

CE 0123

R_x Only

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 resins-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, Rapid Shape or SprintRay for the following applications (see section 8 herein):

- 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. The CROWNTEC material is used for fabricating 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/cm ³	Layer thickness when printing	50 µm
Viscosity*	2.500–6.000 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

Nextdent 5100 Figure 4 (405 nm)

Asiga MAX UV & PRO 4K (385 nm)

Rapid Shape D20 II, D30 II, D40 II, D10+, D20+ cartridge, D20+, D30+ & D50+ (385 nm)

SprintRay K55 & K95 (405 nm)

Phrozen Sonic XL 4K & Sonic 4K

Accuretta Sol & Dentic (405 nm)

Software

Autodesk Netfabb, Composer, 3D Sprint, Rayware, DS Slicer, Alpha 3D

Post Curing Unit

Otoflash G171 (NK-Optik); Signum Hilite Power (Kulzer), LC-3DPrint Box (Nextdent),

Phrozen Cure V2, Curie (Accuretta).

8. Processing Stages

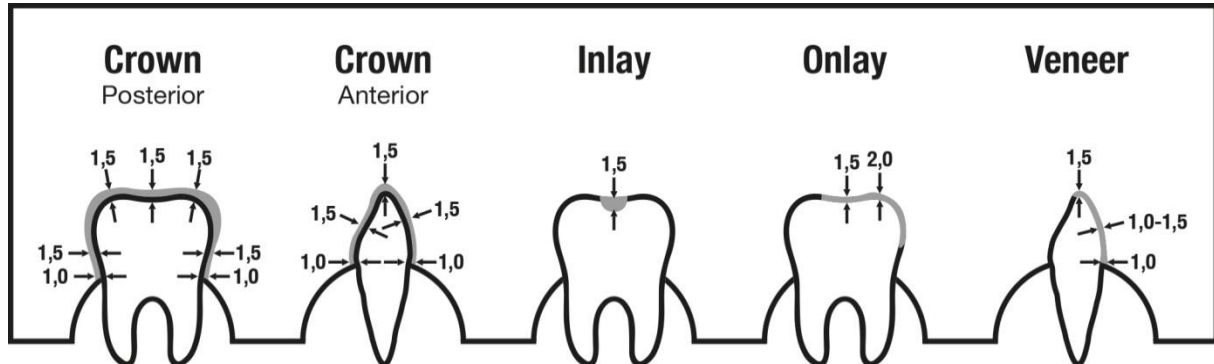
The following instructions have to be observed during tooth preparation:

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.

8.1. Generating Printing File

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

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.

8.1.1 Nextdent Printer (5100 Figure 4) and Software

I. Hardware

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

See the applicable user guides (<http://infocenter.3dsystems.com/nextdent5100/user-guide>)

II. Nextdent printer software – 3D Sprint

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

See the applicable user guides (<https://support.3dsystems.com/s/article/3D-Sprint>)

III. Printing parameters

Printing parameters are automatically loaded into 3D Sprint.

- a. Support parameters are automatically generated in 3D Sprint.
- b. Slice thickness: 50 μm
- c. Optimal orientation: 0 degree tilted orientation
- d. Support parameters are automatically generated in 3D Sprint

Note – The occlusal side must face the build platform.

IV. Environmental Conditions

- a. Temperature of 3D-printing room should be kept at 18-28°C (64.4-82.4°F).
- b. Humidity: 30 – 70 %

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

V. Hardware

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

VI. Asiga printer software – Composer

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

VII. Printing parameters

Download the required parameter set from the ASIGA database. A working temperature of 35°C / 95°F must be maintained.

- e. Slice thickness: 50 μm
- f. Optimal orientation: 0 degree tilted orientation
- g. Support point size: varies based on support type chosen
- h. Support density: perimeter of the restoration and occlusal region.

Note – The occlusal side must face the build platform.

VIII. Environmental Conditions

- c. Max UV print room temperature: 35 \pm 3 °C // 95 \pm 3 °F
- d. Humidity: 20 – 80 %

8.1.3 Rapid Shape Printer (D20 II, D30II, D90II) and software

I. Hardware

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

II. Rapid Shape printer software – Autodesk netfabb

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

III. Printing parameters

- 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. Print temperature: Room temperature; Please refer to the printer`s manufacturer`s manual for this information.
- b. Humidity: 20 – 80 %

8.1.4 SprintRay Printer (K55 and K95) and software

I. Hardware

Please refer to the printer`s manufacturer`s manuals for this information.

II. SprintRay printer software – Rayware

Please refer to the printer`s manufacturer`s manual for this information

III. Printing parameters

- 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 restauration and occlusal region.

Note – The occlusal side must face the build platform.

IV. Environmental Conditions

- a. Print temperature: Room temperature; Please refer to the printer`s manufacturer`s manual for this information
- b. Humidity: 20 – 80 %

8.1.5 Phrozen Printer (Sonic XL 4K & Sonic 4K) and software

V. Hardware

Please refer to the printer`s manufacturer`s manuals for this information.

VI. Phrozen printer software – DS Slicer

Please refer to the printer`s manufacturer`s manual for this information

VII. Printing parameters

Download the required parameter set from the Phrozen database.

- 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 restauration and occlusal region.

Note – The occlusal side must face the build platform.

VIII. Environmental Conditions

- a. Print temperature: Room temperature 25 ± 3 °C // 77 ± 3 °F; Please refer to the

- printer's manufacturer's manual for this information
- b. Humidity: 20 – 80 %

8.1.6 Ackuretta Printer (SOL & DENTIQ) and Software

I. Hardware

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

II. Ackuretta printer software – Alpha 3D

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

Please refer to the [Alpha3D video playlist](#). information

III. Printing parameters

Download the required parameter set from the Ackuretta database.

Slice thickness: 70 µm

Optimal orientation: 0 degree tilted orientation

Support point size: varies based on support type chosen

Support density: perimeter of the restoration and occlusal region.

Note – The occlusal side must face the build platform.

IV. Environmental Conditions

Print temperature: Room temperature; 20 - 28 °C // 36 - 50 °F

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

Humidity: 20 – 80 %”

8.2. 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.

8.3 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.

8.4 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 obtained 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.

Recommended light curing equipment (Post curing process)

Manufacturer & Model	Otoflash G171 (NK-Optics)	Signum HiLite Power (Kulzer)
Supply voltage	100, 117, 230 V	100, 115, 230 V
Lamp power	2 x 100 W	200 W
Light intensity	Not adjustable	Not adjustable
Wavelength	280 – 700 nm	320 – 540 nm
Curing time	2 x 2000 flashes, turn around after 2000 flashes, “UV-bloc bowl” and nitrogen	2 x 180 sec, turn around after 180 sec

Manufacturer & Model	NextDent LC-3D Printbox	Phrozen Cure V2
Supply voltage	AC110-240V 50/60Hz	100-240V, 50-60Hz
Lamp power	Max. 264 W	60 W in total
Light intensity	Not adjustable	Not adjustable
Wavelength	Full light spectrum (300-550 nm)	365, 385, 405nm
Curing time	30 minutes	(1) 2 side x 5 minutes per side curing (turn print in-between) (2) 2min boiling water bath after

		post curing
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Manufacturer & Model	Curie (Accuretta)	
Supply voltage	AC100-240V 50/60Hz	
Lamp power	70 W	
Light intensity	112295 mW/cm ²	
Wavelength	365, 385, 405 nm	
Curing time	T= 2 x 3 minutes P= 16 D= 10 B= ON	

8.5 Fastening

8.5.1. 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 (Al₂O₃, 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 V5 [Kuraray] and Variolink [Ivoclar] are recommended.

8.5.2. Fastening the temporary crowns and bridges, inlays, onlays and veneers

Fasten the finished transitional prosthesis with commercially available provisional cements.

8.5.3. 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 (Al₂O₃, 110 µm), apply a primer and a fixing material, insert in the prosthesis according to the natural shape and polymerize.

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 polymerization 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.

8.6 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.

8.7 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 the Crowntec material with a new batch, if contamination, evident gelation or polymerization is observed after filtering.

Do not mix different batches of Crowntec material

9. 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.

10. 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.

11. 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

12. 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.

13. 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.

14. 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.

15. 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

16. Production / distribution

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info@saremco.ch
www.saremco.ch

Europe: Class IIa medical device

US: Class II medical device

Glossary



Manufacturer



Protect from Sunlight



Batch Code



Temperatur Limitation



Item Number



Expiry Date



CE Marking of
Conformity



Use by only Professionals



Medical Device



Please note
Instructions for use



Prescription Only