
055544		Male part C
055529		Male part K

Auxiliary parts: Mini-SG®

072616		Transfer Jig
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Available components: SG Slide attachment

052159		Female part D
052163		Friction insert G white (normal friction)
05000057		Friction insert G violet (strong friction)
052161		Activating screw O
052164		Mounting screw X
052160		Male part C
052162		Male part K

Auxiliary parts: SG Slide attachment

072502		Duplicating aid G
072566		Transfer Jig

Auxiliary instruments: SG Slide attachment

072627		Special parallelometer insert
070293		Screwdriver insert
070221		Thomas spanner key
070222		Tweezers

Available components: Mini-Dalbo®

050697		Female part E
051662		Female part D
050960		Male part C
051617		Male part K

Auxiliary parts: Mini-Dalbo®

070176		Transfer Jig
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Auxiliary instruments:

070146		Parallelometer insert
070222		Tweezers

Available components: Tecnoroach

055410		Female part E
055409		Male part K

Auxiliary instruments: Tecnoroach

070176		Parallelometer insert
072505		Activator

2.8 Combination products

The main combination products of the slide attachment portfolio are the auxiliary parts and instruments of this product family. These articles are listed above and described in detail in a separate clinical evaluation report (CER).

3 Residual risks and warnings

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, warnings, and preventive measures

Device name	Side effects
M-SG® Star 1, M-SG® Star 2, Mini-SG®, Mini-SG® F/R, Mini-SG® PLUS, Mini-SG® Tuning female part and SG slide attachment, Mini-Dalbo® and Tecnoroach	This product must not be used in patients with allergies or suspected allergies to materials used in the product (see Section 19), or only after prior allergological clarification. Auxiliary instruments may contain nickel. If applied as intended, side effects can be excluded.

Device name	Warnings
M-SG® Star 1, M-SG® Star 2, Mini-SG®, Mini-SG® F/R, Mini-SG® PLUS, Mini-SG® Tuning female part and SG slide attachment	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.
Mini-SG® tuning female part	Upgrading of dentures which are no longer retained adequately on worn Mini-SG® male parts.
Mini-Dalbo® and Tecnoroach	Tooth- and mucosa supported dentures: Free-end denture

Device name	Preventive measures
M-SG® Star 1, M-SG® Star 2, Mini-SG®, Mini-SG® F/R, Mini-SG® PLUS, Mini-SG® Tuning female part and SG slide attachment, Mini-Dalbo® and Tecnoroach	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, wearing protective goggles and a dust mask as well as the use of a suction unit is recommended. Secure parts against aspiration. The mechanical cleaning by patients with a toothbrush and abrasive toothpaste may lead to premature wear.

3.3 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

A slide attachment is a prosthetic retaining element consisting of a female (outer part) and a male component (inner part). The male part is firmly connected to an abutment tooth, the female part is inserted into the removable denture. If implant prosthetics are out of the question, this type of prosthesis is suitable to provide retention of a removable dental prosthesis. The restoration with a slide attachment is successful for smaller and larger gaps between teeth or free-end situations, provided that there are still enough teeth with good prognosis available which can be crowned as abutment teeth or used for an adhesive attachment. As a rule, one abutment tooth on the left and right side is required to ensure stable retention and to protect the retaining teeth from leverage and pressure forces acting on the dentures when worn.

See in addition Chapter 2.1

Identification and justification of potential equivalent device(s)

As requested by the Medical Device Regulation (MDR) Annex XIV, clinical data from similar or equivalent devices were evaluated. Therefore, a market search was performed in order to identify similar devices. For this purpose, the technical, biological, and clinical properties, the intended purpose, as well as type and duration of body contact of already marketed devices were considered in order to select them as similar (Chapter 10.3). SD Attachment from the company Servo-Dental, and CENTRALOCK II from ZL Microdent are similar to M-SG® Star 2 and Mini-SG® Plus, respectively, whereas NAB 2000 from Primardent (Microtecnor) is similar to the Mini-Dalbo® of CM. However, no clinical trial data for similar devices could be identified through a systematic literature search in the clinical PubMed database. Nevertheless, the similar slide attachments manufactured from competitors 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.

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 slide attachments manufactured by CM and the information provided in the scientific textbooks, it can be concluded that the different slide attachments represent “state of the art” technology and materials when used as retainers for tooth-supported dental prostheses. Slide attachments in general can be used to retain removable dental prostheses in case of uni- or bilateral edentulous spaces, free-end situations, or a combination of both (edentulous spaces and free-end situations), and for removable bridge prostheses.

Results from scientific publications in journals

The documented clinical data approve the information received from the analysis of the scientific textbooks: The prosthetic concept of the slide attachment system is widely used for removable dentures supported on two or more abutment teeth. Additionally, the evaluated clinical data confirm that all slide attachment systems perform safely when used as intended for the treatment of patients with removable dentures and with no serious adverse effects and/or complications.

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 slide attachments with the General Safety and Performance Requirements (GSPR) of the MDR. Furthermore, the identified pertinent clinical data support a positive benefits-versus-risks profile of these medical devices.

Results from post-market surveillance (PMS)

According to the complaint statistic overall complaint rate of 0.0169% was registered without serious or reportable incidences in the previous 5 years from 2017 to 2021. Similarly, the complaint rate of 2022 appears also to be low with 0.0146%. This complaint statistic provides a low number of complaints when compared with the number of sales, respectively it demonstrates an acceptable overall complaint rate for the slide attachments.

Therefore, the identified complaint data support a positive benefits-versus-risks profile for the slide attachments demonstrating 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 slide attachments with the GSPR as especially set out in sections 1 and 8 of annex I of the MDR.

An updated complaint statistic is described in Chapter 4.5.

Results from publicly available safety databases

No safety issues could be identified for the slide attachments and its similar devices in the databases of Regulatory Authorities. The slide attachments have been safely used since their market 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 slide attachments 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 post-market clinical follow-up (PMCF) was not deemed necessary before the introduction of the MDR. If Paragraph 6 of Article 61 of the MDR is fulfilled for implantable devices, such as the male parts of the slide attachments are, no clinical study is required, especially if safety and clinical performance of the considered devices is based on sufficient clinical evidence. Since this particular Paragraph of the MDR is fulfilled for the slide attachments, the residual risks are acceptable and no new emerging risks are detectable, a clinical study is still not required. However, regular results from PMCF can be expected and will be collected for 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, and product catalogue are comprehensive and conform to the clinical data and scientific information identified in the corresponding 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 slide attachments, 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 slide attachments 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.

In conclusion, the slide attachment devices 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

According to the post-market clinical follow-up plan the following results can be summarized for the corresponding PMCF report:

The complaint rate of 0.0262% for the report period 2024 is acceptable and comparable to the previous 5 years (2019-2023) total complaint rate of 0.0247%. Based upon the evaluation of these PMS data it can be concluded that the results support compliance of the slide attachment devices with the General Safety and Performance Requirements (GSPR) as set out in the MDR Annex I, especially sections 1 and 8. Although there were no relevant new clinical data identified in the literature searches or the public safety databases, it can be concluded based on these observations and the complaints data collected that the slide attachments perform as intended when used according to the Instructions for Use and are suitable for the intended dental applications.

Furthermore, the described PMCF activities for the current observation period demonstrate that:

- the slide attachments conform to the GSPR of the MDR regarding safety and clinical performance when used as intended,
- they do not show any previously unknown side-effects,
- no emerging risks are identifiable based on factual evidence for the slide attachments,
- the risk-benefit ratio referred according to Annex I of the MDR remains acceptable, and
- no systematic misuse or off-label use of the slide attachments is known indicating that the intended purpose is still correct.

Based on the above assessment, it can be concluded that for the slide attachments the safety and clinical performance is still valid, and a clinical trial is not required for these dental products. Updated results can be expected in the following year.

5 Possible diagnostic or therapeutic alternatives

Conventional complete dentures, partial dentures with clasps.

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 fabrication of dentures and their maintenance may only be performed 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 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 10088-3: Stainless steels - Part 3: Technical delivery conditions for semi-finished products, bars, rods, wire, sections and bright products of corrosion resisting steels for general purposes 1.4435 (stainless steel: Medstahl, Chr Spezial 35)(1028)
 - 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 10993-5: 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

C=Ceramicor®

E=Elitor®

O=OSV

D=Doral

V=Valor

T=Titanium

X=stainless steel

M= med steel (medical grade stainless steel)

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 C, E, and O are used by Cendres+Métaux SA as abbreviations for 3 biocompatible gold alloys, Ceramicor®, Elitor®, and OSV. D and V are the abbreviations for the biocompatible silver alloys Doral and Valor. T is the abbreviation for titanium, which is a pure material composed of this particular chemical element. Analogous to the other 5 mentioned biocompatible alloys, titanium comprises of the same biological features. Furthermore, X is an abbreviation for a corrosion resistant stainless steel and M for a medical grade stainless steel. All these 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
1.0	03.2023	First version of SSCP-slide attachments	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No Language used: english
2.0	03.2024	Preface includes the relevant MDCG document; Chapter 4.5 updated with current complaint data and results from current PMCF report.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No Language used: english
3.0	30.04.2025	Third edition of SSCP is a regular annual update according to MDR with Chapter 4.5 "ongoing and planned PMCF" with current complaint data and results from PMCF.	<input type="checkbox"/> Yes <input type="checkbox"/> No Language used: english

PART D

List of articles

Device number	Product name	Class
050697	Mini-Dalbo® Female part E	Ila
051659	Mini-Dalbo® DK	Ila
051662	Mini-Dalbo® Female part D	Ila
055364	Mini-SG® DK	Ila
055371	Mini-SG® Female part D	Ila
055487	Mini-SG® XK	Ila
05003614	Mini-SG® MK	Ila
055489	Mini-SG® Female part X	Ila
05003615	Mini-SG® Female part M	Ila
055925	Mini-SG® / Mini-SG® F/R Tuning Female part E	Ila
055531	Mini-SG® F/R Female part T	Ila
055532	Mini-SG® F/R TK	Ila
055677	Mini-SG® F/R Female part C	Ila
055699	Mini-SG® F/R CK	Ila
055718	Mini-SG® F/R Retention insert G Orange (normal retention)	Ila
055766	Mini-SG® F/R Retention insert G Violet (strong retention)	Ila
055804	Mini-SG® PLUS TK	Ila
055807	Mini-SG® PLUS Female part T	Ila
055356	Mini-SG® / Mini-SG® F/R / M-SG® Star 1 Friction insert G Red (normal friction)	Ila
055357	Mini-SG® / Mini-SG® F/R / M-SG® Star 1 Friction insert G Green (strong friction)	Ila
055358	Mini-SG® / Mini-SG® F/R / M-SG® Star 1 Friction insert G Blue (extra-strong friction)	Ila
055691	Mini-SG® / Mini-SG® F/R / M-SG® Star 1 Friction insert G Yellow (smooth friction)	Ila
05000432	M-SG® Star 1 TK for casting	Ila
05000433	M-SG® Star 1 Female part T	Ila
05000673	M-SG® Star 1 MK for casting	Ila
05000674	M-SG® Star 1 Female part M	Ila
055774	Mini-SG® PLUS / M-SG® Star 2 Friction insert G Orange (normal friction)	Ila
055775	Mini-SG® PLUS / M-SG® Star 2 Activating screw T	Ila
055811	Mini-SG® PLUS / M-SG® Star 2 Friction insert G Violet (strong friction)	Ila
05000413	M-SG® Star 2 TK for casting	Ila
05000414	M-SG® Star 2 Female part T	Ila
052158	Slide Attachment SG DK	Ila

052159	Slide Attachment SG Female part D	Ila
052161	Slide Attachment SG Activating screw O	Ila
052163	Slide Attachment SG Friction insert G white (normal friction)	Ila
05000057	Slide Attachment SG Friction insert G violet (strong friction)	Ila
055410	Tecnoroach Female part E	Ila
055411	Tecnoroach EK	Ila
050701	Mini-Dalbo® EC	Ila
050960	Mini-Dalbo® Male part C	Ila
055919	Mini-SG® XC	Ila
055534	Mini-SG® F/R TV	Ila
055919	Mini-SG® XC	Ila
055534	Mini-SG® F/R TV	Ila
055543	Mini-SG® F/R TC	Ila
055544	Mini-SG® / Mini-SG® F/R / Mini-SG® PLUS Male part C	Ila
055675	Mini-SG® F/R CC	Ila
055517	Mini-SG® F/R / Mini-SG® PLUS Male part V	Ila
055802	Mini-SG® PLUS TV	Ila
05000407	M-SG® Star 1 / M-SG® Star 2 Male part C for casting-on	Ila
05000429	M-SG® Star 1 TC for casting-on	Ila
05000411	M-SG® Star 2 TC for casting-on	Ila
052157	Slide Attachment SG DC	Ila
052160	Slide Attachment SG Male part C	Ila