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Soprano[®] Surface

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Instruction for Use Soprano® Surface

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

Soprano® Surface is a ready-to-use, translucent, opalescent and fluorescent, paste-like glass-ceramic with pigments. It is used to structure and individualise zirconia, lithium disilicate and veneering ceramic restorations.

Classification according DIN EN ISO 6872; type 1, Class 1

6 Indications

Use on the following framework materials:

- Fully anatomically fabricated crowns and bridges in tetragonal stabilised zirconia (Y -TZP) with a thermal expansion of approx. $10.6 \cdot 10^{-6} \cdot K^{-1}$ (25 - 500 °C).
- Crowns and bridges in tetragonal stabilised zirconia (Y -TZP) with a thermal expansion of approx. $10.6 \cdot 10^{-6} \cdot K^{-1}$ (25 - 500 °C), veneered with a zirconia oxide ceramic, for example Soprano® 10.
- Monolithic lithium disilicate glass ceramic materials with a thermal expansion of approx. $10.0 \cdot 10^{-6} \cdot K^{-1}$ (25 - 500 °C), for example Livento® press.
- Lithium disilicate glass ceramic materials with a thermal expansion of approx. $10.0 \cdot 10^{-6} \cdot K^{-1}$ (25 - 500 °C), for example Livento® press, veneered with Soprano® 10.
- PFM restorations, for example veneered with Soprano® 14

7 Contraindications

- Veneering of non-indexed framework materials
- Mixing with other ceramics (powders, pastes)
- Inlaying with other ceramics (powders, pastes)
- Use of other liquids
- 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

N/A

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

- The product components are supplied non-sterile. For more information see Section 16 "Reprocessing".
- Only original tools and parts may be used for this work. For information and additional details, please contact your Cendres+Métaux SA representative.
- Before any procedure, ensure that all required product components are available in sufficient quantity.
- For your own safety, always wear suitable protective clothing. In particular when grinding, we recommend wearing protective goggles and a dust mask as well as the use of a suction unit.
- Secure parts against aspiration.
- The mechanical cleaning by patients with a toothbrush and toothpaste may lead to premature wear.

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

The Soprano® Surface ceramic is processed in the dental laboratory with already well known, established dental ceramic instruments, processing instruments, mixing plates, furnaces and associated accessories. This means that no new, product-specific accessories are required for the use of Soprano® Surface.

18 Procedure**18.1 Description of the ceramic colours and pastes:**

Flu-Shade; body shade for the colouring of the A, B, C and D colours.

Flu-Stain; effect stains for individual, characteristic colouring.

Surface Base, Mamelon, Fossa and Cuspid; placement of individual characteristics.

Surface Enamel Effect; highlight of individual transpaeffects in the incisal area.

Surface Enamel V; neutral masses with stepped brightness for placing individual features and brightening the tooth shade. V1 has the highest brightness, V3 the lowest brightness.

Surface Enamel Opal, Incisal and Clear; use in the incisal area.

Surface Gingiva; Harmonised pastes and stains for the natural appearance of the gingiva.

18.2 Notes on the ceramic pastes

- Soprano® Surface and Soprano® Stain & Shade pastes should not get in contact with water.
- Always use dry brushes or spatula.
- Mix Soprano® Surface and Soprano® Stain & Shade pastes before any usage with metal-free spatula.
- To adjust the desired consistency of the Soprano® Surface pastes, use only Soprano® Surface Fluid.
- To adjust the desired consistency of the Soprano® Stain & Shade pastes, use only Soprano® Glaze Fluid.
- Moisten brush with Soprano® Surface Fluid, respective Soprano® Glaze Fluid, before application of pastes.

18.3 Framework processing

- Preparation of the frameworks according to the manufacturer's instructions of the framework material.
- Avoid sharp edges and corners at all costs.
- Prepare the surface before application of Soprano® Surface and Soprano® Stain & Shade pastes by careful sandblasting with aluminium oxide (110 µm with 2 bar pressure).
- Before each application, clean the surface well with a steam jet and then dry.

18.4 Structuration

Layer thickness for Soprano® Surface per firing from 0.1 to max. 0.3 mm.



For optimal bonding of Soprano® Surface, wet the framework surface with Soprano® Surface Fluid before initial application. If the fluid can be applied evenly without forming puddles, the surface has been homogeneously blasted and well cleaned. Otherwise, repeat this step.



When mixing an individual paste consistency using Soprano® Surface Fluid, the following must be observed:

- The more fluid is added to the paste, the longer the drying time or closing time of the oven must be set. This allows the additional added fluid to escape completely.
- As a rule, the longer the pre-drying time allowed for the Soprano® Surface Paste to dry gently, the more homogeneous the surface will be.



When applying Soprano® Surface, make sure that the paste is applied thinly and evenly over the entire surface. The thicker the application, the greater the risk of air inclusions.



Make sure that the object to be fired is not placed in a furnace that is still too hot. The maximum starting temperature should be 400 - 450°C. Otherwise, fine blisters may form.

18.5 Colouration

Before the first application of Soprano® Stain & Shade pastes, wet the surface with Soprano® Glaze Fluid.

18.6 Glaze paste application

After grinding the surface, apply Soprano® Glaze Fluid thinly and evenly over the entire restoration.

18.7 Finishing

The level of brilliance can still be individually adjusted after glaze firing using polishing instruments and diamond polishing pastes.

18.8 Firing tables

Firing chart

For lithium disilicate (Livento® press) monolithic or veneered.
Veneering ceramic for zirconia oxide (Soprano® 10).

Starting temperature	Pre-drying	Closing time	Temperature rise	Start vacuum	End vacuum	Firing temperature	Holding time
°C	min	min	K/min	°C	°C	°C	min
450	3	4	45	670	720	720	2

Firing chart

For monolithic zirconia.
Metal-ceramic (Soprano® 14).

Starting temperature	Pre-drying	Closing time	Temperature rise	Start vacuum	End vacuum	Firing temperature	Holding time
°C	min	min	K/min	°C	°C	°C	min
450	3	4	45	670	770	770	1

 For voluminous zirconia work > 3g, long-term cooling is required according to the manufacturer's instructions.

For voluminous restorations, open the furnace with an opening time of 2 minutes!

In case of multiple firings, the final temperature may be reduced by 10-20 °C, depending on the desired degree of gloss!

The firing temperatures given are reference values and may vary depending on the type of furnace used and the age of the device.

19 Materials

All Soprano® Surface and Soprano® Stain & Shade pastes comply to all applicable standards for dental ceramics (DIN EN ISO 6872, ISO 10993). All limits are undercut and thresholds are outperformed.

19.1 Soprano® Surface

Physical-chemical properties according to ISO EN DIN 6872/ ISO 10993-5

Property	Specification	Measured data
Coefficient of thermal expansion (25 – 475°C) [$\times 10^{-6} \times K^{-1} \pm 0.5$]	2 x: 9.5 4 x: 9.5	2 x: 9.5 4 x: 9.5
Glass transformation temperature Tg [°C ± 20]	2 x: 495 4 x: 495	2 x: 495 4 x: 495
Bending strength [MPa]	≥ 50	130 – 150
Solubility [$\mu\text{g}/\text{cm}^2$]	< 100	19 – 35
Radioactivity [Bq·g ⁻¹ U ²³⁸]	< 1	Complies*
Cytotoxicity	no cytotoxicity	Complies**

*) covered by report 170231-20-A, 17-02-01, mds, D-Gilching

***) covered by analysis report 17-10238, 17-01-20, FZ Jülich, D-Jülich

19.2 Soprano® Shade and Stain

Physical-chemical properties according to ISO EN DIN 6872/ ISO 10993-5

Property	Specification	Measured data
Coefficient of thermal expansion (25 – 475°C) [$\times 10^{-6} \times K^{-1} \pm 0.5$]	2 x: 10.0 4 x: 10.0	2 x: 9.8* 4 x: 9.8*
Glass transformation temperature Tg [°C ± 20]	2 x: 460 4 x: 460	2 x: 455* 4 x: 455*
Bending strength [MPa]	≥ 50	> 130*
Solubility [$\mu\text{g}/\text{cm}^2$]	< 100	Complies*
Radioactivity [Bq·g ⁻¹ U ²³⁸]	< 1	Complies**
Cytotoxicity	no cytotoxicity	Complies***

*) data for base material

***) covered by analysis report 17-10237, 17-01-20, FZ Jülich, D-Jülich

****) covered by report 170231-20-C, 17-02-01, mds, D-Gilching

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

21.1 Handling / follow-up

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.

Our endeavours are aimed at using materials that are as optimally matched as possible in order to reduce wear to an absolute minimum. Proper seating of the dentures on the mucosa must be checked at least once each year, and relining must be performed if required to prevent rocking movement (overload). We recommend checking the dentures at intervals of approx. 3 months initially and to replace the auxiliary parts such as retention inserts if necessary.

21.2 Cleaning and care

We recommend cleaning teeth and dentures after every meal. Cleaning of dentures includes cleaning of the connecting element. Gentlest cleaning can be achieved by cleaning the restoration under running water with a soft toothbrush and the connecting element in the mouth with an interdental brush. The most intensive cleaning of the restoration is achieved with the aid of an ultrasonic device and a cleaning additive suitable for dentures.

Never clean the high precision connecting elements with toothpaste as this could lead to damage. Caution should also be exercised in the case of aggressive cleaning agents or tablets as this could damage the high-quality connecting element or impair its function.

Regular cleaning of the anchorage can prevent inflammation of the soft tissue.

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:

Soprano®

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

All Soprano® products are assigned the basic UDI-DI: 764016651000038E8 and all Livento® and Soprano® kits are assigned the number 764016651000039EA.

 The Cat. No. and the UDI-Di Code of the single products corresponds to the refill article.

Cat. No.	Product name	Kit contents	Labelling	UDI-DI
08058206	Soprano® Surface Kit	1	CE 0483	07640239930186
08058207	Soprano® Surface Base 1	4 g	CE 0483	07640239930193
08058208	Soprano® Surface Base 3	4 g	CE 0483	07640239930209
08058209	Soprano® Surface Base 5	4 g	CE 0483	07640239930216
08058210	Soprano® Surface Mamelon mango	4 g	CE 0483	07640239930223
08058211	Soprano® Surface Mamelon cream	4 g	CE 0483	07640239930230
08058212	Soprano® Surface Mamelon honey	4 g	CE 0483	07640239930247
08058213	Soprano® Surface Mamelon salmon	4 g	CE 0483	07640239930254
08058214	Soprano® Surface Fossa	4 g	CE 0483	07640239930261
08058215	Soprano® Surface Cuspid	4 g	CE 0483	07640239930278
08058216	Soprano® Surface Enamel Effect light-blue	4 g	CE 0483	07640239930285
08058217	Soprano® Surface Enamel Effect pink	4 g	CE 0483	07640239930292
08058218	Soprano® Surface Enamel Effect int.-orange	4 g	CE 0483	07640239930308
08058219	Soprano® Surface Enamel Effect sun	4 g	CE 0483	07640239930315
08058220	Soprano® Surface Enamel V1	4 g	CE 0483	07640239930322
08058221	Soprano® Surface Enamel V2	4 g	CE 0483	07640239930339
08058222	Soprano® Surface Enamel V3	4 g	CE 0483	07640239930346
08058223	Soprano® Surface Opal	4 g	CE 0483	07640239930353
08058224	Soprano® Surface Incisal	4 g	CE 0483	07640239930360
08058225	Soprano® Surface Clear	4 g	CE 0483	07640239930377
08058226	Soprano® Surface Fluid	25 ml	CE 0483	07640239930384
08058227	Soprano® Surface Gingiva Kit	1	CE 0483	07640239930391
08058228	Soprano® Surface Gingiva light	4 g	CE 0483	07640239930407
08058229	Soprano® Surface Gingiva violet	4 g	CE 0483	07640239930414
08058230	Soprano® Surface Gingiva dark	4 g	CE 0483	07640239930421
08058231	Soprano® Surface Gingiva orange	4 g	CE 0483	07640239930438
08058232	Soprano® Surface Gingiva brown	4 g	CE 0483	07640239930445
08058225	Soprano® Surface Clear	4 g	CE 0483	07640239930377
08058226	Soprano® Surface Fluid	25 ml	CE 0483	07640239930384
08058233	Soprano® Stain red	5 g	CE 0483	07640239930452
08058234	Soprano® Stain dark-blue	5 g	CE 0483	07640239930469
08058235	Soprano® Stain red-brown	5 g	CE 0483	07640239930476
08058236	Soprano® Stain orange	5 g	CE 0483	07640239930483
08055184	Soprano® Glaze Paste	5 g	CE 0483	07640173094173
08055283	Soprano® Glaze Fluid	25 ml	NO MED	N/A
08058237	Soprano® Surface Bleaching Kit	1	CE 0483	07640239930490
08058207	Soprano® Surface Base 1	4 g	CE 0483	07640239930193
08058215	Soprano® Surface Cuspid	4 g	CE 0483	07640239930278
08058216	Soprano® Surface Enamel Effect light-blue	4 g	CE 0483	07640239930285
08058219	Soprano® Surface Enamel Effect sun	4 g	CE 0483	07640239930315
08058220	Soprano® Surface Enamel V1	4 g	CE 0483	07640239930322
08058222	Soprano® Surface Enamel V3	4 g	CE 0483	07640239930346
08058223	Soprano® Surface Opal	4 g	CE 0483	07640239930353
08058224	Soprano® Surface Incisal	4 g	CE 0483	07640239930360
08058225	Soprano® Surface Clear	4 g	CE 0483	07640239930377
08058226	Soprano® Surface Fluid	25 ml	CE 0483	07640239930384
08058238	Soprano® Flu-Shade Bleach 1 - 2	5 g	CE 0483	07640239930506
08058239	Soprano® Flu-Shade Bleach 3 - 4	5 g	CE 0483	07640239930513
08058241	Soprano® Flu-Stain snow	5 g	CE 0483	07640239930100
08058242	Soprano® Flu-Stain cotton	5 g	CE 0483	07640239930117
08058243	Soprano® Flu-Stain cream	5 g	CE 0483	07640239930124
08055252	Soprano® Flu-Stain navy-blue	5 g	CE 0483	07640173095125
08055254	Soprano® Flu-Stain gray	5 g	CE 0483	07640173095149
08055184	Soprano® Glaze Paste	5 g	CE 0483	07640173094173
08055283	Soprano® Glaze Fluid	25 ml	NO MED	N/A

Cat. No.	Product name	Kit contents	Labelling	UDI-DI
08058240	Soprano® PASTE Stain&Glaze Universal Kit	1	CE 0483	07640239930094
08055181	Soprano® Flu-Shade A	5 g	CE 0483	07640173094142
08055245	Soprano® Flu-Shade B	5 g	CE 0483	07640173095057
08055246	Soprano® Flu-Shade C	5 g	CE 0483	07640173095064
08055247	Soprano® Flu-Shade D	5 g	CE 0483	07640173095071
08055248	Soprano® Flu-Stain white	5 g	CE 0483	07640173095088
08058241	Soprano® Flu-Stain snow	5 g	CE 0483	07640239930100
08058242	Soprano® Flu-Stain cotton	5 g	CE 0483	07640239930117
08058243	Soprano® Flu-Stain cream	5 g	CE 0483	07640239930124
08055249	Soprano® Flu-Stain yellow	5 g	CE 0483	07640173095095
08058244	Soprano® Flu-Stain mango	5 g	CE 0483	07640239930131
08055250	Soprano® Flu-Stain orange	5 g	CE 0483	07640173095101
08055251	Soprano® Flu-Stain intense-orange	5 g	CE 0483	07640173095118
08058245	Soprano® Flu-Stain champagne	5 g	CE 0483	07640239930148
08058246	Soprano® Flu-Stain olive	5 g	CE 0483	07640239930155
08055255	Soprano® Stain pink	5 g	CE 0483	07640173095156
08058247	Soprano® Flu-Stain shadow	5 g	CE 0483	07640239930162
08055252	Soprano® Flu-Stain navy-blue	5 g	CE 0483	07640173095125
08055182	Soprano® Flu-Stain dark-blue	5 g	CE 0483	07640173094159
08055183	Soprano® Flu-Stain brown	5 g	CE 0483	07640173094166
08058248	Soprano® Flu-Stain red-brown	5 g	CE 0483	07640239930179
08055254	Soprano® Flu-Stain gray	5 g	CE 0483	07640173095149
08055253	Soprano® Flu-Stain black	5 g	CE 0483	07640173095132
08055184	Soprano® Glaze Paste	5 g	CE 0483	07640173094173
08055283	Soprano® Glaze Fluid	25 ml	NO MED	N/A

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