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Soprano[®] Stain & Glaze

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Instructions for Use Soprano® Stain & Glaze

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: <https://www.cmsa.ch/docs>.

5 Product description

The Soprano® Stain & Glaze ceramics are available as powders or pastes. The Soprano® stains and glazes are based on a glass ceramic and are offered in a wide range of colour variations. The stains and glazes are suitable for the final colour characterisation of monolithic and veneered frameworks over a wide CTE range.

6 Indications

- Monolithic or zirconia frameworks veneered with Soprano® 10.
- Monolithic or lithium disilicate frameworks veneered with Soprano® 10 (Livento® press)
- Metal ceramics (Soprano® 14)
- Paste ceramics (Soprano® Surface)

7 Contraindications

- Combination with materials outside the described Livento® press and Soprano® 10 product system and/or with materials from third party suppliers
- As a matter of principle, all applications not listed are to be regarded as 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

- Livento® press
- Soprano® 10
- Soprano® 14
- Soprano® Surface

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.

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".
- 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.

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

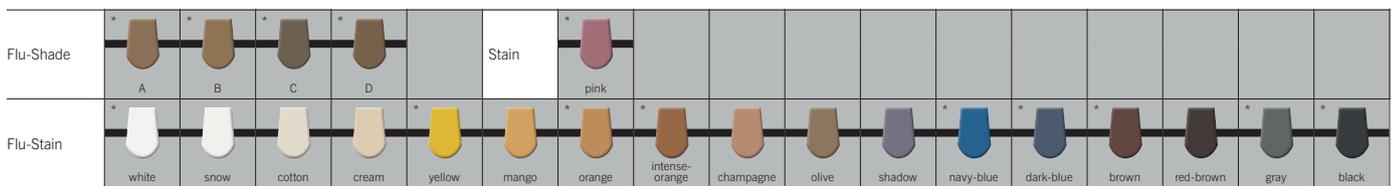
- The prosthetic work, including all system components, must be cleaned, disinfected and, if appropriate, sterilised prior to each work step. Materials made of metal alloys, high-performance polymers (Pekkton®) and ceramics are suitable for steam sterilisation. With the exception of Pekkton®, components 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® ceramic stains are 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 the products.

18 Procedure

18.1 Overview of ceramic stains



* Available as powders.

- The pink stain does not contain any fluorescence.
- Prior to first application, mix all stain and glaze pastes thoroughly for 1-2 minutes. Repeat this procedure at regular intervals to ensure consistent firing quality.

18.2.1 Pastes

Flu-Shade

Highly fluorescent stain corresponding to the base colour A, B, C or D, for use as framework colour or glazing colour.

Flu-Stain

Highly fluorescent stain.

- Can only be used superficially for high melting ceramics.

18.2.2 Powder

Flu-Shade / Flu-Stain

Flu-Shade (4 shades) corresponds to the basic shades A, B, C or D.

Highly fluorescent stains for internal characterisation as stain or for the chromatic enhancement of all ceramic materials.

Universal stains for all ceramics, can be used for mixing with all ceramic materials.

18.3 Preparation of the object

Briefly blast the finished restoration with Al₂O₃ and 1 bar pressure and then clean thoroughly with a steam jet prior to staining or applying the veneer ceramic.

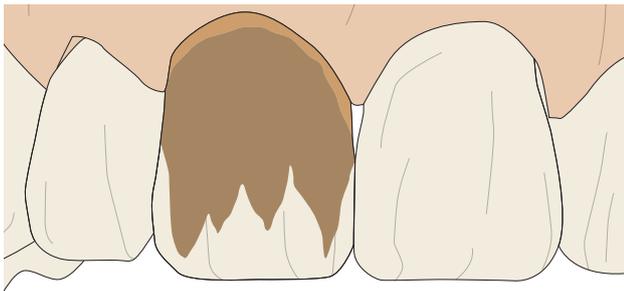
18.4 Staining technique

- Staining pastes separate after longer non-use. Prior to application it is essential to mix well with the spatula included in the kit until homogenous and no more grains are visible. The surface then displays an even satin glow.

If a generous amount of stain is applied, as may be the case with gingival reconstructions, it is essential to extend the drying time or the closing time of the furnace so that the liquid has sufficient time to evaporate.

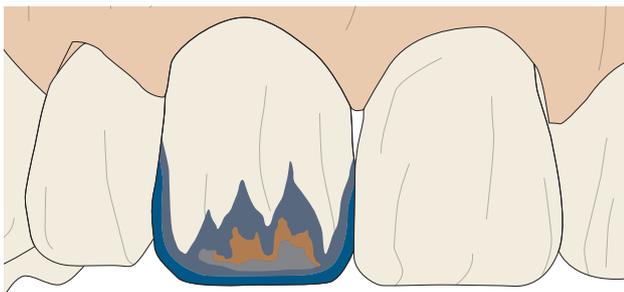
18.5 Basic instructions for staining
(according to Robert Arvai, Chur)

Procedure in anterior region



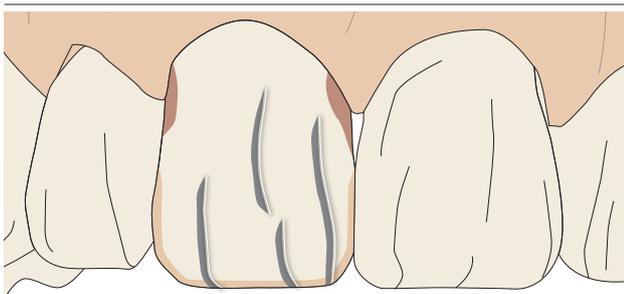
Step 1

- Flu-Shade A, B, C or D
- Flu-Stain orange or intense-orange



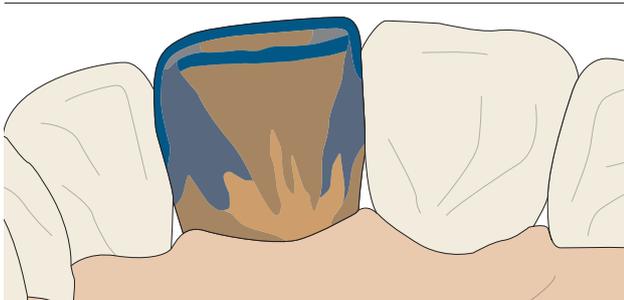
Step 2

- Flu-Stain navy-blue
- Flu-Stain dark-blue
- Flu-Stain intense-orange
- Flu-Stain gray



Step 3

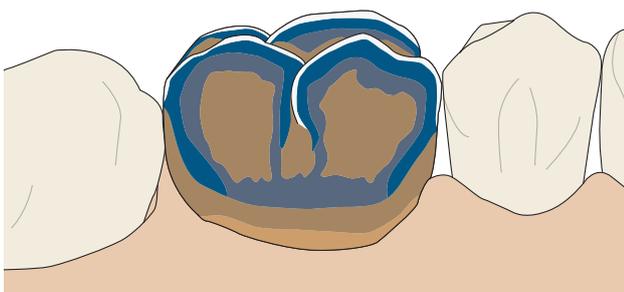
- Flu-Stain gray, staining direction distal
- Flu-Stain white and Flu-Stain orange mixed at 50% each
- Flu-Stain pink, applied very thinly
- Flu-Stain white for enamel cracks



Step 4

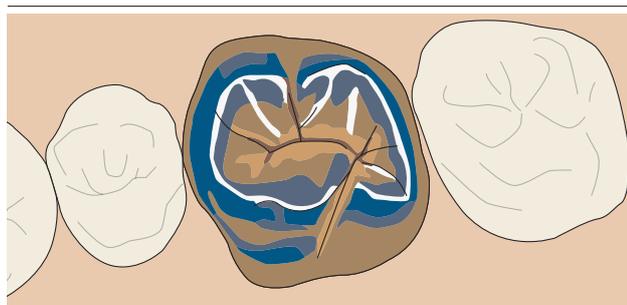
- Flu-Shade A, B, C or D
- Flu-Stain navy-blue
- Flu-Stain dark-blue
- Flu-Stain gray
- Flu-Stain orange or intense-orange

Procedure in posterior region



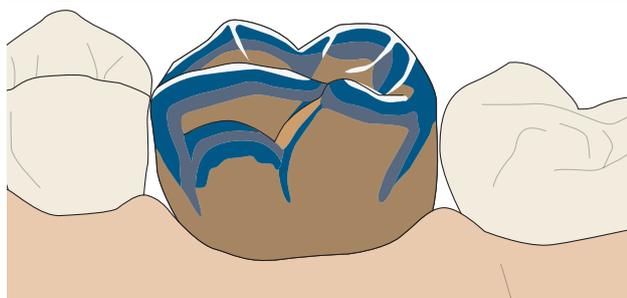
Step 1 (buccal)

- Flu-Shade A, B, C or D
- Flu-Stain orange or intense-orange
- Flu-Stain navy-blue
- Flu-Stain dark blue (gray for A3.5 and A4)
- Flu-Stain white



Step 2 (occlusal)

- Flu-Shade A, B, C or D
- Flu-Stain orange or intense-orange
- Flu-Stain navy-blue
- Flu-Stain dark blue (gray for A3.5 and A4)
- Flu-Stain white
- Flu-Stain brown



Step 3 (palatal)

- Flu-Shade A, B, C or D
- Flu-Stain orange or intense-orange
- Flu-Stain navy-blue
- Flu-Stain dark blue (gray for A3.5 and A4)
- Flu-Stain white

Tips

- Prior to staining, blast the crown matt with 50 µm Al₂O₃ and a maximum of 1 bar pressure.
- Staining (Shade and Stain) without the addition of glazing liquid if at all possible. This avoids clouding or washing of the colour towards the edge.
- Mix glazing material with a little glazing liquid.
- Suction the excess glaze from the posterior teeth occlusally from the fissures with a blotting paper point. Apply the shades from incisal to gingival in thin layers.

Firing table								
	Pre-drying	Closing time	Starting temperature	1st firing	2nd firing	Temperature rise	Vacuum start	Dwell time
	min	min	°C	°C	°C	K/min	°C	min
Stain	3	4	450	750	750	45	without	1
Glaze	3	4	450	750	750	45	without	1

The firing temperature depends on the framework material and the desired degree of gloss. The firing temperature can be increased up to 810°C.

Self-glaze

Performing a "self-glaze" firing (without stains and glaze) is carried out at 785°C, with vacuum, but without dwell time. Subsequent manual polish with suitable polishing agents is then essential to achieve the desired level of gloss.

19 Materials

Material group: Glass ceramic

Composition: Main components bound to the glass ceramic structure: SiO₂, Al₂O₃, K₂O, Na₂O, CaO, B₂O₃

Classification: Type 1, Class 1b, according to ISO EN DIN 6872

CTE range of compatible ceramics: 8.5-14.0×10⁻⁶K⁻¹ from 25°C to 500°C

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

N/A

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:

Livento®, 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 individual products correspond to the refill item

Cat. No.	Product name	Kit contents	Refill contents	Labelling	UDI-DI
08058240	Soprano® PASTE Stain&Glaze Universal Kit			CE 0483	07640239930094
08055181	Soprano® Flu-Shade A	5 g	5 g	CE 0483	07640173094142
08055245	Soprano® Flu-Shade B	5 g	5 g	CE 0483	07640173095057
08055246	Soprano® Flu-Shade C	5 g	5 g	CE 0483	07640173095064
08055247	Soprano® Flu-Shade D	5 g	5 g	CE 0483	07640173095071
08055248	Soprano® Flu-Stain white	5 g	5 g	CE 0483	07640173095088
08058241	Soprano® Flu-Stain snow	5 g	5 g	CE 0483	07640239930100
08058242	Soprano® Flu-Stain cotton	5 g	5 g	CE 0483	07640239930117
08058243	Soprano® Flu-Stain cream	5 g	5 g	CE 0483	07640239930124
08055249	Soprano® Flu-Stain yellow	5 g	5 g	CE 0483	07640173095095
08058244	Soprano® Flu-Stain mango	5 g	5 g	CE 0483	07640239930131
08055250	Soprano® Flu-Stain orange	5 g	5 g	CE 0483	07640173095101
08055251	Soprano® Flu-Stain intense-orange	5 g	5 g	CE 0483	07640173095118
08058245	Soprano® Flu-Stain champagne	5 g	5 g	CE 0483	07640239930148
08058246	Soprano® Flu-Stain olive	5 g	5 g	CE 0483	07640239930155
08055255	Soprano® Stain pink	5 g	5 g	CE 0483	07640173095156
08058247	Soprano® Flu-Stain shadow	5 g	5 g	CE 0483	07640239930162
08055252	Soprano® Flu-Stain navy-blue	5 g	5 g	CE 0483	07640173095125
08055182	Soprano® Flu-Stain dark-blue	5 g	5 g	CE 0483	07640173094159
08055183	Soprano® Flu-Stain brown	5 g	5 g	CE 0483	07640173094166
08058248	Soprano® Flu-Stain red-brown	5 g	5 g	CE 0483	07640239930179
08055254	Soprano® Flu-Stain gray	5 g	5 g	CE 0483	07640173095149
08055253	Soprano® Flu-Stain black	5 g	5 g	CE 0483	07640173095132
08055184	Soprano® Glaze Paste	5 g	5 g	CE 0483	07640173094173
08055283	Soprano® Glaze Fluid	25 ml	25 ml	NO MED	07640173095729

Cat. No.	Product name	Kit contents	Refill contents	Labelling	UDI-DI
08057745	Soprano® POWDER Stain & Glaze Universal Kit			CE 0483	07640173098911
08057511	Soprano® POWDER Flu-Shade A	2 g	2 g	CE 0483	07640173096672
08057746	Soprano® POWDER Flu-Shade B	2 g	2 g	CE 0483	07640173098928
08057747	Soprano® POWDER Flu-Shade C	2 g	2 g	CE 0483	07640173098935
08057748	Soprano® POWDER Flu-Shade D	2 g	2 g	CE 0483	07640173098942
08057749	Soprano® POWDER Flu-Stain white	2 g	2 g	CE 0483	07640173098959
08057750	Soprano® POWDER Flu-Stain yellow	2 g	2 g	CE 0483	07640173098966
08057751	Soprano® POWDER Flu-Stain orange	2 g	2 g	CE 0483	07640173098973
08057752	Soprano® POWDER Flu-Stain intense-orange	2 g	2 g	CE 0483	07640173098980
08057513	Soprano® POWDER Flu-Stain dark-blue	2 g	2 g	CE 0483	07640173096696
08057753	Soprano® POWDER Flu-Stain navy-blue	2 g	2 g	CE 0483	07640173098997
08057512	Soprano® POWDER Flu-Stain brown	2 g	2 g	CE 0483	07640173096689
08057754	Soprano® POWDER Flu-Stain black	2 g	2 g	CE 0483	07640173099000
08057755	Soprano® POWDER Flu-Stain gray	2 g	2 g	CE 0483	07640173099017
08057756	Soprano® POWDER Stain pink	2 g	2 g	CE 0483	07640173099024
08057667	Soprano® POWDER Glaze	7 g	7 g	CE 0483	07640173096702
08055283	Soprano® Glaze Fluid	25 ml	25 ml	NO MED	07640173095729

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