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Dental solders

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Instructions for Use Dental solders

1 Scope of application of Instructions for Use

These Instructions for Use apply to the products listed under Section 29. The issuing of these Instructions for Use renders all previous versions invalid. The manufacturer rejects any liability for damages resulting from non-compliance with these Instructions for Use.

2 Trade name

See Section 29.

3 Intended use

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

4 Expected clinical benefit

Restoration of chewing function and improved aesthetics.

The Summary of Safety and Clinical Performance, SSCP for the implantable devices covered by these Instructions for Use, is available on our website and accessible at this address: www.cmsa.ch/docs.

5 Product description

When soldering, the parts to be connected are heated so much that the solder can flow into the solder joint. The solidus of the alloy must be higher than the liquidus of the solder. For porcelain fused to metal alloys, there are solders before and after the ceramic bond. Pre-solders do not melt during ceramic firing. The highest firing temperature must therefore be below the solidus of the solder. Conversely, a solder used after the ceramic bond should not harm the ceramic during the ceramic firing. The liquidus of these solders should be lower than the lowest firing temperatures of ceramics.

6 Indications

Precious metal solders are used for connecting precious metal alloys.

7 Contraindications

- 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, see Section 19.
- Existing clinical picture in the patient's mouth does not permit the correct application of the products.

8 Compatible products

Assignment of solders to alloys

Ceramic alloys				
	Before firing		After firing	
Ceradelta	S.G 1120		S.G 750	
Ceradelta 2	S.G 1120		S.G 750	
Cerapall 2	S.W 1125	S.G 1080	S.G 750	
Cerapall 6	S.W 1125	S.G 1120	S.G 750	
EcoDelta	S.G 1120		S.G 750	
Esteticor® Accurate 40	S.W 1125		S.G 750	
Esteticor® Actual	S.W 1100		S.G 810	S.G 750
Esteticor® Avenir	S.G 1030		S.G 810	S.G 750
Esteticor® Blancor	S.W 1100		S.G 750	
Esteticor® CC	S.W 1125		S.G 750	
Esteticor® Cosmor H	S.G 1080		S.G 810	S.G 750
Esteticor® Economic	S.W 1100		S.G 810	S.G 750
Esteticor® Ideal H	S.G 1030		S.G 810	S.G 750
Esteticor® NewStart	S.W 1100		S.G 810	S.G 750
Esteticor® N2	S.W 1100		S.G 810	S.G 750
Esteticor® Plus	S.W 1100		S.G 810	S.G 750
Esteticor® Royal H	S.G 1055		S.G 810	S.G 750
V-Classic	S.W 1125		S.G 750	
V-Delta SF	S.W 1125	S.G 1120	S.G 750	
V-Delta Special	S.W 1100		S.G 750	
V-Deltaloy	S.W 1100	S.G 1080	S.G 750	
V-Gnathos Plus	S.W 1030		S.G 750	
V-Supragold	S.G 1080		S.G 750	

Ceramic alloys for dental restorative systems on implants

	Before firing		After firing	
Esteticor® Implant 32	S.G 1055	S.G 1030	S.G 750	
Esteticor® Implant 58	S.G 1055	S.G 1030	S.G 750	
Esteticor® Implant 76	S.G 1055	S.G 1030	S.G 750	

Universal alloys

	Before firing		After firing	
BioEthic	S.G 1030		S.G 810	S.G 750
DGVO8 H	S.G 880		S.G 700	
Esteticor® Ecologic	S.G 920		S.G 700	

Casting alloys for dental restorative systems on implants

Aurofluid 2 PF	S.G 810	S.G 750
Aurofluid 3	S.G 810	S.G 750
Dentalor 60	S.G 810	S.G 750
Medior 3	S.G 810	S.G 750
Neocast 3	S.G 810	S.G 750
Opticast	S.G 810	S.G 750
Pagalin 2	S.G 880	S.G 750
Pallorag 33	S.G 810	S.G 750
Pallorag 35	S.G 810	S.G 750
Pontor MPF	S.G 810	S.G 750
Protor 3	S.G 810	S.G 750
Solaro 3	S.G 810	S.G 750
Solaro 4	S.G 810	S.G 750
Strator 3	S.G 810	S.G 750
Solaro Special	S.G 810	S.G 750
Yellow Special	S.G 750	S.G 700

To fabricate the finished denture, a number of general laboratory supplies are required in addition to the products listed under Section 29. The following gives a selection of materials that Cendres+Métaux SA offers in its portfolio.

080181	CM soldering investment (4 kg)
080229	CM soldering paste
08052307	Legabril Diamond (50 g)

9 Qualification of the specialist

Expertise in professional dentistry and dental technology is assumed. The current Instructions for Use 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.



Important information for the specialist



Warning symbol for increased caution

10 Prescription

Federal laws in the USA prohibit the use by or sale to unlicensed dentists.

11 Side effects

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.

12 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.

13 General information

N/A

14 Preventive measures

- Mixing of different solders or solders of similar types is not allowed!
- The use of solder/alloy combination not listed is subject to the user's risk!
- Wear darkened eye protection and protective gloves when soldering.
- Protect, hands and breathing during pickling.



- The product components are supplied non-sterile. For more information see Section 16 "Reprocessing".
- For your own safety, always wear suitable protective clothing. In particular when grinding, we recommend wearing protective goggles and a dust mask as well as the use of a suction unit.

15 Single use

Products that are intended for single use and are labelled "single-use" accordingly are subject to a certain amount of stress, increased wear, and even loss of functionality during their use.



Multiple application of products labelled «single use» was not tested. This can impair the safety, function and performance of the products as well as increase the risk of transmitting infections.

16 Reprocessing

The prosthetic work, including all system components, must be cleaned, disinfected and, if appropriate, sterilised prior to each work step. Materials made of metal alloys, high-performance polymers (Pekkton®) and ceramics are suitable for steam sterilisation. With the exception of Pekkton®, components made of plastics are not suitable for steam sterilisation. Consider published national guidelines when selecting a disinfection and sterilisation process and the Instructions for Use "Reprocessing of surgical and prosthetic products" (www.cmsa.ch/docs).

17 Scope of application

Fixed and removable dentures.

18 Procedure**18.1 Choosing the correct solder**

The elements to be soldered have to remain in the solid state during the process of soldering. Therefore, it is imperative that the liquidus point of the respective solder is below the solidus point of the alloy to be soldered.

Solders	Melting range	Recommended temperatures when soldering in ceramic furnaces	Recommended flux
S.G 700	650–710 °C	770 (T _L + 60 °C)	CM soldering paste
S.G 750	700–750 °C	810 (T _L + 60 °C)	CM soldering paste
S.G 810	740–810 °C	870 (T _L + 60 °C)	CM soldering paste
S.G 880	840–880 °C	940 (T _L + 60 °C)	CM soldering paste
S.G 920	880–920 °C	980 (T _L + 60 °C)	CM soldering paste
S.G 1030	935–975 °C		CM soldering paste
S.G 1055	990–1040 °C		CM soldering paste
S.G 1080	1020–1070 °C		CM soldering paste
S.G 1120	1060–1080 °C		CM soldering paste
S.W 1100	1060–1155 °C		CM soldering paste
S.W 1125	1010–1100 °C		CM soldering paste

18.2 Soldering flux

In order to avoid a premature oxidation of the surfaces to be soldered it is recommended to cover them completely with a soldering flux before any heat treatment.

The following soldering flux can be used for the soldering of precious metal alloys:

1. Flame soldering: CM soldering paste
2. Soldering in a furnace: CM soldering paste

CM soldering paste

Recommended range of use	Temperature range	Recommended mixtures for flames
Flame soldering for precious metal alloys	600–1160 °C	Mixture: Propane / Oxygen or natural gas / compressed air
Soldering in a ceramic furnace after firings	600–1000 °C	

18.3 Soldering investments

The Cendres+Métaux soldering investment is specified for the fixation of the elements to be soldered. To achieve a precise fit of the soldered work it is advisable to follow the instructions for use of the respective manufacturer of soldering investments.

18.4 Preparation of the surfaces to be soldered

For any type of soldering, a soldering gap of 0.05–0.20 mm will be most appropriate. This ensures that the liquid solder will be aspirated into the soldering gap by capillary force. If the soldering gap is larger than 0.2 mm, it is recommended to place a piece of the same alloy to be soldered into the soldering gap in order to reinforce the soldered connection. The surfaces of the soldering areas should measure at least 6–9 mm² for sufficient stability. In addition, these surfaces should be larger in the vertical than in the horizontal sense for better resistance to masticatory forces.

18.5 Porous soldering joint

After finishing and polishing of the restoration, the solder has to present a surface free of any cavities or porosities to avoid being a source of corrosion.

18.6 Benchcooling of the soldered work

Do not quench neither the soldering blocks nor free-hand soldered restorations, but benchcool to room temperature. Oxides arising on high gold metal alloys and high precious metal alloys can be eliminated by pickling in a warm and freshly prepared (clean) solution of 10 vol.-% sulphuric acid (H₂SO₄). Oxides arising on palladium-based alloys can be eliminated by sandblasting.



When using other pickling agents follow the instructions for use of the respective manufacturer.

19 Materials**19.1 Composition in weight %**

Solders		Cat. No.												
Rods \varnothing 0.8 mm, length 200 mm		Application Flame soldering	Application Soldering in the ceramic furnace	Colour	Au- + Pt-Met.	Au	Pt	Pd	Ag	Cu	Zn	Ir	Others	
S.G 700	01000352	✓	✓	Yellow	72.90	72.40	0.45		10.20	2.90	12.00	0.05	In 2.00	
S.G 750	01000345	✓	✓	Yellow	76.10	75.10	1.00		11.75		12.15			
S.G 810	01000348	✓	✓	Yellow	76.10	75.10	1.00		14.50		9.40			
S.G 880	01000355	✓	✓	Yellow	78.90	75.90	2.90		10.20	5.90	5.00	0.10		
S.G 920	01000354	✓	✓	Yellow	89.10	88.10	0.90		3.00	5.10	2.80	0.10		
S.G 1030	01000350	✓		Yellow	93.75	93.50	0.20		0.50	4.45	1.20	0.05	Fe 0.10	
S.G 1055	01000353	✓		Yellow	85.50	85.00	0.45		13.50		1.00	0.05		
S.G 1080	01000347	✓		Yellow	82.40	80.00	2.40		16.90		0.70			
S.G 1120	01000351	✓		Bright Yellow	83.00	80.00	3.00		17.00					
S.W 1100	01000346	✓		Pale Yellow	78.00	64.50	5.00	8.50	20.00		2.00			
S.W 1125	01000349	✓		White	80.50	72.50		7.90	14.50	4.00		0.10	In 1.00	

More detailed information on the materials as well as their compositions can be found in the product-specific material data sheets, the product information as well as the product list compiled in Section 29. All relevant documents can be found on the website www.cmsa.ch/docs by entering the relevant product name.

20 Notes on storage

Insofar as no specific information on storage is given on the packaging of the product, we recommend storing the product in its original packaging, in a dry place, at room temperature and without direct sunlight. Improper storage can influence the product properties and lead to failure of the restoration.

21 Patient information

On the day of insertion of the dentures at the latest, the patient must be informed that regular follow-up care is necessary to maintain the health of the entire masticatory system and the functionality of the denture. Ensure that the patients are motivated and instructed with regard to caring for their teeth as well as dentures.

Permanent and removable dentures are subject to considerable stress. Signs of wear are normal and cannot be avoided, only reduced. The amount of wear depends on the overall system.

22 Ordering information

The information relevant to your order can be found in the product list in Section 29 of this document. The product information is also helpful. This and other relevant documents can be found on the website www.cmsa.ch/docs by entering the relevant product name.

23 Availability

Some of the products described in this document may possibly not be available in all countries.

24 Traceability of the lot number

The lot numbers of all parts used must be documented to ensure traceability.

25 Complaint

Cendres+Métaux SA must be notified immediately of any incident that has occurred with regard to the product. To do this, please contact your customer advisor or send us your message by e-mail to the address complaints-cmbrand@cmsa.ch. In serious cases, also send a report to the competent authority where you are domiciled.

26 Safe disposal

The products must be disposed of in accordance with local laws and environmental regulations, taking into account the level of contamination. Cendres+Métaux Lux SA would be very pleased to accept precious metal waste. For information and additional details, please contact your Cendres+Métaux SA representative.

27 Trademarks

Registered trademarks of Cendres+Métaux Holding SA, Biel/Bienne, Switzerland include:

N/A

Unless explained specifically, all products marked with "®" are not registered trademarks of Cendres+Métaux Holding SA, but registered trademarks of the respective manufacturer.

28 Disclaimer

The manufacturer rejects any liability for damages resulting from non-compliance with these Instructions for Use. Cendres+Métaux SA products are parts of an overall concept and may only be used or combined with the appropriate original components and instruments. Otherwise, the manufacturer rejects any responsibility and liability. In case of complaints, please always include the lot number.

The use of third party products not distributed by Cendres+Métaux SA in connection with the products mentioned in the product list in Section 29 will void any warranty or other express or implied obligation of Cendres+Métaux SA.

Responsibility regarding the suitability of a product for the specific patient case is at the discretion of the specialist.

Cendres+Métaux SA disclaims any express or implied liability and shall not be responsible for any direct, indirect, punitive or other damages arising from or in connection with errors in professional judgement or practice in the use of Cendres+Métaux SA products.

The specialist is obliged to regularly study the latest developments of the products mentioned in the product list in Section 29 and their applications.

It should be noted that the descriptions contained in this document are not sufficient for the immediate application of Cendres+Métaux SA products. Expertise in dentistry, dental technology and instructions by an experienced specialist in the use of the products mentioned in the product list under Section 29 is always necessary.

In case of inconsistencies in translations, the English language version shall prevail.

29 Product list

Cat. No.	Product name (Material)	Single use	Labelling	UDI-DI	Basic UDI-DI
01000352	S.G 700	Yes	CE 0483	97640173082333	764016651000042DX
01000345	S.G 750	Yes	CE 0483	97640173082265	764016651000042DX
01000348	S.G 810	Yes	CE 0483	97640173082296	764016651000042DX
01000355	S.G 880	Yes	CE 0483	97640173082364	764016651000042DX
01000354	S.G 920	Yes	CE 0483	97640173082357	764016651000042DX
01000350	S.G 1030	Yes	CE 0483	97640173082319	764016651000042DX
01000353	S.G 1055	Yes	CE 0483	97640173082340	764016651000042DX
01000347	S.G 1080	Yes	CE 0483	97640173082289	764016651000042DX
01000351	S.G 1120	Yes	CE 0483	97640173082326	764016651000042DX
01000346	S.W 1100	Yes	CE 0483	97640173082272	764016651000042DX
01000349	S.W 1125	Yes	CE 0483	97640173082302	764016651000042DX

30 Labelling on packaging/symbols

	Date of manufacture
	Manufacturer
	Catalogue number
	Lot number
	Quantity
 www.cmsa.ch/docs	Observe the Instructions for Use, which are available in electronic form at the address specified.
Rx only	Attention: According to US federal law, this product may only be sold by or on behalf of a physician.
 	Cendres+Métaux products with CE labelling meet the requirements of the relevant European requirements.
	Do not re-use
	Non-sterile
	Protect from sunlight
	Attention, observe accompanying documents
 	Clear product identification
 	European Authorised Representative
	Importer
	Medical device