Instruction for Use I **saremco print - CROWNTEC** I US-version

1. Product description
saremco print CROWNTEC is a light-curing, flowable polymer based on methacrylic acid ester for production of 3D-printed permanent crowns, inlays, onlays, veneers, temporary crowns & bridges, and artificial teeth (i.e., complete or partial dentures).

saremco print products are part of an overall concept of 3D printable resin-based materials and may only be used in combination with the specified printers and recommended equipment and in compliance with the manufacturer's instructions.

Note – The use of noncompliant devices might impair the function of the restoration. Sole responsibility for correct application is assumed by the user and is beyond control of SAREMCO Dental AG. SAREMCO Dental AG does not assume any responsibility and liability for damages caused by misuse.

2. Composition
Esterification products of 4,4'-isopropylidiphenol, ethoxylated and 2-methylprop-2enoic acid, silanized dental glass, Pyrogenic silica, initiators. Total content of inorganic fillers (particle size 0.7 µm) is 30 - 50 % by mass.

3. Intended Use
saremco print products provide light-curing 3D printable resin-based materials for the correction or reconstruction of functionally compromised natural dentition (e.g., missing teeth or deficient teeth) by manufacturing of customized 3D-printed dental prostheses.

saremco print CROWNTEC is to be used with 3D-printers from ASIGA)
- Production of permanent crowns, inlays, onlays and veneers
- Production of temporary crowns and bridges, inlays, onlays and veneers
- Production of artificial teeth for subsequent insertion into a denture base

4. Indications for Use
saremco print CROWNTEC is a light-curing 3D-printed material intended as an indirect restorative for both anterior and posterior restorations, including occlusal surfaces. ***saremco print CROWNTEC*** is used for fabrication of permanent restorations such as inlays, onlays, veneers and full crown restorations. ***saremco print CROWNTEC*** can also be used for the fabrication of artificial teeth and temporary crowns & bridges.

5. Contraindications
- ***saremco print CROWNTEC*** is contraindicated for the following applications:
  - Maryland bridge, Inlay bridge
  - All forms of cantilever bridges
  - Bruxism of the patient
  - more than one pontic
- Do not use the product in case of a known allergy to one or more ingredients.
- In case of doubt, clarify and exclude a possible allergy with the help of a specific allergy test before using ***saremco print CROWNTEC***.
- ***saremco print CROWNTEC*** must not be used for any other purposes than those specified in the "Indication" section. Any deviation from this instruction for use may have negative effects on the chemical and physical quality of the restorations produced from ***saremco print CROWNTEC***.

6. Interactions
None known.

7. Material Properties

Color*, **	A1, A2, A3, B1, SW.	Flexural strength**	≥ 120 MPa Average ≥ 135 MPa
Density*	ca. 1.4–1.5 g/cm3	Layer thickness when printing	50 µm
Viscosity*	1.000–5.000 mPa*s	Wavelength 3D-printer	385 or 405 nm

*applies to liquid resin
**applies to cured plastic printed with a 3D-Printer

8. Requirements

Printers
- Asiga MAX UV & PRO 4K (385 nm)

Post Curing Unit
- Otoflash G171 (NK-Optik)
- Signum Hilite Power (Kulzer)

For the complete overview, please refer to section 9.2 compatibility overview.

9. Processing Stages
The following instructions have to be observed during tooth preparation:

Make sure to avoid tangential, spring edge or lip preparations as they are contraindicated with printed restorations. Therefore, exercise special care when using instruments with a round tip and do not introduce them any further than up to half their diameter at maximum. Please note that tangential preparations are technically unfeasible and would result in too thin, i.e. unstable and over-contoured, crown margins.

The following instructions apply to the model modelled on the computer:
Minimum Wall Thickness – The following illustration shows the specified minimum wall thicknesses for the respective indication: the wall thickness must not be undercut even after manual grinding.

The following applies to temporary bridges: connector area at least 16 mm². The connector area should be as large as possible. For physical stability, the height of the connector is more important than the width. Doubling the width results in only doubling the strength, while doubling the height results in eight times the strength. Oval connector area are therefore recommended.
Make sure that enough supports are generated. It is recommended to place the supports on the occlusal surface.

For SAREMCO compatibility overview of officially validated devices, scan QR-Code using camera app or use scan apps such as Lens (Google) or QR-Code-Scanner (QR SCAN Team). Download the compatibility overview (use Mozilla Firefox or Google Chrome) from the homepage saremco.ch/en/download/instructions-for-use/. Look under compatibility overview.

9.3. Cleaning
After the printing process is completed, remove the building platform from the machine. During removing the restoration and the following cleaning steps, wearing gloves (nitrile gloves) and protective goggles are advised.

Place the platform on a piece of paper or cloth with the built jobs facing upwards. Remove the printed jobs from the platform by using a suitable instrument (putty knife). To remove excess material, clean the printed job with an alcohol-soaked (96%) cloth and possibly a brush soaked in an alcohol solution until all resin remains are completely removed. Then dry the printed jobs thoroughly with an air syringe.

Warning – Protect light-curing products from strong light sources.

9.4. Finishing the printed jobs
To achieve the desired material properties and biocompatibility, post-curing of the completely dried and cleaned printed objects is necessary. For final polymerization place the printed jobs in a UV-light box.

Note – time of curing depends greatly on type of lamps / lightbox used. The final properties and the final color depend on the post-curing process. Post-curing is a UV-light treatment to ensure that ***saremco print*** materials obtain full polymer conversion, the residual monomer is reduced to a minimum and the highest mechanical properties are achieved.

This procedure is a necessary step to attain a biocompatible end-product.

It is suggested to use the polymerization unit "Signum HiLite Power" from (2 x 180 sec., turn around after 180 sec.) or the UV-Flash device "Otoflash G171" from NK-Optik (2 x 2000 flashes, turn around after 2000 flashes, UV-bloc bowl and nitrogen). In general, all lightboxes for light-curing veneering materials can be used that cover a wavelength range of 320 - 500 nm. Lightboxes with integrated flashlight allow shorter exposure time compared to conventional lamps. Always follow the respective instruction for use of the polymerization unit.
Blast the surface of the printed job with blast polishing material carefully (e.g., Perlablast micro BEGO). Afterwards remove the support structures by using a cut-off-wheel or a cutter.

Caution – Wearing nitrile gloves, safety glasses and dust mask is advised during this finishing process.

9.5. Fastening

9.5.1. Fastening the definitive crowns, inlays, onlays and veneers
In case of definitive single crowns, the inside of the crowns should be roughened with a sandblast (Al_2O_3, 110 µm). Then, as usual, fix it definitively with a composite cement material. Zinc-phosphate cements as well as glass-ionomer-cements are only of limited suitability, due to their opacity. The fastening composites Panavia VS (Kuraray) and Variolink (Ivoclar) are recommended.

9.5.2. Fastening the temporary crowns and bridges, inlays, onlays and veneers
Fasten the finished transitional prosthesis with commercially available provisional cements.

9.5.3. Connecting of artificial teeth and prosthesis
a) Inserting the printed artificial teeth in a printed, prefabricated denture base.
Roughen the base surface of the printed artificial teeth for example by sandblasting (Al_2O_3, 110 µm), apply a primer and a fixing material, insert in the prosthesis according to the natural shape and polymerise.
Alternatively, ***saremco print CROWNTEC*** can also be used directly as fixing material. Therefore place a small amount of material with a brush on the roughened teeth-surface of the artificial tooth, place it into the prosthesis, eliminate any excess material and light cure it from all sides for at least 20 seconds. The polymerisation light should have at least a light output of 600 mW/cm².
b) Classical pouring method with cold cure resin.
After roughening the teeth, follow classical finishing procedures.

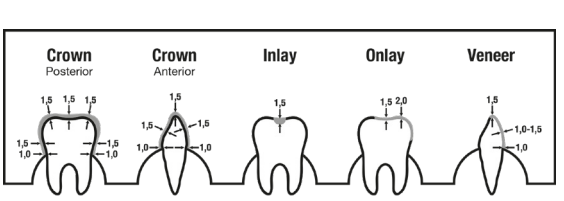
9.6. Finishing, polishing
Prepare the restoration with 40 µ and 12 µ diamond burs. Polish to a high gloss using polishing brushes, polishing discs, strips or silicone polishers.

9.7 Additional advice
Remove the container from the printer and filter the resin through a fine 190 Micron paint strainer, if:
- print has failed partially or completely, or
- particulates of polymerized residues are visible in the container or stick to the bottom.

Discard and replace ***saremco print CROWNTEC*** with a new batch, if contamination, evident gelation, or polymerization is observed after filtering.

Do not mix different batches ***saremco print CROWNTEC***.

10. Storage
Protect this product from strong light and heat sources. The recommended storage temperature is between 4°C and 28°C / 39°F and 82°F. Close the package after each use.



9.1. Generating Printing File
Generate the printing file of the desired restoration by using appropriate software (Composer) and deliver it suitable to the printer. Please observe the corresponding instruction for use of software and printer. Select the build style .dl INI file / material file for ***saremco print CROWNTEC*** in the printer software. Make sure that all software is up to date.

Design temporary (long-term) bridges in the non-visible molar region in the form of a floating bridge (posterior bridge). A floating bridge does not sit firmly on the jaw, but forms a surface that can be rinsed underneath and can therefore be optimally cleaned.

Important Note – Commercially available artificial teeth may be subject of copyright law. When using an STL file of such teeth, copyright laws must be considered.

9.1.1. ASIGA Printer (MAX UV & PRO 4K) and Software

I. Hardware
Please refer to the printer's manufacturer's manual for this information.

II. Asiga printer software – Composer
Please refer to the printer's manufacturer's manual for this information.

III. Printing parameters
Download the required parameter set from the ASIGA database. A working temperature of 35°C / 95°F must be maintained.
a. Slice thickness: 50 µm
b. Optimal orientation: 0 degree tilted orientation
c. Support point size: varies based on support type chosen.
d. Support density: perimeter of the restoration and occlusal region.
Note – The occlusal side must face the build platform.

IV. Environmental Conditions
a. MAX UV print temperature: 35 ± 3 °C // 95 ± 3 °F
b. Humidity: 20 - 80 %

9.2. Printing
Work as clean as possible, as dirty reservoirs or machines can cause deformation/discoloration and therefore failure of the printed objects.
Briefly shake the liquid material and pour it into the reservoir of the 3D-printing machine. Start the printing process by following the instruction for use of the printer.

Caution – Any unauthorized changes to the process equipment, parameters, or software may result in a device that is out of specifications. This is explicitly not recommended and is the responsibility of the user. In case of questions the user should contact the manufacturer for a list of validated software and process hardware.

11. Batch number and expiry date
The batch number is used to identify the product in case of queries. Do not use this product after the expiration date.

12. Precautionary measures
- For dental use only. Keep out of reach of children.
- The use of nitrile gloves while working with ***saremco print CROWNTEC*** is recommended until post-curing. Commercially available medical gloves do not provide effective protection against the sensitizing effect of methacrylates. If the product comes into contact with the glove, remove the glove and dispose of it, wash your hands immediately with soap and water and put on a new glove.
- In case of an allergic reaction, consult a doctor.
- When polishing or removing composites, it is recommended to always use a water-cooling system and a good extraction system, to ventilate the dental laboratory frequently and to wear masks with high particle filtration efficiency for small particle sizes.

Warnings
Hazardous components: ethoxylated Bisphenol A dimethacrylate
H315 causes skin irritation | H317 may cause an allergic skin reaction | H319 causes serious eye irritation | H335 may cause respiratory irritation

Precautionary Statements
P261 avoid breathing dust/fume/gas/mist/vapors/spray
P264 wash with water and soap thoroughly after handling
P271 use only outdoors or in a well-ventilated area
P272 contaminated work clothing should not be allowed out of the workplace
P280 wear protective gloves/protective clothing/eye protection/face protection
P302+P352 IF ON SKIN: wash with plenty of water
P333+P313 if skin irritation or rash occurs: get medical advice/attention
P362+P364 take off contaminated clothing and wash it before reuse
P304+P340 IF INHALED: remove person to fresh air and keep comfortable for breathing
P312 call a POISON CENTER/doctor if you feel unwell
P305+P351+P338 IF IN EYES: rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
P337+P313 if eye irritation persists: get medical advice/attention
P403+P233 store in a well-ventilated place. Keep container tightly closed
P405 store locked up
P501 dispose of contents/container to residual waste as per local and national regulations

13. Emergency Measures
- In case of direct contact of the uncured material with the oral mucosa, rinse with water.
- In case of contact with eyes, rinse thoroughly with water and consult an eye specialist.
- In case of swallowing the restoration, consult a clinician.
- In case of breakage or fracture of the restoration, consult a dentist.
- In case of bleeding caused by the dental restoration, consult a clinician.
- In case of an infection beneath dental restoration caused by the product, consult a dentist.

14. Hygiene
Restorations made of ***saremco print CROWNTEC*** should not be cleaned with chemical products. Cleaning with water is sufficient. The finished restorations can - if necessary - be disinfected with an ethanol solution.

15. Warranty
The product was developed for use in dentistry and must be processed in accordance with the instructions for use. For further damages, namely that caused by non-compliance with the instructions for use or other improper handling or inappropriate use of a product, any liability is rejected. Our liability is restricted to the quality of our products. In the case of a product being of defective quality, only its value is replaced. It is the responsibility of the user to check, before using the products, whether they are suitable for the intended purpose. He expressly assumes all risks associated with using the product and is solely responsible for any resulting damages. Safety data sheets and technical data sheets are available on the website of SAREMCO Dental AG.

16. Scope of delivery

	Contents	Packaging	REF
CROWNTEC, A1	500 g	Bottle	8063
CROWNTEC, A2	500 g	Bottle	8052
CROWNTEC, A3	500 g	Bottle	8051
CROWNTEC, B1	500 g	Bottle	8065
CROWNTEC, SW	500 g	Bottle	8066

17. Production / distribution
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Europe: Class IIa medical device
US: Class II medical device

Glossary

Manufacturer	Protect from Sunlight
LOT Batch Code	Temperatur Limitation
REF Item Number	Expiry Date
CE Marking of Conformity	$R_{x\ Only}$ Use by only Professionals
MD Medical Device	Please note Instructions for use
R_x Prescription Only	

CE 0123

R_x Only